IOWA STATE UNIVERSITY
OF SCIENCE AND TECHNOLOGY

Institutional Review Board
Office for Responsible Research
Vice President for Research
1138 Pearson Hall
Ames, Iowa 50011-2207
515 294-4566
FAX 515 294-4267

Date: 2/3/2014

To: Dr. Wendy S White
1111 Human Nutritional Sciences Bldg

CC:

From: Office for Responsible Research

Title: Measuring the Retinol Activity Equivalence of Beta-Carotene-Biofortified Bananas

IRB ID: 13-376

Approval Date:	1/31/2014	**Date for Continuing Review:**	8/19/2014
Submission Type:	New	**Review Type:**	Full Committee

The project referenced above has received approval from the Institutional Review Board (IRB) at Iowa State University according to the dates shown above. Please refer to the IRB ID number shown above in all correspondence regarding this study.

To ensure compliance with federal regulations (45 CFR 46 & 21 CFR 56), please be sure to:

- **Use only the approved study materials** in your research, **including the recruitment materials and informed consent documents that have the IRB approval stamp.**
- **Retain signed informed consent documents for 3 years after the close of the study**, when documented consent is required.
- **Obtain IRB approval prior to implementing any changes** to the study by submitting a Modification Form for Non-Exempt Research or Amendment for Personnel Changes form, as necessary.
- **Immediately inform the IRB of** (1) **all serious and/or unexpected adverse experiences** involving risks to subjects or others; and (2) **any other unanticipated problems involving risks** to subjects or others.
- **Stop all research activity if IRB approval lapses**, unless continuation is necessary to prevent harm to research participants. Research activity can resume once IRB approval is reestablished.
- **Complete a new continuing review form** at least three to four weeks prior to the **date for continuing review** as noted above to provide sufficient time for the IRB to review and approve continuation of the study. We will send a courtesy reminder as this date approaches.

Please be aware that IRB approval means that you have met the requirements of federal regulations and ISU policies governing human subjects research. **Approval from other entities may also be needed.** For example, access to data from private records (e.g. student, medical, or employment records, etc.) that are protected by FERPA, HIPAA, or other confidentiality policies requires permission from the holders of those records. Similarly, for research conducted in institutions other than ISU (e.g., schools, other colleges or universities, medical facilities, companies, etc.), investigators must obtain permission from the institution(s) as required by their policies. **IRB approval in no way implies or guarantees that permission from these other entities will be granted.**

Upon completion of the project, please submit a Project Closure Form to the Office for Responsible Research, 1138 Pearson Hall, to officially close the project.

Please don't hesitate to contact us if you have questions or concerns at 515-294-4566 or IRB@iastate.edu.

IRB ID: 13-376

INSTITUTIONAL REVIEW BOARD (IRB)
Application for Approval of Research Involving Humans

RECEIVED AUG 09 2013 By IRB

Title of Project: Measuring the Retinol Activity Equivalence of Beta-Carotene-Biofortified Bananas

Principal Investigator (PI): Wendy S. White		Degrees: Ph.D., R.D.
University ID:	Phone: 4-3447	Email Address: wswhite@iastate.edu
Correspondence Address: 220 Mackay Hall		
Department: Food Science and Human Nutrition		College/Center/Institute: CHS

PI Level: ☒ Tenured, Tenure-Eligible, & NTER Faculty ☐ Adjunct/Affiliate Faculty ☐ Collaborator Faculty ☐ Emeritus Faculty
☐ Visiting Faculty/Scientist ☐ Senior Lecturer/Clinician ☐ Lecturer/Clinician, w/ Ph.D. or DVM ☐ P&S Employee, P37 & above
☐ Extension to Families/Youth Specialist ☐ Field Specialist III ☐ Postdoctoral Associate ☐ Graduate/Undergrad Student ☐ Other (specify:)

FOR STUDENT PROJECTS (*Required when the principal investigator is a student*)			
Name of Major Professor/Supervising Faculty:			
University ID:	Phone:	Email Address:	@iastate.edu
Campus Address:		Department:	
Type of Project (check all that apply): ☐ Thesis/Dissertation		☐ Class Project	☐ Other (specify:)

Alternate Contact Person:	Email Address
Correspondence Address:	Phone:

ASSURANCE

- I certify that the information provided in this application is complete and accurate and consistent with any proposal(s) submitted to external funding agencies. Misrepresentation of the research described in this or any other IRB application may constitute non-compliance with federal regulations and/or academic misconduct.
- I agree to provide proper surveillance of this project to ensure that the rights and welfare of the human subjects are protected. I will report any problems to the IRB. See Reporting Adverse Events and Unanticipated Problems for details.
- I agree that modifications to the approved project will not take place without prior review and approval by the IRB.
- I agree that the research will not take place without the receipt of permission from any cooperating institutions, when applicable.
- I agree to obtain approval from other appropriate committees as needed for this project, such as the IACUC (if the research includes animals), the IBC (if the research involves biohazards), the Radiation Safety Committee (if the research involves x-rays or other radiation producing devices or procedures), etc.
- I understand that IRB approval of this project does not grant access to any facilities, materials, or data on which this research may depend. Such access must be granted by the unit with the relevant custodial authority.
- I agree that all activities will be performed in accordance with all applicable federal, state, local, and Iowa State University policies.

WSWhite 8/9/13
Signature of Principal Investigator Date

Signature of Major Professor/Supervising Faculty Date
(*Required when the principal investigator is a student*)

- I have reviewed this application and determined that departmental requirements are met, the investigator(s) has/have adequate resources to conduct the research, and the research design is scientifically sound and has scientific merit.

