From: Tucker, Jessica (NIH/OD) [E] < jessica.tucker@nih.gov>

To: zhang f@mit.edu
'Drew Endy'
Zachary Adelman
Kenneth A Oye

CC:

'Christine Dorosin'
'Phiona Lovett'

O'Reilly, Marina (NIH/OD) [E] Harris, Kathryn (NIH/OD) [C]

Date: 5/26/2017 5:36:45 AM

Subject: Reminder: May 30 Teleconference for NIH Guidelines Workshop

Attachments: Session 4 Telecon\_052617.docx

NIH OSP NIH Guidelines Workshop Public 041717 for posting.pdf

Dear Dr. Zhang, Dr. Endy, Dr. Adelman, and Dr. Oye,

Thank you, again, for your willingness to participate in a one hour teleconference to prepare for the July 18-19 workshop, *NIH Guidelines*: Honoring the Past, Charting the Future.

As a friendly reminder, the teleconference will take place on **Tuesday, May 30, 2017 from 1:00 PM – 2:00 PM EST**. The conference line information was previously sent in a calendar invite, but I have also provided it below for easy reference.

# Please dial: 1-888-552-2815 | Participant Code:

During this call, we will provide you with further details about the workshop and your panel, which is focused on emerging biotechnologies and potential issues they may raise for the current system of biosafety oversight. We will discuss the goals of the workshop and your panel. To help guide our discussion, I've attached a copy of some draft questions we have developed that we would like to explore in the panel. I've also attached the latest copy of the workshop agenda, for easy reference.

Should you have any questions before the call, please feel free to contact me via phone or email.

We look forward to speaking with you, and thanks again!

Best, Jessica

Jessica Tucker, Ph.D.
Director, Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health
301-451-4431



OSP Blog: <u>Under the Poliscope</u> Twitter: @CWolinetzNIH

# <u>SESSION IV – Emerging Biotechnologies:</u> Challenges Raised for Our Current System of Biosafety Oversight

Conference call: Tuesday, May 30<sup>th</sup>, 1:00 pm – 2:00 pm (EST)

Dial in number: 1-888-552-2815

Participant code:

# Call participants:

Jessica Tucker, Ph.D Kathryn Harris, Ph.D. RBP Marina O'Reilly, Ph.D Feng Zhang, Ph.D. - CRISPR/Cas9 Drew Endy, Ph.D. - Synthetic Biology Zach Adelman, Ph.D. - Gene Drives

Kenneth Oye, Ph.D. - Risk assessment/ethical frameworks for emerging biotechnology

Session IV Date: Tuesday 18<sup>th</sup> July 2017
Session IV Time: 2:30 pm - 4:15 pm
Session Length: 1 hour 45 minutes

Formal Remarks: 15 minutes per presenter

Questions and Discussion: 45 minutes

# Purpose of session:

If Asilomar were today, what emerging biotechnologies would be captured in the biosafety oversight system? An overview of various emerging biotechnologies will be presented, along with a discussion of whether there are distinct biosafety issues posed by these technologies. Can these potential challenges be managed by our current framework for risk assessment and biosafety oversight?

# Questions/topics to cover:

# 1. Risks of the technologies

- What are the key advances in these emerging biotechnologies that you feel are particularly transformative when considering the appropriate biosafety framework?
- In the 70's, the risks of the emerging recombinant DNA technology were essentially unknown. Are we in a similar position today in terms of the uncertainty of the potential risks posed by some of the emerging biotechnologies? What might we be concerned about if Asilomar were held today?

- Are the new capabilities of emerging biotechnologies game changers in terms of risk or do they more represent an incremental advance in our capabilities that have a similar risk profile to existing technologies?
- Are there unique concerns surrounding these technologies? Are the concerns related to human health/safety, animals or the environment/ecosystem? Are they associated with basic research or clinical/environmental use?

#### 2. Risk assessment framework

- Do we need to examine our current biosafety risk assessment framework in light of new biotechnological capabilities in the life sciences to ensure we can adequately identify and manage risks?
- Is a new risk assessment paradigm needed for emerging biotechnologies, or does our existing framework, the NIH Guidelines, allow for appropriate oversight? The NIH Guidelines have been frequently amended to remain scientifically responsive, but are there other approaches to consider that would allow risk assessment for emerging biotechnologies to be addressed more proactively?

# 3. Thoughts about possible directions in the future

- Are there emerging biotechnologies that may benefit from additional biosafety guidance to help institutions manage the risks? Would it be possible to craft general guidance on the conduct of risk assessment and risk management or would it need to be tailored to each specific technology?
- Since the inception of the NIH Guidelines the RAC has played a pivotal role in providing a mechanism for public discussion about risks of life science research and biosafety guidance at the national level. Do you see the continued benefit of an advisory committee model (such as the RAC) or other public forum for public discussion of the risk and in providing biosafety guidance related to emerging biotechnologies?

# NIH Guidelines: Honoring the Past, Charting the Future



National Institutes of Health 5635 Fishers Lane Rockville, Maryland 20892 Conference Rooms 508/509

# DAY 1 - Tuesday 18th July 2017

8:00 am - 8:30 am Registration

8:30 am – 9:00 am Welcoming Remarks

Carrie D. Wolinetz, Ph.D.

Associate Director for Science Policy, NIH

9:00 am - 9:15 am Introduction

Francis S. Collins, M.D., Ph.D. Director, NIH

9:15 am - 10:00 am SESSION I - Keynote Presentation

The keynote will provide insights into the historical significance of Asilomar, the 40 year history of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, and the Recombinant DNA Advisory Committee (RAC); and explore the future of biosafety oversight in the life sciences in light of the emergence of new biotechnologies.

David Baltimore, Ph.D.

President Emeritus; Robert Andrews Millikan Professor of Biology, California Institute of Technology

10:00 am - 10:15 am BREAK

10:15 am - 11:30 am

SESSION II – The Current NIH Framework for the Oversight of Research with Recombinant or Synthetic Nucleic Acid Molecules

This session will explore the current framework established by the NIH Guidelines, including the roles of Institutional Biosafety Committees (IBCs) and the RAC.

# Panelists:

Jessica Tucker, Ph.D.

Director, Biosafety, Biosecurity and Emerging Biotechnology Policy Division, Office of Science Policy, NIH

Stephen J. Libby, Ph.D.

IBC Chair, Research Associate Professor, University of Washington

Hans-Peter Kiem, M.D., Ph.D.

Director, Cell and Gene Therapy Program, Fred Hutchinson Cancer Research Center

11:30 am – 12:45 pm Lunch Break

12:45 pm - 2:15 pm

**SESSION III – Role of the** *NIH Guidelines***: Intersection with Other Biosafety Regulations and Guidance** 

The panel will examine the essential elements of the system of oversight established in the NIH Guidelines, and how the NIH Guidelines intersect or complement other biosafety guidance.

# Panelists:

**Federal Representatives** 

2:15 pm – 2:30 pm BREAK

# 2:30 pm - 4:15 pm

# SESSION IV – Emerging Biotechnologies: Issues Raised for the Current System of Biosafety Oversight

If Asilomar were today, what emerging biotechnologies would be captured in the biosafety oversight system? An overview of various emerging biotechnologies will be presented, along with a discussion of whether there are distinct biosafety issues posed by these technologies. Can these potential challenges be managed by the current framework for risk assessment and biosafety oversight?

# Panelists:

Feng Zhang, Ph.D.
Professor in Neuroscience, MIT

Drew Endy, Ph.D.
Associate Professor, Bioengineering, Stanford University

Zach Adelman, Ph.D.
Associate Professor, Department of Entomology, Texas A&M University

Kenneth Oye, Ph.D.

Professor of Political Science, and Data Systems and Society,
MIT

4:15 pm – 4:30 pm

Wrap-up of Day 1

4:30 pm

**ADJOURN** 

# DAY 2 - Wednesday 19th July 2017

8:00 am - 8:15 am

Introduction

8:15 am - 10:15 am

SESSION V - Roundtable Discussion - Future Role of the RAC

This roundtable will include a discussion of the benefits of having a public forum for biosafety discussions, and the types of engagement that would best meet the needs of the scientific community and the public. Questions explored will include, how can the RAC be best used to help ensure the safe advancement of life sciences research? Are there emerging biotechnologies that would benefit from the public engagement provided by RAC discussions? What role should the RAC have in providing biosafety guidance?

### **Moderator:**

Howard Federoff, M.D., Ph.D. Vice Chancellor for Health Affairs and CEO UC Irvine Health System, University of California, Irvine

# **Lead Discussants:**

Marie-Louise Hammarskjöld, M.D., Ph.D.
Professor, Microbiology, Immunology, and Cancer Biology,
University of Virginia

Margaret Foster Riley, J.D.

Professor of Law, University of Virginia

Joseph Kanabrocki, Ph.D, CBSP
Associate Vice President for Research Safety, University of Chicago

Nancy King, J.D.
Professor, Social Sciences and Health Policy, Wake Forest School of Medicine

10:15 am - 10:30 am BREAK

10:30 am – 12:30 pm

# **SESSION VI – Roundtable Discussion - Future Face of Biosafety Oversight**

This roundtable will include a discussion of what the ideal Federal and local oversight systems for helping to ensure the safe conduct of life sciences research might look like. Questions explored will include, what should be the scope of the biosafety oversight system? What are the pros and cons of a biosafety oversight framework that focuses on research with recombinant or synthetic nucleic acid molecules? Are there additional types of research that pose biosafety concerns that warrant oversight, which are not captured in the current system; are there types of research that are part of the current system that no longer require such oversight? How can we help ensure adequate biosafety oversight without unduly burdening the research enterprise?

# **Moderator:**

Joseph Kanabrocki, Ph.D, CBSP Associate Vice President for Research Safety, University of Chicago

# Lead Discussants:

Elizabeth Gilman Duane, M.S., RBP, CBSP Biosafety/Laboratory Safety Service Leader, Environmental Health and Engineering, Inc.

Lydia Sohn, Ph.D IBC Chair, Professor of Mechanical Engineering, University of California, Berkeley

Ara Tahmassian, Ph.D.
Chief Research Compliance Officer, Harvard University

Maureen O'Leary Ph.D., CBSP
President, American Biological Safety Association (ABSA)
International

12:30 pm – 12:45 pm SESSION VII - Open Forum for Stakeholder Input

12:45 pm – 1:00 pm Closing Remarks

Carrie D. Wolinetz, Ph.D.

Associate Director for Science Policy, NIH

1:00 pm ADJOURN

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CC: Alvarado, Jessica Date: 5/17/2017 4:55:37 PM Subject: RE: Trudy MacKay visit Attachments: CV Mackay 05 2017.docx

# Dear Colleagues,

The CVM is hoping to recruit Dr. Trudy MacKay, a Drosophila geneticist, as a TIAS (HIAS) Fellow. She is a member of the NAS and a Wolf Prize winner. In order to accommodate her schedule, we invited her for a preliminary visit on May 29-31 (Mon-Wed). May 29 is Memorial Day, and TAMU is closed, but we are still scheduling her afternoon and evening, as well as the other days.

Would you like to join Dr. MacKay for lunch or dinner on Tuesday, May 30?

Many thanks, Evelyn

Evelyn Tiffany-Castiglioni, Ph.D. Professor and Head Department of Veterinary Integrative Biosciences Associate Dean for Undergraduate Education College of Veterinary Medicine & Biomedical Sciences Texas A&M University College Station, TX 77843-4458 Phone: 979/845.2828

FAX: 979/847.8981 ecastiglioni@cvm.tamu.edu





# CURRICULUM VITAE TRUDY FRANCES CHARLENE MACKAY MAY 2017

Born: September 10, 1952, Moncton, New Brunswick, Canada

NATIONALITY: U. S. A. and Canada

ADDRESS: Department of Biological Sciences, Box 7614, North Carolina State University, Raleigh,

North Carolina 27695-7614

**CONTACT:** Email: trudy mackay@ncsu.edu

Tel: 919-515-5810 Fax: 919-515-3355

#### **EDUCATION**

B. Sc. (Hon)
 Biology
 Dalhousie University, 1974
 M. Sc.
 Biology
 Dalhousie University, 1976
 Ph.D.
 Genetics
 University of Edinburgh, 1979
 Postdoctoral
 Genetics
 Dalhousie University, 1979-1980

#### **HONORS AND AWARDS**

Dalhousie University Entrance Scholarship, 1970-1974

B. Sc. awarded with first class honours in Biology, Dalhousie University, 1974

Dalhousie University Medal in Biology, 1974

National Research Council of Canada Graduate Fellowship, Department of Biology, Dalhousie University, 1974-1975

Killam Graduate Scholarship, Department of Biology, Dalhousie University, 1974-1975

M. Sc. Thesis approved with distinction, Dalhousie University, 1976

Royal Commission for the Exhibition of 1851 Overseas Scholarship, Department of Genetics, University of Edinburgh, 1976-1979

McCauley Award, Department of Genetics, University of Edinburgh, 1979

Natural Sciences and Engineering Research Council of Canada Postdoctoral Fellowship, Department of Biology, Dalhousie University, 1979-1980

Killam Postdoctoral Fellowship, Department of Biology, Dalhousie University (honorary), 1979-1980. Alumni

Outstanding Research Award, College of Agriculture and Life Sciences, NC State University, 2000

Fellow, American Association for the Advancement of Science, 2003

Genetics Society of America Medal, 2004

Fellow, American Academy of Arts and Sciences, 2005

Fellow, Royal Society, 2006

Member, New York Academy of Sciences, 2007

O. Max Gardner Award, University of NC, 2007

Adjunct Professor, Department of Endodontics, School of Dentistry, University of NC, Chapel Hill, 2007

Fellow, National Academy of Sciences of the USA, 2010

North Carolina Award for Science, 2011

Honoris Causa, University of Buenos Aires, Argentina, 2013

Alexander Quarles Holladay Medal for Excellence, NC State University, 2015

Wolf Prize for Agriculture, 2016

Alumni Outstanding Research Award, College of Sciences, NC State University, 2016

NC State University Research Leadership Academy, 2016

5<sup>th</sup> International Conference on Quantitative Genetics Award for Outstanding Contributions in Research and Teaching in Quantitative Genetics, 2016

Honorary Professor, Beijing Forestry University, China, 2016

#### **EMPLOYMENT**

Lecturer, Department of Genetics, University of Edinburgh 1980-1987 (Awarded tenure, 1983)

Associate Professor, Department of Genetics, North Carolina State University, 1987-1993

Professor, Department of Genetics, North Carolina State University, 1993-1996

William Neal Reynolds Professor of Genetics, North Carolina State University, 1996-present

Distinguished University Professor of Genetics, North Carolina State University, 2006-2013

Associate faculty, Department of Entomology, North Carolina State University, 2008-present

William Neal Reynolds and Distinguished University Professor of Biological Sciences, 2013-2017

Distinguished University Professor and Goodnight Innovation Distinguished Chair of Biological Sciences, 2017-present

#### **SOCIETY MEMBERSHIPS**

Genetics Society of America Society for the Study of Evolution American Association for the Advancement of Science Sigma Xi

#### **RESEARCH INTERESTS**

My general research goal is to understand the genetic and environmental factors affecting variation in quantitative (or complex) traits. This is necessary for risk modification of multifactorial human diseases, in theory for a more comprehensive view of the genetic processes underlying phenotypic evolution and in practice for improving production traits in domestic species.

A comprehensive understanding of the genetic architecture of quantitative traits requires that we know (1) at what genetic loci (Quantitative Trait Loci, or QTLs) segregating and mutational variation occurs; (2) the homozygous, heterozygous and epistatic effects, pleiotropic effects on other characters, including fitness; and environmental sensitivities of QTL alleles; and (3) the molecular genetic basis of quantitative variation in nature. This detailed characterization is only feasible in genetically tractable model organisms. Further, the nature of genetic variation for quantitative traits is expected to differ depending on the relationship of the trait to fitness. My research focuses on *Drosophila melanogaster*, which has a wealth of genetic and genomic resources, and morphological, behavioral, physiological and life history characters spanning the gamut of fitness profiles.

Drosophila sensory bristle numbers are morphological traits with high levels of naturally occurring genetic variation and which are thought to be under strong stabilizing selection in the wild. Only when we know what loci contribute to naturally segregating variation for bristle numbers and frequencies of functional allelic variants at these loci will we be able to infer what evolutionary forces lead to the maintenance of substantial genetic variation despite strong selection. Animals display rich behavioral repertoires of responses to environmental stimuli, yet almost nothing is known of the genes underlying quantitative genetic variation in behavioral traits. We are studying olfactory responses to chemicals, mating behavior, aggression, alcohol sensitivity and adult locomotor behavior to understand the genetic architecture of complex behaviors. We also

study longevity and resistance to multiple stressors (starvation, chill coma, oxidative stress) as model life history traits, whose genetic basis may be conserved across taxa, including humans.

We use two complementary approaches to identify QTLs and determine their effects for each of the traits of interest. First, we screen random *P* transposable element insert lines, derived in an inbred background, to identify candidate genes and pathways affecting quantitative trait phenotypes. Second, we map QTLs causing naturally occurring variation for quantitative traits by linkage or association with molecular markers, respectively, in linkage mapping populations and in samples of alleles from random breeding populations. We have derived a population of 205 inbred lines from the Raleigh, NC natural population with complete sequences, which we are currently expanding to 2,000 lines. These lines constitute the *Drosophila* Genetic Reference Panel (DGRP), a community resource for whole genome association mapping of quantitative traits. Because DNA polymorphisms do not directly affect variation in quantitative traits, but do so via networks of interacting transcripts, proteins, and metabolites, we are performing whole genome expression analyses on the DGRP lines to derive causal networks of genetically variable transcripts associated with quantitative traits. Since the effects of QTL alleles can be environment-specific, we incorporate ecologically relevant macro-environments in all the above studies.

# RESEARCH SUPPORT (AMOUNTS GIVEN ARE TOTAL DIRECT COSTS)

#### **PAST SUPPORT**

- 1. GR/C44884. Mutational variation for quantitative traits in *Drosophila melanogaster*. P.I., T. F. C. Mackay. Science and Engineering Research Council (Great Britain). 1983-1986. £65,000 (approximately \$117,000).
- **2.** GR/D76042. Population genetics of transposable elements in *Drosophila*. P.I., T. F. C. Mackay. Science and Engineering Research Council. (Great Britain). 1986-1987. £13,000 (approximately \$23,400).
- 3. P01 GM11546. *P*-element-induced quantitative variation in *Drosophila*. Mackay component, National Institutes of Health Quantitative Genetics Research Program. P.I., C. C. Cockerham. 1987-1990. 1990 Mackay component, \$117,035.
- 4. NC06077. P-element-induced quantitative variation in Drosophila melanogaster. P.I., T. F. C. Mackay. North Carolina State University, North Carolina Agricultural Research Service. 1988-1991. \$21,000 per annum.
- Distribution of effects of mutants on quantitative traits. P.I., T. F. C. Mackay. North Atlantic Treaty Organization, travel grant for collaborative research. co-P.I., Prof. W.G. Hill, Department of Genetics, University of Edinburgh. 1988-1993. Travel and subsistence budget for total award, \$8,700.
- 6. P01 GM45344. Quantitative genetic variation in *Drosophila*. Mackay component, National Institutes of Health Statistical and Quantitative Genetics Research Program. P.I., B. S. Weir. 1990-1995. \$735,571 Mackay component.
- **7.** R01 GM45146. Quantitative trait loci in *Drosophila*. P.I., T. F. C. Mackay. National Institutes of Health. 1991-1995. \$304,273.

- **8.** Quantitative genetics of ovariole number in *Drosophila melanogaster*. National Institutes of Health NRSA Postdoctoral Fellowship. P.I., M. Wayne, Sponsor T. F. C. Mackay. 1994-1997. \$63,900.
- 9. DEB-9317754. The contribution of new mutations to genotype-environment interaction for fitness. P.I., T. F. C. Mackay. National Science Foundation. co-P.I., J. D. Fry. 1994-1997. \$210,000.
- **10.** R01 DC02485. Molecular genetics of olfaction in *Drosophila* . P.I., R. R. H. Anholt; co-P.I., T. F. C. Mackay. National Institutes of Health. 1994-1998. \$581,751.
- **11.** R01 GM45146. Quantitative trait loci in *Drosophila*. P.I., T. F. C. Mackay. National Institutes of Health. 1995-1999. \$554,223.
- **12.** Quantitative genetics of *Drosophila* life history traits. National Institutes of Health NRSA Postdoctoral Fellowship. P.I., J. Leips, Sponsor T. F. C. Mackay. 1997-2000. \$63,900.
- **13.** P01 GM45344. Quantitative genetic variation in *Drosophila*. National Institutes of Health Statistical and Quantitative Genetics Research Program. P.I., B. S. Weir. 1995-2000. \$834,728 Mackay component.
- **14.** R03 TW00997. Quantitative trait loci for longevity in Drosophila. P.I., T. F. C. Mackay; Collaborator, E. G. Pasyukova. National Institutes of Health, Forgarty International Center. 1998-2001. \$50,000.
- **15.** R01 GM59469. Molecular genetics of olfaction in *Drosophila* . P.I., R. R. H. Anholt; co-P. I., T. F. C. Mackay. National Institutes of Health. 1999-2003. \$1,165,718.
- **16.** NC06274. Quantitative genetic variation in *Drosophila melanogaster*. P.I., T. F. C. Mackay. North Carolina State University, North Carolina Agricultural Research Service. \$33,000 per annum.
- **17.** R01 GM45146. Quantitative trait loci in *Drosophila*. P.I., T. F. C. Mackay. National Institutes of Health. 1999-2003. \$1,666,289.
- **18.** F32 GM20897. The genetic basis of variation in olfactory behavior. National Institutes of Health NRSA Postdoctoral Fellowship. P.I., Stephanie M. Rollmann, Sponsors T. F. C. Mackay & R. R. H. Anholt. 2000-2003. \$63,900.
- **19.** F31 MH065051. Quantitative trait loci for *Drosophila* mating behavior. National Institutes of Health NRSA Predoctoral Fellowship. P.I., Amanda J, Moehring, Sponsor T. F. C. Mackay. 2001-2003. \$40,846.
- **20.** DEB-9976997. Quantitative genetic architecture of inflorescence developmental plasticity. Molecular Evolutionary Ecology of Developmental Plasticity in *Arabidopsis thaliana*. P.I. M. D. Purugganan. National Science Foundation. 1999-2004. \$350,329 Mackay component.
- **21.** P01 GM45344. Quantitative trait loci for *Drosophila* lifespan. National Institutes of Health Statistical and Quantitative Genetics Research Program. P.I., B. S. Weir 2000-2005. \$955,914 Mackay component.
- **22.** F32 GM66603. QTL for temperature stress resistance in *Drosophila*. National Institutes of Health NRSA Postdoctoral Fellowship. P.I., Theodore J. Morgan, Sponsor T. F. C. Mackay. 2002- 2005. \$119,124.

- **23.** R01 GM58260. Genetic basis of species differences in Drosophila. P.I. , J. A. Coyne, sub-contract P. I., T. F. C. Mackay. National Institutes of Health. 2002-2006. \$259,816 Mackay sub-contract.
- **24.** R21 AA015348. Genetics of alcohol sensitivity in *Drosophila*. P.I., T. F. C. Mackay. National Institutes of Health. 2004-2006. \$273,375.
- **25.** R01 GM59469. Molecular genetics of olfaction in *Drosophila* . P.I., R. R. H. Anholt; co-P. I., T. F. C. Mackay. National Institutes of Health. 2003-2007. \$1,125,000.
- **26.** F31 MH74161. Genetic architecture of aggression in *Drosophila*. National Institutes of Health NRSA Predoctoral Fellowship. P.I., Alexis C. Edwards, Sponsor T. F. C. Mackay. 2005-2008. \$90,264.
- **27.** R01 GM45146. Quantitative trait loci in *Drosophila*. P.I., T. F. C. Mackay. National Institutes of Health. 2003-2007. \$872,000.
- **28.** R01 EY015873. Comparative genomics of glaucoma, P.I., R. R. H. Anholt; co-P.I., T.F. C. Mackay. National Institutes of Health. 2005-2010. \$1,237,980.
- **29.** R01 GM058260. Genetics of species differences in *Drosophila*, P.I., J. A. Coyne; sub-contract P. I., T. F. C. Mackay. National Institutes of Health. 2006-2010. \$560,678.
- **30.** R01 GM076083. Genetics of aggression in *Drosophila*. P.I., T. F. C. Mackay. National Institutes of Health. 2006-2010. \$770,000.
- **31.** 15-ES-101, ARRA Challenge Grant . Oxidative stress and neurogenetic networks in *Drosophila*. Co-P.I., R. R. H. Anholt, T. F. C. Mackay, E. A. Stone. National Institutes of Health. 2009-2011. \$483,276.
- **32.** ARRA Administrative Supplement to R01 GM45146. Quantitative trait loci in *Drosophila*. Co-P.I., T. F. C. Mackay, R. R. H. Anholt, E. A. Stone. National Institutes of Health. 2009-2011. \$297,270.
- **33.** R01 AA016560. Genetics of alcohol sensitivity in *Drosophila*, P.I., T. F. C. Mackay. National Institutes of Health. 2007-2011. \$1,125,000.
- **34.** R01 GM59469. Molecular genetics of olfaction in *Drosophila* . P.I., R. R. H. Anholt; co-P.I., T. F. C. Mackay. National Institutes of Health. 2008-2012. \$1,455,547.
- **35.** R01 GM45146. Quantitative trait loci in *Drosophila*. Co-P.I., T. F. C. Mackay, R. R. H. Anholt, E. A. Stone. National Institutes of Health. 2009-2013. \$1,400,000 (no-cost extension to 6/30/2014).
- **36.** R21 ES021719. Genetics of lead sensitivity in *Drosophila*. Co-P.I., R. R. H. Anholt (PD), T. F. C. Mackay. National Institutes of Health. 2013-2015. \$275,000 (no cost extension to 06/30/2016)
- **37.** R01 GM076083. Genetics of aggression in *Drosophila*. Co-P.I., T. F. C. Mackay (PD), R. R. H. Anholt, E. A. Stone. National Institutes of Health. 2012-2016. \$1,264,370 (no cost extension to 04/30/2017).
- **38.** R01 GM59469. Molecular genetics of olfaction in *Drosophila*. Co-P.I., R. R. H. Anholt (PD), T. F. C. Mackay. National Institutes of Health. 2013-2017. \$1,174,489.

#### **CURRENT SUPPORT**

- **39.** R01 AA016560. Genetics of alcohol sensitivity in *Drosophila*, Co-P.I., T. F. C. Mackay (PD), R. R. H. Anholt. National Institutes of Health. 2012-2017. \$1,625,525.
- **40.** R01 AG043490. Systems genetics of *Drosophila* lifespan. Co-P.I., T. F. C. Mackay (PD), R. R. H. Anholt. National Institutes of Health. 2013-2018. \$1,250,000.
- **41.** Genomic Selection in Animals and Plants (GenSAP) funded by The Danish Council for Strategic Research. 2013-2018. \$300,000.

#### **PENDING**

U01 DA041613. Genetics of cocaine and methamphetamine sensitivity in *Drosophila*. Co-P.I., T. F. C. Mackay (PD), R. R. H. Anholt. National Institutes of Health. 2016-2021. \$2,826,180.

R35 GM122454. *Drosophila* quantitative genetics. T. F. C. Mackay (P. I.) National Institutes of Health. 2017-2022. \$5,034,161.

#### **TRAINING GRANT SUPPORT**

- **42.** W. M. Keck Program in Behavioral Biology. R. R. H. Anholt, Program Director; T. F. C. Mackay, participating member. 1999-2004. \$800,000.
- **43.** T32 GM 08443. The genetic architecture of quantitative traits. Program Director, T. F. C. Mackay. National Institutes of Health Institutional Training Grant. 1999-2004. \$573,914.
- **44.** T32 GM 08443. The genetic architecture of quantitative traits. Program Director, T. F. C. Mackay. National Institutes of Health Institutional Training Grant. 2004-2009. \$665,100.
- **45.** R25 GM083242. Initiative for Maximizing Student Diversity. Program directors, T. F. C. Mackay and D. Shafer. National Institutes of Health Institutional Training Grant. 2008-2012. \$1,869,824.
- **46.** T32 GM 08443. The genetic architecture of quantitative traits. Program Director, T. F. C. Mackay. National Institutes of Health Institutional Training Grant. 2009-2014. \$751,270.
- **47.** R25 GM083242. Initiative for Maximizing Student Diversity. Program directors, T. F. C. Mackay and D. Shafer. National Institutes of Health Institutional Training Grant. 2012-2017. \$3,397,645.

#### **PENDING**

R25GM083242. Initiative for Maximizing Student Diversity in Biomedical and Behavioral Sciences. Co-P.I., T. F. C. Mackay (P. D.), D. M. Shafer. National Institutes of Health. \$5,522,261.

#### **INVITED SYMPOSIA CONTRIBUTIONS**

26<sup>TH</sup> Poultry Breeders Roundtable, 1984. "Jumping genes and quantitative variation" Hybrid Dysgenesis Workshop, Cambridge, England, 1985. Hybrid dysgenesis-induced response to selection"

- Commission of the European Communities Animal Husbandry Research Programme Seminar, Edinburgh, Scotland, 1985. "Transposable elements in genetic selection"
- Second International Conference on Quantitative Genetics, Raleigh, North Carolina, 1987. "Transposable element-induced quantitative variation in *Drosophila*"
- 16<sup>TH</sup> International Congress of Genetics, Toronto, Canada, 1988. "Transposable elements and fitness in *Drosophila melanogaster*"
- 4<sup>TH</sup> International Congress of Systematic and Evolutionary Biology, College Park, Maryland, 1990. "The pleiotropic effects of new polygenic mutations"
- 4<sup>TH</sup> World Congress on Genetics Applied to Livestock Production, Edinburgh, Scotland, 1990. "Distribution of effects of new mutations affecting quantitative traits"
- Pioneer Hi-Bred Heterosis Conference, Ames, Iowa, 1993. "Quantitative variation and epistasis in *Drosophila*"
- 17<sup>™</sup> International Congress of Genetics, Birmingham, England, 1993. Convener of Symposium entitled "Towards an understanding of the genes controlling quantitative variation", and speaker on "Insertional mutagenesis and quantitative variation"
- Gordon Conference on Quantitative Genetics and Biotechnology, Ventura, California, 1995. "Mutations and quantitative traits"
- 44<sup>TH</sup> Annual National Breeders Roundtable, St. Louis, Missouri, 1995. "The genetic basis of quantitative variation in *Drosophila melanogaster*"
- Society for the Study of Evolution, Montreal, Canada, 1995. "High resolution mapping of QTL affecting bristle number in *Drosophila melanogaster*" and "Mutation and quantitative variation in *Drosophila*"
- European Society for Evolutionary Biology, Edinburgh, Scotland, 1995. "The genetic basis of quantitative variation: Candidate genes and *Drosophila* bristle number"
- International Plant and Animal Genome V Conference, San Diego, CA, 1997. "The nature of quantitative genetic variation: Lessons from *Drosophila*"
- International Conference on Molecular Biology and Evolution, Garmisch-Partenkirchen, Bavaria, Germany, 1997. "Quantitative genetic variation at loci affecting sensory bristle development in *Drosophila melanogaster*"
- National Institutes of Health, The Genetic Architecture of Complex Traits, Washington, DC 1997. "QTL and beyond: Lessons from *Drosophila*"
- 6<sup>TH</sup> World Congress on Genetics Applied to Livestock Production, Armidale, Australia, January 1998. "The nature of quantitative variation: Lessons from *Drosophila*"
- AAAS 1998 Annual Meeting, Philadelphia, PA. Biotechnology and Evolution Symposium. "The nature of quantitative variation: Lessons from *Drosophila*"
- National Institutes of Health, International Consortium to Identify Cancer Modifier Genes in Mice, Washington, DC, July 1998
- Duke University Genetics Program Mini-Symposium on Quantitative Traits, Durham NC, October 1998. "The nature of quantitative variation: Lessons from *Drosophila*"
- 28<sup>th</sup> Annual Meeting of the American Aging Association, 12th Annual Meeting of the American College of Clinical Gerontology. Seattle, WA, June 1999. "QTL mapping of aging genes in *Drosophila melanogaster*"
- 3<sup>rd</sup> International symposium on Proteogenomics, Seattle, WA, October 1999. "Complicated genetics of complex traits: Lessons from *Drosophila*"
- National Institutes of Health., How Many SNPs are Needed For Disease Gene Mapping Meeting. March 2000, Washington, DC
- 41<sup>st</sup> Annual Drosophila Research Conference, Plenary Lecture. Pittsburgh, PA, March 2000. "The nature of quantitative genetic variation"
- University of California, Davis, Major Issues in Modern Biology, April, 2000. "The nature of quantitative genetic variation"

- Evolution 2000 Joint Meeting, Symposium on the Genetics of Adaptation, Bloomington, IN, June 2000. Quantitative trait loci for Drosophila lifespan
- Genetic Mechanisms of Aging III, Jackson Laboratories, Bar Harbor, ME, August, 2000. "Quantitative trait loci for Drosophila lifespan"
- Insect Chemical Ecology in the Molecular Era, Schloss Ringberg, Germany, October, 2000. "Towards an understanding of the molecular genetic basis of adaptation: lessons from *Drosophila*"
- National Institute on Alcohol Abuse and Alcoholism, workshop on "QTL Endgame: Strategies for Identifying Genes Influencing Alcohol-Related Behavior", November, 2000, Washington, DC
- Gordon Research Conference on Quantitative Genetics and Genomics, February, 2001, Ventura, CA.
- Les Treilles Foundation, Workshop on "Quantitative Evolutionary Genetics: Drosophila in the Post-Genome Era", April, 2001, Les Treilles, France
- Duke University Genetics Program Mini-Symposium, "My Genes Made Me Do It? Linking Genetics and Behavior"; Durham, NC, October 2001. "The Genetic Architecture of Complex Behaviors"
- 4<sup>th</sup> Annual Meeting of the International Behavioural and Neural Genetics Society. San Diego, CA, November 2001. "The Genetic Architecture of Complex Behaviors"
- National Human Genome Research Institute, Planning Workshop on Relating Genetic Variation to Health and Disease, August, 2002, Bethesda, MD
- Syngenta Torry Mesa Research Institute, Microarray Users Meeting, October 2002, Orlando, FL. "Drosophila Quantitative Genomics"
- Gordon Research Conference on Aging, March 2003, Ventura, California. "The Genetic Architecture of Drosophila Lifespan"
- BRIDGES to the Future Program Directors meeting, June 2003, Lake Tahoe, CA. "Skills for Scientists in the Post-Genome Era"
- XIX International Congress of Genetics, July 2003, Melbourne, Australia. "The Genetic Architecture of Complex Traits: Lessons From Drosophila". (Also co-organizer, Symposium on Genetics of Complex Traits)
- Keystone Symposium on Natural Variation and Quantitative Genetics, January, 2004. Breckenridge, Colorado. "Molecular Quantitative Genetics of Drosophila Life Span"
- Gordon Research Conference on Behavioral Genetics, February, 2004, Ventura, California. "Genetic Architecture of Drosophila Behavior"
- 54<sup>th</sup> Annual Meeting, American Society of Human Genetics, October, 2004, Toronto, Canada. "Genotype-environment interaction: Lessons From a Model Organism"
- National Academy of Sciences Colloquium on Systematics and the Origin of Species, on Ernst Mayr's 100<sup>th</sup> Anniversary, December, 2004, Irvine, California. "Genetics and Genomics of Drosophila Mating Behavior"
- UK Genetics Society Meeting on Behavioural Genetics: Has Nature Won?, January, 2005, Edinburgh, Scotland. "Quantitative Genetics and Genomics of *Drosophila* Behaviour"
- 34<sup>th</sup> Annual Meeting, American Aging Association, June 2005, San Francisco, California. "Analysis of Gene Expression in *Drosophila*"
- International Behaviour and Neural Genetics Society, June, 2005, Sitges, Spain. "Genetics of Locomotor Behavior in *Drosophila*"
- Gordon Research Conference on Evolutionary and Functional Genomics, August, 2005, Oxford, England. "The genetic architecture of quantitative traits: Lessons from *Drosophila*"
- Evolution and Development: From Molecules to Morphology, Max Planck Institute for Developmental Biology, Tubingen, Germany, September, 2005. "Development and the genetic architecture of quantitative traits: Lessons from *Drosophila*"
- Ecological Genomics Symposium, November, 2005, Kansas. "The genetic architecture of quantitative traits: Lessons from *Drosophila*"

GSA Symposium, Genetic Analysis: From Model Organisms to Human Biology, January, 2006, San Diego. "Drosophila as a model system for understanding the genetic architecture of complex traits"

Keystone Symposium, Genome Sequence Variation and the Inherited Basis of Common Disease and Complex Traits", January, 2006, Big Sky. "Quantitative trait variation in *Drosophila*"

Genetical Society of Canada Symposium, Genetics and Genomics of Complex Phenotypes, June, 2006, London, Ontario, Canada. "The genetic architecture of quantitative traits: Lessons from *Drosophila*"

The Society for the Study of Evolution Symposium, Evolution of Behavior, June, 2006, Stony Brook, New York. "The genetic architecture of *Drosophila* behavior"

NIGMS Workshop on Systems Genetics and Complex Phenotypes, September 2006, Bethesda, Maryland Lausanne Genomics Days Symposium, October, 2006, Lausanne, Switzerland. "Quantitative Genomics and the Genetic Architecture of Complex Traits: Lessons from *Drosophila*"

NIH NHLBI Systems Medicine Workshop, January 2007, Bethesda, Maryland. "The genetic architecture of quantitative traits: Lessons from *Drosophila*"

Workshop on "Integrating the Study of Genotype and Phenotype", February, 2007, Florida State University.

