EXCERPT

IRB COMMITTEE #1 MEETING MINUTES
August 19 2014 – 2:10 PM
1550 Beardshear

IRB ID: 13-376 **Primary Reviewer: Kerry Agnitsch**
Investigator: **Dr. Wendy White**
Protocol Title: Measuring the Retinol Activity Equivalence of Beta-Carotene-Biofortified Bananas
Type of Review: Continuing Review
Name of Study Staff Attending the Meeting[1]: Wendy White at 2:20 PM
Name of Members Leaving the Room Due to Potential Conflict of Interest: none

Purpose and Procedures: The purpose of this study is to determine the vitamin A equivalence of beta-carotene from consumption of bananas that have been genetically modified to produce greater amounts of beta-carotene.

Summary of Controverted Issues and Their Resolution: This project has been the subject of recent media attention, summarizing concerns with genetically modified foods. In response, the PI provided the IRB with a summary of literature and FDA findings regarding safety of genetically modified foods in general and the genetically modified bananas under study. The IRB reviewed the media reports and the supplemental information provided by Dr. White, and requested clarification about the amount of beta-carotene to be consumed by participants during the study.

Specifically, members noted that the amount of beta-carotene and related carotenoids described in the informed consent appeared to be different than the amount noted in the supplemental information . The IRB asked for clarification about this apparent discrepancy, as there are risks associated with the consumption of too much beta-carotene. Dr. White clarified that there is no discrepancy;

Dr. White further explained that the amount of beta-carotene and carotenoids noted in the informed consent had been determined before the research team had the bananas in hand; while the lower number cited in the supplemental information was derived from analysis of the actual bananas. The beta-carotene and carotenoids consumed may be slightly less than the stated in the informed consent document. The IRB agreed this is appropriate, since risks are associated with over-consumption.

The IRB discussed whether and how to inform participants about the media attention to ensure they are fully informed about their participation in the study. Members agreed that the PI should be upfront with participants about the media coverage, and discussed the best method of informing them in a manner that was factual and informative.

The IRB agreed that it is of utmost importance to ensure participants are informed about what they will consume (e.g., that they will consume genetically modified bananas). Members carefully reviewed the previously-approved informed consent document, noting that it clearly states that the bananas are genetically modified, transgenic, and that this is the first trial involving human consumption of the bananas. Accordingly, the IRB agreed that the informed consent document was still acceptable.

Discussion returned to how to best inform participants about the media coverage. As noted earlier, the IRB agreed it is important to be upfront with the participants about the media reports, while at the same time not unduly alarming or upsetting them. Discussion of embedding information about the media coverage within the informed consent document occurred, with members ultimately deciding that a separate fact sheet or brochure addressing it would be more appropriate.

Dr. White agreed that being upfront with participants regarding the media coverage was a priority for her and proposed providing participants with full copies of the NPR and Des Moines Register articles as a part of the informed consent process. The IRB agreed that providing copies of the full articles was certainly acceptable, but felt that the full articles may be overwhelming for participants to read and synthesize in the context of a consent process. Instead, the committee suggested that a bulleted fact sheet or brochure that informs participants of recent media attention and that summarizes key points raised would be more readable and understandable. The fact sheet/brochure should be accompanied by links to or copies of the full articles. Dr. White may also include factual information related to concerns raised in the media articles. The fact sheet/brochure will be provided to and discussed with the participants during the recruitment and consent process to ensure they are comfortable taking part in the study. Dr. White agreed, and she will submit a modification seeking approval of this fact sheet or brochure.

Level of Risk and Rationale for Determination Including Protocol-specific Information: The IRB had previously determined that the study presents minimal risk as the FDA has deemed many genetically modified foods as safe, and much of the general population are consuming a number of genetically modified foods as part of the their regular daily diets.

The IRB agrees that this determination continues to be appropriate.

IRB Decision: A motion to approve the study for an additional one-year period was made and seconded. Review by the convened IRB continues to be required.

Vote: Total = 7 For — 7 Opposed — 0 Abstained — 0