IRB COMMITTEE #1 MEETING MINUTES
August 20, 2013 – 2:10 PM
3590 Beardshear
EXCERPT

IRB ID: 13-376 **Primary Reviewer: Lorraine Lanningham-Foster**
Investigator: Dr. Wendy White
Protocol Title: Measuring the Retinol Activity Equivalence of Beta-Carotene-Biofortified Bananas
Type of Review: New (8/9/13)
Name of Study Staff Attending the Meeting[1]: Dr. Wendy White
Name of Members Leaving the Room Due to Potential Conflict of Interest: None

Purpose and Procedures: The aim 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. Participants are women aged 18-40 who meet a variety of inclusion/exclusion criteria.

Interested participants receive an informed consent document prior to the screening interview. A graduate research assistant administers the "Subject Interview Form"-

Summary of Controverted Issues and Their Resolution:

The IRB discussed the informed consent document and noted several items:

- The IRB noted that monetary compensation is offered to participants. There was some discussion as to when participants would be compensated and if compensation was dependent

on completion of the study. The PI attended the meeting and clarified that participants will be compensated regardless of completion of the study. Therefore, in order to be more clear that the participants will be compensated for participation regardless of *completion* of the study while still encouraging completion, the IRB requested that the PI change the "You will be paid $300 upon completion of each of the 3 study periods or a total of $900" to, "You will be paid $300 at the end of each of the 3 study periods or a total of $900."

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- Further the IRB notes that this is the first trial of the transgenic bananas being consumed by humans. The PI attended the meeting and verified that this would be the first trial of this type of banana on human subjects. Therefore, the IRB requests a statement that includes this information be included in the informed consent document.

- The PI attended the meeting and it was noted that this study will be registered at clinicaltrials.gov. As such, the IRB reminded the PI that there is specific verbiage that must be included in the informed consent document.

The IRB Co-Chair explained that this study was reviewed by the Institutional Biosafety Committee, and the committee was fine with the study as the bananas are sterile (and will not present environmental risk). However, the PI will need to have USDA permits to bring genetically modified bananas onto campus.

Level of Risk and Rationale for Determination Including Protocol Specific Information: The IRB determined that this study presents minimal risk because the FDA has deemed other genetically modified food as safe, and as such the general population is already consuming many genetically modified foods on a daily basis.

IRB Decision: A motion was made and seconded to approve the protocol with contingencies for a 1-year period. The IRB Chair(s) may grant final approval of the protocol. Full board review is still required.

Modifications Required to Secure Approval:

The IRB requested the following revisions to the informed consent document and return of the revised copy:

- The IRB requested that the PI change the "You will be paid $300 upon completion of each of the 3 study periods or a total of $900" to, "You will be paid $300 at the end of each of the 3 study periods or a total of $900."
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- The IRB requests a statement that includes that this is the first trial of transgenic bananas being consumed by humans.
- Since this study will be registered at clinicaltrials.gov, specific verbiage must be included in the informed consent document as required by the FDA. This verbiage is as follows: *A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.*
- The IRB requested that reference to the Office of Research Assurances be replaced with the Office for Responsible Research.

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