"The genetic architecture of quantitative traits: Lessons from *Drosophila*"

Gordon Research Conference on Quantitative Genetics and Genomics, February, 2007, Ventura, CA. "The genetic architecture of behavior: Lessons from *Drosophila*"

American Association for Cancer Research, April, 2007, Los Angeles, CA. "The genetic architecture of complex traits: Lessons from *Drosophila*"

NESCent Catalysis meeting, Evolution in Contemporary Human Populations: Medical, Genetic and Behavioral Implications, Durham, NC, May, 2007

NSF Workshop on Motor Pattern Evolution, June 2007, Arlington, VA

Society for Molecular Biology and Evolution, Plenary Speaker, June 2007, Halifax, NS, Canada. "The genetic architecture of complex traits: Lessons from *Drosophila*"

3<sup>rd</sup> International Conference on Quantitative Genetics, August 2007, Hangzhou, China. "The genetic architecture of complex behaviors: Lessons from *Drosophila*"

GSA Model Organisms Meeting, January 2008, San Diego, CA

Keystone Symposium on Complex Traits: Biologic and Therapeutic Insights (co-organizer and speaker), February 2008, Santa Fe, NM

XX International Congress of Genetics, July 2008, Berlin, Germany (International Organizing Committee) Duke Systems Biology Institute Annual Symposium, October 2008, Durham, NC

4<sup>th</sup> Annual Symposium of the University of Florida Genetics Institute, October 2008, Gainesville, FL

Biology of Genomes, May 2009, Cold Spring Harbor Laboratory, Cold Spring Harbor, NY

Canadian Genetic Epidemiology and Statistical Genetics Meeting, May, 2009, Harrison Hot Springs, BC Canada American Genetic Association Annual Symposium, June 2009, Providence, RI

American Society of Naturalists Vice Presidential Symposium, June, 2009, Moscow, ID

Gordon Research Conference on Chronobiology, July 2009, Salve Regina University, Newport, RI

Lecturer on Genetic and Molecular Analysis of Complex Traits, Advanced Course in Drosophila Genetics and Genomics, Wellcome Trust Genome Centre, Hinxton, UK

Keynote speaker, Genomics of Common Diseases, September 2009, Wellcome Trust Genome Centre, Hinxton, UK

Speaker, Entomological Society of America, 2009 meeting, Celebrating the Role of Entomology in the Genomics Revolution Symposium, Indianapolis, IN, December 2009

Gordon Research Conference on Genes and Behavior, Ventura, CA, March 2010

Complex Trait Consortium, Chicago II, May 2010

Society for the Study of Evolution, 2010 meeting, Towards a Theory of Evolutionary Prediction Symposium, Portland, OR, June 2010

9<sup>th</sup> World Congress in Genetics Applied to Animal Production, Plenary Speaker, Leipzig, Germany, August 2010

Academia Belgica, Deciphering the Molecular Architecture of Complex Traits, Rome, Italy, September 2010

Centre Intégratif de Génomique, Genetics of Behavior, Lausanne, Switzerland, June 2011

Research Triangle Statistical Genetics Conference, Raleigh, NC, October 2011

Drosophila Research Conference, Plenary Speaker, Chicago, IL, March 2012

NIEHS Symposium, Emerging Issues in Analysis and Design of Large Scale Genetic Studies, invited speaker, Research Triangle Park, NC, May 2012

4<sup>th</sup> International Conference on Quantitative Genetics, Invited Speaker, Edinburgh, Scotland, June 2012 Workshop on Behavioral Genetics, Guilford, Surrey, December 2012

NSPR-8 Workshop, Plenary Lecturer, Plant and Animal Genome XXI, San Diego, CA, January 2013

Gordon Research Seminar in Quantitative Genetics and Genomics, Plenary Lecturer, Galveston, TX, February 2013

Drosophila Research Conference, Genomic Workshop speaker, Washington, DC, April 2013

European Society for Evolutionary Biology, Plenary Lecturer, Lisbon, Portugal, August 2013

3<sup>rd</sup> Latin American School of Evolution, Lecturer, Buenos Aires, Argentina, November 2013

Plant and Animal Genome XXII, Plenary Lecturer, San Diego, CA, January 2014

Epistasis Detection in Genetics and Epidemiology, Plenary lecture, Key West, FL, February 2014

Drosophila Research Conference, Plenary Lecturer and workshop speaker, San Diego, CA, March 2014

Systems Genetics of Model (non-Human) Organisms, Invited speaker, Locarno, Switzerland, May 2014

Third Summer Course in Environmental Genomics, Mount Desert Island Biological Lab, Bar Harbor, Maine, August 2014

RTP Illumina User Group Meeting, Research Triangle Park, NC, October 2014

EMBO conference on Experimental Approaches to Evolution and Ecology, Heidelberg, Germany, October 2014

Epistasis Detection in Genetics and Epidemiology, Plenary lecture, Key West, FL, February 2015

Genetics and Environmental Mutagenesis Society Spring Meeting, Plenary Lecturer, Research Triangle Park, NC, April 2015

EMBO Meeting 2015, Invited Speaker, Birmingham, England, September 2015

European Drosophila Research Conference 2015, Plenary Speaker, Heidelberg, Germany, September 2015

Epistasis Detection in Genetics and Epidemiology, Plenary lecture, Key West, FL, February 2016

5<sup>th</sup> International Conference in Quantitative Genetics, Plenary Speaker, Madison, WI, June 2016

National Symposium on Bridging Genomics and Phenomics, Keynote Speaker, Beijing, China, August 2016

Max Planck Symposium on Complex Trait Genetics, Berlin, Germany, October 2016

Epistasis Detection in Genetics and Epidemiology, Plenary lecture, Key West, FL, February 2017

Alberta Children's Hospital Research institute, Plenary Lecture, Symposium on Precision Medicine and Child Health, Calgary AB, Canada, April 2017

# **INVITED SEMINARS**

Department of Genetics, University of Wisconsin, May 1998

Department of Biology, University of Alabama, November 1998

Department of Embryology, Carnegie Institute, December 1998

Department of Biology, Pennsylvania State University, March 1999

Department of Genetics, University of Georgia, April 1999

Department of Evolution and Ecology, University of California, Irvine, May 1999

Department of Biology, University of Nebraska, September 1999

Department of Biology, University of Toronto at Mississauga, November 1999

Department of Ecology and Evolution, University of California, Davis, April 2000

Department of Biology, The Ohio State University, May 2000

Department of Zoology, University of Florida, Gainesville, September 2000

Department of Molecular and Human Genetics, Baylor College of Medicine, September 2000

Department of Botany, University of Knoxville, November 2000. "Genomics, Present and Future" seminar series

Department of Biology, University of Greensboro, November 2000

Department of Biology, University of Rochester, December 2000

Department of Zoology, North Carolina State University, September 2001

Department of Genetics, Duke University, February 2002

University of North Carolina, Chapel Hill, Carolina Consortium on Human Development, February 2002

Department of Biology, Washington University, St. Louis, March 2002

Department of Biology, Brown University, April 2002

Department of Biology, Michigan State University, April 2002

Department of Biology, Indiana University, September 2002

Department of Biology, Morehouse College, November 2002

Pioneer Hybrid International, January 2003

Department of Human Genetics, University of Chicago, October 2003

Department of Ecology and Evolution, University of Chicago, March 2004

Genomics Training Program Seminar Series, University of Michigan, April 2004

Department of Biology, University of Maryland, May 2004

Samuel Lunenfeld Research Institute, Mt. Sinai Hospital, Toronto, Canada, September 2004

Department of Genetics, Washington University in St. Louis, School of Medicine, November 2004

Department of Biology, University of Maryland Baltimore County, December 2004

Department of Ecology and Evolution, Harvard University, March 2005

Department of Biology, University of North Carolina, Chapel Hill, March 2005

Laboratory of Developmental Genetics, University of Leuven, Belgium, May 2005

Department of Molecular Genetics, University of Antwerp, Belgium, May 2005

Department of Human Genetics, University of Michigan, September 2006

Department of Ecology and Evolution, University of Buenos Aires, November 2006

Department of Biology, Indiana University, January 2007

Center for Quantitative and Computational Biology, Columbus Children's Research Institute, Columbus, Ohio, April 2007

Department of Genetics, University of Wisconsin, October 2007

Institute for Genomic Biology, University of Illinois, November 2007

Cold Spring Harbor Laboratory, Watson Genetics Course, December 2007

Cold Spring Harbor Laboratory, Integrative Statistical Analysis of Genome Scale Data Summer Course, June 2008

Department of Integrative Biology, University of Texas, Austin, TX, September 2008

Baylor College of Medicine Sequencing Center, November 2008, Houston TX

Carolina Center for Genome Sciences, University of North Carolina, Chapel Hill, NC, February 2009

Department of Genome Sciences, University of Washington, Seattle, WA, March 2009

Department of Human Genetics, University of Chicago, Chicago IL, April 2009,

Department of Human Genetics, University of Utah, Salt Lake City, UT, May 2009

Department of Genetics, University of Cambridge, Cambridge, UK, September 2009

Institute of Molecular Biology, University of Zurich, Zurich, Switzerland, September 2009

Huck Distinguished Lecturer, Pennsylvania State University, College Park, PA, November 2009

University of Texas Southwestern Medical School, Dallas, TX, November 2009

Higgins Distinguished Lecture, University of Kentucky, Lexington, KY, Department of Biology, December 2009

University of Arizona Medical School, Tucson, AZ, April 2010

Bauer Center for Systems Biology, Harvard University, Boston, MA, May 2010

Center for Ecology and Evolutionary Biology, University of Oregon, Eugene, OR, October 2010

University of Rochester, Department of Biology, Rochester, NY, March 2011

NIEHS Laboratory of Molecular Genetics, Durham, NC, March 2011

University of Idaho Initiative for Bioinformatics and Evolutionary Studies (IBEST) invited speaker, Moscow, ID, March 2011

Cornell University, Cornell Center for Comparative and Population Genomics (3CPG) invited speaker, Ithaca, NY, April 2011

University of Wisconsin, Department of Animal Science, A. B. Chapman Lectures, Madison, WI, April 2011

Department of Human Genetics, University of California, San Diego, CA, September 2011

Department of Human Genetics, University of Michigan, Ann Arbor, MI, November 2011

Wellcome Trust Center for Human Genetics, Oxford, UK, March, 2012

Center for Systems Genetics, University of North Carolina Chapel Hill, Chapel Hill NC, June 2012

Center for Public Health Genomics, University of Virginia, Charlottesville, VA September, 2012

Department of Genetics, University of Cambridge, Cambridge, UK, October 2012

Department of Genetics, University of Georgia, Athens, GA, March 2013

Center for Integrated Animal Genomics, Iowa State University, March 2013

Duke University Program in Genetics and Genomics, Durham NC, October 2013

Monsanto Biotechnology seminar, March 2014

NIEHS Laboratory of Toxicology and Pharmacology, April 2014

Department of Genetics and Department of Cell and Developmental Biology, University of Pennsylvania, Philadelphia PA, April 2014

Institute of Clinical Research of Montreal (IRCM), Montreal, Canada, June 2014

Jackson Laboratories, Bar Harbor, Maine, August 2014

Department of Ecology and Evolution, University of Lund, Sweden, September, 2014

Department of Biology, University of Birmingham, Alabama, November, 2014

Lieber Institute for Brain Development, Baltimore, Maryland, March, 2015

John A. Lynch Lecture, College of Science, University of Notre Dame, Notre Dame Indiana, October, 2015

Department of Biochemistry and Genetics, Clemson University, Clemson SC, October 2015

Volcani Center, Agricultural Research Organization, Bet Dagan, Israel, May 2016

Robert H. Smith Faculty of Agriculture, Food and Environment, Hebrew University of Jerusalem, Rehovot, Israel, June 2016

Departments of Animal Science, Genetics and Ecology and Evolution, Iowa State University, Ames IA, August 2016

Program in Genetics, Texas A&M University, College Station TX, October 2016

Kjeldgaard Lecture, Department of Molecular Biology and Genetics, University of Aarhus, Aarhus, Denmark, November 2016

Osher Lifelong Learning Institute, NC State University, Raleigh NC, November 2016

Department of Genetics and Biochemistry, Clemson University, Clemson SC, March 2017

Buck Institute for Aging Research, Novato CA, April 2017

#### **PROFESSIONAL SERVICE**

### **NATIONAL / INTERNATIONAL SERVICE**

Consulting Editor, *PLoS Genetics* (2005-present) Editorial Board, *Genome Research* (2010-present) Editor, *PNAS* (2010-present) Editorial Board, Genes, Brain, Behavior (2012-present)

Editorial Board, OpenBiology (2012-present)

Editorial Board, Axios Reviews (2013-present)

Executive Editor, American office, Genetical Research (1987-2007)

Executive Editor, American office, Genetics Research (2008-2009)

Chief Executive Editor, Genetics Research (2009-2012)

Associate Editor, Genetics (1991-2002)

Associate Editor, Evolution (1990-1992)

Committee member, Genetical Society (GB). Biometrical and Statistical Genetics Representative, 1985-1988 ad hoc reviewer, National Institutes of Health Genetics Study Section, February 1990, June 1991, November 1993

National Science Foundation, Population Biology Review Panel, October 1992

Panel member, National Institutes of Health Genetics Study Section, 1995-1999

Participant, National Research Council - National Academy of Sciences Expert Meeting on the Biodemography of Ageing, 1995

Board of Directors, Genetics Society of America, 1999-2001

Council Member, American Genetic Association, 1999-2001

External Review Team, Texas A&M Genetics Program, March, 1999

National Institutes of Health Special Study Section, April 2000

National Institutes of Health, Center for Scientific Review, Genetics IRG Working Group, September-December, 2000

External Advisory Board, "Genetics of Age-Sensitive Traits in Mice" Program Project, The Geriatrics Center, University of Michigan, January 2001

National Institutes of Health, Center for Scientific Review, Genetics Study Sections Boundaries Team, November 2002

National Institutes of Health, Special Study Section, Pre-doctoral fellowships for minority students and students with disabilities, June 2003

Board of Scientific Counselors, National Center for Biotechnology Information, National Library of Medicine, 2003-2008

dbGaP Working Group, NCBI, 2007-2009

Drosophila Board, 2005-2010

President, Drosophila Board, 2006-2007

Treasurer, Genetics Society of America, 2006-2010

Council member, American Genetic Association, 2007-2010

President, American Genetic Association, 2008-2009

National Advisory Council, Stanford University School of Medicine, 2009-2012

Scientific Advisory Board, Max Planck Institute for Developmental Genetics, Tubingen, Germany, 2009-2017 (Chair, 2015-2018)

Scientific Advisory Board, Center for Genome Dynamics, The Jackson Laboratory, Bar Harbor, Maine, 2009-2016

Scientific Advisory Board, FlyBase (2010-present)

Chair-Elect (2009), Chair (2010) and Past-Chair (2011), American Association for the Advancement of Science Section G (Biological Sciences) Steering Committee

Member, Royal Society Sectional Committee 9, 2009-2012

National Institutes of Health Special Study Section, Transdisciplinary Cancer Genomics Research: Post-Genome Wide Association Initiative, October 2009

Board of Regents, National Library of Medicine, 2011-2015 (Chair, 2014-2015)

Rosalind Franklin Award selection committee, 2012, 2015

Board of Electors, Balfour Chair of Genetics, University of Cambridge, Cambridge, UK, 2012

External Review Panel, Genomics, Genetics and Bioinformatics Program, University of California, Riverside CA, 2012

National Academy of Sciences, Class Membership Committee, 2013, 2014

National Academy of Sciences, Council Nominating Committee, 2013, 2014

National Academy of Sciences, John J. Carty Award selection committee, 2013

Member, Duke University Program in Genetics External Review Team, March 2013

Member, Advisory committee to the NIH Director, Working Group on the National Library of Medicine (NLM), 2015

Member, Search committee for Director of the National Library of Medicine (NLM), 2015

Royal Society Newton Advanced Fellowship Committee, 2015-2018

Scientific Advisory Board, Leiber Brain Institute, Baltimore MD, 2016-2018

Scientific Advisory Board, CEXS-UPF, Barcelona, Spain, 2016-2018

#### **UNIVERSITY SERVICE**

Member, CALS Structure and Function Subpanel, Strategic Planning Committee, 1993-1994

Member, Search Committee for Department of Statistics Head, 1993-1994

Co-Chair, Department of Genetics Seminar Committee, 1993-1994; 2000-2001

Member, Department of Genetics Admissions Committee, 1988-1993

Department of Genetics Admissions Committee, 1994 to present

Library Representative, Department of Genetics, 1991-1997

Member, Search Committee for Department of Genetics Molecular Evolution Position, 1994-1995

Chair, Search Committee for Department of Genetics Experimental Quantitative Geneticist, 1996-1997

Member, Search Committee for Biomathematics faculty position, 1996-1997

Member, University Research Committee, 1998-2000

Keller Awards Committee, 1998-2002 (Chair, 2001)

William Neal Reynolds Professor Nomination Committee, 2001

Alumni Distinguished Research Award Committee, 2001

Member, Dean's Faculty Advisory Group, 2002-2004

Member, Search Committee for Genetics Department Head, 2008

Member, Genetic Pest Management Search Committee, 2008

Member, Search Committee for Department of Genetics Assistant Professors, 2008-2009

Faculty Committee on Honorary Degrees, 2007-2009

University Promotion and Tenure Committee, 2008-2010

UNC Tomorrow Faculty Team, 2008

Member, NC State University Research Misconduct Investigating Committee, 2008-2009

Member, Provost Search Committee, 2010

Member, Statistics Department Head Search Committee, 2010

Co-Chair (with Daniel Solomon, PAMS Dean), Strategic Planning Task Force on "Faculty Excellence", 2010-2011

Member, NCSU Science Task Force, 2011

Member, Faculty Advisory Committee to the UNC Strategic Directions Initiative, 2012-2013

Chair, Department Head of Biological Sciences Search Committee, 2013-2014

Executive Committee, W. M. Keck Center for Behavioral Biology (2009-present)

Professors of Distinction Review Committee, 2012-present

Director, University-wide Program in Genetics, 2014-present

Director of Graduate Studies, Genetics Graduate Program, 2016-present

Associate Director, Comparative Medicine Institute and Director, Translational Genetics and Genomics Research Group, 2015-present

Member, College of Sciences RPT committee, 2015-present

Outstanding Graduate Faculty Mentor Award Committee, 2015-2016

Member, eRA (electronic research administration) Steering Team, 2016-2017

Member, Research Leadership Academy Task Force, 2016-2019

O. Max Gardner Award Administrative Advisory Committee, 2016-2017

#### **GRADUATE STUDENTS**

#### THESIS SUPERVISOR AND COMMITTEE CHAIR

Pauline D. Ellis, M.Sc., 1985. Department of Genetics, University of Edinburgh

Nicola Wadham, M.Sc., 1986. Department of Genetics, University of Edinburgh

Patricia M. Pignatelli, M.Phil., 1988. Department of Genetics, University of Edinburgh

Chaoqiang Lai, Ph.D., 1990. Department of Genetics, University of Edinburgh. Current position: Scientist, USDA, Tufts University

- Robert McMahon, Ph.D., 1992. Department of Genetics, University of Edinburgh. Current position: Senior researcher, Department of Pathology, University of Cambridge, England
- Wyatt Mangum, Ph.D. 1995. Department of Genetics, North Carolina State University. Current position: self-employed
- Marjorie Gurganus, Ph.D. 1997. Department of Genetics, North Carolina State University. Current position: Patent lawyer
- Grażyna Fedorowicz, M.S. 2000. Department of Genetics, North Carolina State University. Current position: Research associate, Genentech
- Christy Dilda, Ph.D. 2002. Department of Genetics, North Carolina State University. Current position: Postdoctoral research associate, University of Florida, Gainesville
- Indrani Ganguly, Ph.D. 2003. Department of Genetics, North Carolina State University. Current position: Selfemployed
- Gretchen Geiger-Thornsberry, Ph.D. 2003. Department of Genetics, North Carolina State University. Current position: Assistant Professor, Department of Biological Sciences, Northwest Missouri State University, Maryville, Missouri
- Susan Harbison, Ph.D. 2003. Department of Genetics, North Carolina State University. Current position: Earl Stadtman Investigator, NHLBI, NIH
- Amanda Moehring, Ph.D. 2003. Department of Genetics, North Carolina State University. Current position: Assistant Professor and Canada Research Chair II, Department of Biology, University of Western Ontario, Canada.
- David Shuford, M.S. 2004. Department of Genetics, North Carolina State University
- Rhonda Wilson, Ph.D. 2005. Department of Genetics, North Carolina State University. Current position: Self-employed
- Michael Magwire, Ph.D. 2007. Department of Genetics, North Carolina State University. Current position: Quantitative Geneticist, Syngenta, Research Triangle Park, NC
- Katherine Jordan, Ph.D. 2006. Department of Genetics, North Carolina State University. Current position: Postdoctoral Research associate, Department of Plant Pathology, Kansas State University
- Alexis Edwards, Ph.D. 2008. Department of Genetics, North Carolina State University
  - Current Position: Assistant Professor, Department of Psychiatry, Virginia Commonwealth University
- Reba Royster, Master of Genetics, 2007. Department of Genetics, North Carolina State University. Current Position: President, Reaching Your Goals Raleigh, NC

- Julien Ayroles, Ph.D. 2010. Current position: Assistant Professor, Department of Ecology and Evolution and the Lewis-Sigler Institute for Integrative Genomics, Princeton University
- Kultaran Chohan, Ph.D. 2012. Department of Genetics, North Carolina State University. Current Position: Patent Attorney, North Carolina State University
- Lauren Dembeck, Ph.D. 2015. Program in Genetics, North Carolina State University. Current Position:
  Postdoctoral Fellow, Ecology and Evolution Unit, Okinawa Institute of Science and Technology
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#### POSTDOCTORAL RESEARCH ASSOCIATES

- Anthony E. Shrimpton, Department of Genetics, University of Edinburgh, 1985-1988. (Co-director of research, with A. J. Leigh Brown). Current position: Senior Scientist, Western General Hospital, Edinburgh, UK
- Michael S. Jackson, Department of Genetics, North Carolina State University, 1988-1990. Current position: Royal Society Fellow, Department of Genetics, University of Newcastle
- Richard F. Lyman, Department of Genetics, North Carolina State University, 1988-1994. Current position: Senior Researcher, Department of Genetics, North Carolina State University
- Chaoqiang Lai, Department of Genetics, North Carolina State University, 1990-1991. Current position: Scientist, USDA, Tufts University
- James D. Fry, Department of Genetics, North Carolina State University, 1992-1994. Current position: Associate Professor, Department of Biology, University of Rochester
- Sergey V. Nuzhdin, Department of Genetics, North Carolina State University, 1993-1997. Current position: Professor, University of Southern California
- Elena Pasyukova, Department of Genetics, North Carolina State University and Institute of Molecular Genetics, Moscow, Russia. 1995. Current Position: Head, Laboratory of Genomic Variation, Institute of Molecular Genetics of the Russian Academy of Sciences, Moscow, Russia
- Marta L. Wayne, Department of Genetics, North Carolina State University, 1994-1999. Current position: Professor, Department of Zoology, University of Florida, Gainesville
- Cristina Vieira, Department of Genetics, North Carolina State University, 1998. Current position: Assistant Professor, Department of Biology, University of Lyon, France
- Jeff W. Leips, Department of Genetics, North Carolina State University, 1997-2001. Current position: Professor, Department of Biology, University of Maryland, Baltimore
- Maria DeLuca, Department of Genetics, North Carolina State University, 1999-2000; 2002. Current position: Research Assistant Professor, School of Public Health, University of Alabama at Birmingham
- Andrew Simons, Department of Genetics, North Carolina State University, 1999-2000. Current position: Associate Professor, Department of Biology, Carlton University, Ottawa, Canada
- Juan José Fanara, Department of Genetics, North Carolina State University, 1999-2002. Current position:
  Associate Professor, Department of Ecology, Genetics and Evolution, Ciudad Universitaria Pab II,
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- Amanda Moehring, Department of Genetics, North Carolina State University, 2003-2004. Current position:
  Assistant Professor and Canada Research Chair II, Department of Biology, Western University, Ontario,
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- Theodore Morgan, Department of Genetics, North Carolina State University, 2002-2006. Current position: Associate Professor, Department of Biology, Kansas State University
- Stephanie Rollmann, Department of Zoology, North Carolina State University, 2000-2006. Current position: Associate Professor, Department of Biological Sciences, University of Cincinnati
- Mary Anna Carbone, Department of Genetics, North Carolina State University, 2002-2006. Current position: Research Assistant Professor, Department of Biological Sciences, NC State University
- Harland Patch, Department of Genetics, North Carolina State University, 2005- 2008. Current position: Researcher, Department of Entomology, Pennsylvania State University
- Charlene Couch, Department of Genetics, North Carolina State University, 2006- 2011. Current Position: Selfemployed
- Elizabeth Ruedi, Department of Genetics, North Carolina State University, 2007-2010. Current Position: Education Coodinator, Genetics Society of America.
- Julien Ayroles, Department of Genetics, North Carolina State University, 2010. Current Position: Assistant Professor, Department of Ecology and Evolution and the Lewis-Sigler Institute for Integrative Genomics, Princeton University
- Katherine Jordan, Department of Genetics, North Carolina State University, 2006-2012. Current Position: Postdoctoral Researcher, Department of Plant Pathology, Kansas State University
- Susan Harbison, Department of Genetics, North Carolina State University, 2007-2011. Current position: Earl Stadtman Investigator, NHLBI, NIH
- Allison Weber, Department of Genetics, North Carolina State University, 2008-2012. Current Position: Quantitative Geneticist, Monsanto, ST. Louis, MO
- Brittny Calsbeek, Department of Genetics, North Carolina State University, 2010-2012. Current Position: Lecturer, Department of Biology, Dartmouth College.
- Michael Magwire, Department of Genetics, North Carolina State University, 2010-2013. Current Position: Quantitative Geneticist, Syngenta, Research Triangle Park, NC.
- Bryn Gaertner, Department of Genetics, North Carolina State University, 2012-2013. Current position: Postdoctoral fellow, Department of Molecular Biosciences, Northwestern University
- Jason Peiffer, Department of Biological Sciences, North Carolina State University, 2012-2014. Current position, Data Analyst, Pioneer Hybrid International
- Megan Carnes, Department of Biological Sciences, North Carolina State University, 2014-2015. Current Position: Postdoctoral Fellow, NIEHS
- Terry Campbell, Department of Biological Sciences, North Carolina University, 2009-2015. Current Position: unemployed.
- Shanshan Zhou, Department of Biological Sciences, North Carolina State University IBC postdoctoral fellow, 2011-present
- Wen Huang, Department of Biological Sciences, North Carolina State University IBC postdoctoral fellow, 2011present
- Logan Everett, Department of Biological Sciences, North Carolina State University IBC postdoctoral fellow, 2014-present
- Chad Highfill, Department of Biological Sciences, North Carolina State University, 2016-present

#### **TEACHING EXPERIENCE**

UNIVERSITY OF EDINBURGH (1980-1987)

**Genetics 3A** (third year undergraduate general genetics); 8 lectures in population and quantitative genetics; molecular evolution.

**Genetics 3B** (third year undergraduate). Advanced course in evolutionary genetics; 50 hours of lectures and 40 hours of practicals/tutorials. Lecture topics covered population genetics, quantitative genetics, evolutionary theory (including molecular evolution), and statistics. The practicals were designed to give experience in problem solving and statistical analysis, as well as the execution of a small research project studying evolution in Drosophila populations.

**Genetics 4h** (genetics honours undergraduates). 12 lectures in population and quantitative genetics. **Diploma/M.Sc in Animal Breeding** (postgraduate course). 12 lectures in population and quantitative genetics, plus tutorials.

#### NORTH CAROLINA STATE UNIVERSITY (1987 - PRESENT)

**Genetics 703** Population and Quantitative Genetics; 3 credit hours, 45 lecture hours. 1988-2008.

**Genetics 641** Graduate colloquium in genetics; 2 credit hours, 30 lecture hours. Spring 1990. "Mapping Quantitative Trait Loci"; co-taught with C. Stuber and B. S. Weir.

**Genetics 810P** Graduate colloquium in genetics; 2 credit hours, 30 lecture hours. Fall 1999. "Genetics of Speciation"; co-taught with M. Purugganan.

**Summer Institute in Statistical Genetics**, Quantitative Genetics Module, 1996-2005; Behavior Genetics Module, 2004-2005.

Genetics 810-001 Evolutionary Genomics Journal Club. Offered yearly Fall semester.

**Genetics 820D** Professional development course, 2005, 2007, 2010, 2012, 2014, 2016; co-taught with R. R. H. Anholt.

Genetics 810-002 Behavioral Genetics, 2008, 2010; co-taught with R. R. H. Anholt.

#### **PUBLICATION BIBLIOGRAPHY**

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- 2. Mackay, T. F. C. & Doyle, R. W. 1978. An ecological genetic analysis of the settling behaviour of a marine polychaete. I. Probability of settlement and gregarious behaviour. Heredity 40: 1-12.
- 3. Mackay, T. F. C. 1980. Genetic variance, fitness, and homeostasis in varying environments: An experimental check of the theory. Evolution 34: 1219-1222.
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- 11. Bjorklund, T., Engstrom, G., Mackay, T. F. C. & Liljedahl, L. E. 1988. Search for age-dependent as compared to mutagen-induced mutations on the *X* chromosome affecting viability in *Drosophila melanogaster* males. Gén. Sél. Evol. 20: 409-416.
- 12. Pignatelli, P. M. & Mackay, T. F. C. 1989. Hybrid dysgenesis-induced response to selection in *Drosophila melanogaster*. Genet. Res. 54: 183-195.
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- 14. Mackay, T. F. C. & Langley, C. H. 1990. Molecular and phenotypic variation in the *achaete-scute* region of *Drosophila melanogaster*. Nature 348: 64-66.
- 15. Shrimpton, A. E., Mackay, T. F. C. & Leigh Brown, A. J. 1990. Transposable element-induced response to artificial selection in *Drosophila melanogaster*: Molecular analysis of selection lines. Genetics 125: 803-811. PMCID: PMC1204106
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### Invited Papers (Conference proceedings, reviews, Commentaries)

- 1. Mackay, T. F. C. 1984. Jumping genes and quantitative variation. In *Proceedings of the 26th British Poultry Breeders Roundtable*.
- 2. Mackay, T. F. C. 1986. Transposable elements in genetic selection. pp. 113-121 in *Exploiting New Technologies in Animal Breeding: Genetic Developments*. Edited by C. Smith, J. W. B. King and J. C.

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- 3. Mackay, T. F. C. 1987. Speciation: Finding pieces of the puzzle. Nature 327: 279-280.
- 4. Mackay, T. F. C. 1988. Transposable element-induced quantitative genetic variation in *Drosophila*. pp. 219-235 in *Proceedings of the 2nd International Conference on Quantitative Genetics*. Edited by B. S. Weir, E. J. Eisen, M. M. Goodman and G. Namkoong. Sinauer, Sunderland, Mass.
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- 7. Mackay, T. F. C. 1990. Alan Robertson (1920-1989). Genetics 125: 1-7.
- 8. Mackay, T. F. C. 1990. Distribution of effects of new mutations affecting quantitative traits. pp. 219-227 in *Proceedings of the 4th World Congress on Genetics Applied to Livestock Production*. Edited by W. G. Hill, R. Thompson and J. A. Woolliams. Organizing Committee, 4th World Congress on Genetics Applied to Livestock Production, Edinburgh.
- 9. Lai, C. & Mackay, T. F. C. 1990. Mapping and characterization of *P* element-induced polygenic mutations in *Drosophila melanogaster*. pp. 349-352 in *Proceedings of the 4th World Congress on Genetics Applied to Livestock Production*. Edited by W. G. Hill, R. Thompson and J. A. Woolliams. Organizing Committee, 4th World Congress on Genetics Applied to Livestock Production, Edinburgh.
- 10. Mackay, T. F. C. 1998. The nature of quantitative variation: Lessons from Drosophila. *Proceedings of the 6th World Congress on Genetics Applied to Livestock Production*.
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- 14. Hill, W. G. & Mackay, T. F. C. 2004. Douglas Falconer. Genetics 167: 1529-1536.
- 15. Mackay, T. F. C. 2004. The genetic architecture of quantitative traits: lessons from Drosophila. Curr. Opin. Genet. Dev. 14: 253-257.
- 16. Mackay, T. F. C. 2004. Douglas Scott Falconer (1913-2004). Heredity 93: 119-121.
- 17. Mackay, T. F. C. 2004. Methods for genetic dissection of complex traits. Sci. Aging Knowl. Environ. 2004 (17), pe17. [DOI: 10.1126/sageke.2004.17.pe17]

- 18. Mackay, T. F. C. 2004. Complementing complexity. Nat. Genet. 36: 1145-1147.
- 19. Mackay, T. F. C. 2007. Wild populations are smaller than we think: a commentary on 'Effective population size/adult population size ratios in wildlife: a review' by Richard Frankham. Genet Res. 89: 489.
- 20. Mackay, T. F. C. 2007. What prevents transposable elements from taking over the genome? A commentary on 'A test for the role of natural selection in the stabilization of transposable element copy number in a population of *Drosophila melanogaster*' by Elizabeth Montgomery, Brian Charlesworth and Charles H. Langley. Genet Res. 89: 433-434.
- 21. Mackay, T. F. C. 2009. Q&A: Genetic analysis of quantitative traits. J. Biol. 8: 23.
- 22. Mackay, T. F. C. 2009. A-maize-ing diversity. Science 325: 688-689.
- 23. Mackay, T. F. C. & Moore, J. H. 2014. Why epistasis is important for tackling complex human disease genetics. Genome Med. 6: 42. PMCID: PMC4062066.
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## **BOOKS AND BOOK CHAPTERS**

- 1. Hill, W. G. & Mackay, T. F. C. 1989. *Evolution and Animal Breeding: Reviews on Molecular and Quantitative Approaches in Honour of Alan Robertson*. 313 pp. C. A. B. International, Wallingford.
- 2. Falconer, D. S. & Mackay, T. F. C. 1996. *Introduction to Quantitative Genetics*, 4/e. Addison Wesley Longman.
- 3. *Encyclopedia of Ecology and Environmental Management*. 1996. Contributor, quantitative genetics and transposable element entries. Blackwell Science, Oxford.
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- 6. Mackay, T. F. C., Roshina, N. V., Leips, J. W. & Pasyukova, E. G. 2006. Complex genetic architecture of Drosophila longevity. Pp. 181-216 in *Handbook of the Biology of Aging, Sixth Edition*, edited by E. J. Masaro and S. N. Austad.
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- 8. Anholt, R. R. H., Mackay, T. F. C. & Stone, E. A. 2014. Systems genetics of behavior in *Drosophila*. In

Handbook of Behavioral Genetics of Drosophila melanogaster, edited by J. Dubnau.