Ruth MacDonald
Printed Name of Department Chair/Head/Director

Signature of Department Chair/Head/Director Date

For IRB Use Only					
		Full Committee Review:	☑	Review Date:	August 20, 2013
		EXPEDITED per 45 CFR 46.110(b): Category Letter		Approval/Determination Date:	January 31, 2014
Approval Not Required:	☐			Approval Expiration Date:	August 19, 2014
Not Research:	☐	EXEMPT per 45 CFR 46.101(b):			
No Human Subjects:	☐	Not Approved:	☐	Risk: Minimal ☑	More than Minimal ☐
IRB Reviewer's Signature		Kerry A Agnitsch		January 31, 2014	

Research Involving Humans Study Information

Please provide answers to all questions, except as specified. Incomplete forms will be returned without review.

PART A: KEY PERSONNEL

List all members and relevant qualifications of the project personnel and define their roles in the research. Key personnel include the principal investigator, co-principal investigators, supervising faculty member, and any other individuals who will have contact with the participants or the participants' data (e.g., interviewers, transcribers, coders, etc.). This information is intended to inform the committee of the training and background related to the specific procedures that each person will perform on the project. For more information, please see Human Subjects – Persons Required to Obtain IRB Training.

NAME	Interpersonal contact or communication with subjects, or access to private identifiable data?	Involved in the consent process?	Contact with human blood, specimens, or other biohazardous materials?	Other Roles in Research	Qualifications (i.e., special training, degrees, certifications, coursework, etc.)	Human Subjects Training Date
Wendy S. White, Ph.D., R.D.	☒	☒	☒	PI; Will direct human subject protocols and monitor the safety and well being of the subjects	Bloodborne Pathogens Training; directed 10 previous human metabolic studies at ISU; 10 years research experience with transgenic biofortified crops	ISU Human Subjects Training (classroom) 7/20/00
M.S.	☒	☒	☒	Graduate Research Assistant; Will supervise subject participation and process blood samples	Bloodborne Pathogens Training; successfully implemented a previous human metabolic study at ISU; one year of research experience with transgenic biofortified crops at ISU; M.S. in biochemistry and molecular biology	NIH online training in the protection of human research participants 2/27/09
M.S.	☒	☒	☒	Graduate Research Assistant; Will supervise subject participation and process blood samples	Bloodborne Pathogens Training; one year of research experience with transgenic biofortified crops at ISU; M.S. in food science	1/31/2014 Pending
	☐	☐	☐			
	☐	☐	☐			
	☐	☐	☐			

	☐	☐	☐			
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	☐	☐	☐			

Please complete additional pages of key personnel as necessary.

PART B: FUNDING INFORMATION AND CONFLICTS OF INTEREST

☒ Yes	☐ No	1.	**Is or will the project be externally funded?**
			If ***No***, skip to question 8.
			If ***Yes***, please identify the type(s) of source(s) from which the project is directly funded. ☐ Federal agency ☐ State/local government agency ☐ University or School ☐ Foundation ☒ Other Non-Profit Institution ☐ For-Profit Business ☐ Other; specify:
☒ Yes	☐ No	2.	**Is ISU considered to be the Lead or Prime awardee for this project?**
☐ Yes	☒ No	3.	**Are there or will there be any subcontracts issued to others for this project?**
☐ Yes	☒ No	4.	**Is or will this project be funded by a subcontract issued by another entity?**
☐ Yes	☒ No	5.	**If ISU is the recipient of the subcontract, does it involve any federal funding, such as federal flow-through funds?**

6. If this project will be externally funded, please provide the complete name(s) of the funding source(s); please do not use acronyms. If any subcontracts will be issued to others, please describe and include a list of all entities.

The project will be funded by HarvestPlus. HarvestPlus is a global leader in biofortification and part of the CGIAR (Consultative Group on International Agricultural Research) Research Program on Agriculture for Nutrition and Health. The HarvestPlus program is coordinated by two CGIAR research centers -- The International Food Policy Research Institute, Washington, DC and the International Center for Tropical Agriculture (CIAT), Cali, Colombia. The funds for the current research project originated from the Bill and Melinda Gates Foundation's Grand Challenges in Global Health program.

pgs 4-19 from revised app sent 1/30/2019

☒ Attached	7. **Please attach a complete and final copy of the entire grant proposal or contract from which the project is or will be funded.**
☐ Yes ☒ No	8. **Do or will any of the investigators or key personnel listed on this application have a conflict of interest management plan in place with the Office of the Vice President for Research & Economic Development?**

PART C: GENERAL OVERVIEW – PURPOSE AND EXPECTED BENEFITS

1. Research Objectives – Briefly explain in language *understandable to a layperson* the purpose and specific aim(s) of the study.

To determine the vitamin A equivalence in human subjects of the beta-carotene in a single serving of transgenic beta-carotene-biofortified bananas. The biofortified bananas have been genetically modified to produce more beta-carotene in the fruit. Vitamin A equivalence is a measurement of the extent to which the beta-carotene is available to be absorbed and converted to vitamin A in the human body.

2. Broader Impacts/Significance – Explain in language *understandable to a layperson* why this research is important and how the information gained in this study is expected to advance knowledge and/or serve the good of society.

Beta-carotene-biofortified bananas present a promising agricultural solution to the problem of widespread vitamin A deficiency in Uganda and other parts of East Africa where cooking bananas are the major dietary staple. Vitamin A deficiency is a major public health problem in Uganda and other countries in Sub-Saharan Africa and leads to decreased survival in children, impaired immune function, and blindness. To evaluate the efficacy of beta-carotene-biofortified bananas in improving vitamin A status, it will be important to evaluate the extent to which the beta-carotene is available to be absorbed in the human intestine and converted to vitamin A.

☐ Yes ☒ No	3. **Benefits to Participants** – Are there any expected direct benefits to research participants from participation in the research? **Note:** Monetary compensation is ***not*** considered to be a benefit of participation in research.
	If ***Yes***, please describe the expected benefits to participants.

PART D: PARTICIPANT SELECTION

1. How many individuals do you plan to include in the study (including those involved in screening procedures)? The

number listed here is the **maximum number** of participants that may be included in the study.

We plan to enroll subjects. To identify subjects who meet our screening criteria, we expect that we may need to screen up to subjects.

2. Inclusion Criteria – Describe the specific characteristics of persons that will be included in your study, and provide justification for these requirements.

Criteria for inclusion: general good health as determined by interview, blood biochemistry profile, and complete blood count; antecubital veins amenable to blood collection. Only women will be enrolled in the study. Women and preschool children are most vulnerable to vitamin A deficiency in developing countries. It is not feasible to collect multiple blood samples from preschool children.

Subjects must be age 18-40 years old
per 8/9/13 email from PI (VL)

3. Exclusion Criteria – Describe the characteristics of persons who will not be allowed to participate in your study, and provide justification for their exclusion.

Criteria for exclusion:

4. Do you intend, or is it likely, that your study will include any persons from the following vulnerable populations? (Check all that apply.)

- ☐ Children (any persons under age 18; including ISU/college students who may be under age 18)
  Specify age range:
- ☐ Prisoners
- ☐ Persons with impaired decision-making capacity, such as those with dementia or severe cognitive impairment, those declared incompetent, persons in life-threatening situations, etc.
- ☐ Wards of the State
- ☐ Persons who are institutionalized
- ☐ Pregnant women or fetuses
- ☐ Neonates
- ☐ Educationally disadvantaged
- ☐ Economically disadvantaged
- ☐ Students in a class taught by the researchers
- ☐ Employees or subordinates of the researchers
- ☐ Other vulnerable population, given the setting of your research; please describe:

☒ Yes ☐ No	5. **Will ISU students or other college students be asked to participate in your study?**
☐ Yes see 5.a.(2) ☒ No see 5.a.(1)	5.a. If ***Yes***, do you plan to ***include*** college students who may be under age 18?
	5.a.(1) If ***No*** *(i.e., students under 18 will be* ***excluded*** *from your study)*, please describe how you will ensure college students under 18 do not participate in the study. Recruiting announcements will specify that only women age 18 years and older will be eligible to participate. During the screening interview, study applicants will be asked to provide both their age and birthdate.
	5.a.(2) If ***Yes*** *(i.e., students under 18 will be* ***included*** *in your study)*, please be sure to describe the parental consent and minor assent processes in Appendix E.

PART E: RECRUITMENT PROCEDURES

1. How will you identify or search for potential participants? (Check all that apply.)

- ☐ Review of public records (e.g., voter lists, utilities lists, phone directory, ISU directory, etc.)
- ☐ Review of private records (e.g., medical records, student records, other private records)
- ☐ Purchased mailing lists
- ☐ Personal contacts/knowledge
- ☐ "Snowball" sampling
- ☒ Participant responses to posted advertisements (electronic or hardcopy) or flyers
- ☐ Other; please describe:

2. Please describe the details of how each of the methods checked in #1 above will be implemented.

Subjects will be recruited from the ISU campus by online advertisement via listserves and web sites. Telephone inquiries in a voice mailbox or e-mail inquiries will be collected by the Graduate Research Assistant. She will contact the interested women and will briefly describe the study protocol and the requirements for participation. An interview will then be scheduled for interested applicants who appear to qualify. Before the interview, each study applicant will be instructed to read a copy of the informed consent form approved by the ISU Institutional Review Board (IRB). The Graduate Research Assistant will then ask if the applicant has questions. After any questions have been addressed, the applicant will be asked if she would like to sign the informed consent form. Those who sign the form and remain interested in participation will be interviewed to collect relevant health, dietary, and anthropometric information using a standardized interview form.

For those applicants who appear to qualify for participation in the study, the Graduate Research Assistant will make an appointment for collection of a blood sample by a licensed medical technician

3. What methods will you use to contact potential participants? (Check all that apply.)

- ☐ Letter or email
- ☐ Phone call
- ☐ Posting flyers
- ☒ Posting announcement on website (Check all that apply.)
  - ☐ ISU Department of Psychology SONA system

☒ ISU Office of the Vice President for Research and Economic Development
☒ ISU Departmental/Research Project websites
☐ Other; please describe:

☒ Distribution of email or advertisement via Listserves or online bulletin-boards
☐ Television or radio advertisements
☐ Personal or verbal announcement, such as in a class, meeting, etc.
☐ Informal, personal communication
☐ Other; please describe:

4. Please describe the details of how each of the methods checked in #3 above will be implemented.

The website announcement and e-mail advertisement will have been previously approved by the IRB. Interested individuals will be instructed to contact the Vitamin A Study Group using a designated voice mail box or e-mail address.

☒ Yes ☐ No **5. Attached are copies of any letters, emails, phone/verbal scripts, flyers, announcements, or advertisements that will be used. Please know the IRB must review final and complete copies of all materials used to contact or recruit subjects. For verbal processes, a script or list of points to be covered during the discussion must be provided.**

If ***No***, please explain why:

PART F: SCREENING PROCEDURES

☒ Yes ☐ No **1. Will participants be asked to provide any information about themselves (e.g., medical history, personal characteristics) for screening purposes prior to enrollment in the study?**

If ***Yes***, please describe:

Subjects will be asked to provide information about medical history and personal characteristics as it relates to the inclusion and exclusion criteria for the study. The format for the screening interview will be a standardized interview form that will be verbally administered by the Graduate Research Assistant.