- 9. Mackay, T. F. C. 2015. Epistasis for quantitative traits in *Drosophila*. Methods Mol. Biol. 1253: 47-70.
- 10. Mackay, T. F. C. 2015. The nature of quantitative genetic variation. Encyclopedia of Evolutionary Biology.

From: Teresa Gold <t-gold@tamu.edu>

To: Zach Adelman

Date: 5/17/2017 11:24:13 AM

Subject: RE: Registering for the Syn Bio online forum

# Perfect! © Thank you.

From: Zachary Adelman [mailto:zachadel@tamu.edu]

Sent: Wednesday, May 17, 2017 11:24 AM

To: Teresa Gold <t-gold@tamu.edu>

Subject: Re: Registering for the Syn Bio online forum

yes, i have already heard from them.

On Wed, May 17, 2017 at 11:22 AM, Teresa Gold < t-gold@tamu.edu > wrote:

Welcome. They sent a confirmation email stating they would be in touch with you.

From: Zachary Adelman [mailto:zachadel@tamu.edu ]

**Sent:** Wednesday, May 17, 2017 11:21 AM **To:** Teresa Gold < <a href="mailto:t-gold@tamu.edu">t-gold@tamu.edu</a> >

Subject: Re: Registering for the Syn Bio online forum

thanks!

On Tue, May 16, 2017 at 10:11 AM, Teresa Gold < t-gold@tamu.edu > wrote:

Letter has been sent to synbio@ . I have copied you with that email. Let me know if you need anything else.

Thanks!

Teresa ©

From: Zachary Adelman [mailto:<u>zachadel@tamu.edu</u> ]

Sent: Tuesday, May 16, 2017 9:15 AM
To: David Ragsdale < dragsdale@tamu.edu >
Cc: Teresa Gold < t-gold@tamu.edu >

Subject: Fwd: Registering for the Syn Bio online forum

David

I am just following up to see if you had a chance to sign the draft letter and send along with the attached bio for the Convention on Biological Diversity's Synthetic Biology online forum.

thanks zach

----- Forwarded message -----

From: **Zachary Adelman** <<u>zachadel@tamu.edu</u> >

Date: Tue, Apr 18, 2017 at 8:36 AM

Subject: Re: Registering for the Syn Bio online forum

To: David Ragsdale < dragsdale @tamu.edu >

Thanks. Attached is a draft letter and bio. Please send them to synbio

On Mon, Apr 17, 2017 at 4:52 PM, David Ragsdale < dragsdale@tamu.edu > wrote:

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My policy for such items is to ask you to draft the letter, I'll modify it to put it in my voice and then sign it and send it back to you (or onto the agency). Please pull together a draft of the letter and send it to me.

## David

David W. Ragsdale Professor and Head Department of Entomology Texas A&M University

Phone: 979-845-2510

From: Zachary Adelman [mailto:<u>zachadel@tamu.edu</u> ]

Sent: Monday, April 17, 2017 2:25 PM

To: David Ragsdale

Subject: Fwd: Registering for the Syn Bio online forum

#### David

I have been nominated to participate as an expert in an online forum hosted by the Convention of Biological Diversity on the topic of gene drive. In order to register for the forum, they require a letter from you (see the form letter below). This is a good opportunity to engage with non-scientists on a topic of immense importance to my research program in a fairly political environment. Thanks in advance for your support.

zach

----- Forwarded message -----

From: Isabelle Coche

Date: Thu, Apr 13, 2017 at 4:58 AM

Subject: Registering for the Syn Bio online forum To: Zachary Adelman < <u>zachadel@tamu.edu</u> >

Cc: Stephanie James < sjames@ >, Benjamin Robinson <

## Dear Zach

See below a quick note on how to register for the online forum. Nominations are now being received so if you want to proceed that will ensure you are 'set' for the online forum over the summer. As I mentioned, I am talking to a few people over the next few weeks and we will then organise a briefing call with the people who volunteered to walk through the topics and give guidance on how to engage.

If you don't mind, would you let me know once you are registered? If you encounter any issues, do reach out also.

Best,

Isabelle

How to register for the CBD online forum?

Have your administrator or head of department send a letter or email of nomination to synbio

This version of Total Outlook Converter  $\ensuremath{\mathsf{Pro}}$  is not registered.

• Sample letter/email text:

To whom it may concern:

[Name of the organisation or institution] wishes to nominate [Prof/Dr/Mr/Ms] [full name, position, affiliation] to participate in the open-ended online forum on synthetic biology. [He/she] can be contacted at [email]. Please [find attached is a short biography OR see link to online profile].

Kind regards,

[name position contact information]

The letter or email **must come from an 'official' of your organisation or institution**. For example a department head or administrator, not from the individual being nominated.

Once the nomination is sent, the CBD secretariat will get in touch to ask for more information before the nominees are confirmed.

For more information: <a href="https://bch.cbd.int/synbio/nomination\_natl\_experts/">https://bch.cbd.int/synbio/nomination\_natl\_experts/</a>

From: Zachary Adelman <zachadel@tamu.edu>

To: Teresa Gold

Date: 5/17/2017 11:23:34 AM

Subject: Re: Registering for the Syn Bio online forum

yes, i have already heard from them.

On Wed, May 17, 2017 at 11:22 AM, Teresa Gold < t-gold@tamu.edu > wrote:

Welcome. They sent a confirmation email stating they would be in touch with you.

From: Zachary Adelman [mailto:<u>zachadel@tamu.edu</u> ]

**Sent:** Wednesday, May 17, 2017 11:21 AM **To:** Teresa Gold < t-gold@tamu.edu >

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Thanks!

Teresa ©

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Sent: Tuesday, May 16, 2017 9:15 AM

To: David Ragsdale < dragsdale@tamu.edu >

Cc: Teresa Gold < t-gold@tamu.edu >

Subject: Fwd: Registering for the Syn Bio online forum

David,

I am just following up to see if you had a chance to sign the draft letter and send along with the attached bio for the Convention on Biological Diversity's Synthetic Biology online forum.

thanks,

zach

Dear Zach

n	n of Total Outlook Converter Pro is not registered.	
	Forwarded message From: Zachary Adelman < <u>zachadel@tamu.edu</u> >  Date: Tue, Apr 18, 2017 at 8:36 AM  Subject: Re: Registering for the Syn Bio online forum  To: David Ragsdale < <u>dragsdale@tamu.edu</u> >	
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	David	
	David W. Ragsdale	
	Professor and Head	
	Department of Entomology	
	Texas A&M University	
	Phone: 979-845-2510	
	From: Zachary Adelman [mailto:zachadel@tamu.edu] Sent: Monday, April 17, 2017 2:25 PM To: David Ragsdale Subject: Fwd: Registering for the Syn Bio online forum	
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	zach	
	Forwarded message From: Isabelle Coche < > Date: Thu, Apr 13, 2017 at 4:58 AM Subject: Registering for the Syn Bio online forum	
	To: Zachary Adelman < <u>zachadel@tamu.edu</u> > Cc: Stephanie James >, Benjamin Robinson < >	
I	Ou. Otophanie danies , Denjaniin Nobinson >	

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pos	ition
con	tact information]

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From: Teresa Gold <t-gold@tamu.edu>

To: Zach Adelman

Date: 5/17/2017 11:22:30 AM

Subject: RE: Registering for the Syn Bio online forum

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From: Zachary Adelman <zachadel@tamu.edu>

To: Teresa Gold

Date: 5/17/2017 11:20:36 AM

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	David W. Ragsdale
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	Texas A&M University
	Phone: 979-845-2510
	From: Zachary Adelman [mailto: <u>zachadel@tamu.edu</u> ] Sent: Monday, April 17, 2017 2:25 PM To: David Ragsdale Subject: Fwd: Registering for the Syn Bio online forum
	David,
	I have been nominated to participate as an expert in an online forum hosted by the Convention of Biological Diversity on the topic of gene drive. In order to register for the forum, they require a letter from you (see the form letter below). This is a good opportunity to engage with non-scientists on a topic of immense importance to my research program in a fairly political environment. Thanks in advance for your support.
	zach
	Forwarded message From: Isabelle Coche Date: Thu, Apr 13, 2017 at 4:58 AM Subject: Registering for the Syn Bio online forum To: Zachary Adelman < <u>zachadel@tamu.edu</u> > Cc: Stephanie James < <u>s</u> >, Benjamin Robinson
	Dear Zach
	See below a quick note on how to register for the online forum. Nominations are now being received so if you want to proceed that will ensure you are 'set' for the online forum over the summer. As I mentioned, I am talking to a few people over the next few weeks and we will then organise a briefing call with the people who volunteered to walk through the topics and give guidance on how to engage.
	If you don't mind, would you let me know once you are registered? If you encounter any issues, do reach out also.
	Best,

ı	of Total Outlook Converter Pro is not registered.
	Isabelle
	How to register for the CBD online forum?
	Have your administrator or head of department send a letter or email of nomination to <a href="mailto:synbio">synbio</a> Sample letter/email text:
•	Sample letter/email text.
To	o whom it may concern:
th	Name of the organisation or institution] wishes to nominate [Prof/Dr/Mr/Ms] [full name, position, affiliation] to participally open-ended online forum on synthetic biology. [He/she] can be contacted at [email]. Please [find attached is a short ography OR see link to online profile].
Ki	ind regards,
[n	name
рс	osition
cc	ontact information]
	The letter or email must come from an 'official' of your organisation or institution. For example a depart head or administrator, not from the individual being nominated.
	Once the nomination is sent, the CBD secretariat will get in touch to ask for more information before the nominare confirmed.
	For more information: <a href="https://bch.cbd.int/synbio/\partial_2nomination_natl_experts/">https://bch.cbd.int/synbio/\partial_2nomination_natl_experts/</a>

From: Biosafety Clearing-House <bch@cbd.int>

To: Zach Adelman

Date: 5/17/2017 8:53:01 AM

Subject: Your CBD account profile has been updated



Your CBD account profile has been updated.

Dear Mr. Zach Adelman,

We are pleased to inform you that your Convention on Biological Diversity (CBD) user profile has been updated as follows:

Summary of your contact information:

Your registered email address is: zachadel@tamu.edu

Your government affiliation is: [not specified]

Mr. Zach Adelman Designation: Associate Professor Department: Entomology

Organization: Texas A&M University Address: 329A Heep Center College Station City:

State: Texas

Country: United States of America 77843

Zip:

Email CC:

19794583107 Phone:

The following role(s) has been added:

• Synbio forum – Organization

Your current role(s), which allow you to use sections with limited access, are:

• Synbio forum – Organization

You may update your profile at <a href="https://bch.cbd.int/user/profile.shtml">https://bch.cbd.int/user/profile.shtml</a> or access the system management centre at <a href="https://bch.cbd.int/user/profile.shtml">https://bch.cbd.int/user/profile.shtml</a> <u>bch.cbd.int/managementcentre/</u> by signing in with your registered email address and password.

If you have forgotten your password you may request a new one at <a href="http://bch.cbd.int/user/passwordreset.shtml">http://bch.cbd.int/user/passwordreset.shtml</a> .

This message is being sent to you automatically by the CBD system after your national nomination or because one or more changes were made in your registered profile.

If you have any questions about the content of this message please contact the CBD Secretariat at: bch@cbd.int

Secretariat of the Convention on Biological Diversity www.cbd.int



22 May 2017-International Day for Biological Diversity: Biodiversity and Sustainable Tourism

From: Biosafety Clearing-House <bch@cbd.int>

To: Zach Adelman

Date: 5/17/2017 8:45:56 AM

Subject: Status of BCH Record (Request #640103)

Dear Mr. Zach Adelman,

This is an automated message generated by the Biosafety Clearing-House (BCH) to notify you regarding the status of the following record.

Record summary:

Common format: Expert on Synthetic Biology

Record title: Mr. Zach Adelman

Record number: 111911

Status of the record: The request to validate a new record has been approved and

the record has been published

# This information is also available on the BCH at <a href="http://bch.cbd.int/managementcentre/">http://bch.cbd.int/managementcentre/</a>.

To access this page you will be requested to sign-in with your BCH registered email address (the one to which this email is addressed) and your password. If you have forgotten your password you may request a new one at <a href="http://bch.cbd.int/member/passwordreset.shtml">http://bch.cbd.int/member/passwordreset.shtml</a>

If you have any suggestions or questions about the use of this service, please see the Frequently Asked Questions (FAQs) page at  $\frac{http://bch.cbd.int/help/faq/}{help.faq}$  or contact the BCH Team at  $\frac{bch@cbd.int}{help.faq}$ .

Kind Regards

The BCH Team



<u>22 May 2017-International Day for Biological Diversity:</u>
<u>Biodiversity and Sustainable Tourism</u>

From: Biosafety Clearing-House <bch@cbd.int>

To: Zach Adelman

Date: 5/17/2017 8:45:56 AM

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Kind Regards

The BCH Team



<u>22 May 2017-International Day for Biological Diversity:</u>
<u>Biodiversity and Sustainable Tourism</u>

This version of Total Outlook Converter Pro is not registered. From: <u>Isabelle Coche <</u> To: Zachary Adelman CC: Benjamin Robinson Date: 5/17/2017 5:11:40 AM Subject: Re: Upcoming events at the Convention on Biological Diversity Hi Zach Thanks for the update, that's very useful. On our side we are waiting for more details on the programme of the consultation to be made available and then we'll organise a briefing call for the people who volunteered to participate. I'll be in touch soon. Best Isabelle From: Zachary Adelman <zachadel@tamu.edu> **Date:** Tuesday, 16 May 2017 22:34 To: Isabelle Coche Cc: Benjamin Robinson Subject: Re: Upcoming events at the Convention on Biological Diversity Isabelle. Thanks for the reminder. I had to pass it along to my Department Head to submit the nomination letter. It has now been submitted and I just filled out the online form; my status is pending. On Mon, May 15, 2017 at 4:38 AM, Isabelle Coche < > wrote: Hi Zach I hope you are well. I was wondering if you had managed to register for the online forum. I know people are getting a little daunted by the multiple questions they need to answer, so if you need any help, please let me know! Best,

> wrote:

Isabelle

From: Zachary Adelman < <a href="mailto:zachadel@tamu.edu">zachadel@tamu.edu">zachadel@tamu.edu</a>

Date: Monday, 10 April 2017 15:36

To: Isabelle Coche

Subject: Re: Upcoming events at the Convention on Biological Diversity

ok great. also, attached is a short bio.

On Mon, Apr 10, 2017 at 9:35 AM, Isabelle Coche

Hi Zach

Great, thanks. I will send the instructions on how to register shortly.

Isabelle

From: Zachary Adelman < <a href="mailto:zachadel@tamu.edu">zachadel@tamu.edu">zachadel@tamu.edu</a> >

**Date:** Monday, 10 April 2017 15:32

**To:** Isabelle Coche <

Subject: Re: Upcoming events at the Convention on Biological Diversity

Isabelle,

Nice talking to you. Here is the link to the editorial i wrote for the MIT tech review:

"When extinction is a humanitarian cause"

zach

On 4/4/2017 9:20 AM, Isabelle Coche wrote:

Hi Zach

Apologies for the belated response. I have sent you an invite for the 9<sup>th</sup> at 9am central. If this no longer works, let me know. I could do an hour later or the next day at the same time.

Bes

Isabelle

From: Zachary Adelman <a href="mailto:</a> <a href="mailto:zachadel@tamu.edu">zachadel@tamu.edu</a>

**Date:** Thursday, 30 March 2017 21:45

To: Isabelle Coche ≤

Subject: Re: Upcoming events at the Convention on Biological Diversity

Isabelle

Sure. I can talk on the 10th or 11th at 9am or 10am central.

zach

On Thu, Mar 30, 2017 at 3:30 PM, Isabelle Coche

> wrote:

Dear Zach

Thank you for your offer to help. I think maybe the easiest would be for us to speak so I can explain a bit our current thinking and we can discuss what would be ok for you in terms of engagement. If that's ok, could you let me know if any of the times proposed below would work for you? If not, let me know what might and I'll work around it.

5 april - 9 am central / 3pm London

6 april - 10am central / 4pm London

6 april - 11 am central / 5pm London

6 april - 12 central / 6pm London

7 april - 8am central / 2 pm London 10 april - 8am central / 2 pm London 10 april - 9 am central / 3pm London 10 april - 10am central / 4pm London 11 april - 8am central / 2 pm London 11 april - 9 am central / 3pm London 11 april - 11 am central / 5pm London

Best,

Isabelle

Sent from my iPad

On 28 Mar 2017, at 22:46, Zachary Adelman < <u>zachadel@tamu.edu</u> > wrote:

Isabelle,

I am happy to provide any expertise I can on the subject of gene drive and biocontainment, please let me know what I can do.

best,

Zach Adelman Associate Professor Department of Entomology Texas A&M University

On Tue, Mar 28, 2017 at 12:33 PM, James, Stephanie (FNIH) [T]

> wrote:

Dear Tony, Zach, David and Margareth,

The Convention on Biological Diversity is starting up its activities on synthetic biology again, which will include restarting the discussion on gene drive technology that began last December in Cancun. Please see the attached notice for more details.

By way of this email, I would like to introduce you to Isabelle Coche. Isabelle will be working on efforts to get a broader scientific perspective represented in these discussions. She is looking for a few good scientists who have a broad perspective on the issues around gene drive and are mature enough to be able to deal with the kinds of conversations that can arise within the CBD arena. I have suggested that you folks fit both of those descriptions.

Isabelle would like the chance to explain what this all means and what activities will be needed to fight back the gene drive moratorium proponents before the next CBD meeting in 2018. Ultimately, she is looking to get some volunteers to help in this cause. I hope you will all be interested enough to get back in touch with her to learn more about what this might entail. I'm sorry to say that these next few years are going to be critical and we are going to have to take the fight outside the laboratory. I hope you will get back to Isabelle to learn more about how you can contribute.

Thanks in advance for considering this. Best, Stephanie

--

Associate Professor
Department of Entomology
Texas A&M University
329A Minnie Belle Heep Center
370 Olsen Blvd, College Station, TX 77843
979-458-3107

From: Biosafety Clearing-House <bch@cbd.int>

To: Zach Adelman

Date: 5/16/2017 4:35:01 PM

Subject: Your CBD account profile has been updated



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Dear Dr. Zach Adelman,

We are pleased to inform you that your Convention on Biological Diversity (CBD) user profile has been updated as follows:

Summary of your contact information:

Your registered email address is: zachadel@tamu.edu

Your government affiliation is: [not specified]

Dr. Zach Adelman Designation: Associate Professor Department: Entomology Organization: Texas A&M University

Address: 329A Heep Center City: College Station

State: Texas

United States of America Country: 77843

Zip:

Email CC:

19794583107 Phone:

You may update your profile at <a href="https://bch.cbd.int/user/profile.shtml">https://bch.cbd.int/user/profile.shtml</a> or access the system management centre at <a href="https://bch.cbd.int/user/profile.shtml">https://bch.cbd.int/user/profile.shtml</a> <u>bch.cbd.int/managementcentre/</u> by signing in with your registered email address and password.

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Secretariat of the Convention on Biological Diversity www.cbd.int



22 May 2017-International Day for Biological Diversity: Biodiversity and Sustainable Tourism

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Dear Zach	
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Isabelle

Sent from my iPad

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**Associate Professor** 

Department of Entomology

Texas A&M University

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Thanks in advance for considering this.

Best,

Stephanie

Zach N. Adelman
Associate Professor
Department of Entomology
Texas A&M University
329A Minnie Belle Heep Center
370 Olsen Blvd, College Station, TX 77843
979-458-3107

From: Biosafety Clearing-House <bch@cbd.int>

To: <u>Dr. Zach Adelman</u> Date: 5/16/2017 4:24:15 PM

Subject: Welcome to the Biosafety Clearing-House

Welcome Dr. Zach Adelman,

Thank you for becoming a registered user of the Biosafety Clearing-House. You have subscribed as user zachadel@tamu.edu. Your temporary password is

The next time you visit the Management Center of the Biosafety Clearing-House you will need to sign in to your account by typing in the email address with which you registered (zachadel@tamu.edu) and the password above. The first time you log in, you will be requested to change this temporary password as a security measure.

# FORGOTTEN PASSWORD

If you have forgotten your password, please visit <a href="http://bch.cbd.int/member/passwordreset.shtml">http://bch.cbd.int/member/passwordreset.shtml</a> to have a new password sent to your official e-mail address.

#### **FURTHER ASSISTANCE**

If you have any questions, suggestions or problems with the use of this service, please contact the Secretariat of the Convention on Biological Diversity at: <a href="mailto:secretariat@cbd.int">secretariat@cbd.int</a>



22 May 2017-International Day for Biological Diversity:

Biodiversity and Sustainable Tourism

From: Adelman, Zach N <zachadel@tamu.edu>

To: <u>f-anzualda@tamu.edu</u>
Date: 5/16/2017 4:20:17 PM

Subject: Fwd: RE: Invitation to participate in an upcoming NIH Workshop--July 18 and July 19, 2017

Attachments: NIH OSP NIH Guidelines Workshop Public 041317.pdf

Felicita.

Attached is the draft agenda for the NIH workshop in Washington DC.

thanks,

zach

------ Forwarded Message ------

Subject: RE: Invitation to participate in an upcoming NIH Workshop--July 18 and July 19, 2017

Date:Fri, 14 Apr 2017 19:55:23 +0000

From:Tucker, Jessica (NIH/OD) [E] <jessica.tucker@nih.gov>

To:Zachary Adelman <zachadel@tamu.edu>

CC:Harris, Kathryn (NIH/OD) [C] <a href="mailto:HarrisKath@mail.nih.gov">HarrisKath@mail.nih.gov</a>, Singh, Jyoti (NIH/OD) [E]

<jyoti.singh@nih.gov>

Dear Zach,

½'غï

Thank you, again, for agreeing to participate in the upcoming workshop, *NIH Guidelines*: Honoring the Past, Charting the Future.� I wanted to provide you with some updates since we�ve last communicated.�

1⁄2/خ

Please find attached a copy of the draft agenda for the workshop. As you can see, we would like to make a minor modification and move Session 4 - Emerging Biotechnologies: Issues Raised for the Current System of Biosafety Oversight to 2:30 PM it 4:15 PM on July 18, 2017 (rather than 2:30 PM it 3:45 PM), to allow more time for discussion. it 3:45 PM i

I hope this small proposed change will not cause any challenges for you, but please let me know, via email or phone, whether or not this minor schedule adjustment will work for you. it is an be reached at 301-451-4431. it

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My team will reach out to you in late April or early May to schedule a teleconference regarding this panel.� If there is another person we should reach out to for scheduling, please let us know.� �

Finally, as mentioned earlier, Ms. Carly Sullivan from Palladian Partners will contact you shortly regarding airfare and lodging.� (Apologies for the delay on that, as we had to ensure the agenda was finalized before we could proceed with that step.) If you are still available, we would very much appreciate your participation in the entire workshop.� In particular, we welcome your participation in the roundtables on July 19, where we plan to invite all the workshop panelists and speakers to be at the table to contribute to the discussion.

12/2

Thank you so much, again, and we look forward to having you.

ïè½ Sincerely, ïè½ Jessica

٪ځ۶ ٪ځ۶

From: Tucker, Jessica (NIH/OD) [E]
Sent: Wednesday, March 01, 2017 1:33 PM
To: 'Zachary Adelman' <a href="mailto:sachadel@tamu.edu">sachadel@tamu.edu</a>

Subject: RE: Invitation to participate in an upcoming NIH Workshop--July 18 and July 19, 2017 17,1/2 Hi Zach, 1⁄2 إ Thanks for your message. We are really looking forward to having you as part of the workshop. Carly Sullivan from Palladian Partners will contact you early next week to arrange travel and lodging, so please be on the look-out for that e-mail. ï¿1/2 We look forward to working with you on this important meeting, and thanks again for agreeing to participate. 1⁄2 إ Best, 1⁄2′غ Jessica 12/2 From: Zachary Adelman [mailto:zachadel@tamu.edu] Sent: Wednesday, March 01, 2017 11:48 AM To: Tucker, Jessica (NIH/OD) [E] < jessica.tucker@nih.gov > Cc: Harris, Kathryn (NIH/OD) [C] < HarrisKath@mail.nih.gov >; Singh, Jyoti (NIH/OD) [E] < iyoti.singh@nih.gov > Subject: Re: Invitation to participate in an upcoming NIH Workshop--July 18 and July 19, 2017 2/ئآز Jessica,� Thanks for the follow-up. I am very happy to discuss the challenges associated with gene drive, and I will be available for both the 18th and 19th of July. I will be making my air travel reservations shortly, so please let me know if there are any restrictions besides the obvious (coach ticket), or if there is a specific travel agent i am required to work through.  $1/\sqrt{2}$ thanks again, and I am looking forward to the workshop. i; 1/2 best, zach 1/.1/2Zach Adelman Associate Professor Texas A&M University iز 1⁄2 On Mon, Feb 27, 2017 at 3:48 PM, Tucker, Jessica (NIH/OD) [E] < <u>jessica.tucker@nih.gov</u> > wrote: Dear Zach, 1⁄2 خآ Thank you for accepting our invitation to participate in a workshop on the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) that will be held on July 18 and 19 at the National Institutes of Health in Rockville, Maryland. ĭ¿ 1/2 As indicated by Dr. Collins, the workshop will revisit the history of the scientific movement that led to the development of the�NIH Guidelines, and discuss the future of biosafety oversight.�The workshop aims to seek input from stakeholders on paths forward as NIH carefully examines the existing oversight framework for research with recombinant or synthetic nucleic acid molecules, given the current landscape of risks and benefits inherent in the conduct of this research today. In particular, we are hoping you might be available to participate in a panel to explore challenges raised for our current system of biosafety oversight by certain emerging biotechnologies. With your perspective as a prominent scientist in the field, we would request that you address gene drives in your remarks.� The panel will take place from 2:30 PM � 3:45 PM on Tuesday, July 18, 2017, and we would very much appreciate your participation in the entire workshop, if you are available, as well. We plan to have roundtable discussions on July 19 to conclude the meeting, and your input at that time would also be extremely useful. Please know that you will be reimbursed for travel expenses.� Please let me know if you have any questions, as l�d be happy to answer them via e-mail or to speak with you over the phone. I can be reached at 301-451-4431.�In the coming weeks/ months, we also plan to organize teleconferences for panelists to further discuss the session and what we hope to achieve. Thank you so much, again, and we look forward to having you. Your perspective will be invaluable. 1⁄2 خ Sincerely,

Cc: Harris, Kathryn (NIH/OD) [C] < HarrisKath@mail.nih.gov> ; Singh, Jyoti (NIH/OD) [E] < iyoti.singh@nih.gov>

Francis Collins, M.D., Ph.D.

� Jessica Tucker, Ph.D. Director, Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy Office of Science Policy National Institutes of Health 301-451-4431 1⁄2 ئ 1⁄2 خ National Institutes of Health OSP Blog: <u>Under the Poliscope</u> Twitter: @CWolinetzNIH ½ ځï 2∕ئ≼ڙ 1⁄2 ن From: Zachary Adelman [mailto:zachadel@tamu.edu ] Sent: Tuesday, February 21, 2017 5:09 PM **To:** Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov > Cc: Wolinetz, Carrie (NIH/OD) [E] < carrie.wolinetz@nih.gov >; Harris, Kathryn (NIH/OD) [C] < HarrisKath@mail.nih.gov >; Tucker, Jessica (NIH/OD) [E] <<u>jessica.tucker@nih.gov</u> >; Singh, Jyoti (NIH/OD) [E] <<u>jyoti.singh@nih.gov</u> > Subject: Re: Invitation to participate in an upcoming NIH Workshop--July 18 and July 19, 2017 2<sup>1</sup>/3 Dr. Collins,� � Thank you for the invitation. I am very happy to participate in the upcoming workshop. I agree our systems of governance and oversight must evolve as quickly or quicker than our technologies do, and I look forward to providing my perspective on this process.� ï;½ Best,� 1/<sub>2</sub>/ Zach Adelman Texas A&M University On Tue, Feb 21, 2017 at 3:36 PM, Collins, Francis (NIH/OD) [E] < collins f@od.nih.gov > wrote: Dear Dr. Adelman, ï;½ I am writing to invite you to serve as a panelist in an upcoming workshop on the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).ïį ½ This event will take place July 18 and 19, 2017, at the National Institutes of Health in Bethesda, Maryland. iز½2 In light of the recent 40<sup>th</sup> anniversary of the *NIH Guidelines*, the workshop will revisit the history of the scientific movement that led to this watershed document, and discuss the future of biosafety oversight. 7½ The workshop also aims to seek input from stakeholders on specific paths forward as NIH carefully examines the biosafety oversight framework, and considers whether certain emerging technologies and other areas of life science research may raise scientific, safety, and ethical concerns that should be included in such a system. 1<sup>1</sup>/<sub>2</sub> You have unique perspectives and insights to add to the program, so we are very much hoping that you will be able to be a part of this event. 1/2 If you are interested in participating in this workshop, my staff will be happy to provide you with further information. 7/2 Please contact Jessica Tucker at <u>Jessica Tucker@nih.gov</u> for additional details. Thank you so much for considering this invitation. � Sincerely,  $1/_{2}^{1/_{2}}$ 

This version of Total Outlook Converter  $\ensuremath{\mathsf{Pro}}$  is not registered.

	Director, NIH
	$ \mathrm{i}_{\dot{\mathcal{L}}}'_2 $
	$\ddot{l}_{\dot{\mathcal{L}}}^{1/2}$
ï	$i_0^{1/2}$

# NIH Guidelines: Honoring the Past, Charting the Future



National Institutes of Health 5635 Fishers Lane Rockville, Maryland 20892 Conference Rooms 508/509

# DAY 1 - Tuesday 18th July 2017

8:00 am - 8:30 am Registration

8:30 am - 9:00 am Welcoming Remarks

Carrie D. Wolinetz, Ph.D.

Associate Director for Science Policy, NIH

9:00 am - 9:15 am Introduction

Francis S. Collins, M.D., Ph.D. Director, NIH

9:15 am - 10:00 am SESSION I - Keynote Presentation

The keynote will provide insights into the historical significance of Asilomar, the 40 year history of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, and the Recombinant DNA Advisory Committee (RAC); and explore the future of biosafety oversight in the life sciences in light of the emergence of new biotechnologies.

David Baltimore, Ph.D.

President Emeritus; Robert Andrews Millikan Professor of Biology, California Institute of Technology

10:00 am - 10:15 am BREAK

10:15 am - 11:30 am

SESSION II – The Current NIH Framework for the Oversight of Research with Recombinant or Synthetic Nucleic Acid Molecules

This session will explore the current framework established by the NIH Guidelines, including the roles of Institutional Biosafety Committees (IBCs) and the RAC.

#### Panelists:

Jessica Tucker, Ph.D.

Director, Biosafety, Biosecurity and Emerging Biotechnology Policy Division, Office of Science Policy, NIH

Stephen J. Libby, Ph.D.

IBC Chair, Research Associate Professor, University of Washington

Hans-Peter Kiem, M.D., Ph.D.

Director, Cell and Gene Therapy Program, Fred Hutchinson Cancer Research Center

11:30 am - 12:45 pm

Lunch Break

12:45 pm - 2:15 pm

SESSION III – Role of the *NIH Guidelines*: Intersection with Other Biosafety Regulations and Guidance

The panel will examine the essential elements of the system of oversight established in the NIH Guidelines, and how the NIH Guidelines intersect or complement other biosafety guidance.

#### Panelists:

**Federal Representatives** 

2:15 pm - 2:30 pm

**BREAK** 

#### 2:30 pm - 4:15 pm

# SESSION IV – Emerging Biotechnologies: Issues Raised for the Current System of Biosafety Oversight

If Asilomar were today, what emerging biotechnologies would be captured in the biosafety oversight system? An overview of various emerging biotechnologies will be presented, along with a discussion of whether there are distinct biosafety issues posed by these technologies. Can these potential challenges be managed by our current framework for risk assessment and biosafety oversight?

# Panelists:

Feng Zhang, Ph.D.
Professor in Neuroscience, MIT

Drew Endy, Ph.D.
Associate Professor, Bioengineering, Stanford University

Zach Adelman, Ph.D.
Associate Professor, Department of Entomology, Texas A&M University

Kenneth Oye, Ph.D.

Associate Professor of Political Science and of Engineering Systems, MIT

4:15 pm – 4:30 pm Wrap-up of Day 1

4:30 pm ADJOURN

# DAY 2 - Wednesday 19th July 2017

8:00 am - 8:15 am

Introduction

8:15 am - 10:15 am

SESSION V - Roundtable Discussion - Future Role of the RAC

This roundtable will include a discussion of the benefits of having a public forum for biosafety discussions, and the types of engagement that would best meet the needs of the scientific community and the public. Questions explored will include, how can the RAC be best used to help ensure the safe advancement of life sciences research? Are there emerging biotechnologies that would benefit from the public engagement provided by RAC discussions? What role should the RAC have in providing biosafety guidance?

#### **Moderator:**

Howard Federoff, M.D., Ph.D. Vice Chancellor for Health Affairs and CEO UC Irvine Health System, University of California, Irvine

# **Lead Discussants:**

Marie-Louise Hammarskjöld, Ph.D.
Professor, Microbiology, Immunology, and Cancer Biology,
University of Virginia

Margaret Foster Riley, J.D.

Professor of Law, University of Virginia

Joseph Kanabrocki, Ph.D, CBSP
Associate Vice President for Research Safety, University of Chicago

Nancy King, J.D.
Professor, Social Sciences and Health Policy, Wake Forest School of Medicine

10:15 am - 10:30 am BREAK

10:30 am – 12:30 pm

# **SESSION VI – Roundtable Discussion - Future Face of Biosafety Oversight**

This roundtable will include a discussion of what the ideal Federal and local oversight systems for ensuring the safe conduct of life sciences research might look like. Questions explored will include, what should be the scope of the biosafety oversight system? What are the pros and cons of a biosafety oversight framework that focuses on research with recombinant or synthetic nucleic acid molecules? Are there additional types of research that pose biosafety concerns that warrant oversight, which are not captured in the current system; are there types of research that are part of the current system that no longer require such oversight? How can we ensure adequate biosafety oversight without unduly burdening the research enterprise?