☒ Yes ☐ No **2. Will participants be asked to take part in any interventions (e.g., fasting, blood draws, etc.) for screening purposes prior to enrollment in the study?**

If ***Yes***, please describe:

After the initial interview, those applicants who appear to qualify for participation in the study and who signed the informed consent form will be invited to complete a blood draw for the purpose of health screening. The Graduate Research Assistant will make an appointment for collection of a blood sample by a licensed medical technician

3. If *Yes* to question 1 and/or 2, please describe how you will obtain the informed consent of participants PRIOR to their participation in screening activities.
Before the screening interview, each study applicant will be instructed to read a copy of the informed consent form approved by the ISU Institutional Review Board (IRB). The Graduate Research Assistant will then ask if the applicant has questions. After any questions have been addressed, the applicant will be asked if she would like to sign the informed consent form. Those who sign the form and remain interested in participation will be interviewed to collect relevant health, dietary, and anthropometric information using a standardized interview form. For those applicants who appear to qualify for participation in the study, the Graduate Research Assistant will make an appointment for collection of a blood sample by a licensed medical technician

PART G: COMPENSATION

☒ Yes ☐ No	**1. Will participants receive any of the following types of compensation for their participation in your research? (Check all that apply.)** ☒ Money (cash or check) ☐ Gift cards ☐ Gifts ☐ Reimbursement for expenses (i.e., costs of travel to lab, child care, meals, etc.) ☐ Course credit (including extra credit) ☐ Other; specify:
	2. If ***Yes***, please answer questions 2a through 2d. ***This information should also be provided in the informed consent document.***
	2.a. Describe the specific amount of compensation to be provided (i.e., in monetary terms, points for course credit, value of gifts, etc.).
	Subjects will be paid $300 upon completion of each of the 3 study periods or a total of $900.
	2.b. Explain how compensation will be provided if the participant withdraws prior to completion of the study. **Note**: Completion of all study procedures cannot be a requirement for research participants to receive compensation.
	Subjects will be compensated $300 for each study period in which they participate even if the subject withdraws prior to completing the study period.

2.c. If course credit is given, describe alternative ways students can earn the same amount of credit and how these alternatives are *genuinely comparable* to participation in the study in terms of time and effort.
N/A
2.d. If the study involves multiple visits, sessions, or time-points, how will compensation be prorated (e.g., how much will be provided per visit/session/time-point)?
Subjects will be paid $300 upon completion of each of the 3 study periods or a total of $900.
Note: Compensation plans must be in accordance with policies set forth by the ISU Controller's Department. Detailed information is available here.

PART H: RESEARCH PLAN

1. Research Procedures – Using *layperson's terminology*, please describe in detail your plans for collecting data from participants. Include a description of **all** *procedures, tasks, or interventions* participants will be asked to complete during the research (e.g., random assignment, any conditions or treatment groups into which participants will be divided, mail survey or interview procedures, observation protocols, sensors to be worn, amount of blood drawn, etc.). **Note: When referencing attached documents (i.e., surveys, interview protocols, copies of stimuli, instructions for tasks, etc.), please ensure that each attachment is clearly labeled and clearly referenced in this section.**

RESEARCH INVOLVING DECEPTION OR INCOMPLETE DISCLOSURE

☐ Yes ☒ No	**2. Will participants be *deceived or misled* about anything during the study?** If ***Yes***, please answer questions 2a through 2d in **Appendix A**. If ***No***, please skip to question 3.
☐ Yes ☒ No	**3. Do you plan to *intentionally withhold* information from participants, such as the full purpose of the study, a full description of procedures, etc.?** If ***Yes***, please answer questions 3a through 3d in **Appendix A**. If ***No***, please skip to question 4.

RESEARCH INVOLVING EXISTING DATA OR INFORMATION FROM RECORDS

☐ Yes ☒ No	**4. Does the research involve the collection or study of currently existing data or information to be gathered from records, such as the following? (Check all that apply.)** ☐ Student/educational records (including collection of class assignments, tests, etc.) ☐ Medical records (If checked, submit the Application for Use of Protected Health Information.) ☐ Data collected for a previously conducted study ☐ Information from government databases, such as the US Census, Iowa Dept. of Public Health records, etc. ☐ Samples from specimen/tissue banks ☐ Other; please describe: If ***Yes***, please answer questions 4a through 4g in **Appendix B**. If ***No***, please skip to question 5.

RESEARCH INVOLVING OBSERVATION

☐ Yes	☒ No	5. **Does the research involve collection of data from observation of people's behaviors or activities?** If ***Yes***, please answer 5a through 5d in **Appendix C**. If ***No***, please skip to question 6.

RESEARCH INVOLVING INTERNATIONAL RESEARCH

☐ Yes	☒ No	6. **Will the research take place in an international setting?** If ***Yes***, please answer 6a through 6c in **Appendix D**. If ***No***, please skip to question 7.

RESEARCH INVOLVING INVESTIGATIONAL DRUGS, DEVICES, DEXA/CT SCANS, X-RAYS, OR HUMAN CELLS OR TISSUES

☐ Yes	☒ No	7. **Does this project involve an investigational new drug (IND)?** Number:
☐ Yes	☒ No	8. **Does this project involve an investigational device exemption (IDE)?** Number:
☐ Yes	☒ No	9. **Does this project involve DEXA/CT scans or X-rays?**
☒ Yes	☐ No	10. **Does this project involve human blood components, body fluids, or tissues?**
☐ Yes	☒ No	11. **Does this project involve human cell or tissue cultures (primary or immortalized)?** **If you answered *Yes* to either question 10 or 11 and the cells, body fluids, etc., have not been documented to be free of blood-borne pathogens, personnel handling these substances are required to take Blood-borne Pathogens Training annually.** Bloodborne Pathogens training is on-line via the EH&S website. If you have any questions, contact EH&S at (515) 294-5359.

PART I: DATA ANALYSIS

1. Describe how the data will be analyzed (*e.g., statistical methodology, statistical evaluation, statistical measures used to evaluate results*).

PART J: CONSENT PROCESS

According to federal regulations, participants can only be included in research if they, or their legally authorized representative, provide legally-effective informed consent. In some cases, the IRB can waive this requirement.

I. Consent for Adult Participants

☒ Yes ☐ No	**A. Will you obtain the informed consent of all participants?**
If A is *Yes*, please answer the following questions:	
	1. Describe the process you will use to inform participants about the study.
	Before the screening interview, each study applicant will be instructed to read a copy of the informed consent form approved by the ISU Institutional Review Board (IRB). The Graduate Research Assistant will then ask if the applicant has questions. After any questions have been addressed, the applicant will be asked if she would like to sign the informed consent form. Those who sign the form and remain interested in participation will be interviewed to collect relevant health, dietary, and anthropometric information using a standardized interview form. For those applicants who appear to qualify for participation in the study, the Graduate Research Assistant will make an appointment for collection of a blood sample by a licensed medical technician
	2. Who, in general, will obtain informed consent from participants (i.e., explain the study, collect signed forms, etc.)? Please do not list actual names of study staff; rather, describe their role such as "the principal investigator," "research assistants," etc.
	Graduate Research Assistants
	2.a. What training have they received or will they receive regarding how to appropriately obtain informed consent?
	They will complete the required NIH online training on the protection of human research participants. The Principal Investigator will provided instructions regarding the specific IRB-approved procedures for this study.
	3. Information conveyed to participants must be in a language understandable to them.

	Please describe the measures you are taking to ensure the informed consent process is understandable (e.g., translation into another language, using commonly understood terminology, assessing reading level of the consent form, etc.).
	The informed consent form is similar to those previously approved by the IRB. The language is non-technical and metric units are also given in commonly used measures such as tablespoons or cups.
	3.a. If translation is required, please provide the name of the person(s) who conducted the translation(s) and his/her qualifications for doing so.
	N/A
	4. When will informed consent be obtained in relation to beginning data collection?
	Due to the time requirements for subject recruitment and health screening, informed consent may be obtained up to 6 weeks before the subjects begin the first study period.
☒ **Yes** ☐ **No**	**5. Will all participants sign a consent form to document the consent process? Note:** Signatures must be handwritten by the participant; typing one's name on a form does not constitute a legally valid signature according to federal regulations. If ***No***, please explain why.
☐ **Yes** ☒ **No**	**6. Do any of the researchers or key personnel involved in the study have a supervisory, evaluative, or other position of "power" over participants?** If ***Yes***, please describe the measures you are taking to minimize any coercion or undue influence (real or perceived).
☐ **Yes** ☒ **No**	**7. Are any participants likely to be unable to provide consent for themselves, such as those who have severe cognitive impairments, dementia, are in life-threatening situations, cannot communicate, etc.?** If ***Yes***, please describe plans to obtain consent from the participant's legally authorized representative.
	7.a. To the extent possible, given the condition of the participant, how will you ensure they agree to take part in the research?
	If A is *No*, (i.e., you will NOT obtain informed consent from all participants), please answer the following:
	8. Please provide strong and compelling justification for why you cannot carry out your study if you had to obtain informed consent. Note: The fact that obtaining consent would be inconvenient or time consuming is **not** considered to be sufficient justification.

N/A
9. **Please explain why participants' rights and welfare will not be adversely affected if you do not obtain their consent.**
N/A

II. Parent/Legal Guardian Consent and Child Assent (applies when participants are under age 18 or are considered to be children in the country where the research takes place)

☐ Yes ☒ No	A. **Does your study involve children?**
If **A** is ***Yes***, please complete the questions in **Appendix E**.	

PART K: RISKS/DISCOMFORTS

☒ Yes ☐ No see 1.a.-1.g.	1. **Are there any foreseeable risks or discomforts to participants from taking part in your research?**
	If ***No (i.e., there are no foreseeable risks or discomforts to participants)***, please explain why you believe this is the case:
	If ***Yes***, please answer ***Yes*** or ***No*** to items **1.a through 1.g** below. Indicate whether the following types of risks/discomforts are foreseeable. When ***Yes***, please describe the risks/discomforts and explain how each will be mitigated or minimized.
☒ Yes ☐ No	**1.a.** Physical Risks (e.g., injury, bruising from a blood draw, pain, side-effects from drugs administered, allergic reactions, etc.)
	While participating in this study subjects may experience risks pertaining to insertion of a butterfly needle or syringe needle into a peripheral forearm vein for collection of blood samples. Risks accompanying use of a needle for blood collection include infection and excessive blood loss. Infection is not expected to be a significant risk because the licensed medical technicians who will draw the blood will be experienced and trained to follow safe procedures. The risk of anemia is considered to be minimal because only of blood will be collected during each of the 3 study periods. As a safeguard, subjects will be tested for anemia as well as other blood indicators of good health before they are enrolled in the study; if found to be anemic, they will not be allowed to participate. While participating in this study subjects may experience discomfort pertaining to placement of a needle in a forearm vein. The discomforts involved are: slight pain during insertion of the butterfly needle and bruising caused by minor seepage of blood around the site of insertion. The discomfort is expected to be minor because the