# **Moderator:**

Joseph Kanabrocki, Ph.D, CBSP Associate Vice President for Research Safety, University of Chicago

# **Lead Discussants:**

Elizabeth Gilman Duane, M.S., RBP, CBSP Biosafety/Laboratory Safety Service Leader, Environmental Health and Engineering, Inc.

Lydia Sohn, Ph.D IBC Chair, Professor of Mechanical Engineering, University of California, Berkeley

Ara Tahmassian, Ph.D.
Chief Research Compliance Officer, Harvard University

Maureen O'Leary Ph.D., CBSP
President, American Biological Safety Association (ABSA)
International

12:30 pm – 12:45 pm **SESSION VII - Open Forum for Stakeholder Input** 

12:45 pm – 1:00 pm **Closing Remarks** 

Carrie D. Wolinetz, Ph.D.
Associate Director for Science Policy, NIH

1:00 pm **ADJOURN** 

From: Synbio

To: Zach Adelman

Date: 5/16/2017 11:11:01 AM

Subject: Texas A&M University- Completing your registration to participate in the Open Ended Online Forum

on Synthetic Biology

Dear Mr. Zach Adelman,

You have been nominated by Texas A&M University to participate in the Open Ended Online Forum on Synthetic biology as established in <a href="decision XIII/24">decision XIII/24</a> of the Conference of the Parties to the Convention on Biological Diversity (COP) and extended in <a href="COP decision XIII/17">COP decision XIII/17</a>.

In order to facilitate the completion of your registration we would like to request that you complete an online form outlining your experience in the field of synthetic biology. Kindly complete the registration form **as soon as possible** so that you may be included on the mailing list for updates related to the activities on synthetic biology.

The form can be found at <a href="http://bch.cbd.int/managementcentre/edit/syntheticBiologyExpert.shtml">http://bch.cbd.int/managementcentre/edit/syntheticBiologyExpert.shtml</a>

Once you click on the link you will be taken to the Biosafety Clearing House (BCH) website. You will be required to log into the BCH in order to access the form. If you already have a BCH account you can sign-in using your existing username and password. If you do not have a BCH account you will be required to create one by clicking on the link marked "Sign Up for a BCH Account".

If you require any assistance while completing the registration process please do not hesitate to contact us at any time.

Kind regards,

### **Melissa Willey**

Administrative Assistant, Cartagena Protocol on Biosafety Secretariat of the Convention on Biological Diversity UN Environment 413 rue St. Jacques, Suite 800 Montreal, QC, H2Y 1N9 (514) 287-6689 www.cbd.int





22 May 2017-International Day for Biological Diversity: Biodiversity and Sustainable Tourism

From: Synbio

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The form can be found at <a href="http://bch.cbd.int/managementcentre/edit/syntheticBiologyExpert.shtml">http://bch.cbd.int/managementcentre/edit/syntheticBiologyExpert.shtml</a>

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If you require any assistance while completing the registration process please do not hesitate to contact us at any time.

Kind regards,

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Administrative Assistant, Cartagena Protocol on Biosafety Secretariat of the Convention on Biological Diversity UN Environment 413 rue St. Jacques, Suite 800 Montreal, QC, H2Y 1N9 (514) 287-6689 www.cbd.int





22 May 2017-International Day for Biological Diversity: Biodiversity and Sustainable Tourism

From: Synbio < synbio

To: Teresa Gold

CC: David Ragsdale

Zach Adelman

Date: 5/16/2017 11:09:10 AM

Subject: RE: Registering Dr. Zach Adelman for the Syn Bio Online Forum

Dear Ms. Gold,

Thank you for nominating an expert from Texas A&M University to participate in the Open-ended Online Forum on Synthetic Biology.

We will be contacting Dr. Zach Adelman shortly to facilitate the completion of his registration.

Best regards,

#### **Melissa Willey**

Administrative Assistant, Cartagena Protocol on Biosafety Secretariat of the Convention on Biological Diversity UN Environment 413 rue St. Jacques, Suite 800 Montreal, QC, H2Y 1N9 (514) 287-6689

From: Teresa Gold [mailto:t-gold@tamu.edu]
Sent: Tuesday, May 16, 2017 11:11 AM

To: Synbio

www.cbd.int

Cc: David Ragsdale; Zach Adelman

Subject: Registering Dr. Zach Adelman for the Syn Bio Online Forum

Please see attached nomination letter for Dr. Zach Adelman to participate in the Syn Bio online forum. If you need anything else, please let me know.

Regards,

Teresa

#### Teresa Gold

Senior Administrative Coordinator 1 Texas A&M University Department of Entomology Minnie Belle Heep Center Rm. 412 College Station, TX 77843-2475

# t-gold@tamu.edu

*Ph*: 979.845.2510 *Fax*: 979.845.6305



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22 May 2017-International Day for Biological Diversity: Biodiversity and Sustainable Tourism From: Teresa Gold <t-gold@tamu.edu>

To: Zach Adelman

Date: 5/16/2017 10:11:36 AM

Subject: RE: Registering for the Syn Bio online forum

Letter has been sent to synbio

. I have copied you with that email. Let me know if you need anything else.

Thanks!

Teresa 😊

From: Zachary Adelman [mailto:zachadel@tamu.edu]

Sent: Tuesday, May 16, 2017 9:15 AM
To: David Ragsdale <dragsdale@tamu.edu>
Cc: Teresa Gold <t-gold@tamu.edu>

Subject: Fwd: Registering for the Syn Bio online forum

David,

I am just following up to see if you had a chance to sign the draft letter and send along with the attached bio for the Convention on Biological Diversity's Synthetic Biology online forum.

thanks, zach

----- Forwarded message -----

From: **Zachary Adelman** <<u>zachadel@tamu.edu</u> >

Date: Tue, Apr 18, 2017 at 8:36 AM

Subject: Re: Registering for the Syn Bio online forum To: David Ragsdale < dragsdale@tamu.edu >

Thanks. Attached is a draft letter and bio. Please send them to s

On Mon, Apr 17, 2017 at 4:52 PM, David Ragsdale < dragsdale@tamu.edu > wrote:

Zach,

My policy for such items is to ask you to draft the letter, I'll modify it to put it in my voice and then sign it and send it back to you (or onto the agency). Please pull together a draft of the letter and send it to me.

David

David W. Ragsdale Professor and Head Department of Entomology Texas A&M University

Phone: 979-845-2510

From: Zachary Adelman [mailto:<u>zachadel@tamu.edu</u> ]

**Sent:** Monday, April 17, 2017 2:25 PM

To: David Ragsdale

Subject: Fwd: Registering for the Syn Bio online forum

David,

I have been nominated to participate as an expert in an online forum hosted by the Convention of Biological Diversity on the topic of gene drive. In order to register for the forum, they require a letter from you (see the form letter below). This is a good opportunity to engage with non-scientists on a topic of immense importance to my research program in a fairly political

If you don't mind, would you let me know once you are registered? If you encounter any issues, do reach out also.

that will ensure you are 'set' for the online forum over the summer. As I mentioned, I am talking to a few people over the next

few weeks and we will then organise a briefing call with the people who volunteered to walk through the topics and give

Best,

guidance on how to engage.

Isabelle

# How to register for the CBD online forum?

- · Have your administrator or head of department send a letter or email of nomination to
- Sample letter/email text:

To whom it may concern:

[Name of the organisation or institution] wishes to nominate [Prof/Dr/Mr/Ms] [full name, position, affiliation] to participate in the open-ended online forum on synthetic biology. [He/she] can be contacted at [email]. Please [find attached is a short biography OR see link to online profile].

Kind regards,

[name position contact information]

The letter or email must come from an 'official' of your organisation or institution. For example a department head or administrator, not from the individual being nominated.

Once the nomination is sent, the CBD secretariat will get in touch to ask for more information before the nominees are confirmed.

For more information: <a href="https://bch.cbd.int/synbio/nomination\_natl\_experts/">https://bch.cbd.int/synbio/nomination\_natl\_experts/</a>

From: Teresa Gold <t-gold@tamu.edu>

To:

CC: <u>David Ragsdale</u>

Zach Adelman

Date: 5/16/2017 10:10:38 AM

Subject: Registering Dr. Zach Adelman for the Syn Bio Online Forum

Attachments: 5.16.2017CBD Adelman nomination.pdf

Adelman Biography 2017.pdf

Please see attached nomination letter for Dr. Zach Adelman to participate in the Syn Bio online forum. If you need anything else, please let me know.

Regards,

Teresa

# Teresa Gold

Senior Administrative Coordinator 1 Texas A&M University Department of Entomology Minnie Belle Heep Center Rm. 412 College Station, TX 77843-2475

# t-gold@tamu.edu

*Ph*: 979.845.2510 *Fax*: 979.845.6305



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all information from your system.





DEPARTMENT OF ENTOMOLOGY

May 16, 2017

To whom it may concern:

Texas A&M University and Texas A&M AgriLife Research wishes to nominate Dr. Zach N. Adelman, Associate Professor, Department of Entomology, to participate in the open-ended online forum on synthetic biology. He can be contacted at <a href="mailto:zachadel@tamu.edu">zachadel@tamu.edu</a>. Please find attached a short biography.

Kind regards,

Dr. David Ragsdale Professor and Head

David W. Ragedale

**Department of Entomology** 

Dr. Zach N. Adelman is an associate professor in the Department of Entomology at Texas A&M University. Following earlier work on the generation of pathogen-resistant mosquitoes, Dr. Adelman's research has more recently focused on the development of novel gene editing/gene replacement approaches for disease vector mosquitoes as well as understanding genetic interactions between arthropod-borne viruses and their mosquito vectors. In addition to managing his research program, Dr. Adelman has served as a member of his local Institutional Biosafety Committee for eight years, including four years serving as its Chair. Most recently, Dr. Adelman began a 3-year term on the Recombinant DNA Advisory Committee that provides advice to the NIH director concerning recombinant DNA technology. Dr. Adelman serves as a member of the steering committee of the Insect Genetic Technologies Research Coordination Network (an NSF-funded project), and is a lead instructor in the IGTRCN workshop on gene editing. Dr. Adelman has also recently served as editor on a 19-chapter volume entitled "Genetic Control of Malaria and Dengue" published in 2016, and serves as an editor for the journal PLoS One; his work is funded through several grants from the National Institute for Allergies and Infectious Disease at the National Institutes of Health. Dr. Adelman received his B.A. degree in Biochemistry from Ithaca College and Ph.D. in Microbiology from Colorado State University; he joined the faculty at Virginia Tech in 2005, and recently moved to Texas A&M University in 2016.

From: Zachary Adelman <zachadel@tamu.edu>

To: <u>David Ragsdale</u> CC: <u>Teresa Gold</u>

Date: 5/16/2017 9:14:36 AM

Subject: Fwd: Registering for the Syn Bio online forum

Attachments: CBD Adelman nomination.DOCX

Adelman Biography 2017.docx

# David,

I am just following up to see if you had a chance to sign the draft letter and send along with the attached bio for the Convention on Biological Diversity's Synthetic Biology online forum.

thanks,

zach

----- Forwarded message -----

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Date: Tue, Apr 18, 2017 at 8:36 AM

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My policy for such items is to ask you to draft the letter, I'll modify it to put it in my voice and then sign it and send it back to you (or onto the agency). Please pull together a draft of the letter and send it to me.

David

David W. Ragsdale

Professor and Head

**Department of Entomology** 

Texas A&M University

Phone: 979-845-2510

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**Sent:** Monday, April 17, 2017 2:25 PM

To: David Ragsdale

Subject: Fwd: Registering for the Syn Bio online forum

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zach
Forwarded message From: Isabelle Coche < Date: Thu, Apr 13, 2017 at 4:58 AM Subject: Registering for the Syn Bio online forum To: Zachary Adelman < <u>zachadel@tamu.edu</u> > Cc: Stephanie James < <u>sjames</u> >, Benjamin Robinson <
Dear Zach
See below a quick note on how to register for the online forum. Nominations are now being received so if you want to proceed that will ensure you are 'set' for the online forum over the summer. As I mentioned, I am talking to a few people over the next few weeks and we will then organise a briefing call with the people who volunteered to walk through the topics and give guidance on how to engage.
If you don't mind, would you let me know once you are registered? If you encounter any issues, do reach out also.
Best,
Isabelle
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<ul> <li>Have your administrator or head of department send a letter or email of nomination to</li> <li>Sample letter/email text:</li> </ul>
To whom it may concern:

This vers

For more information: <a href="https://bch.cbd.int/synbio/nomb0ination\_natl\_experts/">https://bch.cbd.int/synbio/nomb0ination\_natl\_experts/</a>





DEPARTMENT OF ENTOMOLOGY

April 18<sup>th</sup>, 2017

To whom it may concern:

Texas A&M Agrilife Research wishes to nominate Dr. Zach N. Adelman, Associate Professor, Department of Entomology, to participate in the open-ended online forum on synthetic biology. He can be contacted at zachadel@tamu.edu. Please find attached a short biography.

Kind regards,

Dr. David Ragsdale

Head, Department of Entomology

Dr. Zach N. Adelman is an associate professor in the Department of Entomology at Texas A&M University, Following earlier work on the generation of pathogen-resistant mosquitoes, Dr. Adelman's research has more recently focused on the development of novel gene editing/gene replacement approaches for disease vector mosquitoes as well as understanding genetic interactions between arthropod-borne viruses and their mosquito vectors. In addition to managing his research program, Dr. Adelman has served as a member of his local Institutional Biosafety Committee for eight years. including four years serving as its Chair. Most recently, Dr. Adelman began a 3-year term on the Recombinant DNA Advisory Committee that provides advice to the NIH director concerning recombinant DNA technology. Dr. Adelman serves as a member of the steering committee of the Insect Genetic Technologies Research Coordination Network (an NSF-funded project), and is a lead instructor in the IGTRCN workshop on gene editing. Dr. Adelman has also recently served as editor on a 19-chapter volume entitled "Genetic Control of Malaria and Dengue" published in 2016, and serves as an editor for the journal PLoS One; his work is funded through several grants from the National Institute for Allergies and Infectious Disease at the National Institutes of Health. Dr. Adelman received his B.A. degree in Biochemistry from Ithaca College and Ph.D. in Microbiology from Colorado State University; he joined the faculty at Virginia Tech in 2005, and recently moved to Texas A&M University in 2016.

From: PathogenGH <p
To: Zachary Adelman
CC: Crisanti, Andrea
Date: 5/16/2017 4:29:34 AM
Subject: Re: PGH Gene Drive issue

Thank you Zach, that's great news. I look forward to seeing your paper in July.

If I can be of any help in the mean time please get in touch. You'll find instructions for authors on our website

All the best

Christo Hall
Editorial Assistant
Pathogens and Global Health
Imperial College London

From: Zachary Adelman <zachadel@tamu.edu>

Sent: 15 May 2017 17:52:44

To: PathogenGH

Subject: Re: PGH Gene Drive issue

Christo,

Thanks, July31st will work for us. Our topic will be "Development and importance of rigorous standard operating procedures for laboratory gene drive research"

zach

On Mon, May 15, 2017 at 6:03 AM, PathogenGH <

> wrote:

Dear Zach,

Thanks for the reply and for your interest in contributing to this issue. We would like to give time to our reviewers to offer a substantial peer review before considering papers for publication but we could still fast-track your paper through peer review if you could submit by 31st July?

If this could work for you then please send a brief note on what your suggested topic is and I will share it with Andrea.

All the best

Christo Hall
Editorial Assistant
Pathogens and Global Health
Imperial College London

From: Zachary Adelman < <a href="mailto:zachadel@tamu.edu">zachadel@tamu.edu">zachadel@tamu.edu</a>

Sent: 08 May 2017 15:42:01

To: PathogenGH

Subject: Re: PGH Gene Drive issue

Christo,

I would like to participate in this special issue, but i will not be able to make a June30th deadline. I could submit in August.

best, zach

On Fri, Apr 28, 2017 at 9:11 AM, PathogenGH <

> wrote:

Dear Zach,

We now have the research line-up together for our special issue edition of Pathogens and Global Health. Which is the following:

Population modification of Anopheline species to control malaria transmission (Tony James)

Mutations: off-target effects and natural mutations (Kevin Esvelt)

Policy and regulatory roadblocks (Megan Palmer)

Modelling of anti- gene drive approaches (Austin Burt)

Current state and future directions (Andrea Crisanti lab)

Protection against the spread of gene drives through accidental release into the wild (Andrea Beaghton, Drew Hammond + Sam O Laughlin)

Prof Crisanti is still keen on having your contribution and it isn't too late. If you'd like to author a review on a topic that isn't yet covered then please submit a proposal as soon as you can.

The proposed deadline for the first draft is Friday June 30th.

All the best

Christo Hall
Editorial Assistant
Pathogens and Global Health
Imperial College London

From: PathogenGH

Sent: 27 March 2017 12:30:45

To: Zachary Adelman

Subject: Re: PGH Gene Drive issue

Dear Zach.

Thank you for the reply and apologies for the slow response, I wanted to get Andrea's feedback before responding.

The stimulus for the issue is to publish a series of articles that present the methods and applications of gene drive that have public health benefit, in particular in order to engage with policy and regulation issues, and review the ethical controversies as a result of its potential implementation. We aim to bring together a group of leading scientists to present a particular element (e.g. mutations; species-specific control; protection against accidental release), all of which will consider the risks and benefits of building and implementing gene drives. As a whole, the issue will bridge the technical and policy issues of implementation and create a dialogue with other non-research groups, which we will put together through a series of commentaries from stakeholders from other fields, including governments.

Regarding formats, we are looking for reviews that present an up-to-date overview of the current status of a particular subject. Usually our reviews are 2,500-4,000 words but we consider each paper on its own merits. A flexible structure is encouraged (i.e. sections of your own making as long as they engage with the above) and co-authors are fine.

Let me know if you have any questions and if you are able to contribute please submit a suggested topic. We will be sending out a guide for submission in April.

Many thanks

Christo Hall
Editorial Assistant
Pathogens and Global Health
Imperial College London

From: Zachary Adelman < <a href="mailto:zachadel@tamu.edu">zachadel@tamu.edu">zachadel@tamu.edu</a>

Sent: 09 March 2017 14:46

To: PathogenGH

Subject: Re: PGH Gene Drive issue

Christo

Thanks for the invitation. Can you provide more information on the format/structure/length of the contributions you are looking for? Also, what in particular is the special issue trying to achieve in regards to gene drive? More detail on the background that drove the decision to produce this issue would be helpful.

Best, zach

Zach Adelman Texas A&M University

On Thu, Mar 9, 2017 at 5:49 AM, PathogenGH <p | Dear Dr Adelman,

> wrote:

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Please let me know if you have any questions regarding the issue. We are open to your specific suggestion of a topic and to co-authors. The deadline is June.

All the best

Christo Hall
Editorial Assistant
Pathogens and Global Health
Imperial College London

From: Zachary Adelman <zachadel@tamu.edu>

To: PathogenGH

Date: 5/15/2017 11:52:44 AM Subject: Re: PGH Gene Drive issue

## Christo,

Thanks, July31st will work for us. Our topic will be "Development and importance of rigorous standard operating procedures for laboratory gene drive research"

On Mon, May 15, 2017 at 6:03 AM, PathogenGH < pathogengh@

> wrote:

Dear Zach,

Thanks for the reply and for your interest in contributing to this issue. We would like to give time to our reviewers to offer a substantial peer review before considering papers for publication but we could still fast-track your paper through peer review if you could submit by 31st July?

If this could work for you then please send a brief note on what your suggested topic is and I will share it with Andrea.

All the best

Christo Hall **Editorial Assistant** Pathogens and Global Health Imperial College London

From: Zachary Adelman < <u>zachadel@tamu.edu</u> >

Sent: 08 May 2017 15:42:01

To: PathogenGH

Subject: Re: PGH Gene Drive issue

I would like to participate in this special issue, but i will not be able to make a June30th deadline. I could submit in August.

best,

zach

On Fri, Apr 28, 2017 at 9:11 AM, PathogenGH < pathogengh Dear Zach,

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We now have the research line-up together for our special issue edition of Pathogens and Global Health. Which is the following:

- Population modification of Anopheline species to control malaria transmission (Tony James)
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- Policy and regulatory roadblocks (Megan Palmer)
- Modelling of anti- gene drive approaches (Austin Burt)
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Prof Crisanti is still keen on having your contribution and it isn't too late. If you'd like to author a review on a topic that isn't yet covered then please submit a proposal

The proposed deadline for the first draft is Friday June 30th.

All the best

Christo Hall
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Imperial College London

From: PathogenGH

Sent: 27 March 2017 12:30:45

To: Zachary Adelman

Subject: Re: PGH Gene Drive issue

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The stimulus for the issue is to publish a series of articles that present the methods and applications of gene drive that have public health benefit, in particular in order to engage with policy and regulation issues, and review the ethical controversies as a result of its potential implementation. We aim to bring together a group of leading scientists to present a particular element (e.g. mutations; species-specific control; protection against accidental release), all of which will consider the risks and benefits of building and implementing gene drives. As a whole, the issue will bridge the technical and policy issues of implementation and create a dialogue with other non-research groups, which we will put together through a series of commentaries from stakeholders from other fields, including governments.

Regarding formats, we are looking for reviews that present an up-to-date overview of the current status of a particular subject. Usually our reviews are 2,500-4,000 words but we consider each paper on its own merits. A flexible structure is encouraged (i.e. sections of your own making – as long as they engage with the above) and co-authors are fine.

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Many thanks

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Pathogens and Global Health
Imperial College London

From: Zachary Adelman < <u>zachadel@tamu.edu</u> >

**Sent:** 09 March 2017 14:46

To: PathogenGH

Subject: Re: PGH Gene Drive issue

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From: Isabelle Coche <I
To: Zachary Adelman
CC: Benjamin Robinson
Date: 5/15/2017 4:38:54 AM

Subject: Re: Upcoming events at the Convention on Biological Diversity

Hi Zach

I hope you are well. I was wondering if you had managed to register for the online forum. I know people are getting a little daunted by the multiple questions they need to answer, so if you need any help, please let me know!

Best,

Isabelle

From: Zachary Adelman <zachadel@tamu.edu>

**Date:** Monday, 10 April 2017 15:36

To: Isabelle Coche <

Subject: Re: Upcoming events at the Convention on Biological Diversity

ok great. also, attached is a short bio.

On Mon, Apr 10, 2017 at 9:35 AM, Isabelle Coche <

> wrote:

Hi Zach

Great, thanks. I will send the instructions on how to register shortly.

Isabelle

From: Zachary Adelman < <a href="mailto:zachadel@tamu.edu">zachadel@tamu.edu">zachadel@tamu.edu</a>

Date: Monday, 10 April 2017 15:32

To: Isabelle Coche >

Subject: Re: Upcoming events at the Convention on Biological Diversity

Isabelle,

Nice talking to you. Here is the link to the editorial i wrote for the MIT tech review:

"When extinction is a humanitarian cause"

zach

On 4/4/2017 9:20 AM, Isabelle Coche wrote:

Hi Zach

	Apologies for the belated response. I have sent you an invite for the 9 <sup>th</sup> at 9am central. If this no longer works, let me know. I could do an hour later or the next day at the same time.			
	Best			
Isabelle				
	From: Zachary Adelman <a href="mailto:sabelle"><a <="" href="mailto:sabelle" th=""></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a></a>			
	Dear Zach  Thank you for your offer to help. I think maybe the easiest would be for us to speak so I can explain a bit our current thinking and we can discuss what would be ok for you in terms of engagement. If that's ok, could you let me know if any of the times proposed below would work for you? If not, let me know what might and I'll work around it.  5 april - 9 am central / 3pm London 6 april - 10am central / 5pm London 6 april - 11 am central / 5pm London 7 april - 8am central / 2 pm London 10 april - 8am central / 2 pm London 10 april - 9 am central / 4pm London 11 april - 8am central / 2 pm London 11 april - 9 am central / 3pm London 11 april - 10am central / 3pm London 11 april - 11 am central / 5pm London 11 april - 11 am central / 5pm London			
	Sent from my iPad  On 28 Mar 2017, at 22:46, Zachary Adelman < zachadel@tamu.edu > wrote:  Isabelle, I am happy to provide any expertise I can on the subject of gene drive and biocontainment, please let me know what I can do. best,  Zach Adelman Associate Professor			

Texas A&M University

On Tue, Mar 28, 2017 at 12:33 PM, James, Stephanie (FNIH) [T] <

Dear Tony, Zach, David and Margareth,

The Convention on Biological Diversity is starting up its activities on synthetic biology again, which will include restarting the discussion on gene drive technology that began last December in Cancun. Please see the attached notice for more details.

> wrote:

By way of this email, I would like to introduce you to Isabelle Coche. Isabelle will be working on efforts to get a broader scientific perspective represented in these discussions. She is looking for a few good scientists who have a broad perspective on the issues around gene drive and are mature enough to be able to deal with the kinds of conversations that can arise within the CBD arena. I have suggested that you folks fit both of those descriptions.

Isabelle would like the chance to explain what this all means and what activities will be needed to fight back the gene drive moratorium proponents before the next CBD meeting in 2018. Ultimately, she is looking to get some volunteers to help in this cause. I hope you will all be interested enough to get back in touch with her to learn more about what this might entail. I'm sorry to say that these next few years are going to be critical and we are going to have to take the fight outside the laboratory. I hope you will get back to Isabelle to learn more about how you can contribute.

Thanks in advance for considering this. Best, Stephanie

Zach N. Adelman
Associate Professor
Department of Entomology
Texas A&M University
329A Minnie Belle Heep Center
370 Olsen Blvd, College Station, TX 77843
979-458-3107

This version of Total Outlook Converter  $\ensuremath{\mathsf{Pro}}$  is not registered.

From: Hoyle, Stefan L B

To: zachadel@tamu.edu

Date: 5/12/2017 11:46:03 AM

Subject: Pic of large cages

Stef

Sent from my Windows Phone

This version of Total Outlook Converter  $\ensuremath{\mathsf{Pro}}$  is not registered.



From: Zachary Adelman <zachadel@tamu.edu>

To: Quinlan, Megan M
Date: 5/12/2017 11:10:38 AM

Subject: Re: Email or Skype message if you're ready to join us by Skype

my skype crashed when our call went through. restarting.

On Fri, May 12, 2017 at 11:05 AM, Zachary Adelman < <u>zachadel@tamu.edu</u> > wrote:

Megan,

I am signed into skype.

zach

On Fri, May 12, 2017 at 9:38 AM, Zachary Adelman <<u>zachadel@tamu.edu</u> > wrote:

ok.

On Fri, May 12, 2017 at 9:38 AM, Quinlan, Megan M < m.quinlan We are meeting again at Europe 6 pm, about 90 min from now.

> wrote:

I'll set up and try skyping you then.

On 12 May 2017, at 16:01, Zachary Adelman < <u>zachadel@tamu.edu</u> > wrote:

no problem. my day is just beginning.

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Maybe you were calling me when I was adding you but we are pretty well done until we go to the hotel now.

Want to speak in an hour or so?

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yes, i am. i tried calling in but there was no answer.

On Fri, May 12, 2017 at 8:44 AM, Quinlan, Megan M < m.quinlan@

> wrote:

It looks like you're on?

Sent from my iPhone On 12 May 2017, at 15:42, Zachary Adelman <<u>zachadel@tamu.edu</u> > wrote: ok, will try again in 10 min. On Fri, May 12, 2017 at 8:39 AM, Quinlan, Megan M < m.quinlan@ wrote: Can we make it 5-10 min? I'm not too good on these clock reading skills Sent from my iPhone On 12 May 2017, at 15:35, Zachary Adelman < <u>zachadel@tamu.edu</u> > wrote: Megan, you were 1 hr off. it is 8:30am for me now, i can join by skype or by phone anytime. zach On Fri, May 12, 2017 at 7:27 AM, Quinlan, Megan M <m.quinlan@ > wrote:

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This version of Total Outlook Converter Pro is not registered.						
,						

From: Zachary Adelman <zachadel@tamu.edu>

To: Quinlan, Megan M
Date: 5/12/2017 8:54:30 AM

Subject: Re: Email or Skype message if you're ready to join us by Skype

no, i tried to call to your skype account but you did not respond. if you are already talking on skype, you will need to add me to the call.

On Fri, May 12, 2017 at 8:52 AM, Quinlan, Megan M < m.quinlan@

> wrote:

So you're able to hear us? Sorry we can't hear you if you ..

Sent from my iPhone

On 12 May 2017, at 15:51, Zachary Adelman <<u>zachadel@tamu.edu</u> > wrote:

yes, i am. i tried calling in but there was no answer.

On Fri, May 12, 2017 at 8:44 AM, Quinlan, Megan M < m.quinlan@

> wrote:

It looks like you're on?

Sent from my iPhone

On 12 May 2017, at 15:42, Zachary Adelman < <u>zachadel@tamu.edu</u> > wrote:

ok, will try again in 10 min.

On Fri, May 12, 2017 at 8:39 AM, Quinlan, Megan M < m.quinlan@

> wrote:

Can we make it 5-10 min?

I'm not too good on these clock reading skills

Sent from my iPhone

On 12 May 2017, at 15:35, Zachary Adelman < <u>zachadel@tamu.edu</u> > wrote:

Megan,

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From: Zachary Adelman <zachadel@tamu.edu>

To: Quinlan, Megan M
Date: 5/12/2017 8:51:26 AM

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From: Quinlan, Megan M < m.quinlan@

To: Zachary Adelman
Date: 5/12/2017 8:44:28 AM

Subject: Re: Email or Skype message if you're ready to join us by Skype

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On Fri, May 12, 2017 at 7:27 AM, Quinlan, Megan M < m.quinlan@

From: Zachary Adelman <zachadel@tamu.edu>

To: Quinlan, Megan M
Date: 5/12/2017 8:41:48 AM

Subject: Re: Email or Skype message if you're ready to join us by Skype

ok, will try again in 10 min.

On Fri, May 12, 2017 at 8:39 AM, Quinlan, Megan M < m.quinlan

> wrote:

Can we make it 5-10 min?

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zach

On Fri, May 12, 2017 at 7:27 AM, Quinlan, Megan M < m.quinlan@

From: Quinlan, Megan M < m.quinlan@

To: Zachary Adelman
Date: 5/12/2017 8:39:06 AM

Subject: Re: Email or Skype message if you're ready to join us by Skype

Can we make it 5-10 min?

I'm not too good on these clock reading skills

Sent from my iPhone

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On Fri, May 12, 2017 at 7:27 AM, Quinlan, Megan M < m.quinlan@

From: Teresa Gold <t-gold@tamu.edu>

To: <u>Aaron Tarone</u>

Adrienne Brundage

Carla Smith

Cecilia Tamborindeguy

**Craig Coates** 

David Ragsdale

Edward Vargo

**Gabriel Hamer** 

**Gregory Sword** 

Hojun Song

Jeffery Tomberlin

James Woolley

John Oswald

Juliana Rangel Posada

Bernal, Julio S

**Kevin Myles** 

Keyan Zhu Salzman

Kevin Heinz

Michel Slotman

Micky Eubanks (m-eubanks@tamu.edu)

Patricia Pietrantonio

Pete Teel

Raul Medina

Robert N. Coulson (r-coulson@tamu.edu)

Robert Puckett

Johnston J Spencer

Spencer T Behmer (s-behmer@tamu.edu)

Zach Adelman

Szczepaniec, Adrianna

Allen Knutson

Charles T Allen (ct-allen@tamu.edu)

**David Kerns** 

Bynum Jr, Edsel D

Forrest Mitchell

<u>Ismael Badillo</u>

Way, Michael O

Megha Parajulee

Michael Brewer Mike Merchant

Pat Porter (p-porter@tamu.edu)

Bowling, Robert D

Robert Puckett

Swiger, Sonja L

Vyavhare, Suhas S

Wilson, Lloyd T

Date: 5/12/2017 8:35:54 AM

Subject: FW: Application for a postdoctoral position

Attachments: Curriculum Vitae+Guan-Heng Zhu.pdf

#### Forward on behalf of Dr. Ragsdale

From: 朱冠恒 [<u>mailto:</u> Sent: Friday, May 12, 2017 3:35 AM

To: David Ragsdale

**Subject:** Application for a postdoctoral position

Dear Prof. David Ragsdale,

Here is Guan-Heng Zhu, a PhD candidate supervised by Prof. Shuang-Lin Dong at Department of Entomology of Nanjing Agricultural University, China. I will graduate and get the PhD degree in June, 2017. I am writing this letter to apply a postdoctoral research position in your lab.

]

My dissertation title is "Functional characterization of PBP and BLOS2 genes in *Spodoptera litura* by CRISPR/Cas9 mediated genome editing". The research mainly dealt with establishing mutant lines of three PBP genes individually and in combination by CRISPR/Cas9, and then determining the functional differentiation of the three PBP genes *in vivo* by electrophysiological (electroantennogram, EAG) and behavioral experiments. The results on *SlitPBP3* has been published on Insect Biochemistry and Molecular Biology (75, 1-9), which is the first report of functional study with insect olfactory related genes by using CRISPR/Cas9. The results obtained from mutant moth lines with other two SlitPBP genes knocked out individually are expected to generate a second paper published in IBMB or other journals.

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Attached please find my CV with the statement of my research interest. With the experience and skills, I believe I will be helpful and make a deserved contribution to your lab, if I can obtain a postdoctoral position. I am more than willing to answer any questions concerning my application and research.

Thank you very much for your consideration.

Yours truly, Guan-Heng Zhu

--

Guan-Heng Zhu

Department of Entomology, Nanjing Agricultural University;

Key Laboratory of Integrated Management of Crop Diseases and Pests,

Ministry of Education

Nanjing 210095,

China

# **CURRICULUM VITAE**

Name: Guan-Heng hu

Gender: Male

**Date of Birth:** September

**Current Position:** Ph candidate in Lab of Insect Biochemistry,

Physiology Molecular Biology, College of Plant

Protection, Nanjing Agricultural University

Address: Weigang NO., uanwu district, Nanjing, , China

Phone: - - 3 (work)
E-mail: huguanheng .com



### Research background

I have three years of research experience in C ISP /Cas system and interested in expanding the C ISP /Cas system on non-model lepidopteran pests, for use in both gene functional study and novel pest control strategy development. In my work, each of the 3 pheromone binding protein genes (PBPs) in *Spodoptera litura* were knocked out by C ISP /Cas , and the *in vivo* functional analysis of PBPs were performed by electroantennography (EAG) and behavioral experiments. To explore the molecular interaction between PBP genes and other genes involved in sex pheromone perception, transcriptomic expression profiling of antennae in response to *SlitPBP1* knock out were performed and analy ed by means of NA-seq quantification. The results on *SlitPBP3* has been published on Insect Biochemistry and Molecular Biology ( , - ), which is the first report of functional study with insect olfactory related genes by using C ISP /Cas . The results obtained from mutant moth lines with other two *SlitPBP* genes knocked out individually are expected to generate a second paper published in IBMB or other journals.

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Dissertation: "C ISP /Cas system based functional characteri ation of PBP and BLOS in Spodoptera litura"

Advisor Prof. Shuang-Lin ong

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- ◆ Oct 3- an , Exchange student of Prof. ong-Ping Huang, ey Laboratory of Insect evelopmental and Evolutionary Biology, Institute of Plant Physiology and Ecology, Chinese Academy of Sciences, Shanghai Institutes for Biological Sciences, Shanghai, China
- ◆ September , , Oral Presentation, the <sup>nd</sup> International Conference of Insect Genomics (ICIG ).

Chongqing, China.

Title "High rate and heritable mutagenesis of pheromone binding protein gene by C ISP /Cas mediated genome editing in *Spodoptera litura*" Page - .