	licensed medical technician who will place the needle and collect the blood samples will have extensive experience and be trained to minimize discomfort.
☒ Yes ☐ No	**1.b.** Psychological Risks (e.g., emotional discomfort from answering questions, stress or anxiety from procedures, mood alterations, viewing offensive or "shocking" materials, etc.)
	Some study applicants may have an aversion to blood donation. In the informed consent document, applicants who have a psychological aversion to blood donation will be advised that they should not participate in the study. Advertisements used to recruit subjects will specify that the study involves collection of blood samples.
☐ Yes ☒ No	**1.c.** Social Risks (e.g., harm to reputation, embarrassment, or stigmatization if participation becomes known, disruption of personal or family relationships, etc.)
☐ Yes ☒ No	**1.d.** Economic Risks (e.g., loss of money, loss of or harm to employment, etc.)
☐ Yes ☒ No	**1.e.** Legal Risks (e.g., criminal liability if information about participants' illegal behaviors is collected)
☐ Yes ☒ No	**1.f.** Informational Risks (e.g., harm if information collected about the participant were disclosed or overheard, such as embarrassment, retribution, stigmatization, disruption of personal relationships, legal liability, etc.)
☐ Yes ☐ No	**1.g.** Other Risks, given the setting of your research

PART L: PRIVACY AND CONFIDENTIALITY

1. Describe how participants' privacy will be protected during recruitment and data collection (e.g., discussions/procedures will be conducted in private locations, messages regarding the research will not be left on answering machines without permission of participant, documents or recordings will be kept secure, etc.).
To ensure confidentiality to the extent permitted by law, the following measures will be taken. Information collected as a result of the subjects' participation in the study will be shared only among the investigators involved. When personal identifiers such as their name or initials are used to record data, data sheets will be stored in a locked file cabinet and will be accessible only to the investigators. Electronic data files containing personal identifiers will be stored in a password-protected computer. Identifier codes will be removed from data sheets within a 5-year period after publication of the results of the research project. .
2. Please answer the following questions to describe the methods you will employ to maintain confidentiality and security of the data at all points in the research process (e.g., during data collection, during analysis, etc.):
2.a. Who will have access to the data and study records?
The Principal Investigator and the Graduate Research Assistants
2.b. Describe how/where physical copies (i.e., paper files, samples, etc.) of data and study records will be stored (e.g., in cabinets, desks, shelves, etc.).
Physical copies will be stored in a locked cabinet that is accessible only to the investigators.
2.c. Describe security measures in place to maintain security of physical/paper data, samples, or study records (e.g., how access will be controlled, locks, etc.).
The cabinet will be locked and only the investigators will have the capability to unlock the cabinet.
2.d. Describe how/where electronic data will be stored (e.g., a desktop computer,

	laptop, portable drive, shared drive, etc.).
	Electronic data will be stored only in a password-protected computer.
	2.e. Describe the measures in place to maintain security of electronic data (e.g., encryption, password-protection, firewalls, using university controlled systems, etc.).
	Electronic data will be stored only in a password-protected computer.
☐ Yes ☒ No	**2.f.** Will your data include any audio recordings and/or video recordings of participants? If ***Yes***, please answer the following:
	2.f.(a) Who will have access to the audio and/or video recordings?
	2.f.(b) Describe how/where the audio and/or video recordings will be stored (e.g., in a cabinet, on a computer, etc.).
	2.f.(c) Describe the measures in place to maintain security and confidentiality of the audio and/or video recordings (e.g., how access will be controlled, locks, password protection, firewalls, etc.).
☐ Yes ☐ No	**2.f.(d)** Will the actual recordings or images of participants from recordings be shared in any dissemination (e.g., manuscripts, reports, presentations, etc.) of the study results? If ***Yes***, what measures will you take to disguise their identity (i.e., blurring facial images, voice alteration methods, etc.)?
☒ Yes ☐ No	**2.g.** Will any identifiers or identifiable information (e.g., names, social security numbers, addresses, phone numbers, exact dates of birth, etc.) be collected with or linked to the study data at any time? If ***Yes***, please answer the following:
	2.g.(a) Describe the identifiers that will be collected or linked to the study data.
	The subjects names, addresses, and dates of birth will be collected during the initial interview. Subsequent data sheets will not contain personal identifiers.
	2.g.(b) Why is it necessary to collect identifiers or link identifiers to the study data?
	We need to have a record of the subjects names so that we may communicate with them and process their compensation. We need to record the subjects birthdates to ensure that they meet the inclusion criteria and to describe the age range of the subjects in the subject characteristics section of the published manuscript.

	2.g.(c) When will identifiers be separated or removed from the data?
	Within a 5-year period after the study results are published.
	2.g.(d) Please describe any coding systems you will use to maintain confidentiality of identifiable data (e.g., plans to replace names with ID codes or pseudonyms).
	Once a subject is enrolled, she will be assigned an ID code. She will wear a label with the ID code when she participates in the study protocol. Her data will be recorded using the ID code. Thus it will not be necessary to identify her by name.
☒ **Yes** ☐ **No**	**2.g.(e)** Will you create a "key" linking identifiers with any ID codes or pseudonyms?
	If ***Yes***, how will you maintain control of the key and ensure the key is kept secure? **Note:** Best practice is to store the key in a separate location from the study data. The key will be stored in a separate file in a password-protected computer.
	When will the key be destroyed? Within a 5-year period after the study results are published.
☐ **Yes** ☒ **No**	**2.h.** Have you or will you obtain a Federal Certificate of Confidentiality for this study? If ***Yes***, please submit a copy of the certificate materials with this application. **Note:** Certificates of Confidentiality are designed to protect identifiable research records against forced disclosure (e.g., subpoena). Certificates can be sought from the National Institutes of Health in certain circumstances. Visit the **Certificates of Confidentiality Kiosk for more information.**
☐ **Yes** ☒ **No**	**2.i.** Will the data be shared or submitted to a repository or registry, such as the Clinical Trial Registry Databank (ClinicalTrials.gov), the Database of Genotypes or Phenotypes, or via other data sharing agreements? If ***Yes***, please describe.
3. What specific steps will you take to ensure participants are not identifiable (directly or indirectly via "deductive disclosure") when research results are reported?	
data for the subjects will be provided only in aggregate (mean and standard deviation). The remaining data will be derived from laboratory analyses and thus could not be deductively disclosed.	
☒ **Yes**	**4.** Please check here to confirm that you will retain research records (i.e., signed consent forms, approved IRB applications, etc.) for at least 3 years after the study is complete. Doing so is required by federal regulations.

PART M: REGISTRY PROJECTS

☐ Yes ☒ No	**1. Does this project establish a registry or databank?** **Note:** To be considered a registry or databank: (1) the individuals whose data are in the registry/databank might be contacted in the future; and/or (2) the names and/or data pertaining to the individuals in the registry/databank might be used by investigators other than the one maintaining the registry/databank.
	If ***Yes***, please answer the following questions:
	1.a. What information/data will be included in the registry?
	1.b. What is the reason for establishing a registry (i.e., how will data from the registry be used)?
	1.c. Who will be involved in establishing and providing oversight of the registry?
☐ Yes ☐ No	**1.d.** Will the data in the registry be available to anyone other than the investigator(s) who maintain the registry?

ISU IRB # 1	13-376
Approved Date:	31 January 2014
Expiration Date:	19 August 2014

Human Subjects Needed

Introduction

Cooked bananas are a major component of diets in Uganda and other parts of East Africa. To alleviate widespread vitamin A deficiency in East Africa, scientists at Queensland University of Technology, Brisbane, Australia developed transgenic bananas which have been genetically modified to produce more beta-carotene in the fruit. Beta-carotene is converted in the body to vitamin A.

Purpose of the study:

To measure the vitamin A value of the beta-carotene in transgenic bananas which have been genetically modified to contain more beta-carotene.

Subject requirements

- Female, healthy, nonsmokers, 18-40 years
- Willing to eat a diet provided by the investigators for 4 days during each of 3 study periods
- Willing to donate blood samples
- Available during selected weeks (months to be specified)
- Participation is voluntary; subject information will be confidential.

Compensation

- Participants will receive up to $900 in compensation.

Contact: Vitamin A Study Group, Dept of Food Science and Human Nutrition, Phone: 296-3746

ISU IRB # 1	13-376
Approved Date:	31 January 2014
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INFORMED CONSENT DOCUMENT

Title of Study: "Measuring the Retinol Activity Equivalence of Beta-Carotene-Biofortified Bananas"

Investigators: Wendy S. White, Ph.D., R.D., M.S., M.S.

This is a research study. Please take your time in deciding if you would like to participate. Please feel free to ask questions at any time.

INTRODUCTION

Cooked bananas are a major component of diets in Uganda and other parts of East Africa. To alleviate widespread vitamin A deficiency in East Africa, the Bill and Melinda Gates Foundation funded scientists at Queensland University of Technology, Brisbane, Australia to develop transgenic beta-carotene-biofortified bananas. These bananas are genetically modified to produce more beta-carotene. *The purpose of the current research is to determine the vitamin A value of the beta-carotene in these transgenic beta-carotene-biofortified bananas.*

Beta-carotene is a yellow-orange pigment that occurs naturally in many fruits and vegetables. Beta-carotene is converted to vitamin A in the body. Low amounts of beta-carotene are naturally present in conventional bananas; however, these amounts are too low to improve vitamin A nutrition.

This will help scientists to evaluate the value of the transgenic beta-carotene-biofortified bananas in combating vitamin A deficiency. You are being invited to participate in this study because you are a resident of Ames or the surrounding communities from which we are recruiting our study population.

DESCRIPTION OF PROCEDURES

To determine if you are eligible to participate in the study, a trained interviewer will collect relevant health and medical history information using a standardized questionnaire. If you remain eligible to participate, the interviewer will make an appointment for you to donate a small blood sample to be used for additional health screening.

If you are eligible and agree to participate in the study, your participation will involve 3 study periods

During each of 3 study periods, you will be asked to complete the following protocol:

RISKS

While participating in this study you may experience risks pertaining to insertion of a butterfly needle or syringe needle into a peripheral forearm vein for collection of blood samples. Risks accompanying the use of a needle for blood collection include infection and excessive blood loss. Infection is not expected to be a significant risk because the licensed medical technicians who will draw the blood are experienced and trained to follow safe procedures. The risk of anemia is considered to be minimal because only of blood will be collected during each of the 3 study periods. As a safeguard, you will be tested for anemia as well as other blood indicators of good health before you are enrolled in the study; if found to be anemic, you will not be allowed to participate.