◆ September 3- , Oral Presentation, the <sup>th</sup> Asia-Pacific Association of Chemical Ecology (APAEC) Conference.

California, USA

Title "High rate and heritable mutagenesis of *SlitPBP1* in *Spodoptera litura* by C ISP /Cas mediated genome editing" Page 3.

 uly - , Oral Presentation, the <sup>th</sup> Conference of the Chinese Association of Chemical Ecology.

Wuhan, China

Title "Functional characterization of *SlitPBP3* in *Spodoptera litura* by C ISP /Cas mediated genome editing".

# **Publications** ( Corresponding author)

- . **Zhu GH**, u , Cui , ong T, e F, Niu , Huang P and ong SL ( ) Functional characteri ation of *SlitPBP3* in *Spodoptera litura* by C ISP /Cas mediated genome editing. *Insect Biochem Mol Biol*. .
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# **Research Skills**

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**Computer skill:** Microsoft Word, Microsoft Excel, Microsoft PowerPoint, Photoshop, Snap Gene, MEGA, uantity One, GraphPad Prism, EndNote, and biological databases.

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- ◆ The first award reporter in the th Conference of the Chinese Association of Chemical Ecology.
   ( )
- ◆ First Academic Scholarship ( )
- ◆ First Academic Scholarship ( )
- ◆ Third Academic Scholarship ( )

# References

I respectfully submit that the following individuals would be my references

- Prof. Shuang-Lin ong, Education Ministry ey Laboratory of Integrated Management of Crop isease and Pests, College of Plant Protection, Nanjing Agricultural University, Nanjing, China. Email <a href="sldong njau.edu.cn">sldong njau.edu.cn</a>.
- Prof. hao- un Han, Education Ministry ey Laboratory of Integrated Management of Crop isease and Pests, College of Plant Protection, Nanjing Agricultural University, Nanjing, China. Email <a href="mailto:jhan\_njau.edu.cn">jhan\_njau.edu.cn</a>.
- Prof. ohn Pickett, National Academy of science (US) Foreign Associate, Michael Elliott istinguished esearch Fellow, othamsted esearch, West Common, Harpenden, Hertfordshire, AL , U . Email john.pickett rothamsted.ac.uk.

From: Zachary Adelman <zachadel@tamu.edu>

To: Quinlan, Megan M
Date: 5/12/2017 8:35:08 AM

Subject: Re: Email or Skype message if you're ready to join us by Skype

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zach

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This version of Total Outlook Converter  $\ensuremath{\mathsf{Pro}}$  is not registered.

From: Quinlan, Megan M < m.quinlan@

To: <u>zachadel@tamu.edu</u>
Date: 5/12/2017 7:27:50 AM

Subject: Email or Skype message if you're ready to join us by Skype

From: <u>朱冠恒 <z</u>

To: <a href="mailto:zachadel@tamu.edu">zachadel@tamu.edu</a>
Date: 5/12/2017 2:58:07 AM

Subject: Application for a postdoctoral position Attachments: Curriculum Vitae+Guan-Heng Zhu.pdf

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Thank you very much for your consideration.

Yours truly,

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Key Laboratory of Integrated Management of Crop Diseases and Pests,

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Nanjing 210095,

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Gender: Male

**Date of Birth:** September

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E-mail: huguanheng .com



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- ◆ Third Academic Scholarship ( )

From: Zachary Adelman <zachadel@tamu.edu>

To: Quinlan, Megan M
Date: 5/11/2017 2:56:37 PM
Subject: Re: Possible focus for Zach

all are word documents, but i haven't had a chance to actually mark any of them up at this point. I just have some notes and will ask some questions. will make detailed comments on each document after we meet tomorrow.

On Thu, May 11, 2017 at 2:14 PM, Quinlan, Megan M < m.quinlan@

wrote

I can't recall are they all PDF? I can try to get Word versions if you want to edit directly.

Sent from my iPhone

On 11 May 2017, at 19:09, Zachary Adelman < <u>zachadel@tamu.edu</u> > wrote:

Meghan.

I am happy to contribute in terms of reporting and conflicts of interest; i also will have comments on many of the other SOPs.

zach

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Hi Zach

Just to update you remote participants, we haven't added photos because we couldn't enter the site today due to a water leak incident.

We will do that tomorrow. I copied Scott to say that.

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Zach, given the weight of documents added with little time before now, would you be comfortable focusing on the Code (under SOPs folder) and the materials under personnel (both under internal docs and resources) with the aim of:

Clarifying lines of reporting and responsibilities in terms of conflict of interest or lack of clarity -

I was thinking as reading that a chart of who reports to whom by topic is interesting in the upper levels. I'm not clear who has the final say or oversight. Let me know if this makes sense and if you'd prefer to focus elsewhere.

If you have particular questions send an email but otherwise we will try to clarify a few things in the morning and be ready for your input and questions later in the day. I understand you're online from 8:30 am and will bring you in by Skype or email the revised timing.

Thanks, speak tomorrow

Megan

From: Quinlan, Megan M < m.quinlan@

To: Zachary Adelman

Date: 5/11/2017 2:14:20 PM

Subject: Re: Possible focus for Zach

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Megan

From: Zachary Adelman <zachadel@tamu.edu>

To: Quinlan, Megan M
CC: sweaver@UTMB.EDU
Date: 5/11/2017 12:09:47 PM
Subject: Re: Possible focus for Zach

#### Meghan,

I am happy to contribute in terms of reporting and conflicts of interest; i also will have comments on many of the other SOPs.

zach

On Thu, May 11, 2017 at 10:23 AM, Quinlan, Megan M < m.quinlan@

> wrote:

Hi Zach

Just to update you remote participants, we haven't added photos because we couldn't enter the site today due to a water leak incident.

We will do that tomorrow. I copied Scott to say that.

---

Zach, given the weight of documents added with little time before now, would you be comfortable focusing on the Code (under SOPs folder) and the materials under personnel (both under internal docs and resources) with the aim of:

Clarifying lines of reporting and responsibilities in terms of conflict of interest or lack of clarity -

I was thinking as reading that a chart of who reports to whom by topic is interesting in the upper levels. I'm not clear who has the final say or oversight. Let me know if this makes sense and if you'd prefer to focus elsewhere.

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Megan

From: Quinlan, Megan M < m.quinlan@

To: zachadel@tamu.edu
CC: sweaver@UTMB.EDU
Date: 5/11/2017 10:23:17 AM
Subject: Possible focus for Zach

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\_\_\_

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Thanks, speak tomorrow Megan

From: Kevin Myles <mylesk@tamu.edu>

To: Madhav Erraguntla
CC: Zachary Adelman
Date: 5/9/2017 4:46:12 PM

Subject: Re: DURC Attachments: 1534.full.pdf

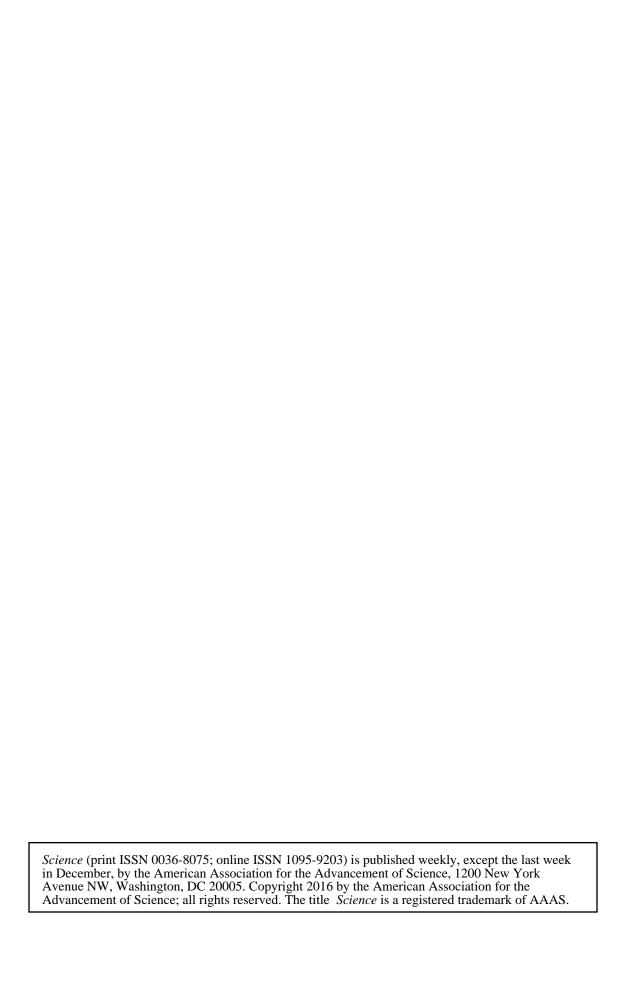
ATT00002.html

UW bird flu research seen as bioterror threat.pdf

ATT00004.html nature10831.pdf ATT00006.html

Madhav,

Please find two Avian Influenza papers attached







#### **WISCONSIN NEWS**

# UW bird flu research seen as bioterror threat

By Don Walker and Karen Herzog of the Journal Sentinel

Dec. 16, 2011

A University of Wisconsin-Madison scientist who is an expert on the avian flu virus is under scrutiny because of concerns his new research may fall into the wrong hands.

The scientist is Yoshihiro Kawaoka, an eminent professor of virology in the School of Veterinary Medicine who has done research on H5N1, also known as the avian bird flu. His work and similar research independently done by a Dutch scientist have raised concerns in science journals and on an NBC News report that aired Thursday night that touched on such controversial issues as bioterrorism and scientific freedom

Kawaoka has created a contagion virus in his lab, a UW official confirmed. But the official said he couldn't discuss the nature of the virus because it would compromise the publication of Kawaoka's research.

A Science magazine report detailing the work done by Dutch scientist Ron Fouchier of the Erasmus Medical Center in the Netherlands reported that Fouchier had developed a man-made H5N1 avian influenza strain that had been genetically altered and is now easily transmissible between ferrets. Fouchier reported that studies show that any influenza strain passed among ferrets has also been transmissible among humans and vice versa.

The Science report, which focused on Fouchier's studies, said Kawaoka's research came up with comparable results.

"The research by the Kawaoka and Fouchier teams set out to answer a question that has long puzzled scientists. Does H5N1, which rarely causes human disease, have the potential to trigger a pandemic?" the magazine reported.

In response, UW spokesman Terry Devitt said Science magazine had not seen Kawaoka's research. "Equating the two ... is a mistake," Devitt said in an email.

Devitt said Kawaoka's work was no longer under review by the National Science Advisory Board for Biosecurity. That board provides advice to the National Institutes for Health regarding research that may pose a threat to public health and/or national security.

The board "made recommendations regarding the contents of the manuscript, and those recommendations will be respected as we work with the journal," Devitt said.

A spokesman for the advisory board was not available for comment.

# **Security Defended**

Interim UW Chancellor David Ward said he had been briefed about Kawaoka's research about a month ago and said he was confident that the level of security involving Kawaoka's research was adequate.

"In general, I am very comfortable with the way the university has created security around this. . . . We do deserve questions from the public about the fact that this could potentially, you know, be a problem. But the people doing the research were conscious of this right from the start, evaluated the trade-offs, and I think my conclusion was there is really no public threat with what has happened."

Ward added that he supported the publication of Kawaoka's findings.

Devitt added that the H5N1 virus had been studied on campus and elsewhere for years. He said it would be inaccurate to describe H5N1 as a pandemic virus.

"We have comprehensive and stringent biosafety and biosecurity measures in place," Devitt said. "Those measures are constantly reviewed and updated. Also, the university is subject to federal oversight of work with this and other agents, including unannounced inspections."

# **Warning Made**

Nevertheless, the leaders of the Center for Biosecurity at the University of Pittsburgh Medical Center raised questions about the research.

"We are playing with fire," said an editorial published online Thursday by the center.

The editorial warned that researchers went too far when they genetically engineered an avian flu strain that could be spread quickly among humans.

"There are no guarantees that such a deadly strain of avian flu would not escape accidentally from the laboratory," said the editorial in the peer-reviewed journal, Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science.

The article was written in response to the Dutch research, but it also applies to avian flu research at UW, a spokeswoman for the Center for Biosecurity said Friday.

The Dutch experiment was performed by internationally respected scientists in biosafety conditions considered top of the line, the editorial noted. "The risk of a person accidentally becoming infected and starting an outbreak with this strain is low. But it is not zero," it said.

An accidental escape of an influenza strain from a lab in 1977 led to widespread flu epidemics, the editorial says. "Given the potential global consequences of an accident with the newly modified strain of avian flu, we are playing with fire."

The Center for Biosecurity said in its editorial that it didn't oppose research in high-containment labs using dangerous pathogens, including H5N1, but research to develop diagnostics, medicines and vaccines for the most-threatening infectious diseases does not require engineering lethal viruses to make them more transmissible between humans.

A critical tenet of the advancement of science is the publication of new research in a form that allows other scientists to reproduce the work, the editorial notes, adding: "This principle should be followed in almost all conceivable circumstances. But in this circumstance, it shouldn't.

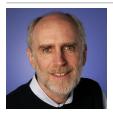
"Publishing the methods for transforming the H5N1 virus into a highly transmissible strain would show other scientists around the world how to do it in their own labs," it continued. "One concern is the possibility that the strain would be recreated for malevolent purposes. Even disregarding this risk (which we shouldn't), scientific publication would encourage others that this is a research initiative worthy of additional exploration. . . . Whether this experiment is published or not, it is a reminder of the power of biology and its potential. We need new approaches for the rapid development of large quantities of medicines or vaccines to protect us against new emerging viruses. But engineering highly transmissible strains of avian flu is not the way to get us there."

Devitt added that officials feel publishing Kawaoka's work won't pose a risk beyond what is already known about influenza viruses.

"For example, the genome of the 1918 flu virus, which is far more pathogenic than the virus in question, is already publicly available," he said.

Devitt said Kawaoka's research and the work of other scientists is the best defense against a virus that could become pandemic in nature.

"Based on a review of the research by the National Science Advisory Board for Biosecurity and at their recommendation, any publication will be crafted to minimize the opportunity for misuse," Devitt said.



**About Don Walker** 

Don Walker covers Milwaukee's City Hall and the business of sports.



**About Karen Herzog** 

Karen Herzog covers higher education. She also has covered public health and was part of a national award-winning team that took on Milwaukee's infant mortality crisis.

#### Find this article at:

http://archive.jsonline.com/news/wisconsin/uw-bird-flu-research-causes-concern-v43 fjm5-135778778.html

Check the box to include the list of links referenced in the article.



From: O'Reilly, Marina (NIH/OD) [E] < OReillyM@OD.NIH.GOV>

To: Michael B. Atkins

'Cho, Mildred'

'Curry William T'

'Donahue, Kevin'

'Hardison, Angelica'

'Hearing Patrick'

'Kaufman, Howard'

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'Ross, Lainie'

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'Albritton, Lorraine M'

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Vatsan, Ramjay (FDA/CBER)

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Beckham, Shayla (NIH/OD) [E]

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'hibe@partners.org'

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'sadavis@peds.uab.edu'

Date: 5/9/2017 4:11:37 PM

Subject: June RAC meeting

Dear RAC and incoming members,

The RAC will not be convened for the meeting scheduled for June 21-23rd. OSP has completed the evaluation of protocols submitted by the deadline for this quarter, and none warranted in-depth review and discussion. Thank you for holding the dates until now and would you please hold the dates for the upcoming meetings?

Sept. 28-29, 2017 Dec. 7-8, 2017 March 7-8, 2018

I'll be sending you soon updated info about the upcoming workshop: NIH Guidelines: Honoring the Past, Charting the Future on July 18-19th. If anyone else would like to attend in person, please let me know so that we can help with travel arrangements. The meeting will also be webcast and archived.

Please let me know if you have any questions. We hope we might see some of you at the ASGCT meeting this week.

Thanks, The RAC team

Marina O'Reilly, Ph.D. Director, Recombinant DNA Activities Program Division of Biosafety, Biosecurity, and Emerging Biotechnologies Policy Office of Science Policy Office of the Director

National Institutes of Health 6705 Rockledge Dr., Suite 750 Bethesda, MD 20892 (301) 594-1974 (direct) (301) 496-9838 (OSP office) oreillym@od.nih.gov

Please follow us on Twitter: @CWolinetzNIH
Subscribe to "<u>Under the Poliscope</u>" NIH OSP's new blog!

Hall, Lee (NIH/NIAID) [E]

Claudia Emerson (claudia.emerson

mcapurro@

aajames@uci.edu CC: Tountas, Karen (FNIH) [T]

Claudia Emerson

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Date: 5/8/2017 5:11:48 PM

Subject: RE: Talking about Gene Drive

Attachments: Draft agenda - Talking About Gene Drive v4.docx

#### Dear colleagues,

Based on demonstration of interest, the Foundation for the National Institutes of Health (FNIH) will sponsor a one day workshop on the topic of "Talking about Gene Drive" – to be held just before the annual American Society of Tropical Medicine and Hygiene (ASTMH) meeting on November 4, 2017, in Baltimore, MD.

The intent of the workshop will be to:

- discuss how gene drive technology is being described in the media and at venues such as the Convention on Biological Diversity;
- consider ways to work together to enhance communication and clarify public perception about gene drive technology;
- share some basic communications skills that might come in handy in the future

A revised draft agenda responding to various initial comments is attached.

The workshop is open to those working on gene drive technology for public health and conservation goals. We believe this will provide an important venue for bringing both groups together to discuss plans for communicating about the technology with the public. Please let me know if there are others not included on this list who might be interested in attending. FNIH will open a registration page closer to the time in order to judge logistics requirements.

FNIH will support the cost of the meeting space, food (breakfast and lunch) and speaker travel. We are holding this workshop in conjunction with the ASTMH meeting because many interested parties are already planning to attend that meeting. We regret that FNIH cannot support the participation of all attendees. We assume that most of you have some travel support from other sources, but please let me know if that is not the case. We hope that you will add this to your calendar and plan to join us for some lively conversation!

Best regards,
Stephanie
Stephanie James, PhD, FASTMH
Director, Science Division
Foundation for the National Institutes of Health
9650 Rockville Pike | Bethesda, MD 20814 | www.fnih.org
Direct (301) 451-2810 | Fax (301) 480-1661 | Email s



For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that exceeds industry standards.

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# **Talking About Gene Drive: Communications Workshop**

# Baltimore, MD Nov 4, 2017

#### **Location TBD**

# **Draft Agenda:**

Time	Session	Moderator
8:30 - 9:00	Breakfast and networking	N/A
9:00 - 9:15	Introductions and meeting objectives	Stephanie James, FNIH
9:15 – 10:00	Media landscape A look at gene drive media coverage over the past 18 months and benchmarking against past scientific developments	Kalina Kamenova, McMaster University
10:00 – 10:30	Conventions and regulatory landscape A review of gene drive discussions within the International Union for the Conservation of Nature, the Convention on Biological Diversity and in the regulatory space	Heath Packard, Island Conservation Isabelle Coche, Emerging Ag Bob Friedman, Venter Institute
10:30 – 11:00	Public perception  Moderated discussion on how different public audiences view GM mosquitoes	TBD
11:00 – 12:00	Gene drive terminology Presentation of preliminary findings of testing gene drive concepts and terminology with stakeholders and informed publics	Isabelle Coche, Emerging Ag Jeff Chertack, BMGF
12:00 - 1:00	Lunch	
1:00 – 2:00	Applied communications Shared past experiences with reporters, government officials, the public; what works and what doesn't	All (moderated by Communications expert)
2:00 – 4:30	Communications skills  Tips and strategies for effective scientific communications	Communications expert
4:30 – 4:45	Wrap up Thoughts on what more is needed – additional materials, discussion sessions, etc.	Stephanie James, FNIH
4:45 – 5:15	<b>Discussion on follow up</b> Other topics that might benefit from collective thinking?	Stephanie James, FNIH

Hall, Lee (NIH/NIAID) [E]

Claudia Emerson (claudia.emerson

mcapurro@

aajames@uci.edu CC: Tountas, Karen (FNIH) [T]

Claudia Emerson

This version of Total Outlook Converter Pro is not registered. From: James, Stephanie (FNIH) [T] To: 'Zachary Adelman' 'Zhijian Tu' 'aajames@uci.edu' 'Friedman, Robert 'gclanzaro@ucdavis.edu' 'omar.akbari@ucr.edu' 'Cinnamon Bloss' 'sentelle@uci.edu' 'john.marshall@berkeley.edu' 'Kevin Esvelt' 'fcatter@hsph.harvard.edu' Fred Gould 'dfwirth@hsph.harvard.edu' 'pagre@jhu.edu' a.burt@ Nolan, Tony F J George Dimopoulos (gdimopo1@jhu.edu) Ethan Bier (ebier@ucsd.edu) 'ljacob13@jhu.edu' 'luke.alphey@ 'kykanesh@hawaii.edu' 'Heath Packard' 'J Royden Saah' Isabelle Coche 'ssubramani@ucsd.edu' 'Scott Miller' 'Jeff Chertack' 'Wegrzyn, Renee' 'Cheever, Anne (contr-bto)' 'Sarah Carter' 'Ryan Phelan' Anna Buchman Fred Gould Crisanti, Andrea Christophides, George K Windbichler, Nikolai a.burt@ Fredros Okumu 'Emerson, Claudia' Brindley, Paul (pbrindley@email.gwu.edu) Costero-Saint Denis, Adriana (NIH/NIAID) [E] Rao, Malla (NIH/NIAID) [E]

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# Baltimore, MD Nov 4, 2017

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4:45 – 5:15	<b>Discussion on follow up</b> Other topics that might benefit from collective thinking?	Stephanie James, FNIH

From: Zachary Adelman <zachadel@tamu.edu>

To: PathogenGH

Date: 5/8/2017 9:42:01 AM
Subject: Re: PGH Gene Drive issue

Christo,

I would like to participate in this special issue, but i will not be able to make a June30th deadline. I could submit in August.

best,

zach

On Fri, Apr 28, 2017 at 9:11 AM, PathogenGH < pathogengh@

> wrote:

Dear Zach.

We now have the research line-up together for our special issue edition of Pathogens and Global Health. Which is the following:

- Population modification of Anopheline species to control malaria transmission (Tony James)
- Mutations: off-target effects and natural mutations (Kevin Esvelt)
- Policy and regulatory roadblocks (Megan Palmer)
- Modelling of anti- gene drive approaches (Austin Burt)
- Current state and future directions (Andrea Crisanti lab)
- Protection against the spread of gene drives through accidental release into the wild (Andrea Beaghton, Drew Hammond + Sam O'Laughlin)

Prof Crisanti is still keen on having your contribution and it isn't too late. If you'd like to author a review on a topic that isn't yet covered then please submit a proposal as soon as you can.

The proposed deadline for the first draft is Friday June 30th.

All the best

Christo Hall
Editorial Assistant
Pathogens and Global Health
Imperial College London

From: PathogenGH

Sent: 27 March 2017 12:30:45

To: Zachary Adelman

**Subject:** Re: PGH Gene Drive issue

Dear Zach,

Thank you for the reply and apologies for the slow response, I wanted to get Andrea's feedback before responding.

The stimulus for the issue is to publish a series of articles that present the methods and applications of gene drive that have public health benefit, in particular in order to engage with policy and regulation issues, and review the ethical controversies as a result of its potential implementation. We aim to bring together a group of leading scientists to present a particular element (e.g. mutations; species-specific control; protection against accidental release), all of which will consider the risks and benefits of building and implementing gene drives. As a whole, the issue will bridge the technical and policy issues of implementation and create a dialogue with other non-research groups, which we will put together through a series of commentaries from stakeholders from other fields, including governments.

Regarding formats, we are looking for reviews that present an up-to-date overview of the current status of a particular subject. Usually our reviews are 2,500-4,000 words but we consider each paper on its own merits. A flexible structure is encouraged (i.e. sections of your own making – as long as they engage with the above) and co-authors are fine.

Let me know if you have any questions and if you are able to contribute please submit a suggested topic. We will be sending out a guide for submission in April.

Many thanks

Christo Hall
Editorial Assistant
Pathogens and Global Health
Imperial College London

From: Zachary Adelman < <a href="mailto:zachadel@tamu.edu">zachadel@tamu.edu">zachadel@tamu.edu</a>

Sent: 09 March 2017 14:46

To: PathogenGH

Subject: Re: PGH Gene Drive issue

Christo.

Thanks for the invitation. Can you provide more information on the format/structure/length of the contributions you are looking for? Also, what in particular is the special issue trying to achieve in regards to gene drive? More detail on the background that drove the decision to produce this issue would be helpful.

Best, zach

Zach Adelman Texas A&M University

On Thu, Mar 9, 2017 at 5:49 AM, PathogenGH pathogengh@

Dear Dr Adelman,

> wrote:

I hope this email finds you well. I am emailing you on behalf of my editor, Professor Andrea Crisanti. Andrea is the editor-in-chief of Pathogens and Global Health, an infectious disease journal based in Imperial College London.

We're soliciting a special issue on gene drive, and so far we've received a very encouraging response from the community, including confirmed contributions from Tony James, Kevin Esvelt, Austin Burt, Megan Palmer and Andrea's team at Imperial. Andrea would like to extend his invitation to you if you are able to contribute something for the issue?

Please let me know if you have any questions regarding the issue. We are open to your specific suggestion of a topic and to coauthors. The deadline is June.

All the best

Christo Hall
Editorial Assistant
Pathogens and Global Health
Imperial College London

From: Madhav Erraguntla
To: Zachary Adelman

Kevin Myles

Date: 5/5/2017 2:14:28 PM

Subject: DURC

Attachments: Framework for transmittal duplex 9-10-07.pdf

Pages 26-30 of the attached document contains 7 research topics that are current focus of DURC. Most of the science aspects were beyond my comprehension, but it might make more sense to you. Anyway, we will discuss on Tue.

Have a good weekend.

Madhav

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

# Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information









A Report of the National Science Advisory Board for Biosecurity (NSABB)

June 2007

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#### ABBREVIATIONS AND ACRONYMS

**DNA** Deoxyribonucleic acid

**EMBO** European Molecular Biology Organization

**HHS** (U.S. Department of) Health and Human Services

**IACUC** Institutional Animal Care and Use Committee

**IBC** Institutional Biosafety Committee

IRB Institutional Review Board
NIH National Institutes of Health

NIH Guidelines NIH Guidelines for Research Involving Recombinant DNA Molecules

NRC National Research Council (of the U.S. National Academies)

**NSABB** National Science Advisory Board for Biosecurity

PI Principal Investigator

**Qs&As** Questions & Answers

RAC (NIH) Recombinant DNA Advisory Committee

**RNA** Ribonucleic acid

**RNAi** RNA interference

**U.S.** United States

**U.S.C.** United States Code

siRNA Small interfering RNA

#### **Executive Summary**

Life sciences research has a critical role in understanding life at the ecosystem, organism, biological system, organ, cellular, and molecular levels. Advances in the life sciences have led to new pharmaceuticals, diagnostic procedures, preventive strategies, treatments, and cures for myriad acute and chronic diseases and conditions and has contributed to improvements in animal and plant health and the food supply.

However, the information gained from life sciences research also could be used for destructive purposes that could threaten the health and safety of life on our planet. Over the past several years, especially following the terrorist attacks of September 11 and the subsequent anthrax attacks utilizing the U.S. Postal Service, there have been increasing calls to consider the possibility that new information from life sciences research could be subverted for malevolent purposes and that new biosecurity measures should be instituted to minimize this risk.

This threat has been recognized and articulated by individuals, organizations, and governments around the world. In this country, the National Science Advisory Board for Biosecurity (NSABB) was established by the U.S. Government to advise on strategies for dealing with the generation and communication of information and new technologies from life sciences research that have the potential for both benevolent and malevolent application—referred to in this report as "dual use research"—along with the subset of dual use research with significant potential for generating information that could be misused—referred to as "dual use research of concern."

The NSABB's tasks include proposing an oversight framework for the identification, review, conduct, and communication of life sciences research with dual use potential in consideration of protecting both national security concerns and the progress of the life sciences. The NSABB strongly promotes the free and open exchange of information in the life sciences to the maximum extent possible and believes that the best way to address concerns regarding dual use research is to raise awareness of the issue and strengthen the culture of understanding and responsibility within the scientific community and the public as well as instituting new oversight procedures to minimize the risk of misuse of research information.

The recommendations of the NSABB in the report that follows are not intended as guidelines but rather as a framework for the development—by the federal government—of a comprehensive system for the responsible identification, review, conduct, and communication of dual use research. In this report, the NSABB identifies principles that should underpin the oversight of dual use life sciences research, lists key features of such oversight (e.g., federal guidelines, awareness and education, evaluation and review of research for dual use potential, assessment and management of risk, compliance, and periodic evaluation at the local (e.g., research institution) and federal levels of the impact and effectiveness of oversight procedures) and proposes roles and responsibilities for researchers, institutions, the institutional review entity, and the NSABB and other federal government entities. The report also describes the major steps in local oversight of dual use life sciences research, including evaluation of life sciences research for its dual use potential, review of research identified as being potentially dual use of concern, conduct of dual use research of concern in accordance with risk management strategies, and responsible communication of research with dual use potential.

One of the fundamental tasks of the NSABB was to develop criteria for identifying dual use research of concern. The proposed criterion is "research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or materiel." As guidance for those assessing research for its dual use potential, the NSABB identified seven broad categories of information that might be generated by life sciences research that has a high potential for being dual use of concern.

NSABB members agreed that the principal investigator, using the criterion set forth above, should conduct the initial evaluation of his or her research for its potential as dual use research of concern. Those projects initially identified as dual use research of concern—and NSABB members anticipate that there will be very few projects that are truly dual use of concern—would undergo additional institutional review that involves interactive discussion among reviewers to assess the potential for and the ways in which information, technologies, or biological agents from the research could be misused to pose a threat; the likelihood that the information might be misused; the potential impacts of misuse; and the strategies for mitigating the risks that information from the research could be misused. To guide this review process, the NSABB developed "Points To Consider in Risk Assessment and Management of Research Information That Is Potentially Dual Use of Concern."

The NSABB also recommends strategies and has developed tools to help ensure that research information with dual use potential is communicated responsibly, and in a manner that addresses both biosecurity concerns and the need for open sharing of research results and technologies. These tools include a set of principles for the responsible communication of research with dual use potential; points to consider for identifying and assessing the risks and benefits of communicating research information with dual use potential, including options for the communication of such research information; and considerations for the development of a communication plan for research with dual use potential.

In fulfillment of one of its specific charges, the NSABB also provides recommendations on the development of a code of conduct for scientists and all laboratory personnel that could be adopted by professional organizations and institutions engaged in the performance of life sciences research. These are articulated in "Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences," which provides a conceptual foundation for understanding the dual use issue, describes the nature and utility of codes of conduct, articulates the fundamental principles of responsible conduct with regard to dual use research, and provides guidance on addressing the dual use issue in specific phases of the research process.

This report also addresses the importance of education and training in biosecurity issues for all life scientists and describes previous, ongoing, and future approaches to meet these goals, including the use of focus groups and roundtables, presentations at meetings of scientists and other stakeholders, exhibits at scientific meetings to educate attendees about biosecurity matters and the development of related federal policy and international dialogs. During the federal policymaking process, the NSABB recommends soliciting comment through notice in the *Federal Register*, federal government sponsorship of town-hall style regional meetings, and the

establishment of a publicly accessible docket for the collection of public comments on policy. Once requirements on the oversight of dual use research are formally agreed on by the federal government, a communications plan should be prepared for the rollout of the new federal policies as well as an intensive and ongoing campaign of workshops, presentations, print and electronic materials, exhibits, and other activities to educate all affected constituencies and promote compliance with the new requirements.

The NSABB intends to address in more detail additional aspects of oversight of dual use research issues, including outreach and education and compliance and enforcement strategies. These topics are better addressed once federal policies are more fully developed. The NSABB also strongly recommends that the U.S. Government seek broad input from the public on these and other issues presented in this report and encourage the development of education and guidance tools concerning dual use research issues by institutions, scientific associations, and professional societies. Because research is a global activity, the NSABB also recommends that the U.S. engage in dialog on these issues with other countries.

#### Introduction

Purpose of This Document. This document sets forth recommendations of the National Science Advisory Board for Biosecurity (NSABB) for the oversight of publicly funded life sciences research as a means of minimizing the potential that information, products, or technologies resulting from this research will be misused for harmful purposes. These recommendations are not intended as comprehensive guidelines for such oversight but rather to serve as a framework or springboard for the U.S. Government to develop a comprehensive and coordinated oversight policy. The NSABB hopes and expects that there will be an iterative process of consultation with the public and the government and anticipates modifying this framework in response to this input and as it addresses additional oversight issues in the future.

The Critical Role of Life Sciences Research. Life sciences research encompasses a diverse array of approaches to understanding life at the level of ecosystems, organisms, biological systems, organs, cells, and molecules. Advances in molecular and cell biology, genetics, microbiology, and other life sciences disciplines have made it possible to routinely manipulate aspects of biological systems as part of an ongoing quest to better understand the health and disease states and the life cycles of humans, animals, plants, insects and microorganisms.

Advances in the life sciences have led to new pharmaceuticals, diagnostic procedures, preventive strategies, treatments, and cures for myriad acute and chronic diseases and conditions and for emerging and reemerging infectious diseases that affect humans and exact a heavy toll in terms of quality of life, medical costs, and productivity. Similar advances have contributed to improvements in animal and plant health and the food supply.

Across the globe, researchers are manipulating microorganisms to gain a deeper understanding of how they cause disease to identify new targets for the development of novel and improved treatments for the diseases these microbes cause, identify new strategies for the control of microorganisms, and develop measures to prevent infection with or illness caused by microorganisms.

Plant biologists are utilizing similar approaches to enhance crop yield and nutritional content and explore the potential for using plants to manufacture products such as vaccines, antibodies, and other biological products. Similar efforts are underway in the field of animal husbandry in an effort to produce animals for human consumption that are heartier and better sources of nutrition. In other arenas, life scientists are developing environmental remediation technologies and creating new materials and even energy sources.<sup>1</sup>

The Dual Use Research Issue. Information from life sciences research is clearly vital to improving public health, agriculture, and the environment and maintaining and strengthening our national security and economy. Yet the very information and tools developed to better the health, welfare, and safety of humankind also can be misused for harmful purposes. Information

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<sup>&</sup>lt;sup>1</sup> Globalization, Biosecurity, and the Future of the Life Sciences, a 2006 report of the National Research Council's Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats, pp. 1, 83.

from legitimate life sciences research can be misapplied to create dangerous pathogens for employment as weapons, bypass countermeasures or threaten in other ways the health and safety of humans, animals, plants, and the environment or to cause harmful consequences to materiel.<sup>2</sup>

This was recognized by the European Molecular Biology Organization (EMBO) at its 2006 meeting<sup>3</sup> and was also eloquently articulated in a statement by an august group of scientific journal editors and authors: "The process of scientific publication, through which new findings are reviewed for quality and then presented to the rest of the scientific community and the public, is a vital element in our national life. New discoveries reported in research papers have helped improve the human condition in myriad ways: protecting public health, multiplying agricultural yields, fostering technological development and economic growth, and enhancing global stability and security. But new science, as we know, may sometimes have costs as well as benefits. . . . As a result, questions have been asked by the scientists themselves and by some political leaders about the possibility that new information published in research journals might give aid to those with malevolent ends." <sup>4</sup>

The development of new technologies and the generation of information with the potential for benevolent and malevolent purposes are referred to in this report as "dual use research." This dual use quality is inherent in a significant portion of life sciences research. In fact, it can be argued that virtually all life sciences research has dual use potential. Later in this report, we describe a subset of dual use research that has the highest potential for generating information that could be misused, which we call "dual use research of concern."

The NSABB gave a great deal of thought to the issue of how much life sciences research might reasonably be considered dual use research of concern. Although it was not possible to quantify the exact amount of dual use research of concern that is generated in the U.S. or elsewhere in a given period such as a year, preliminary analyses suggested that the number of cases of true dual use research of concern will be quite small. Similarly, it was not possible to quantify the risk of misuse of information from that research, but there was a consensus among NSABB members that there is indeed the potential for misuse with severe consequences to public health and safety and other areas presented herein. Misuse of dual use research of concern is therefore a low-probability but potentially high-consequence event, and this is a significant factor in the NSABB's formulation of oversight recommendations.

Calls to Action. Over the past several years, especially following the terrorist attacks of September 11, 2001 and the subsequent anthrax attacks utilizing the U.S. Postal Service over the course of several weeks beginning on September 18, 2001, there have been increasing calls to consider the possibility that new information from life sciences research could be subverted for malevolent purposes and to institute new biosecurity measures to minimize this risk.

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<sup>&</sup>lt;sup>2</sup>Materiel includes food, water, equipment, supplies, or material of any kind.

<sup>&</sup>lt;sup>3</sup>EMBO Reports, vol. 7, Special Issue on Science and Society (2006).

<sup>&</sup>lt;sup>4</sup>Journal Editors and Authors Group, *Statement on the Consideration of Biodefence and Biosecurity. Nature* vol. 421, February 20, 2003.

<sup>&</sup>lt;sup>5</sup>The NSABB Charter also describes dual use research. See Appendix 1.

Concerns about the dual use potential of biotechnology research have been articulated in reports from the National Research Council (NRC) of the U.S. National Academies, together with a number of recommendations for addressing such concerns. <sup>6,7</sup> One of the reports noted that, "[w]ith regard to oversight of research, no country has developed guidelines and practices to address all aspects of biotechnology research. . . . [E]xisting domestic and international guidelines and regulations for the conduct of basic or applied genetic engineering research may ensure the physical safety of laboratory workers and the surrounding environment from contact with or exposure to pathogenic agents or 'novel' organisms. However, they do not currently address the potential for misuse of the tools, technology, or knowledge base of the research enterprise for offensive military or terrorist purposes. In addition, no national or international review body currently has the legal authority or self-governance responsibility to evaluate a proposed research activity prior to its conduct to determine whether the risks associated with the proposed research, and its potential for misuses outweigh its potential benefits.... [T]he existing fragmentary system must be adapted, enhanced, supplemented, and linked to provide a system of oversight that will give confidence that the potential risks of misuse of dual use research are being adequately addressed while enabling vital research to go forward."8

Similarly, the Royal Society and the Wellcome Trust noted that "[r]esearch institutions and funding agencies need to consider how to build on existing processes for reviewing research projects to ensure that risks of misuse are assessed in an appropriate and timely manner." Likewise, a group of distinguished journal editors and authors convened to consider biodefense and biosecurity recommended that "[s]cientists and their journals should consider the appropriate level and design of processes to accomplish effective review of papers that raise such security issues.",10

U.S. Government Response. In acknowledgment that the threat of the misuse of research information is important and real, the U.S. Government agreed that new biosecurity measures were warranted to minimize the risk that information from life sciences research might be misused to threaten public health and safety and other aspects of national security. One of these biosecurity initiatives was the establishment of an advisory body, the NSABB. The NSABB charter states that its purpose is to recommend strategies for the efficient and effective oversight of federally conducted or supported dual use biological research (see Appendix 1 for the NSABB charter and the current roster of NSABB members.)

The NSABB is charged with a significant set of specific tasks, including proposing an oversight framework for the identification, review, conduct, and communication of life sciences research with dual use potential. In doing so, the NSABB was instructed to consider both national security concerns and the needs of the life sciences research community. The latter directive acknowledges the vital role of life sciences research in public health and in national security and

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<sup>&</sup>lt;sup>6</sup>Biotechnology Research in an Age of Terrorism. Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology, National Research Council. National Academies Press, Washington, DC (2004).

<sup>&</sup>lt;sup>7</sup>Globalization, Biosecurity, and the Future of the Life Sciences. Op. cit.

<sup>&</sup>lt;sup>8</sup>Biotechnology Research in an Age of Terrorism, p.3. Op. cit.

<sup>9</sup> Report of a Royal Society-Wellcome Trust meeting. Do no harm: Reducing the potential for the misuse of life science research. October 7, 2004, p.1.

10 Statement on the Consideration of Biodefence and Biosecurity. Op. cit.

the need to ensure that whatever oversight measures are put in place for dual use research do not unduly burden or slow the progress of life sciences research. Although the purview of the NSABB is life sciences research, the Board acknowledges that there is increasing overlap between biology and other disciplines and recommends that the oversight of dual use research extend beyond the traditional life sciences disciplines. The same concerns about not unduly hindering the progress of science would apply to these other fields as well.

NSABB Considerations. Although the potential for misuse of scientific information exists, and the consequences could be severe, one of the major concerns of the NSABB is that the response to this threat be carefully measured lest more harm than good be done in the name of biosecurity. No oversight system can bring the risk of misuse of information to zero, nor can it completely prevent those that are intent on doing harm from doing so. The goal is to implement reasonable precautions to minimize the risk of misuse while still maintaining a vibrant research enterprise. Oversight measures should not create impediments to legitimate life sciences research.

The continued rapid progress of the life sciences is paramount since findings from life sciences research directly and indirectly underpin medical progress, the safety and quality of the food supply, the quality of our environment, advances and productivity in numerous commercial sectors, and the status of public health and safety.

Indeed, in a statement on science and security in an age of terrorism that predates the formation of the NSABB, presidents of the three U.S. National Academies (National Academy of Sciences, National Academy of Engineering, and Institute of Medicine) noted that, "[i]n meeting this responsibility, the scientific, engineering, and health research community also recognizes a need to achieve an appropriate balance between scientific openness and restrictions on public information. Restrictions are clearly needed to safeguard strategic secrets; but openness also is needed to accelerate the progress of technical knowledge and enhance the nation's understanding of potential threats."

Subsequently, a report from the National Academies emphasized the need to promote the free and open exchange of information in the life sciences to the maximum extent possible, noting "the many ways that biological knowledge and its associated technologies have improved and can continue to improve biosecurity, health, agriculture. . . . [C]onversely, restrictive regulations and the imposition of constraints on the flow of information are not likely to reduce the risks that advances in the life sciences will be utilized with malevolent intent in the future. In fact, they will make it more difficult for civil society to protect itself against such threats and ultimately are likely to weaken national and human security. Such regulation and constraints would also limit the tremendous potential for continuing advances in the life sciences and its related technologies to improve health, provide secure sources of food and energy, contribute to economic development in both resource-rich and resource-poor parts of the world, and enhance the overall quality of human life." The report further recommended ensuring "that any biosecurity policies or regulations implemented are scientifically sound and are likely to reduce risks without unduly hindering progress in the biological sciences and associated technologies." <sup>12</sup>

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<sup>&</sup>lt;sup>11</sup>Alberts B, Wulf WA, Fineberg H. Statement on Science and Security in an Age of Terrorism. October 18, 2002.

<sup>&</sup>lt;sup>12</sup>Globalization, Biosecurity, and the Future of the Life Sciences., pp. 6-8. Op. cit.

Similar concerns have been voiced elsewhere. For example, a report from the Royal Society and Wellcome Trust noted that "the threat of advances in the life sciences being used for harmful purposes is a real one" and that "the challenge that the scientific community faces is to identify what measures can be taken to manage or reduce this risk without jeopardizing the enormous potential benefits from research advances.... Research institutions and funding agencies need to consider how to build on existing processes for reviewing research projects to ensure that risks of misuse are assessed in an appropriate and timely manner."

The current inability to quantify dual use research of concern and the risk of misuse of research information raises challenges for proposing an oversight framework. The NSABB recognized some parallels with recombinant deoxyribonucleic acid (DNA) research, which provides an important historical precedent for managing risk when its magnitude is unknown. The system of oversight for recombinant DNA has stood the test of time in part because it is capable of evolving with technological developments and new scientific understanding. Oversight of recombinant DNA research is not imbedded in regulation; this provides greater facility to adapt to advancing science while nonetheless establishing a standard of practice that is embraced by public and private sectors.

The NSABB has drawn from the recombinant DNA research oversight system in proposing oversight measures for dual use research of concern. The current proposals are for guidelines rather than regulations so that course corrections can be made more easily and new technological advances can be addressed as needed with relative ease. One concern that has been raised by NSABB members and also by members of the public is that the NSABB charter currently states that the scope of oversight for dual use research is federally conducted or supported biological research. The NSABB recognizes that a significant amount of life sciences research, some of which may be dual use of concern, is conducted with private funds. Regardless of whether life sciences research is publicly or privately funded, the fundamental principles regarding the responsible conduct and communication of dual use research should be followed.

Need for Engagement of the Life Sciences Community. The NSABB strongly believes that one of the best ways to address concerns regarding dual use research is to raise awareness of dual use research issues and strengthen the culture of responsibility within the scientific community. The stakes are high for public health, national security and the vitality of the life sciences research enterprise. Responsible scientists have a duty to be aware of the potential for misuse of their scientific findings and of their obligation to help inform and shape critical policy decisions about biosecurity in the life sciences.

As noted previously, there have been numerous calls for consideration of the security implications of life sciences research findings and for establishing processes to minimize the risk of misuse of those findings with dual use potential. This has been voiced in many different quarters: the scientific community, including journal authors and editors, researchers, academies (national and international), and professional societies; the U.S. Congress and other legislative and policymaking bodies; the federal agencies that fund and conduct life sciences research; the federal entities involved in national security; and members of the public. Thus, it is almost a

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<sup>&</sup>lt;sup>13</sup>Report of a Royal Society-Wellcome Trust meeting, Op. cit.

certainty that new oversight procedures will be implemented in the life sciences to protect against the threat of misuse of research information.

Participating in the development of those measures is an opportunity to ensure that the open process of scientific discovery that has been so critical to the progress and achievements in life sciences research remains open. Life scientists have been and must continue to be fully committed to the free flow of scientific inquiry. It is in the life sciences community's interest to engage and demonstrate to the public and policymakers that life scientists are taking responsibility for the implications of their work.

This view has been echoed in commentaries and editorials in prestigious international scientific journals. For example, one commentator noted that "[b]iologists must begin a process of selfregulation for projects that have potential applications in developing bioweapons—or risk the imposition of restrictive controls from outside."<sup>14</sup> Another stated that "[b]iologists should involve themselves in the debate over biological weapons—both to ensure that we have the means to counter the threats that such weapons pose and to help keep those threats in perspective. . . . By becoming more aware of the issues and engaging more vigorously in discussions on bioweapons, biologists can also help to ensure that threats are not blown out of proportion. . . . But if biologists stick their heads in the sand and pretend that their work has nothing to do with warfare, they will be doing the world a disservice." Yet another noted that "[t]he greatest concern is in the need for clarity. It is important to develop clear guidelines about what research is considered sensitive, what is expected of researchers whose work produces dual-use outcomes, and how the government should in practice respond without losing the priceless virtues of open scientific scrutiny. Without such clarity, officials insensitive to those virtues may institute precautionary measures that reach far beyond what is appropriate." <sup>16</sup> Indeed, a senior official of the U.S. Government cautioned that "[t]he science community ought to come up with a process before the public demands the government do it for them, and that will be driven by the rate at which controversial papers hit the streets."<sup>17</sup>

The NSABB recognizes that broad consultation with the scientific and security communities and with the public is essential in order for its recommendations regarding an oversight system to be useful, relevant, practicable and acceptable. As the three Presidents of the National Academies observed, "[a]chieving the purpose of scientific and technological activity—to promote the welfare of society and to strengthen national security—will require ingenuity from our science, engineering, and health community, as well as from the many agencies of the federal, state, and local governments involved in counterterrorism. The nation's safety and the continued improvement of our standard of living depend on careful, informed action on the part of both governments and the scientific, engineering, and health community. A continuing, meaningful dialogue needs to begin—one that produces a true collaboration for the many decisions that need to be made." Similar thoughts were articulated in a report of the Royal Society and the Wellcome Trust: "The challenge is to think beyond the obvious and identify those avenues of

 $<sup>^{14}</sup>$  Aldous P. Biologists urged to address risk of data aiding bioweapon design. Nature 2001. 414(6861):237-8.  $^{15}$  A call to arms. Nature 2001. 411(6835):223.

<sup>&</sup>lt;sup>16</sup>Risks and benefits of dual-use research. Nature 2005. 435(7044):855.

<sup>&</sup>lt;sup>17</sup>Check E. US officials urge biologists to vet publications for bioterror risk. Nature 2003. 421(6920):197.

<sup>&</sup>lt;sup>18</sup>Alberts B. et al. Op. cit.

research and technologies that present risks of being misused for harmful purposes that are quite distinct from the original aims of the work. This needs imaginative thinking as the vast majority of work falls into the grey area of having some potential for misuse."<sup>19</sup>

It is the NSABB's expectation that its recommendations will be a useful springboard for the U.S. Government in the development and implementation of a comprehensive system for the responsible identification, review, conduct, and communication of dual use research. To this end, the NSABB emphasizes that comments are welcome on any and all aspects of this report. Specific questions are posed in Appendix 2, but input need not be limited to these questions. In addition, the NSABB notes that, in keeping with its charge, as the oversight system is further developed by the U.S. Government, the Board will address certain issues in more detail in the near future, including compliance and enforcement and education and outreach.

# Guiding Principles for Oversight of Dual Use Life Sciences Research

As a first step in proposing a framework for oversight, the NSABB identified a number of principles that should underpin any oversight of dual use life sciences research:

- Life sciences research underpins advances in public health, agriculture, the environment, and other pertinent areas and contributes significantly to a strong national security and economy. The life sciences are a global enterprise and becoming ever more so. The free and open conduct and communication of life sciences research is vital to a robust scientific enterprise; thus the "default" position should be the unfettered progress and communication of science. Any decision to do otherwise should be undertaken very carefully.
- However, life sciences research has the potential to produce information or technology that can be misused to pose a threat to public health and safety, and therefore it is appropriate to have in place a framework and tools for the responsible oversight, conduct, and communication of such research.
- Effective oversight will help maintain public trust in the life sciences research enterprise by demonstrating that the scientific community recognizes the implications of dual use research and is acting responsibly to protect public welfare and security. The federal agencies that fund life sciences research, the institutions that are the recipients of those public funds, and the individuals who conduct this research share this oversight responsibility.
- Any oversight system must balance the need for security with the need for research progress. The degree of oversight should be consistent with the likelihood and possible consequences of misuse.
- The foundation of oversight of dual use research includes investigator awareness, peer review, and local institutional responsibility. Such oversight allows input directly from

<sup>&</sup>lt;sup>19</sup>Report of a Royal Society-Wellcome Trust meeting, p.1. Op. cit.

the investigators, facilitates timely review, offers appropriate opportunities for public input, and demonstrates to the public that scientists are taking responsibility for their research.

- The responsible conduct and communication of dual use research of concern depend largely on the individual conducting such activities. No criterion or guidance document can anticipate every possible situation. Motivation, awareness of the dual use issue, and good judgment are key to the responsible evaluation of research for dual use potential. It is incumbent on the institution and the investigator to adhere to the intent of such guidance as well as to the specifics.
- Life sciences research is by nature dynamic and can produce unanticipated results and therefore must be periodically evaluated for dual use potential.
- For the oversight system to be effective, it is essential that the various federal government agencies involved pursue a harmonized approach to the oversight of dual use research.
- The effectiveness of an oversight framework depends on awareness by the scientific community and the public of the dual use potential of research.
- An efficient and effective oversight system also requires ongoing dialogs among the scientific communities, governmental agencies, and the public.
- The responsible communication of dual use research of concern is essential to maintain public confidence in the scientific community.
- The oversight process for dual use research must be periodically evaluated both for effectiveness and impact on the research enterprise.

Below are the key features and roles and responsibilities proposed by the NSABB for the oversight of life sciences research with dual use potential.

# **Key Features of the Proposed Oversight System**

Following are descriptions of seven key features of the proposed oversight system:

Federal Guidelines. Federal guidelines for oversight of dual use life sciences research should be developed by the relevant federal agencies with a role or interest in life sciences research. The guidelines should take into consideration the recommendations of the NSABB, including the considerations for a code of conduct and the specific tools/guidances developed for identifying dual use research of concern, for assessing and managing risk, and for communicating dual use research responsibly—as well as public comments on the NSABB recommendations.

The guidelines will assist scientists, institutions, other entities, and the federal government in determining and implementing safeguards regarding dual use research. The guidelines should address at a minimum:

• Scope and applicability of the guidelines

- Definitions
- Research covered by the guidelines, including criteria for identifying dual use research of concern and points to consider in applying the criteria
- Guidance for the review of research that is potentially dual use of concern, including points to consider in risk assessment and strategies for risk management
- Roles and responsibilities of entities and individuals engaged in life sciences research
- Criteria for referring issues from the local level to the federal level
- Processes and procedures for addressing dual use research issues at the federal level
- Compliance and penalties for noncompliance

The guidelines should be clearly written, well organized, and understandable to both the scientific community and the general public. The guidelines should also be periodically updated to keep pace with developments in the life sciences.

Awareness. Researchers, research personnel, and research administrators should be fully aware of dual use research concerns, issues, and policies. An enhanced culture of awareness is essential to an effective system of oversight and is a critical step in scientists taking responsibility for the dual use potential of their work.

*Education*. Awareness will be enhanced through ongoing, mandatory education about dual use research issues and policies. This will ensure that all individuals engaged in life sciences research are aware of the concerns and issues regarding dual use research and their roles and responsibilities in the oversight of such research.

The federal government should develop training and guidance materials on federal requirements that can be used as educational resources at the local level. Furthermore, scientific societies, professional associations, and others in the private sector have an important contribution to make in promoting a culture of awareness and responsibility by educating broadly about dual use research, the associated tenets of responsible research, and the best practices in identifying and overseeing dual use research. The federal government can foster the development of such private sector training and education initiatives by providing appropriate resources for their development. Research institutions and associations should utilize these materials, tailoring them as needed to different audiences as part of promoting an awareness of dual use research issues among those involved in life sciences research.

Local Evaluation and Review of Research for Dual Use Potential. The initial evaluation of the dual use potential of life sciences research should be conducted by the investigator, after appropriate training. Additional review by others at the research institution may also be appropriate to ensure an unbiased and comprehensive evaluation and application of the criteria for identifying dual use research of concern. Local evaluation and review ensure that those with the appropriate expertise and the best understanding of local personnel, facilities, and ethos are assessing research for dual use potential. Local evaluation and review also demonstrate to the public that scientists and their institutions are attending to the biosecurity implications of dual use research and facilitates the timeliness of the oversight process.

*Risk Assessment and Risk Management.* The degree of oversight should be commensurate with the degree of risk and the potential impact of any misuse of research information. Risk assessment and management should be the foundation for local oversight of dual use research of concern. This will help minimize the potential for misuse of dual use research information while minimizing any negative impact on the conduct of science and will facilitate the responsible conduct of life sciences research.

*Periodic Evaluation*. There is a need for periodic evaluation, at the local and federal levels, of the need for oversight of dual use life sciences research, of the effectiveness of the oversight system, and of the administrative burden of the oversight system. Assessing the need for and effectiveness of the oversight system in minimizing the risks associated with dual use research of concern, while allowing important research to go forward, will promote the conduct of life sciences research and its efficient and effective governance and will facilitate the implementation of course corrections as appropriate.

Compliance. As the oversight framework is formalized into policy and guidelines by the U.S. Government, mechanisms at both the federal and local level for ensuring compliance will be an important consideration and will need to be addressed in detail. The NSABB will advise on this topic as necessary in the future. Thus, the NSABB recommends that federal agencies develop consistent mechanisms for enforcement, including penalties for noncompliance, perhaps by making compliance a term and condition of funding.

It is also understood that the applicability of the federal policy for oversight of dual use research, at least initially, will be to federally conducted or funded dual use life sciences research. The NSABB recommends that the applicability of federal policy for dual use research be as wide as possible. For example, the applicability of the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* goes beyond research that is funded by the National Institutes of Health (NIH); it extends to all research that is conducted at or sponsored by an institution that receives any support for recombinant DNA research from the NIH, including research that is privately funded. Such a mechanism should be considered for dual use life sciences research as well. The NSABB recognizes that this still will not cover all entities engaged in dual use life sciences research. Nonetheless, the NSABB anticipates that the dual use research issue will be appreciated by those entities engaged in life sciences research that are not subject to the federal policy and that these entities will voluntarily comply with dual use research oversight guidelines. The effectiveness of voluntary compliance by noncovered entities should be evaluated at a designated time after Federal policies are implemented to inform decisions as to whether other federal enforcement mechanisms should be contemplated.

The NSABB also notes that lines between biology and other disciplines are increasingly blurred as multidisciplinary approaches are employed for addressing complex biological problems. For example, mathematical modeling and chemical engineering approaches are often combined with more traditional biologic techniques to solve a problem. Consequently, disciplines not ordinarily considered to fall within the life sciences may yield dual use biological information. Therefore, the NSABB recommends that the U.S. Government consider the need to apply dual use research oversight measures beyond what is usually thought of as the traditional life sciences disciplines.

# Roles and Responsibilities in Oversight of Life Sciences Research With Dual Use Potential

Researchers. Researchers are the most critical element in the oversight of dual use life sciences research. They know the work best and are in the best position to anticipate the types of knowledge, products, or technologies that might be generated, the potential for misuse, and the degree of immediacy of that threat. However, to fulfill this responsibility, the principal investigator (PI) must be cognizant of the concept of dual use research of concern and aware of the risk that technologies or information produced by life sciences research may be misused. Researchers thus have a professional responsibility to be aware of dual use research issues and concerns, to be aware of the implications of their work and the various ways in which information from their work could be misused, and to take steps to minimize misuse of their work. This includes being knowledgeable about and complying with all local and federal policies for oversight of dual use research, ensuring that their own dual use research training and that of their staff is current, assessing their own work and that of their research personnel for dual use potential on an ongoing basis, and communicating dual use research in a responsible manner.

Researchers should carry out their work in an ethical and responsible manner, adhering to the standards of conduct described in the NSABB document "Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences" (see Appendix 3).

On an annual basis, researchers should also provide formal assurance to their institutions that they are assessing their work for potential dual use of concern. The NSABB also recommends that there be a mechanism, such as a check box, on new grant applications and competing renewals, indicating that the dual use potential of the proposed work has been evaluated and whether there is such potential. The NSABB recognizes that these mechanisms will need to be implemented by science funding entities.

*Research Institutions*. Institutions have a number of general responsibilities regarding the oversight of life sciences dual use research:

- Ensuring that life sciences research is conducted in conformance with applicable federal, state, local (e.g., municipal), and institutional policies.
- Establishing and implementing internal policies and practices that provide for the effective and efficient oversight of dual use research of concern. The degree of oversight should be consonant with the degree of risk of misuse and the potential impact of misuse of research information. Policies and practices for oversight of dual use research should minimize any negative impact on the conduct of life sciences research.
- Establishing mechanism(s) for advising on dual use research issues and assisting investigators in complying with dual use research policies. This should include the designation of a point of contact within the institution for questions regarding dual use research.

- Providing appropriate education on dual use research for individuals involved in life sciences research. This can utilize educational and training materials developed by the federal government.
- As necessary, assisting the PI in deciding whether her or his research meets the criterion for dual use research of concern and thus requires further review or oversight. In the great majority of cases, it is anticipated that the institution will rely on the judgment of the researcher. In some cases, however, the researcher may request additional review by an individual with sufficient knowledge and/or expertise to assist in these determinations. Such an independent evaluation of the dual use potential of the research may bring to bear additional objectivity, perspective, and knowledge and may assist in considering the ways in which the information from the research could be misused.
- Establishing an internal mechanism for investigators to appeal local decisions regarding dual use research.
- Addressing internal requests for referral of dual use research issues to the federal level.
- Upon request and as appropriate and consistent with applicable laws, making available to the public information pertaining to institutional oversight of dual use research.
- Periodically assessing the effectiveness of internal policies for oversight of dual use research, including feedback from investigators and other stakeholders.
- Reporting significant violations of federal dual use research policies as specified by an institution or by federal policy.

Institutions also have specific responsibilities regarding the evaluation of research for dual use potential and the review of research that has been identified as dual use of concern:

- Establishing an institutional mechanism for expert committee review (including risk assessment and risk management) of research that has been identified as dual use of concern.
  - This local committee should be constituted in a manner so as to have the necessary expertise to consider the dual use implications of research and to recommend and oversee risk management strategies.
  - O When institutions already have an Institutional Biosafety Committee (IBC) in place, they should consider using this existing mechanism for the review of dual use research of concern. Many of the kinds of experiments raising dual use considerations entail recombinant DNA and would otherwise be subject to IBC review, helping minimize any additional burdens. Dual use expertise could be brought to the IBC through the use of ad hoc members.
  - O Alternative approaches should also be acceptable—such as establishing a committee exclusively for dual use review or utilizing an externally administered committee (e.g., an IBC at a neighboring institution or a commercial IBC)—as long as the committee is competent to conduct dual use review.

• Institutions should strive to develop review processes that do not encumber the conduct of life sciences research that is not dual use of concern.

Institutions also have some administrative responsibilities regarding the oversight of dual use life sciences research:

- As may be required by federal policy, registering their review mechanism and updating that registration annually
- Designating an institutional point of contact on dual use research issues
- Collecting and maintaining records of personnel training on dual use research and of investigator assurances, provided on an annual basis, that the researchers are assessing their research for dual use potential

Institutional Review Entity. The review entity utilized to fulfill the institution's responsibility to review work that has been identified as dual use research of concern should have, or be able to provide on an ad hoc basis, sufficient breadth of scientific expertise to assess the dual use potential of the range of research conducted at a given research facility. The review entity must have knowledge of dual use issues, concerns, and policies and understand risk assessment and risk management considerations. Risk assessment and management considerations should include, but not necessarily be limited to, those in the guidance developed by the NSABB and described below.

At institutions subject to the *NIH Guidelines*, the most suitable review entity will likely be the IBC, supplemented as appropriate with expertise pertinent to dual use research. Alternatively, institutions may wish to establish a committee exclusively dedicated to the review of dual use research. However this review function is established, the review entity should be sufficiently empowered by the institution to be able to ensure compliance with dual use research policies.

*NSABB*. The NSABB should continue to carry out the functions specified in its charter. This includes recommending strategies for the efficient and effective oversight of dual use life sciences research, taking into consideration both national security concerns and the needs of the research community. This includes, but is not limited to, advising on federal and local oversight of dual use research, contributing to the development of federal guidelines for dual use research, recommending procedures and practices for communicating dual use research results and methodologies, advising on interpretation and application of federal guidelines for dual use research, and recommending strategies for outreach and education at national and international levels.

In addition, the NSABB should also periodically evaluate the oversight system for dual use research, both for effectiveness and impact on the research enterprise.

As requested and appropriate, the NSABB should also serve as a resource to the research community, including the scientific publishing community, on dual use research issues.

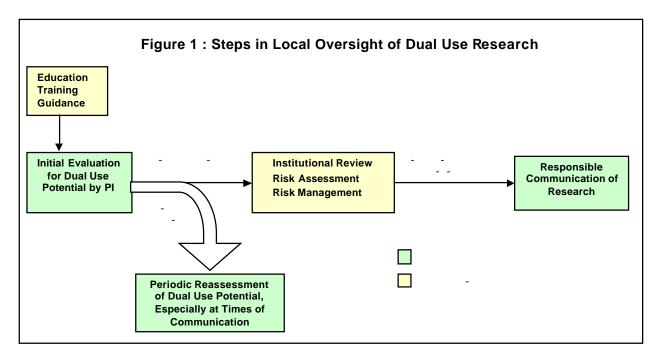
*U.S. Federal Government*. The government is responsible for ensuring that any oversight system is efficient and effective and should also ensure that any negative impact on life sciences research is minimized. This includes ensuring a harmonized governmental approach to the oversight of dual use research. Thus, those federal entities with a role or interest in dual use research should work together on the development of policy that aligns with their agency mission and organizational function for the effective oversight of dual use research, including compliance mechanisms, penalties for noncompliance, and processes for adjudication. There will also need to be harmonized interpretations of policy in the future. A related and key responsibility is periodic federal government evaluation of the oversight system, for both effectiveness and impact on the research enterprise.

Proper oversight of dual use research should not be an unfunded mandate. Thus, the federal government should ensure that sufficient resources are provided to institutions in the fulfillment of this responsibility. The provision of resources for oversight should not be at the expense of existing research programs.

Additional roles and responsibilities include education and outreach to affected entities about dual use issues, policies, and applicable regulations and the development and encouragement of the development of training tools and materials for use at the local level to educate employees about dual use issues and their responsibilities.

The federal government is also responsible for the support and administration of the NSABB and should conduct expert consultations and solicit public comment as appropriate on dual use research and biosecurity issues.

# Major Steps in Local Oversight of Dual Use Life Sciences Research



The critical underpinnings of the oversight system will be education about dual use issues and all applicable policies as well as the provision of guidance and tools that facilitate compliance with the policies.

With that as a backdrop, the major steps or stages of local oversight are as follows (see also Figure 1 above):

- Evaluation of life sciences research for its dual use potential. This should be done at the inception of any research and periodically throughout the research process.
- Review of research identified as being potentially dual use of concern.
  - O Assessment of any biosecurity risk(s) associated with the findings, technologies, or biological agents<sup>20</sup> that might be generated from the research. This includes:
    - Identification of the ways in which the information, technologies, or biological agents could be misused
    - Consideration of the potential consequences if the research information, technologies, or biological agents are misused
  - o Recommendation of strategies for mitigating or managing the risk of misuse.
- Conduct of dual use research of concern in accordance with risk management strategies.

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<sup>&</sup>lt;sup>20</sup>As is consistent with 18 U.S.C. § 178, a biological agent is "any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance, capable of causing - (A) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; (B) deterioration of food, water, equipment, supplies, or material of any kind; or (C) deleterious alteration of the environment; . . "

• Responsible communication of research with dual use potential. This should be done throughout the research process.

Each of these steps will be further elaborated in the text that follows.

# Criterion and Considerations for Identifying Dual Use Research of Concern

The biosecurity concerns that the NSABB is tasked with addressing pertain to the misapplication of information, technologies, or biological agents resulting from legitimate dual use research, not the conduct of the research itself. The goal of identifying dual use research of concern is to initiate a process aimed at reducing the potential that knowledge, products, or technology derived from certain life sciences research could be misapplied to threaten public health and safety or other aspects of national security. To facilitate consistent determinations of the dual use potential of research, the NSABB developed a criterion as a tool for those involved in any aspect of life sciences research.

During the process of developing the criterion, the NSABB identified a number of considerations and key concepts that are discussed below and are reflected in the final criterion:

- Because arguably most life sciences research has some potential for dual use, the NSABB strove to delineate a threshold that would identify that subset of life sciences research with the highest potential for yielding knowledge, products, or technology that could be misapplied to threaten public health or other aspects of national security. This subset of research is referred to herein as "dual use research of concern."
- It is important to emphasize that evaluation of the dual use potential of research should be based on a *current understanding* of the implications of the research results and whether it is reasonable to anticipate that such information could be misapplied to pose a threat. The results of research are of concern when they can be <u>directly</u> misapplied to pose a threat.
- In addition, the NSABB focused on the *scope* of a potential threat as a key consideration in evaluating research for dual use potential. Thus, the criterion captures threats with *broad* potential consequences to public health or other aspects of national security (e.g., that threaten populations rather than individuals).
- It cannot be overemphasized that characterization of research as dual use research of concern should not be viewed pejoratively. Such a characterization does not automatically mean that this type of research should not be conducted or communicated, rather that the conduct and communication of that research should be carefully considered from the outset and throughout the research process. The oversight process is about the responsible conduct and communication of research, not the restriction of research.

- The concern regarding dual use research is that the information, technologies, or products developed from it could be misused to threaten national security. The NSABB found that there are many different understandings of the term "national security," so it identified the relevant aspects and used the collective terms. Thus, the criterion refers to the potential for threats to public health and safety, agricultural crops and other plants, animals, the environment, and/or materiel. This would include threats to farming, livestock, aquaculture, terrestrial and marine wildlife, companion animals, domestic and wild plants and trees, ecological systems, and other natural resources, as well as manmade resources.
- An evaluation of research for its dual use potential will require scientific expertise and logical, sound judgment about the probability or foreseeability that others could misapply/misuse research results. It is important to acknowledge, however, that any such evaluation is subjective and will be influenced by the individual's knowledge, experience, and judgment.
- Life sciences research is an extraordinarily dynamic field that encompasses many diverse disciplines; therefore, it will be important to periodically review the criterion and modify it as necessary to ensure its relevance in the face of new advances and technologies.

With these concepts in mind, the NSABB proposes the following criterion for identifying dual use research of concern:

# Criterion for Identifying Dual Use Research of Concern

Research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or materiel.

Determining the applicability of this criterion is a subjective and sometimes challenging task. To assist those who need to make a determination as to whether research is potentially dual use of concern, the NSABB also delineated some categories of information, products, or technologies that might be especially likely to meet the threshold within the criterion for dual use research of concern, and thus deserve careful consideration with regard to the applicability of the criterion. It is important to emphasize that not all research that fits the categories below is necessarily dual use research of concern; rather, it is research for which the criterion needs to be especially carefully considered. Moreover, it is also the case that research that does *not* fall into the categories below might also meet the criterion for being dual use research of concern.

Finally, it is important to acknowledge that the starting point for the categories below was the seven "experiments of concern" from the NRC report referenced in footnote 1. However, the

NSABB categories have a different purpose and meaning from those of the NRC report. In the NRC report, the seven experiments of concern are classes of experiments that the NRC Committee believed illustrated the types of endeavors or discoveries that would require review and discussion by informed members of the scientific and medical community before they are undertaken or, if carried out, before they are published in full detail. The NSABB categories below, which in some cases are modifications of the NRC categories, are descriptors of information, products, or technologies that, if produced from life sciences research, might define that research as meeting the criterion for being dual use research of concern. Therefore, such research should be especially carefully assessed for meeting the criterion for dual use research of concern.

The NSABB categories are knowledge, products, or technologies that could enable any of the following:

1. Enhance the harmful consequences<sup>21</sup> of a biological agent<sup>22</sup> or toxin.<sup>23</sup> The rationale for this category is that enhancing the pathogenic consequences of an agent or toxin could increase the likelihood of disease and compromise the ability to treat the disease(s) they cause if extant therapeutics are no longer effective. Of note, enhancing the pathogenic consequences of an agent includes rendering a nonpathogenic microbe pathogenic. Information that would fall into this category and would likely be considered dual use of concern would be how to make a seasonal strain of the influenza virus as deadly as the 1918 pandemic strain.

An example of information that would fall under this category, but is unlikely to be dual use of concern, includes routine techniques for restoring the virulence of viral stocks by back-passaging in animal hosts, identification of virulence factors through genome-wide screening or gene knockout techniques, and standard genetic manipulation to study the virulence of an organism.

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<sup>&</sup>lt;sup>21</sup> Harmful consequences: The ability of a biological agent or toxin to critically alter normal biological functions, inflict damage on public health resources, materiel, and public safety. This would include augmenting properties such as virulence, infectivity, stability, transmissibility, or the ability of the biological agent or toxin to be disseminated.

<sup>&</sup>lt;sup>22</sup>Biological agent: As is consistent with 18 U.S.C. § 178, "any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance, capable of causing - (A) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; (B) deterioration of food, water, equipment, supplies, or material of any kind; or (C) deleterious alteration of the environment; . ."