While participating in this study you may experience discomfort pertaining to the placement of a needle in a forearm vein. The discomforts involved are: slight pain during insertion of the butterfly needle and bruising caused by minor seepage of blood around the site of insertion. The discomfort is expected to be minor because the licensed medical technician who will place the needle and collect the blood samples will have extensive experience and be trained to minimize discomfort. If you have a psychological aversion to blood donation, you should not participate in the study.

Note:
The current study will be the first time that these transgenic bananas will be consumed by human subjects.

The FDA agreed with the biotechnology companies that the evidence indicated that the foods derived from these genetically-modified plants were as safe as the foods derived from conventional varieties.

Note:

The current study will be the first time that bananas containing the will be consumed by human subjects.

The transgenic bananas will contain more beta-carotene and related yellow-orange carotenoids when compared with conventional bananas. The maximum total amount of beta-carotene and other carotenoids in the single transgenic banana portion that you will consume will be about There is no known risk due to consuming this amount of beta-carotene and related carotenoids.

You will consume the bananas with a small amount of peanut butter. If you are allergic to nuts or have other food allergies, you should not participate in the study.

BENEFITS

If you decide to participate in this study there will be no direct benefit to you. It is hoped the information gained in this study will benefit society by developing a sustainable, cost-effective, agricultural solution to the problem of vitamin A deficiency; a solution that will be accessible to the rural poor in developing countries.

COSTS AND COMPENSATION

You will not have any costs from participating in this study. You will be compensated for participating in this study. You will be paid $300 at the end of each of the 3 study periods or a total of $900.

To meet governmental reporting requirements for the $300 payments, you will need to complete a University form that requires that you provide your social security number. The form will be kept in a locked cabinet until it is delivered to the Iowa State University Controller's Office where precautions are in place to keep the information secure. You may forego receipt of payment(s) and continue in the research study if you do not wish to provide your social security number and address. Information regarding documentation required for participant compensation may be obtained from the Controller's Department, 294-2555 or http://www.controller.iastate.edu.

Please know that payments may be subject to tax withholding requirements, which vary depending upon whether you are a legal resident of the U.S. or another country. If required, taxes will be withheld from the payments you will receive.

PARTICIPANT RIGHTS

Your participation in this study is completely voluntary and you may refuse to participate or may leave the study at any time. If you decide to not participate in the study or leave the study early, it will not result in any penalty or loss of benefits to which you are otherwise

entitled. If you are found to have forearm veins that are not suitable for blood collection, if you develop a medical or other condition that would preclude your safe or appropriate participation, or if you are noncompliant with required study procedures, your participation may be terminated.

RESEARCH INJURY

Emergency treatment for any injuries that may occur as a direct result of participation in this research is available at the Iowa State University Thomas B. Thielen Student Health Center, and/or referred to Mary Greeley Medical Center or another physician or medical facility at the location of the research activity. Compensation for any injuries will be paid if it is determined under the Iowa Tort Claims Act, Chapter 669 Iowa Code. Claims for compensation should be submitted on approved forms to the State Appeals Board and are available from the Iowa State University Office of Risk Management and Insurance.

CONFIDENTIALITY

Records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations and will not be made publicly available. However, federal government regulatory agencies, the Food and Drug Administration, HarvestPlus (the research sponsor) and the Institutional Review Board (a committee that reviews and approves human subject research studies) may inspect and/or copy your records for quality assurance and data analysis. These records may contain private information.

To ensure confidentiality to the extent permitted by law, the following measures will be taken. Information collected as a result of your participation in the study will be shared only among the investigators involved. When personal identifiers such as your name or initials are used to record data, data sheets will be stored in a locked cabinet and will be accessible only to the investigators. Electronic data files containing personal identifiers will be stored in a password-protected computer. Identifier codes will be removed from data sheets within a 5-year period after publication of the results of the research project. When the results of the study are published, your identity will remain confidential.

CLINICAL TRIAL REGISTRATION

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.

QUESTIONS OR PROBLEMS

You are encouraged to ask questions at any time during this study. For further information about the study contact Wendy S. White, Ph.D., Department of Food Science and Human Nutrition, 1111 Human Nutritional Sciences Building, (515) 294-3447.

If you have any questions about the rights of research subjects or research-related injury, please contact the IRB Administrator, (515) 294-4566; IRB@iastate.edu, or Director, Office of Responsible Research, (515) 294-3115; 1138 Pearson Hall, Ames, IA 50011.

SUBJECT SIGNATURE

Your signature indicates that you voluntarily agree to participate in this study, that the study has been explained to you, that you have been given the time to read the document and that your questions have been satisfactorily answered. You will receive a copy of the signed and dated written informed consent prior to your participation in the study.

Subject's Name (printed) _____

_____ _____

(Subject's Signature) (Date)

INVESTIGATOR STATEMENT

I certify that the participant has been given adequate time to read and learn about the study and all of their questions have been answered. It is my opinion that the participant understands the purpose, risks, benefits and the procedures that will be followed in this study and has voluntarily agreed to participate.

_____ _____

(Signature of Person Obtaining Informed Consent) (Date)

Measuring the Retinol Activity Equivalence of Beta-Carotene-Biofortified Bananas

Subject Interview Form

Please respond to the following questions as accurately as possible. The information obtained will be used by the investigators to ensure the safe and appropriate participation of subjects.

You may skip any question that you do not wish to answer or that makes you feel uncomfortable. However, failure to answer a question may exclude you from participation in the study. Information obtained will remain confidential and available only to the investigators.

Date of Interview _____
Interviewer _____

Personal data

Dietary data

Health data

Miscellaneous

Anthropometric data

****

I attest that all of the above information is accurate to the best of my knowledge.

Signature _____ Date _____