<sup>23</sup>Toxin: As is consistent with 18 U.S.C. § 178, "the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever the origin and method of production, and includes - (A) any poisonous substance or biological product that may be engineered as a result of biotechnology that is produced by a living organism; or (B) any poisonous isomer or biological product, homolog, or derivative of such a substance; .."

2. Disrupt immunity<sup>24</sup> or the effectiveness of an immunization<sup>25</sup> without clinical and/or agricultural justification. The rationale for this category is that immunity is a key component in a host's defense against pathogens and toxins, thus rendering an immunization ineffective or disrupting immunity could have harmful consequences for public health, agricultural crops and other plants, and animals. For instance, rendering an immunization ineffective could make a host population vulnerable to the pathogenic consequences of a microbe from which the host population would have otherwise been protected or for which protection, such as a vaccine, was available.

An example of information that fits this category and might qualify as dual use of concern is the insertion of an immunosuppressive cytokine into a viral genome to render the antiviral immune response less effective. Information about the immunosuppressive properties of chemotherapeutic drugs for cancer or autoimmune disorders could also fit this category, although it is unlikely to be dual use of concern.

3. Confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions<sup>26</sup> against that agent or toxin or facilitate their ability to evade detection methodologies. The main concept is that anything that might compromise the ability to detect, treat, or prevent disease or illness (human or agricultural) caused by biological agents or toxins could result in a significant public health and/or economic burden.

Examples of information that might fit this category and be considered dual use of concern include conferring doxycycline resistance to *Vibrio vulnificus* or conferring antibiotic resistance to agriculturally relevant microbes, such as rendering *Ralstonia solanacearum* (a bacterium on the U.S. Department of Agriculture list of high-consequence organisms) resistant to rifampin. Examples of research that might fit this category, but are unlikely to be dual use of concern, include the use of standard laboratory selection procedures with antibiotics using host-vector systems that do not present a significant risk to health or the environment (e.g., transforming a nonpathogenic/nontoxigenic *Escherichia coli* strain with a construct for the expression of a nontoxin protein or conferring rifampin resistance to *Pseudomonas fluorescens*.

<sup>2.</sup> 

<sup>&</sup>lt;sup>24</sup> *Immunity:* Encompasses all aspects of host immunity (e.g., active, adaptive, adoptive, passive, innate, and immune modulators).

<sup>&</sup>lt;sup>25</sup>Immunization: Refers to the active or passive induction of immunity through inoculation (e.g., natural inoculation or vaccination) with an immunizing agent or with antibodies; this includes antitoxins and toxoids.

<sup>&</sup>lt;sup>26</sup>Clinically and/or agriculturally useful prophylactic or therapeutic interventions: Includes first- or second-line prevention and treatment measures or alternative therapeutics used with special populations (e.g., pregnant women and pediatric patients) in the form of vaccines, antibiotics, antivirals, antiparasitics, antibodies, herbicides, fungicides, algaecides, insecticides, etc. "Agriculture" encompasses all methods of production and management of livestock, crops, vegetation, and soil. Therefore, useful prophylaxes and therapeutics would include herbicides, fungicides, algaecides, insecticides, rodenticides, etc.

4. Increase the stability,<sup>27</sup> transmissibility,<sup>28</sup> or the ability to disseminate<sup>29</sup> a biological agent or toxin. The rationale for this category is that increasing an agent's stability, transmissibility, or ability to disseminate could facilitate the purposeful malevolent use of a biological agent or toxin and increase the rate or ease by which an agent could spread, impeding attempts to contain disease outbreak. Uncontained outbreaks could lead to a large infected host population, which may not receive adequate care and treatment due to limited resources, allowing the disease to spread. Effective dissemination of a pathogenic agent or toxin could result in large-scale exposure and the inability to prevent or treat ensuing disease and/or damage in a host population. The inability to prevent or treat the disease or toxicity due to the lack of resources or therapeutics could result in a significant threat to the health of the host population(s). Of note, this category includes transmission between hosts of the same species or between hosts of differing species. The use of the term "weaponization" was carefully considered for this category, but since the term is not uniformly understood within the life sciences community, the concept of dissemination, which is a key component of weaponization, seems more appropriate.

Examples of research that falls within this category and that might be considered dual use of concern include changing genetic factors to increase transmissibility and altering the route of transmission or vector to increase the ease and effectiveness by which an agent may be transmitted. With regard to increasing the capability of an agent or toxin to be disseminated, there are inherent challenges in deciding whether information that falls into this category is dual use of concern. Some of the challenge relates to issues of scale and intent. For example, work on vectors to increase their activity for gene therapy may also enable the wide-scale dissemination of a pathogenic agent or toxin. Research on adjuvants, methods, and tools for the increased efficacy of biocontrol agents in agriculture may also encompass work with equipment such as agricultural sprayers that may need to be examined for their dual use potential.

5. Alter the host range  $^{30}$  or tropism  $^{31}$  of a biological agent or toxin. The rationale for this category is that altering the host range or tropism of a pathogenic agent or toxin could endanger a host population that normally would not be susceptible. Prevention and therapy measures for the newly vulnerable host population may be lacking, possibly allowing for the uncontrolled spread of disease. An example of research information that would fall under this category and that may be dual use of concern

<sup>&</sup>lt;sup>27</sup>Stability: The ability of a biological agent to remain viable when exposed to various environmental factors, including temperature, relative humidity, atmospheric pollution, and sunlight. Stability also includes persistence in a

<sup>&</sup>lt;sup>28</sup>Transmissibility: The ease with which an agent spreads from host to host or from vector to host, e.g., via arthropod

<sup>&</sup>lt;sup>29</sup>Dissemination: The process by which infectious diseases or toxins are dispersed. The same routes of entry pertinent to the natural spread of diseases are also relevant when their etiologic agents are delivered intentionally (e.g., inhalation of biological agent disseminated as an aerosol or ingestion of a biological agent disseminated through a water supply).

<sup>&</sup>lt;sup>30</sup>Host range: The number of different species or populations that can become infected by a biological agent, causing disease in the host or allowing the host to become a carrier.

31 Tropism: The specificity of a biological agent or toxin for a particular host tissue or cell.

includes converting nonzoonotic agents into zoonotic agents, altering the tropism of viruses, and expanding the varieties of the same plant that a pathogenic agent could infect. Certain vaccine research and the development of animal models for infectious disease, which may involve alterations of the host range or tropism, are unlikely to constitute dual use research of concern. Specifically, the attenuation of viruses for vaccine development, whereby the attenuation procedure relies on a change in host range to reduce human virulence, is unlikely to constitute dual use research of concern.

6. Enhance the susceptibility of a host population.<sup>32</sup> Information about rendering host populations more susceptible to the pathogenic consequences of an agent or toxin could be used to compromise immune responses and enable the acquisition and spread of disease on an epidemic scale. Of note, the distinction should be made that research applicable to this category would not alter the susceptibility of an individual host or research cohort but rather that of a host population.

Thus, examples of research information that would fall under this category and might be considered dual use of concern include creation of a stable recombinant *Lactobacillus casei* that could effectively block the host's ability to synthesize an important immune signal, such as tumor necrosis factor alpha, which may directly facilitate the evasion of normal host defenses. Examples of research that generates information unlikely to be considered dual use of concern are research on the systemic exposure to immunostimulatory and immunosuppressive DNA and their effect on host susceptibility to local inflammatory challenge, studies to develop immunosuppressive drugs for cancer or transplantation, and delivery of a small interfering ribonucleic acid (RNA) (siRNA)<sup>33</sup> to a mouse that makes it hypersensitive to ionizing radiation, an infectious agent, or a toxin.

7. Generate a novel pathogenic agent<sup>34</sup> or toxin or reconstitute an eradicated<sup>35</sup> or extinct<sup>36</sup> biological agent. The rationale for this category is that host populations may not be immune to novel agents and reconstituted eradicated agents and there may not

<sup>33</sup> Small interfering RNA (siRNA): Known as "short interfering RNA" or "silencing RNA"; a class of RNA molecules that play a variety of roles in biology, most notably, siRNA is involved in the RNA interference (RNAi) pathway where the siRNA interferes with the expression of a specific gene.

<sup>&</sup>lt;sup>32</sup>Host population: A collection of organisms that constitutes a specific group or occurs in a specified habitat. In the context of the criteria, this phrase implies that the misapplication of the knowledge, products, or technologies derived from the research has the potential to broadly impact a population of host organisms.

<sup>&</sup>lt;sup>34</sup>Novel agent: An agent that has not existed previously and is considered unique based on biological or other properties and traits (e.g., genotype and phenotype). Novel agents of concern are those for which there is no known or widely available prophylactic or therapeutic interventions, those that could evade detection, or those for which there is no known immunity.

<sup>&</sup>lt;sup>35</sup>Eradicated agent: A biological agent that has been exterminated through surveillance and containment resulting in the permanent reduction to zero of the worldwide incidence in the transmission of the agent and the infection/disease it causes; intervention measures are no longer needed. Eradicated agents are thought to no longer exist in circulation in plants, animals, or the environment. Note: Reconstituted eradicated agents of concern are those for which there are no known or widely available prophylactic or therapeutic interventions, those that could evade diagnostics, or those for which there is no known immunity.

<sup>&</sup>lt;sup>36</sup>Extinct agent: These agents are thought to no longer exist in nature or in the laboratory.

be existing diagnostics or known or widely available prophylaxes or therapeutics for such agents.

Examples that would fall into this category and that might be considered dual use of concern include the de novo construction of a microbial pathogen using wholly unique gene sequences or combinations of sequences that do not exist in nature and reconstitution of a pathogen that no longer exists in nature, such as the reconstruction of the 1918 pandemic influenza virus. Research that is not likely to be dual use of concern includes standard experimentation that generates knockouts, mutants, reassortants, complement strains, or infectious molecular clones of viruses that are similar to naturally occurring agents.

#### **Evaluation of Life Sciences Research for Dual Use Potential**

The NSABB members agreed that the PI should conduct the initial evaluation of his or her research for its potential as dual use research of concern, using the criterion set forth above as guidance for decision-making. This observation notwithstanding, an independent assessment can be valuable. It is important to emphasize, however, that there may be significant variation in the assessment of the dual use potential of any particular research project when it is considered by two or more different, equally expert reviewers. In many cases, there may be no clearly right or wrong answer. During the NSABB discussions of the oversight process and how the criterion would be applied in the initial evaluation for dual use of concern potential, the Board found significant differences in assessments made by individual NSABB members. In such cases, interactive discussion among multiple evaluators helped in the development of consensus regarding the dual use potential. Given the difficulties inherent in explicitly defining the point at which the magnitude and/or immediacy of the threat of misuse makes dual use research "of concern," there should be an emphasis at the institutional level on education and enhanced PI awareness of the dual use issue. In the long term, an enhanced awareness and understanding of the risks of dual use research is likely to be the greatest benefit of the oversight system.

The NSABB also recommends a formal, annual attestation by researchers that they have been evaluating their work on an ongoing basis for its potential as dual use research of concern.

# Review of Research That Is Potentially Dual Use of Concern: Risk Assessment and Risk Management

After life sciences research is initially evaluated for its potential as dual use research of concern, the subset that may be considered dual use of concern should undergo more thorough review to determine whether the research in question does indeed constitute dual use research of concern and, if so, how the potential for misuse should be managed. The review should address:

• The potential for, and the ways in which, information, technologies, or biological agents from the research could be misused to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment or materiel

- The likelihood that the information might be misused
- The potential impacts of misuse
- Strategies for mitigating the risks that information from the research could be misused

The NSABB developed a tool for guiding this review process, "Points To Consider in Risk Assessment and Management of Research That Is Potentially Dual Use of Concern," which can be found in Appendix 4 for consideration and comment.

# Responsible Communication of Life Sciences Research With Dual Use Potential

One of the major charges to the NSABB is to recommend strategies to help ensure that research information with dual use potential is communicated responsibly, in a manner that addresses both biosecurity concerns and the need for open sharing of research results and technologies so that the research can be validated and used for further research. Toward this end, the NSABB developed a set of tools to facilitate consistent decisionmaking about the responsible communication of research information with dual use potential.

#### These tools consist of:

- A set of principles for the responsible communication of research with dual use potential
- Points to consider for identifying and assessing the risks and benefits of communicating research information with dual use potential, including options for the communication of such research information
- Considerations for the development of a communication plan for research with dual use potential

It is important to note that it is *not* the intent of the NSABB that every potential communication of research—be it an abstract, poster, seminar, or manuscript—be assessed using the communication tools. Rather, the tools may be utilized for the subset of life sciences research or research information determined to be dual use research of concern.

Because research findings are communicated at many points along the research continuum (e.g., during project concept and design, in funding applications, in seminars, and in publication of manuscripts), it is important to be aware of the potential for misuse of information at every point. The communication tools are designed to help individuals identify and assess the risks and benefits of communicating information with dual use potential. The tools can be employed by a variety of users in a number of settings. These include researchers who are developing research proposals; investigators engaged in dual use research who are preparing abstracts, posters, seminars, and manuscripts about their work; and individuals involved in the prepublication review of such information, such as research supervisors and administrators, peers, and dual use

research review entities. The tools might also be useful to the scientific publishing community and for science ethics courses.

The variety of potential uses and users of these communication tools makes it likely that not all aspects of the tools will be applicable at all times. Thus, users are encouraged to tailor and format the tools for their specific purpose(s). For example, students in an ethics course might use the "Points To Consider in Assessing the Risks and Benefits of Communicating Research Information With Dual Use Potential" (see Appendix 5) to analyze actual manuscripts, and so would need to provide detailed answers to the questions posed. Alternatively, an institution might want a researcher developing a manuscript or poster about research with dual use potential to attest to having considered the risks and benefits of communicating that research; thus, it might be helpful to format the assessment framework with checkboxes to indicate that the points had been considered and perhaps to add a signature line. Scientific journals might find this "Points To Consider" tool most useful as a hyperlink in whatever system the journal employs for instructing authors and manuscript reviewers, especially those reviewing for biosecurity concerns.

Principles for the Responsible Communication of Research With Dual Use Potential.

- 1. The open and unfettered sharing of information and technologies has been a hallmark of the life sciences and has fostered a steady stream of scientific advances that underpin public health and safety, a strong and safe food supply, a healthy environment, and a vigorous economy.
- 2. Progress in the life sciences relies heavily on the communication of research findings so that the findings can be both validated and used for further research.
- 3. Life sciences research should be communicated to the fullest extent possible to ensure the continued advancement of human, animal, plant, and environmental health. Consequently, any restriction of scientific communication should be the rare exception rather than the rule.
- 4. There is a need for reasonable balance in decisions about the communication of research with dual use potential. It is important to recognize the potential for the deliberate and malevolent misuse of dual use research findings and to consider whether the disclosure of certain information might reasonably pose a threat to national security (i.e., public health and safety, agricultural crops and other plants, animals, the environment, or materiel). If the communication of dual use research *does* pose potential security risks, the logical next step is a risk-benefit analysis of communicating the information.
- 5. After weighing the risks and benefits of communicating dual use research findings, the decision regarding communication is not necessarily a binary (yes/no) one. Rather, a range of options for communication should be identified and considered. The options available will depend on the research setting (e.g., academia, government, or private). They could range from full and immediate communication, to delayed and/or modified communication, to restricted/no communication, and could be recommended singly or in appropriate

- combinations on a case-by-case basis, depending on the nature of the dual use finding and the potential risks associated with its communication.
- 6. Paradigms for the responsible communication of research with dual use potential should also take into consideration that the communication of dual use research can occur at multiple points throughout the research process, that is, at points well upstream of the publication stage (see Figure 2 below). Thus, it is important to apply principles and practices of responsible communication at these early stages as well.
- 7. It is important to consider not only *what* is communicated but also the *way* in which it is communicated. Investigators and sponsors of research with dual use potential should recognize that the communication of certain dual use information is likely to raise biosecurity concerns, not only within the scientific community but also within the general public. Consideration should be given to the potential for public concern and misunderstanding and for sensationalism. Thought should be given to the need for the inclusion of contextual and explanatory information that might minimize such concerns and misunderstanding.
- 8. Public trust is essential to the vitality of the life sciences research enterprise. It has always been important for life scientists to participate in activities that enhance public understanding of their research. However, because of the potential for public misunderstanding of and concerns about dual use research, it is especially important that life scientists conducting research with dual use potential engage in outreach on a regular basis to increase awareness of the importance of the research and to reassure the public that the research is being conducted and communicated responsibly.

Figure 2. Examples of Points of Communication of Dual Use Research
During the Research Process

Project Concept and Design	Funding Application and Award	Institutional Approval	Ongoing Research	Development of Manuscript or Other Research	Publication of Manuscript or Other Research	_ \
Design	Process			Product	Product	7/
Presentation of preliminary data  Discussions with collaborators  Draft application review by peers, institution administration etc.	Review by IC staff and study section Research award notices/ description on CRISP etc.	Review by Institutional Committee Members  Project descriptions on institution Web page or in PI CV	Training of lab staff, students, visiting scientists  Presentations at departmental seminars  Presentations or posters at National or International Conferences  Evaluation by other faculty if thesis project	Peer review of manuscript/ research product	Public dissemination of research findings or products	

Points To Consider in Assessing the Risks and Benefits of Communicating Research Information With Dual Use Potential. The NSABB developed a tool to guide researchers, manuscript reviewers, and others in identifying and assessing the risks and benefits of communicating research information that may be dual use of concern. This tool includes a series of questions that can be considered as well as options for the communication of research information judged to be dual use of concern; this tool is found at Appendix 5 for consideration and comment.

Considerations in the Development of a Communication Plan. Because of the potential for misuse of dual use research results, concerns on the part of the public, including members of the scientific community, about the sharing of such information can be anticipated. In addition, the public is increasingly sensitive to issues pertaining to research involving dangerous microbes and the risk of accidental or intentional release of such agents. A lack of public understanding and appreciation for the reason for conducting and communicating dual use research, sensationalism of dual use research findings, and concerns about public safety and national security all serve to undermine public trust in the life sciences research enterprise. Therefore, it is the responsibility of the scientific community to ensure that dual use research results and technologies are communicated responsibly.

Depending on the nature of the dual use research result/technology being communicated and the potential impact of communicating the information, it may be prudent to consider steps to maximize public understanding of, and appreciation for, the research effort and the decision to communicate the information. This can be achieved through the development of a plan for the responsible communication of dual use research information. For example, it may be important

to address the following issues, both in the content of the work product and in the activities associated with dissemination of the work product:

- The significance of the research findings for public health and/or safety, agriculture, the environment, or materiel
- How the new information or technology will be useful to the scientific community
- The biosafety measures in place during the conduct of the research
- The dual use aspects of the information and the careful consideration given to biosecurity concerns in the decision to publish

In addition to including this type of information in the content of the work product, the following are some additional means for conveying the types of contextual information listed above. These means can be employed either singly or in any combination as deemed appropriate:

• Editorials are useful tools for providing contextual information, messages, and opinions. Editorials may be in the journal that publishes the dual use research manuscript. This type of editorial could be written by an individual who is not directly involved with the work, perhaps is not even in the same field, but who is nevertheless held in high regard by the scientific community. The editorial might speak to the significance of the research findings for public health, agriculture, the environment, or materiel; how the new information or technology will be useful to the scientific community; and the biosafety measures in place as the research was carried out and might acknowledge the dual use aspects of the information and that careful consideration was given to the biosecurity concerns in the decision to publish.

Editorials may also be in the popular press and issued at the same time as the manuscript or shortly afterwards. This type of editorial would be geared toward the general public and should be written in nontechnical language to the greatest extent possible. Nevertheless, it should address the same issues as described above (i.e., the nature and importance of the scientific discovery/technology; the significance of the research findings for public health, agriculture, the environment, or materiel; the safety precautions in place as the work was conducted; the dual use aspects of the information; and the consideration that was given to the biosecurity concerns in the decision to publish). Ideally, the author would be an individual who is known to and trusted by the general public.

• Press releases are commonly used by research institutions to highlight significant scientific advances for the media. They also provide an opportunity to provide contextual information (regarding issues that may be of concern to the public) and scientific perspectives on the findings (via quotes from other scientists). If the project involves investigators from multiple institutions, it will be important to coordinate the preparation and release of the announcement. In addition to including a description of the findings and their scientific significance, a press release might also address the significance of the research findings for public health, agriculture, the environment, or materiel; the biosafety and biocontainment measures in place as the work was conducted; the dual use

aspects of the information; and the consideration that was given to the biosecurity concerns in the decision to publish.

- A <u>press conference</u> is usually reserved for highlighting the most significant and/or sensitive advances and provides an opportunity for direct interaction with the media. The investigator(s) and institutional representatives are usually present, but press conference organizers also should consider having other experts on hand who can address questions about the potential for misuse of the dual use information, biosafety, etc. A press release is usually provided to the media at a press conference (see above), but additional relevant materials can also be made available, such as backgrounders and fact sheets.
- Questions and Answers (Qs &As) are useful tools for preparing to respond to queries from the press, the general public, or others. They might address:
  - o The nature of the dual use advance
  - o Reasons for conducting the work
  - O Whether the public is/was at risk from the work
  - o The potential for misuse of the research findings
  - o Safety procedures utilized during experimentation
  - o The review process prior to publication
- <u>Talking Points</u> are developed and employed for responding to questions from the press, the general public, or others. Talking points might include:
  - o An explanation of the biosafety and biocontainment conditions that were employed to safeguard laboratory workers and the public (if applicable)
  - O Acknowledgment that, along with significant benefits (to public health, agriculture, the environment, or materiel) of sharing the information widely, there are also some potential risks to publicly disseminating the information
  - o Assurances that the national security implications of making such information publicly available was thoroughly considered
  - o A description of how the information contained within the research findings is critical for developing public health countermeasures

# Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences

One of the charges to the NSABB is to provide recommendations on the development of a code of conduct for scientists and laboratory workers that could be adopted by professional organizations and institutions engaged in the performance of life sciences research. The NSABB has taken this charge to heart, recognizing that the process of developing, adopting, and adhering to a code of conduct can serve a critically important educational role in raising the awareness of the scientific community to the dual use issue and in sustaining a culture of responsibility.

In fulfillment of its charge, the NSABB developed *Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences* as a resource for scientific societies,

professional associations, and research institutions to use in the development of codes on this topic. This document:

- Provides a conceptual foundation for understanding the dual use issue
- Describes the nature and utility of codes of conduct
- Articulates the fundamental principles of responsible conduct with regard to dual use research
- Provides guidance on addressing the dual use issue in specific phases of the research process

Organizations can adopt portions of the document verbatim in developing their own codes, or modify the content as appropriate to the research activities of their members and employees. Either way, the concepts presented in the NSABB's resource document should be considered and discussed broadly as part of the process of educating scientists and laboratory staff about their responsibilities in this arena.

"Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences" is presented in Appendix 3 for consideration and comment.

#### **Outreach and Education**

One of the charges to the NSABB is to advise on mandatory programs of education and training in biosecurity issues for all life scientists at federally funded institutions. The educational content of these training programs will derive in part from specific federal policy and requirements, which are still under development.

In the meantime, the NSABB has conducted outreach with two key purposes in mind: (1) to hone the development of its recommendations by taking into account the concerns and perspectives of diverse stakeholders and (2) to promote broader awareness of the dual use issue and to sensitize life scientists to its importance. Indeed, the NSABB has observed throughout this document that creating awareness about the dual use issue is of fundamental importance and critical to the success of an effective oversight system.

Toward these ends, NSABB members and staff have been engaged in the efforts described below:

• The development of all of the NSABB work products and recommendations entailed stakeholder consultation solicited through such means as <u>focus groups and roundtables</u>. This process helped the NSABB better understand the concerns of these groups and led to the development of recommendations that were meant to be reflective of the diverse perspectives of the various communities within the life sciences. These activities had the collateral benefit of raising awareness of the issue with key thought leaders and promoting dialog within the organizations they represent.

- The NSABB members and staff<sup>37</sup> regularly deliver <u>presentations on the dual use issue</u> and the NSABB's activities at meetings of scientists, biosafety officers, IBC members, research compliance staff, the public and other stakeholders. These presentations are an essential means of sensitizing the research community to this issue and keeping it apprised of evolving federal policymaking activities. These interactions also provide opportunities for feedback from stakeholder groups as the NSABB develops recommendations in this area. There should be continued efforts to identify key stakeholder groups and find opportunities to present to their memberships.
- The NIH staff has developed and staffed at major scientific and professional society meetings an <a href="mailto:example color: blue;">exhibit about dual use research issues</a> to educate attendees about dual use research and biosecurity matters and the development of related federal policy. Exhibits represent an opportunity to educate at the individual level and enhance the visibility of the issue with key constituencies. These activities should continue to highlight educational materials and specific federal requirements as they are developed.
- Under the aegis of the NSABB's Working Group on International Collaboration, the Board hosted a successful <u>international roundtable</u> with individuals from 20 countries and international organizations. The purpose of the meeting was to share perspectives on the dual use issue and to inform participants about the NSABB's activities. This effort was an important first step in awareness building and information sharing at the international level, and the momentum created by this event will be sustained through continuing activities of this Working Group.

As NSABB recommendations are transformed into federal policy, additional types of outreach and education will become appropriate, initially to ensure public input into the policymaking process and subsequently to educate about emerging federal requirements. Thus, the NSABB believes that a vigorous program of outreach to the research community and education of those involved in life sciences research is a logical and essential follow-on to the formal transmittal of its oversight recommendations to the U.S. Government.

With those considerations in mind, the NSABB makes the following observations and recommendations about public outreach during the federal policymaking process:

• By definition, "outreach" means going out into the community, and thus the federal government should sponsor <u>town-hall style regional meetings</u> orchestrated in conjunction with nongovernmental partners (such as universities) as a means of heightening awareness locally and creating more locally accessible forums for scientists and others to have input into the federal policymaking process.

As formal federal policy is developed, it will be key to solicit public comment through formal channels. This includes notice in the *Federal Register* and the establishment of a <u>publicly accessible docket</u> for the collection of public comments on policy that the government is considering or proposing, as well as formal analysis by federal agencies.

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<sup>&</sup>lt;sup>37</sup>The NSABB is funded by the U.S. Government and is staffed by the NIH, an agency of the U.S. Department of Health and Human Services.

Other outreach efforts described here would supplement these important and federally required modes of informing and soliciting input from the public.

Finally, when requirements on the oversight of dual use research are formally adopted by the U.S. Government, a communications plan will be needed for the <u>rollout</u> of the new federal policies, as well as an <u>intensive and ongoing campaign</u> of workshops, presentations, print and electronic materials, exhibits, and other activities to educate about and promote compliance with new requirements. These materials and venues will be used by the federal government to educate institutions and their staffs, as well as by institutions in training their own investigators.

The NSABB also makes the following observations and recommendations regarding ongoing educational and awareness-building strategies:

- The NSABB should play a <u>continuing advisory role in outreach and education strategies</u>, consulting as appropriate with representatives of professional societies and government who are knowledgeable and involved in education and public relations. Specifically, the NSABB should advise on the (1) identification of key stakeholder groups, (2) formulation of message points and educational content to promote awareness of the dual use issue, (3) development of training curricula mapped to federal policy when it emerges, and (4) development of tools to convey educational content effectively to the research community. The NSABB would also advise as appropriate on the development and implementation of specific efforts, such as those described below.
- Educational programs help foster a culture of responsibility, which is important to cultivate early in the development of future scientific talent. Consequently, <u>educational efforts on dual use research should have a broad reach</u>. Although instruction in the responsible conduct of research is an essential ingredient of collegiate and graduate education, instructional materials and resources should be developed for incorporation into high school and even junior high school science programs. Programs should also be developed for U.S. commercial research entities and international audiences.
- The NIH currently requires formal training in the responsible conduct of research for all
  recipients of NIH-funded training grants and fellowships. The NIH outlines various
  topics that these training programs may include, and <u>institutions should routinely</u>
  <u>incorporate the topic of dual use research into the content of NIH-mandated training
  programs.</u>
- Although the federal government has a responsibility and is best poised to educate about federal policies and requirements, domestic and international nongovernmental organizations—particularly scientific associations and professional societies—have special contributions to make with respect to promoting responsible research conduct generally, including best practices, and a number of important and impressive efforts are already underway. The federal government should stimulate educational initiatives on the part of nongovernmental organizations, including the development of case studies, course curricula, and multimedia educational tools.

# **APPENDICES**

- 1. NSABB Charter and Roster
- 2. Questions for Comment
- 3. Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences
- 4. Points To Consider in Risk Assessment and Management of Research Information That Is Potentially Dual Use of Concern
- 5. Points To Consider in Assessing the Risks and Benefits of Communicating Research Information With Dual Use Potential

# APPENDIX 1. NSABB Charter and Roster



H S C H L H D HUM S IC S

#### **CHARTER**

#### NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

# **PURPOSE**

The purpose of the National Science Advisory Board for Biosecurity (NSABB) is to provide advice, guidance, and leadership regarding biosecurity oversight of dual use research, defined as biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security. The NSABB will advise the Secretary of the Department of Health and Human Services (HHS), the Director of the National Institutes of Health (NIH), and the heads of all federal departments and agencies that conduct or support life sciences research. The NSABB will advise on and recommend specific strategies for the efficient and effective oversight of federally conducted or supported dual use biological research, taking into consideration both national security concerns and the needs of the research community. The NIH shall manage and provide support services for the NSABB.

# **AUTHORITY**

42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended. The NSABB is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

#### **FUNCTION**

The NSABB will advise the Secretary of HHS, the Director of NIH, and the heads of all federal departments and agencies that conduct or support life sciences research. The NSABB will advise on and recommend specific strategies for the efficient and effective oversight of federally conducted or supported dual use biological research, taking into consideration both national security concerns and the needs of the research community.

The NSABB will be composed of nongovernmental subject matter experts as well as ex officio members from the federal departments and agencies listed below and will perform the following activities:

- Develop criteria for identifying dual use research and research results.
- Develop guidelines for the oversight of dual use research, including guidelines for the risk-benefit analysis of dual use biological research and research results.
- Provide recommendations on the development of a code of conduct for scientists and laboratory workers that can be adopted by professional organizations and institutions engaged in the performance of life sciences research.

- Provide recommendations on the development of mandatory programs for education and training in biosecurity issues for all scientists and laboratory workers at federally funded institutions.
- Advise on national policies regarding the conduct of dual use biological research. This
  includes strategies for addressing national security concerns while at the same time
  fostering continued rapid progress in public health research and food and agriculture
  research (e.g., new diagnostics, treatments, vaccines and other prophylactic measures, and
  detection methods).
- Advise on national policies governing the publication, public communication, and dissemination of dual use research methodologies and results.
- Advise on national policies governing local review and approval processes for dual use biological research, including the development of guidelines for the case-by-case review and approval by Institutional Biosafety Committees (IBCs).
- Advise on criteria and processes for referral of classes of research or specific experiments by IBCs to the NSABB for guidance.
- Review and provide guidance on specific experiments insofar as they exemplify a significant or particularly complex permutation of an existing category of dual use research or represent a novel category of dual use research that requires additional guidance from the NSABB.
- Respond to requests submitted by research institutions for the interpretation and application of the guidelines to specific research proposals in instances where a proposal has been denied by an IBC and the institution seeks additional advice.
- Recommend strategies for fostering international collaboration for the effective oversight of dual use biological research.
- Address any other issues as directed by the Secretary of HHS.

As necessary, subcommittees may be established to perform functions within the Board's jurisdiction. The advice/recommendations of that subcommittee must be deliberated by the parent advisory committee. A subcommittee may not report directly to a federal official unless there is statutory authority to so.

Subcommittee membership may be drawn in whole or in part from the parent advisory committee. All subcommittee members may vote on subcommittee actions and all subcommittee members count toward the quorum for a subcommittee meeting. Ad hoc consultants do not count toward the quorum and may not vote. Subcommittee members who are not members of the parent committee may attend closed sessions of the parent committee meeting, but they may not count toward the quorum of the parent committee, and they cannot vote on committee actions. The NSABB may call upon special consultants; assemble ad hoc working groups; and convene conferences, workshops, and other activities necessary to the fulfillment of the NSABB's responsibilities.

#### **STRUCTURE**

The NSABB shall consist of not more than 25 voting members, including the Chair. Members will be appointed by the Secretary of HHS in consultation with the heads of federal departments and agencies that conduct or support life sciences research. The Secretary will designate the Chair. All members will hold security clearances at the level of Secret or higher. A member of the NIH Recombinant DNA Advisory Committee (RAC) will serve as a voting member of the NSABB.

Areas of expertise/perspectives to be represented on the NSABB, include inter alia:

- Molecular Biology/Genomics
- Microbiology (Bacteriology)

- Microbiology (Virology)
- Clinical Infectious Diseases/Diagnostics
- Laboratory Biosafety and Biosecurity
- Public Health/Epidemiology
- Health Physicist/Radiation Safety
- Pharmaceutical Production
- Veterinary Medicine
- Plant Health
- Food Production
- Bioethics
- National Security
- Military Biodefense Programs and Military Medicine
- Intelligence
- Biodefense
- Law
- Law Enforcement
- Academia
- Scientific Publishing
- Industry Perspective
- NIH RAC Experience/Perspective
- Public Perspective
- IBC Perspective
- Export Controls

There may be nonvoting ex officio members from each of the following departments and agencies:

- Executive Office of the President
- Department of Health and Human Services
- Department of Energy
- Department of Homeland Security
- Department of Veterans Affairs
- Department of Defense
- Department of the Interior
- Environmental Protection Agency
- Department of Agriculture
- National Science Foundation
- Department of Justice
- Department of State
- Department of Commerce
- Intelligence Community
- National Aeronautics and Space Administration
- Others as appropriate

Members shall be invited to serve for overlapping terms of two to four years; terms of more than two years are contingent upon the renewal of the NSABB's Charter by appropriate action prior to its expiration. A member may serve after the expiration of the member's term until a successor has been appointed.

Management and support services for the NSABB shall be provided by the Office of Biotechnology Activities, the Office of Science Policy, and the Office of the Director, NIH. HHS and NIH staff will hold security clearances at the level of Secret or higher, as needed, to provide support to the NSABB.

#### **MEETINGS**

Meetings shall be held at least twice a year and may be convened on an as-needed basis, at the call of the HHS Designated Federal Official who shall also approve the agenda. The Designated Federal Official shall be present at all meetings.

Meetings of the NSABB will be open to the public except as determined otherwise by the Secretary of HHS, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act. Notice of all meetings will be given to the public. Meetings will be conducted, and records of the proceedings kept, as required by applicable laws and Departmental policies.

# **QUORUM**

A quorum for the NSABB and each of its subcommittees shall consist of a majority of the appointed members eligible to vote. The nonvoting agency representatives shall not be counted in calculating a quorum. Of the voting members, any who are disqualified from participating in an action on a particular issue (e.g., due of a conflict of interest) shall not be counted in calculating the quorum. All votes relating to any review of a recommendation by the NSABB shall be open to the public unless the meeting has been closed to the public in accordance with the Government in the Sunshine Act and the Federal Advisory Committee Act.

## **COMPENSATION**

Members shall be paid at the rate of \$200 per day for each meeting day, plus per diem and travel expenses as authorized by Section 5703, Title 5 U.S.C., as amended, for persons in Government service employed intermittently. Members who are officers or employees of the U.S. Government shall not receive compensation for service on the NSABB.

# **ANNUAL COST ESTIMATE**

The estimated annual cost for operating the Committee, including compensation and travel expenses for members but excluding staff support, is \$449,527. The estimated annual person-years of staff support are 4.5, at an estimated cost of \$650,073.

### **REPORTS**

Annual reviews and reports will be prepared, filed, and retained as required by applicable laws and Departmental policies. In the event a portion of a meeting is closed to the public, an annual report shall be prepared that shall contain, at a minimum, a list of the members and their business addresses; the NSABB's functions, dates, and places of meetings; and a summary of the NSABB's activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

# **TERMINATION DATE**

Unless renewed by appropriate action prior to its expiration, the Charter for the National Science Advisory Board for Biosecurity shall expire April 7, 2008.

# <u>APPROVED</u>

MAR 16 <b>2006</b>	mitulo. Laning
Date	Secretary

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# Roster National Science Advisory Board for Biosecurity

#### Chair

#### Dennis L. Kasper, M.D.

William Ellery Channing Professor of Medicine and Professor of Microbiology and Molecular Genetics Harvard Medical School Director Channing Laboratory Department of Medicine Brigham and Women's Hospital Boston, MA

#### Other Voting Members

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# Lynn W. Enquist, Ph.D.

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#### Michael T. Osterholm, Ph.D., M.P.H.

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Center for Infectious Disease Research and Policy

Associate Director

Department of Homeland Security

National Center for Food Protection and Disease

Professor

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Professor and Head

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National Institute of Standards and Technology

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#### **APPENDIX 2.** Questions for Comment

- 1. The proposed institutional responsibility for expert review of research that has been identified by the principal investigator (PI) as dual use of concern may have significant implications for institutions in terms of cost, administrative burden, and workload. We are especially interested in feedback regarding these concerns and estimates of the number of projects conducted at a given institution that might meet the criterion for dual use research of concern and therefore warrant specific local review for dual use risk assessment and management.
  - What is the most appropriate entity for conducting risk assessment of research that has been identified as potential dual use research of concern? For example, should it be the Institutional Biosafety Committee (IBC), augmented with additional expertise, or should it be a separate committee?
  - If the IBC, what additional expertise would be needed to facilitate the review of dual use research of concern?
  - Is a single institution likely to have the necessary in-house expertise for this review?
  - Depending on how many projects an institution anticipates will require dual use review, would it be more efficient and effective to have the option to utilize a regional or central review entity? Would it be helpful to have the option of utilizing a commercial review entity or the review entity at another institution?
- 2. We anticipate that true instances of dual use research of concern will be fairly rare and so tried to design a criterion and guidance that would result in the identification of only those few cases. At the same time, we wanted to make the criterion sufficiently inclusive that it would indeed capture those instances of genuine dual use research of concern.
  - Is the criterion sufficiently specific and understandable so that research personnel can apply it consistently?
  - Will the criterion capture research that is not appropriately considered as being dual use of concern?
  - Does the criterion need to capture additional types of information?
- 3. Is the guidance (considerations) that follows the criterion for identifying dual use research of concern helpful and sufficient? Is it clear and understandable?
  - Should additional categories of research that may yield dual use findings of concern be included in the guidance (e.g., bioinformatics, synthetic biology, development of bioregulators, psychological/psychosocial studies of terrorists, etc.)?

- How much research at your institution would be captured with this criterion for dual use research of concern?
- 4. Is it sufficient to have the PI make the initial determination as to whether his or her research might be considered dual use of concern in a supportive environment, or should the initial evaluation always be made with input from others? If the latter, who else should participate in the initial evaluation?
- 5. Is additional guidance needed for any aspect of the proposed oversight process?
- 6. The NSABB is very concerned that the oversight system put in place achieves a reasonable balance between protecting against the misuse of information from life sciences and maintaining the free and open communication of life sciences research. We are especially mindful of the potential burden imposed by the proposed requirement for specific, additional review of that subset of research identified by investigators as possibly being dual use research of concern. We are aware that there are concerns that all institutions do not have the expertise for this and that additional resources would be required, in addition to the increased workload.
  - How much of a burden would this proposed oversight system pose to your institution? Please keep in mind that while it is a (proposed) institutional responsibility to ensure review of research that is potentially dual use of concern, it may not be necessary to conduct the review "in house" (i.e., it may be possible to conduct the reviews at a regional or central locus and/or to use commercial review entities).

### APPENDIX 3. Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences

#### INTRODUCTION

Important benefits to society have been achieved in no small measure by scientists who have strived to conduct their work conscientiously and with integrity. This commitment forms the basis of a culture of responsibility in which scientists consider the risks and implications of their research and take appropriate measures to ensure that they carry out their work safely, ethically, and in a manner that warrants continued public trust and support. To achieve this aim, scientists should consider the relevant standards and guideposts for ethical and responsible research conduct as well as the potential impact their research may have on society. The importance of thoughtful consideration of ethics and research is amplified when scientists engaged in well-intended research are confronted with its potential for misuse.

In recent years, increased attention has been directed to the possibility that the knowledge, products, or technologies derived from some life sciences research may be misapplied to pose a threat to public health, agriculture, plants, animals, the environment, or materiel. Research with this potential is known as "dual use research of concern." All those involved in life sciences research have a responsibility to avoid or minimize the foreseeable risks and harm that could result from malevolent use of research outcomes.

The National Science Advisory Board for Biosecurity (NSABB) has given extensive consideration to the characteristics that define dual use research of concern. Following its charge, the NSABB is proposing a series of recommendations and tools to help the scientific community identify and manage the risks associated with this type of research. The NSABB has observed that there is a need not only to raise life scientists' awareness of the dual use potential of their research but also to provide and promote principles of research conduct that will sustain a culture of responsibility within the scientific community.

One useful tool for raising awareness of the potential for dual use research and promoting responsible research behavior is a code of conduct. Typically developed by societies, associations, and institutions, a code of conduct articulates shared values and standards of conduct. Codes also can be used to educate people regarding their ethical responsibilities. The value of a code is reinforced when it is discussed in training sessions, at meetings, and during the course of routine activities.

#### Using This Document

The following document lays a foundation for a code of conduct that explicitly addresses dual use research of concern by:

- Describing the general utility and potential applications of such a code
- Articulating a core set of responsibilities related to dual use research that can serve as a foundation for a code

• Delineating additional responsibilities related to specific phases of the research process and research-related activities

The core set of responsibilities and the additional specific responsibilities outlined below provide a template that users of this document can adopt verbatim, modify, or use as the basis for developing more specific guidance on ethical behavior. This document is intended to be used in tandem with other elements of the framework of policy and guidance pertinent to this issue that are now under development.

#### Audiences for This Document

Every individual associated with the life sciences should be aware of the potential dual use of scientific knowledge, products, or technology and be knowledgeable of the ethical obligations that ensue in regard to research that can be considered "dual use of concern." Specifically, the considerations in this document are intended to apply to the following audiences:

Life sciences societies and associations. Life sciences societies and associations are important sources of guidance for scientists on the ethical standards that apply to their disciplines. These organizations are encouraged to enhance their bylaws or codes of conduct to address the considerations within this document. They may choose to adopt any portion of this document into an existing code or to modify its contents in order to adapt them to a specific discipline and context. Alternatively, organizations may choose to adopt or create a stand-alone document to give it particular salience. In either case, organizations generally adopt or modify their codes through a governance process involving broad discussion with the membership; therefore, the process of considering the ethical standards applicable to dual use research of concern is a valuable exercise in its own right. Whatever the manner in which a society chooses to develop and adopt a code on dual use research of concern, the code should be widely disseminated to members (for example, by publishing it in society newsletters and journals). It should be revisited frequently at annual membership meetings and other events in order to refresh and reinforce its impact and to address evolving issues.

Research institutions. Whether public or private, academic or industrial, research institutions are responsible for the integrity of their research programs. Institutions that oversee a body of research typically have rules, guidelines, and standard operating procedures to guide staff on how to conduct research in an ethical and legal manner, as well how to conform to institution-specific policies and requirements. Institutions should consider the adoption and dissemination of specific guidance on dual use research in faculty handbooks, procedures manuals, institutional Web sites, training and education of students and staff, and other appropriate venues. Many such institutions also offer formalized employee orientation programs and courses of instruction in the responsible conduct of research. It would be appropriate and helpful to incorporate the topic of dual use research, along with related guidance on ethical and legal responsibilities, in such courses and programs.

**Industry.** Life scientists who are engaged in research for commercial purposes share the same responsibilities for safeguarding the public welfare as their colleagues in the academic or public

sectors. Each commercial organization will have its own mechanisms for raising awareness of dual use research of concern and for developing policies to address related issues.

**Research leadership** Scientists who have risen to leadership positions (for example, society presidents, medical school deans, and department chairs in universities) serve as role models for other scientists. In particular, those who are responsible for oversight of research programs should consider how their institutions are addressing the responsibilities outlined in this document. For example, it is important to ensure that issues related to dual use research of concern are well understood by life scientists, that dual use research of concern is reported in accordance with institutional policies, and that life scientists are aware of and compliant with other applicable requirements. All those who have gained the respect of other scientists through their work can play a critical role in assuring that the issues associated with dual use research of concern are thoughtfully addressed.

**Individual life scientists.** Scientists bear the primary responsibility for the integrity of their own research. By their actions and explicit guidance, they can foster a sense of ethical responsibility in the research team and an awareness of applicable laws and guidelines. This document may aid in increasing their awareness of their responsibilities in the area of dual use research of concern and help them mentor students, trainees, and technical staff. Mentors are encouraged to involve these individuals in laboratory discussions of dual use research of concern, the ethical responsibilities that are outlined in this document, and the relevance of these responsibilities to their work.

**Technicians, trainees, and others involved in the research process.** Technical staff, postdoctoral fellows, students, and others who contribute to research activities bear their own measure of responsibility for the integrity of these projects. These individuals are also encouraged to review this document carefully, consider how it may apply to current work, and engage their instructors and mentors in addressing any questions they may have regarding its relevance.

**Funding agencies/institutions.** Institutions and agencies that fund research establish the framework for decisions about the research considered eligible for funding and provide oversight to ensure responsible stewardship of funds. In order to avoid endangering public health, agriculture, plants, animals, the environment, or materiel, they are responsible for ensuring that projects that could be considered dual use research of concern are identified prior to funding. When a project meets the criteria for this type of research, the funders should ensure that a process is in place to manage risks through a thoughtful and informed consideration of options that could mitigate or manage them.

**Journal editors, reviewers, and publishers.** Those who play decisionmaking roles in the process of communicating scientific information have an ethical responsibility to consider whether the information being considered for publication could be used to endanger public health, agriculture, plants, animals, the environment, or materiel. Depending on their analysis of the risks and benefits of communications regarding information or technology that meet criteria for dual use research of concern, they may choose to proceed in a way that mitigates or manages the risks associated with communication, for example, by adding contextual information not

found in the original article or delaying communication until a time at which the risks would be reduced.

### CORE RESPONSIBILITIES OF LIFE SCIENTISTS IN REGARD TO DUAL USE RESEARCH OF CONCERN

The following page identifies the fundamental responsibilities of all life scientists with regard to dual use research of concern. These obligations flow from the underlying principle of concern for the public good and should lie at the heart of any code of conduct that addresses this topic.

# LIFE SCIENTISTS: CORE RESPONSIBILITIES REGARDING DUAL USE RESEARCH OF CONCERN

Life sciences research is a critically important endeavor that has benefited society by advancing our understanding of living systems. Critical to the future of scientific progress and freedom is the preservation of public trust and support, which scientists have earned through their attention to responsible research practice. Despite a scientist's conscientious approach to research conduct, the knowledge, products, or technologies derived from some life sciences research may be misused by others to pose a threat to public health, agriculture, plants, animals, the environment, or materiel. Research with this potential is known as "dual use research of concern."

Individuals involved in any stage of life sciences research have an ethical obligation to avoid or minimize the risks and harm that could result from malevolent use of research outcomes.

Toward that end, scientists should:

- Assess their own research efforts for dual use potential and report as appropriate
- Seek to stay informed of literature, guidance, and requirements related to dual use research
- Train others to identify dual use research of concern, manage it appropriately, and communicate it responsibly
- Serve as role models of responsible behavior, especially when involved in research that meets the criteria for dual use research of concern
- Be alert to potential misuse of research

#### RESPONSIBILITIES IN THE RESEARCH PROCESS

Research is a complex, iterative process, and the potential for dual use may be recognized at many junctures and through different activities. Consequently, while it is valuable to be mindful of the core responsibilities articulated above, those involved in life sciences research may also benefit from a more specific review of their responsibilities in regard to dual use research of concern.

#### **Proposing Research**

When designing and proposing research, the ethical responsibilities of life scientists include:

- 1. Considering whether the knowledge, products, or technology resulting from the research could be deliberately misused to endanger public health, agriculture, plants, animals, the environment, or materiel
- 2. Striving to design research that promotes beneficial scientific advances, while avoiding or minimizing elements of study design that raise concerns about dual use
- 3. Weighing carefully the benefits of study elements presenting dual use concerns that cannot be completely eliminated against the harm that could occur through their deliberate misuse
- 4. Considering ways to modify the research design to manage and mitigate potential misuse when it is clear that the benefits of the research with dual use potential outweigh the potential harm

#### Managing Research

The ethical responsibilities of persons who manage research programs, whether within the public or private sector, include the following:

- 1. Promoting awareness of dual use research of concern and the ethical responsibilities it entails
- 2. Developing and maintaining systems, policies, and training to ensure that dual use research of concern is identified and managed appropriately
- 3. Implementing federal, state, and other appropriate guidelines specific to dual use research of concern

#### Reviewing Research

The ethical responsibilities of those responsible for establishing and managing the review process (e.g., funding agencies) include the following:

1. Ensuring that when research proposals are reviewed, appropriate systems are in place to identify the possibility of dual use of concern and to address related issues. Examples of common means of reviewing research proposals include Institutional Animal Care and Use Committees (IACUCs), Institutional Biosafety Committees (IBCs), Institutional Review Boards (IRBs), and peer review groups.

- 2. Ensuring that both researchers and reviewers are knowledgeable of, and adhere to, all ethical, institutional, and legal requirements that apply to the review of possible dual use research of concern.
- 3. Reconsidering institutional review systems periodically to ensure that they reflect current criteria defining dual use research of concern and are consistent with applicable federal and state guidelines.

The ethical responsibilities of individuals serving on peer review groups or otherwise engaged in research review include the following:

- 1. Becoming well educated about dual use research of concern and related ethical, legal, and institutional requirements, as well as applicable federal and state guidelines
- 2. Being mindful during the review process of whether the research could meet the criteria for dual use of concern
- 3. Using methods in keeping with the reviewer's charge and context to make appropriate people aware that the research being reviewed meets the criteria for dual use research of concern

#### **Conducting Research**

The ethical responsibilities of life scientists engaged in research include the following:

- 1. Observing safe practices<sup>1</sup> and ethical behaviors in the laboratory, clinic, field, and classroom and ensuring that subordinate personnel do so as well
- 2. Using appropriate security measures and continually reassessing their adequacy as concerns about potential misuse evolve
- 3. Observing applicable guidelines for the responsible conduct of dual use research of concern
- 4. Being attentive to the dual use potential of the knowledge, products, or technology resulting from research activities as they emerge
- 5. Alerting responsible institutional officials when dual use research of concern is identified and when decisions must be made to manage associated risks

#### Collaborating on Research

Research endeavors frequently involve the participation and cooperation of multiple laboratories and disciplines, which can be subject to different management, codes of conduct, cultural values, or operating procedures. Besides the ethical responsibilities associated with conducting research, scientists involved in such collaborations have the additional obligations of:

<sup>1</sup> 

<sup>&</sup>lt;sup>1</sup>Safe laboratory practices are embodied in such documents as *CDC-NIH Biosafety in Microbiological and Biomedical Laboratories* (http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm), *NIH Guidelines for Research Involving Recombinant DNA Molecules* (http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html), and *Biological Safety: Principles and Practices* (ASM Press, http://www.asm.org/), and applicable occupational and safety regulations and standards.

- 1. Engaging in open dialog regarding whether knowledge, products, or technology resulting from the research could be considered dual use research of concern; when such research is pursued, ensuring that all parties are aware of their ethical responsibilities
- 2. Agreeing on specifically assigned responsibilities to ensure ethical oversight of all aspects of research with dual research potential, including its outcomes.
- 3. Considering and respecting expressions of concern regarding the possible dual use of knowledge, products, or technology resulting from the research and ensuring that these concerns are raised with those charged with responsibility for research oversight
- 4. Considering appropriate measures to reduce or eliminate risks to public health, agriculture, plants, animals, the environment, or material resulting from the research project
- 5. Maintaining a current awareness of national and international standards and policies regarding dual use research of concern

#### Communicating the Results of Dual Use Research of Concern

Regardless of the stage of the research process and the form of the communication, those involved in communications regarding knowledge, products, or technology that can be considered dual use research of concern have the following ethical responsibilities:

- 1. Being aware of ethical and legal considerations relevant to communications regarding knowledge, products, or technology that can be considered dual use research of concern.
- 2. Analyzing potential risks to public health, agriculture, plants, animals, the environment, or materiel that could result from research-related communications, balancing them against the potential benefits.
- 3. Considering options for communication that may reduce or eliminate risks when communicating information with dual use potential is clearly warranted by its benefits. Examples of mitigating strategies may include a delay in releasing the information, the addition of appropriate contextual information, or communicating the information to a more limited audience.

#### Scientific Education and Mentorship

Practicing scientists who serve as role models to developing scientists (e.g., their trainees, students, and staff) have the following ethical responsibilities:

- 1. Raising developing scientists' awareness of what constitutes dual use research of concern and why it matters
- 2. Informing developing scientists of their ethical, legal, and institutional responsibilities when engaged in dual use research of concern, as well as applicable federal and state guidelines
  - Encouraging open and respectful discussion of issues related to dual use research
    of concern, including whether or not a particular project could be considered dual
    use research of concern

## APPENDIX 4. Points To Consider in Risk Assessment and Management of Research That is Potentially Dual Use of Concern

Could this research yield information that could be intentionally misused to threaten public health and safety or other aspects of national security?

- What is the nature of that information?
- Is the information novel?
- Is the information applicable to other, perhaps common, organisms, biologics, etc.?
- Could the information be directly misused to pose a threat? For example, even if the information would need to be combined with other information/technologies in order to pose a threat, is that other information/technology currently available?
- Does the information need to be combined with other information to pose a threat?
- If so, is that other information already available?

What is the nature of the threat that could be posed from intentional misapplication of the information, and what are the potential consequences?

- What is the potential nature (e.g., economic, agricultural, public health, and/or public terror), and what is the potential impact of the threat?
- What is the scope of the potential threat (e.g., how many/which people, plants, animals might be adversely affected?
- Are there currently countermeasures for this threat?
- What type of technical expertise and/or physical resources would be needed to apply the information for malevolent purposes?
- In what timeframe might the information be misused? Is there concern about immediate or near-future potential use, or is the concern about misuse in the distant future?
- Would it require a low or high degree of technical skill and sophistication to use the dual use information for harmful purposes?

Based on the above considerations, how likely (reasonably anticipated) is it that the information could be used to pose a threat to public health and safety or other aspects of national security?

(If there is no discernable potential threat, then there is no need to continue the analysis.)

Could this research yield information that could potentially benefit the life sciences and/or public health and safety and other aspects of national security?

- If so, what is the nature of that information?
- What is the nature of the potential benefit?
- How much of a benefit might there be?

Do the potential risks outweigh the potential benefits?

- If not, determine applicable risk management strategies (see below).
- If so, consider whether the research should be modified or discontinued.

Potential Risk Management Strategies (more than one may be applicable)

- Ongoing review or monitoring of research
- Modification of experiment (e.g., can an alternative antibiotic or a different strain of organism be used?).
- Discontinuation of experiment. This may need to be discussed at a higher level, either within the local institution or at the federal level.
- Utilize the "Points to Consider in Assessing the Risks and Benefits of Communicating Research Information With Dual Use Potential" (Appendix 5):
  - Identify and assess the risks and benefits of communicating research with dual use potential
  - Weigh the risks versus the benefits
  - Formulate a decision for responsible communication; address the content, timing, and extent of communication
- Develop a comprehensive communication plan:
  - Consider the need to address the following issues in a communication:
    - The significance of the research findings for public health and safety, agriculture, the environment, and/or materiel
    - How the new information or technology will be useful to the scientific community
    - o The biosafety measures in place as the research was conducted
    - o The communication of less detailed findings
    - o The dual use aspects of the information and that careful consideration was given to the biosecurity concerns in the decision to publish
  - Determine whether additional venues are appropriate for conveying the research information and contextual/background information.

## APPENDIX 5. Points To Consider in Assessing the Risks and Benefits of Communicating Research Information with Dual Use Potential

- 1. General Overview of the Research Information With Dual Use Potential
  - a. What information is provided?
  - b. To what extent is it novel?

#### 2. Risk Analysis

- a. Are there reasonably anticipated risks to public health and safety from direct misapplication of this information?
  - i. E.g., is novel scientific information provided that could be intentionally misused to threaten public health and/or safety?
  - ii. E.g., does the information point out a vulnerability in public health and/or safety preparedness?
- b. Is it reasonably anticipated that this information could be directly misused to pose a threat to agriculture, plants, animals, the environment, or materiel (e.g., does the information point out a vulnerability with respect to agriculture, plants, animals, the environment, or materiel)?
- c. If a risk has been identified, in what timeframe (e.g., immediate, near future, years from now) might this information be used to pose a threat to public health and/or safety, agriculture, plants, animals, the environment, or materiel?
- d. If the information were to be broadly communicated "as is," what is the potential for:
  - i. Public misunderstanding, that is, what might be the implications of such misunderstandings (e.g., psychological, social, health/dietary decisions, economic, commercial etc.)?
  - ii. Sensationalism (i.e., in what way might it result in widespread concern or even panic about public health or other safety/security issues?)

If no risk has been identified, no further dual use communication considerations are necessary. If a risk has been identified, continue on.

#### 3. Benefit Analysis

- a. Are there potential benefits to public health and/or safety from application or utilization of this information?
- b. Are there potential benefits of the information for agriculture, plants, animals, the environment, or materiel (e.g., what potential solution does it offer to an identified problem or vulnerability)?
- c. Will this information be useful to the scientific community? If so, how?
- d. If a benefit has been identified, in what timeframe (e.g., immediate, near future, years from now) might this information be used to benefit science, public health, agriculture, plants, animals, the environment, or materiel?

#### 4. Risk versus Benefit Assessment

Based on the risks and benefits identified and considering the timeframe in which these might be realized:

a. Do the benefits of communicating the information outweigh the risks?

- b. Do the risks outweigh the benefits?
- 5. Formulation of Recommendation Regarding Communication
  Decisions about how to responsibly communicate research with dual use potential should address content, timing, and possibly extent of distribution<sup>1</sup> of the information.

#### a. Content

- i. Communicate as is.
- ii. Communicate with addition of appropriate contextual information. For example, it may be important to address:
  - (1) The significance of the research findings for public health and/or safety, agriculture, the environment, or materiel
  - (2) How the new information or technology will be useful to the scientific community
  - (3) The biosafety measures in place as the research was conducted
  - (4) The dual use potential of the information
  - (5) The careful consideration that was given to the dual use concerns in the decision to publish
- iii. Recommend communicating a modified version of the product. For example, is it possible to "decouple" the material that poses security concerns from some or all of the potentially useful scientific information, or should specific information be removed (e.g., technical details about an enabling technology)?

#### b. Timing

- i. Communicate immediately.
- ii. Recommend that communication be deferred until a clearly defined and agreed-upon endpoint is reached (e.g. a condition is met such that communication no longer poses the same degree of risk).

#### c. Distribution<sup>2</sup>

- i. No limit on distribution.
- Limit access to selected individuals on a "need to know" basis. It will be necessary to identify categories of individuals who should have access and under what circumstances.
- iii. Recommend that the product not be published or otherwise made accessible to the public.

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<sup>2</sup>Ibid.

<sup>&</sup>lt;sup>1</sup>The relevance and/or feasibility of considering limits on the distribution of dual use research will depend on the specific situation (e.g., timing of the communication in terms of the maturity of the research, the nature of the information and the risks associated with its communication, and the relevant audience for the information). For example, while limiting distribution is not a consideration for most scientific journals, it might be a reasonable consideration early on in a research project that yielded information of special significance to public health or homeland security experts and for which countermeasures might need to be initiated prior to broader communication of the information.

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Title: National Science Advisory Board for Biosecurity

Subject:

Author: Mary Groesch

Keywords: Comments:

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From: Zachary Adelman <zachadel@tamu.edu>

To: yphuang CC: <u>aajames</u>

Date: 5/3/2017 10:04:49 AM

Subject: Re: Re: Genome editing workshop (IWIGE2017)

Attachments:

Yongping,

Attached is CV.

zach

On Tue, May 2, 2017 at 6:29 PM, yphuang

<yphuang@</pre>

> wrote:

Dear Zach:

We are sorry that you could not participate this Workshop. But, we will looking for another opportunities.

s CV to me. I need it to ask the permission from our institute funding managers. If Would you please send they agree, I will send invitation to

With best regards.

Sincerely yours Yongping

From: Zachary Adelman
Date: 2017-05-02 22:58

To: <u>aajames</u>; **Subject:** Re: Genome editing workshop (IWIGE2017)

Yongping,

Thank you so much for the invitation, I certainly had a wonderful time during my last visit. I spoke with Tony about this a few days ago, and unfortunately I already have a commitment for this time at the Virginia Academy of Sciences: http://www.vasem.org/2017-p\*summit/

If possible, I could send a senior member of my lab to present some of our recent work on my behalf. ) has been an author on several of our gene editing publications and has quickly become one of our leading experts. I have already spoken with him, and he is very happy to take my place.

Thanks again, and I hope things are well with you.

Best.

Zach Adelman

Associate Professor

Texas A&M University

On Tue, Apr 25, 2017 at 6:25 PM, yphuang <yphuang</pre> > wrote:

Dear Dr. Zach Adelamn:

Tony and I am trying to organize a symposium on insect genome editing in Shanghai by the end of October, 2017. We would like to invite you to parcipate the meeting if your time is convenient. We could cover all of your expenses including international airfee (Economic class) and registration and accommondation fee during the meeting.

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Enclosed please find the following file:

- 1. Invitation letter;
- 2. Visa information page (same file to the invitation letter); and
- 3. Flyer of the symposium

The end of the October is the best season in a year of China, the weather is not hot and not cold. We will be very happy to have many researchers in the world to come for the workshop. Of course, you are one of the most expected participants.

We will be very happy to have your positive response and are looking forward to meeting you in Shanghai.

With best regards.

Sincerely Yours
Prof. Anthony James,
Chairman of Academic Committee
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**Education and employment history** 

Texas A&M University	PhD student	July 2016-current
Virginia Polytechnic Institute and State University	PhD student	August 2013-July 2016
Virginia Polytechnic Institute and State University	Biology	BS, 2013
Virginia Polytechnic Institute and State University	Philosophy	BA, 2013

#### **Skills**

- Design, development and implementation of genome editing in the yellow fever mosquito *Aedes aegypti*.
  - Expertise in genome editing using CRISPR/Cas9, including designing guide RNAs and transgenic constructs to be inserted via homology directed repair.
  - Expertise in detecting and monitoring of mutations by PCR and High Resolution Melt Curve Analysis (HRMA).
  - Establishment and care of insectary housing transgenic mosquitoes. Husbandry of transgenic Ae. aegypti lines. Extensively involved in all aspects of mosquito colony care and maintenance for multiple transgenic strains.
- Extensive practical experience in specialized transgenic techniques including construct design, microinjection of *Ae. aegypti* embryos and ovaries, thoracic injection of *Ae. aegypti*, DNA extraction, fluorescence microscopy and *Ae. aegypti* dissections.
- Development of dual luciferase assay to screen for increases/decreases in non-homologous end joining in *Ae. aegypti* embryos, utilization of both NHEJ and SSA dual luciferase assays via microinjection.
- Development of Bleomycin assays to screen for sensitivity to DNA double stranded breaks.
- Extensive practical experience in standard molecular biology techniques including DNA cloning and sequencing; related techniques such as PCR, HRMA, genomic DNA purification, plasmid purification, fluorescence microscopy, and luminescence assays.
- Basic experience in cell culture maintenance, cell transfection (lipofectamine), Western blotting, mRNA production, dsRNA production.
- Experience in utilization of Flybase, Vectorbase, DNAStar, and GraphPad.

#### **Current Projects**

- Study the basic biology of the classical non-homologous end joining pathway in *Aedes aegypti*.
  - o Generation of knockout lines missing key components of the C-NHEJ pathway, assessment of DNA repair, longevity, fecundity and viability
- Study the basic biology and application of pigmentation associated genes (*yellow*, *tan*, *ebony*) in *Aedes aegypti* 
  - o Generation of knockout lines and overexpression constructs to assess the *yellow*, *tan* and *ebony* genes, assessment of longevity, fecundity and viability

#### **Publications**

Aryan A, Myles KM, Adelman ZN. 2015. Understanding the DNA damage response in order to achieve desired gene editing outcomes in mosquitoes. Chromosome Res 23(1): 31-42.

Basu S\*, Aryan Samuel, GH. Anderson, MA. Dahlem, TJ. Myles, KM. Adelman, ZN. 2015. Silencing of end-joining repair for efficient site-specific gene insertion after TALEN/CRISPR mutagenesis in *Aedes aegypti*. Proc Natl Acad Sci U S A 112(13): 4038-4043. \*:co first authors

Z.N. Adelman, Chapter One - Progress in Gene Editing Transgenesis Genome Manipulation in Mosquitoes, In: Alexander S. Raikhel, Editor(s), Advances in Insect Physiology, Academic Press, 2016, Volume 51, Pages 1-35, ISSN 0065-2806, ISBN 9780128024577, https://doi.org/10.1016/bs.aiip.2016.05.001.

#### **Oral presentations**

, and Zach N. Adelman. DNA damage repair and vector genomic engineering. Oral Presentation by . In: Texas A&M Vector Biology Seminar, College Station, TX, November  $4^{th}$ , 2016.

, Azadeh Aryan, Kevin M. Myles, and Zach N. Adelman. Knockout of DNA damage repair genes in the disease vector *Aedes aegypti*. Oral Presentation by In: 25<sup>th</sup> International Congress of Entomology, Orlando, FL, September 25-30, 2016.

, Azadeh Aryan, Kevin M. Myles, and Zach N. Adelman. Knockout of DNA damage repair genes in the viral vector *Aedes aegypti*. Oral Presentation by . In: 35<sup>th</sup> Annual meeting of the American Society for Virology, Blacksburg, VA, June 18-22, 2016.

#### Poster presentations

, Azadeh Aryan, Kevin M. Myles and Zach N. Adelman. Knockout of classical non-homologous end joining protein Ku70 and Lig4 in Aedes aegypti induces embryonic lethality. Poster presentation by In: 64<sup>th</sup> Annual Meeting of the American Society of Tropical Medicine and Hygiene, Philadelphia Marriott Downtown, Philadelphia Pennsylvania, October 25-29, 2015.

Sanjay Basu, Azadeh Aryan, , Glady Hazitha Samuel, Michelle A. E. Anderson, Timothy J. Dahlem, Kevin M. Myles, and Zach N. Adelman. Silencing of end-joining repair for efficient site-specific gene insertion after TALEN/CRISPR mutagenesis in *Aedes aegypti*. Poster presentation by . In: Proceeding of the 9<sup>th</sup> Annual Arthropod Genomic Symposium, K-State Alumni Center, Kansas State University, Manhattan, Kansas, June 17-19, 2015.

#### **Teaching and Educational Experience**

- Extensive experience teaching post-doctorate fellows embryonic microinjection and transgenesis techniques in *Aedes aegypti*
- Extensive experience mentoring undergraduates in maintenance of *Aedes aegypti*
- Experience in mentoring staff and undergraduate students in the construction, implementation and analysis of high level experiments.
- Teaching Assistant, *Insects and Human Society* (ENT 2004), Spring 2015.
- Hokie Bug Camp presenter, Summer 2014-15

#### **Service**

- Contributing author to the Insect Genetic Technology Research Coordination Network blog (http://igtrcn.org/)
- Volunteer workshop assistant, the 35th Annual Meeting for the American Society for Virology, Virginia Tech, Blacksburg, VA, June, 18-22, 2016.
- Virginia Science Festival, Virginia Tech, 2015
- Member, W. B. Alwood Society, Virginia Tech, 2013-2015
- Hokie Bugfest, booth sponsor, Virginia Tech, 2013-2015

From: Insect Genetic Technology Research Coordination Network <admin=igtrcn.org@mail124.suw13.rsgsv.net>

To:

Date: 5/2/2017 12:04:11 AM

Subject: DNA-free gene editing in medfly - Ceratitis capitata

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Updates from the blog

### Technology Topics

Insect Genetic Technologies Research Coordination Network

In the 05/02/2017 edition:

#### Positisions available

By Site Admin on May 01, 2017 11:03 am
Two positions – Postdoctoral Research Associate &
Research Scientist Dr. Donald Jarvis is seeking two
motivated individuals for Ph.D.-level research
positions. One will serve as a postdoctoral Research
Associate in Dr. Jarvis' academic lab in the
Department of Molecular Biology ...

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# DNA-free genome editing in the agricultural pest Ceratitis capitata

By Alys Jarvela on May 01, 2017 10:54 am
The genome editing revolution creates new
opportunities to improve pest management
strategies, yet biosafety concerns over off-target
effects and the use of foreign DNA present
roadblocks to the development of modified
organisms destined for field use. In a recent addition

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### Here are a couple of recent papers you may have missed:

Nanoparticle-bound, Aerosolized siRNA Knockdown in Aphids

Exciting Post Doc opportunity in Mosquito Gene

Drive research

Western Corn Rootworm, Diabrotica virgifera virgifera, germline transformation.

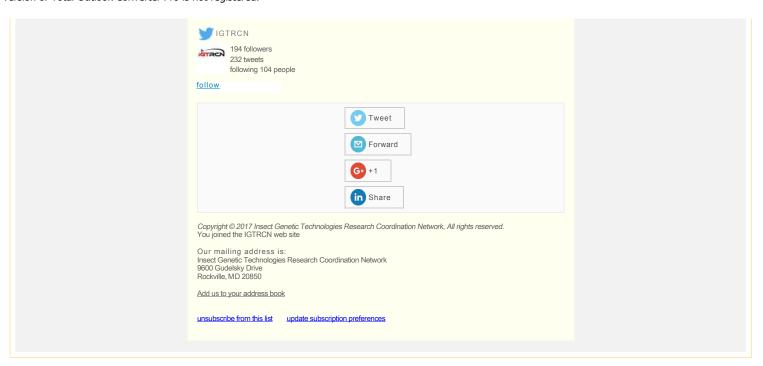


IGTRCN Technical Workshop

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To: Zachary Adelman

Ibartholomay@wisc.edu Brockhouse, Charles L

Sara Cherry Joanna C Chiu

Christophides, George K
Anupama Dahanukar
Megan Lindsay Fritz
kuhnr@purdue.edu

alistair.miles
Rita Rio
Denis Tagu
Gregg Thomas

Date: 5/1/2017 11:33:54 AM

Subject: Response requested: Dietary restrictions for AGS meal planning

#### Hello Everyone,

AGS organizers would like to know of any dietary restrictions you may have. Would you please reply to this email and let me know of any you may have so can be sure these are addressed?

Thank you.

Katie Cybulski

Katie (Merz) Cybulski Project Administrator for VectorBase and Notre Dame Research University of Notre Dame 315 Galvin Life Science Center

Notre Dame, IN 46556 Tel: 574-631-8045 Fax: 574-631-3996 Email: merz.3@nd.edu NDR website: research.nd.edu

VectorBase website: http://vectorbase.org

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