Official Approval Letter for IRB project #14525

December 23, 2014

Devin Rose
Department of Food Science and Technology
252 FYH, UNL, 68583-0919

Sandrayee Brahma
Department of Food Science and Technology
3405 HOLDREGE STREET LINCOLN, NE 68503

IRB Number: 20141214525FB
Project ID: 14525
Project Title: Promoting gastrointestinal health and reducing subclinical inflammation in obese individuals though intake of whole wheat products in comparison with fruits and vegetables

Dear Devin:

This letter is to officially notify you of the approval of your project by the Institutional Review Board (IRB) for the Protection of Human Subjects. It is the Board's opinion that you have provided adequate safeguards for the rights and welfare of the participants in this study based on the information provided. Your proposal is in compliance with this institution's Federal Wide Assurance 00002258 and the DHHS Regulations for the Protection of Human Subjects (45 CFR 46).

Date of Full Board review: 11/17/2014

Risk Classification: Not greater than Minimal Risk; Expedited review procedures under category 9.

You are authorized to implement this study as of the Date of Final Approval: 12/23/2014. This approval is Valid Until: 11/16/2015.

We wish to remind you that the principal investigator is responsible for reporting to this Board any of the following events within 48 hours of the event:
* Any serious event (including on-site and off-site adverse events, injuries, side effects, deaths, or other problems) which in the opinion of the local investigator was unanticipated, involved risk to subjects or others, and was possibly related to the research procedures;
* Any serious accidental or unintentional change to the IRB-approved protocol that involves risk or has the potential to recur;
* Any publication in the literature, safety monitoring report, interim result or other finding that indicates an unexpected change to the risk/benefit ratio of the research;
* Any breach in confidentiality or compromise in data privacy related to the subject or others; or
* Any complaint of a subject that indicates an unanticipated risk or that cannot be resolved by the research staff.

For projects which continue beyond one year from the starting date, the IRB will request continuing review and update of the research project. Your study will be due for continuing review as indicated above. The investigator must also advise the Board when this study is finished or discontinued by completing the enclosed Protocol Final Report form and returning it to the Institutional Review Board.

If you have any questions, please contact the IRB office at 472-6965.

Sincerely,

Julia Torquati, Ph.D.
Chair for the IRB

NUgrant

University of Nebraska-Lincoln
Institutional Review Board (IRB)
402-472-6965
irb@unl.edu

FOR OFFICE USE ONLY
IRB #: 20141214525FB
IRB Decision Date: 12/23/2014
Date Received: 09/10/2014
NUgrant Project ID: 14525
Form ID: 22327
Status: Approved by the IRB

Basic Project Information

*** 1. Project Title:**
If this is a funded project, please use the same title as that on the funding application. This will allow for easier communication with the Sponsored Programs Office.

Promoting gastrointestinal health and reducing subclinical inflammation in obese individuals though intake of whole wheat products in comparison with fruits and vegetables - (CT.gov registered - SF)

*** 2. Principal Investigator's Status:**

Faculty

*** Principal Investigator is:**

Devin Rose - drose3@unl.edu - 4024722802

*** Principal Investigator's Department**

Department of Food Science and Technology

3. Secondary Investigator is:

Sandrayee Brahma - sbrahma2@unl.edu -

Secondary Investigator's Department

Department of Food Science and Technology

Type of Project

*** 4. Project Type:**

Research

*** 5. Does the research involve an outside institution/agency other than UNL?**

No

Note:
Research can only begin at each institution after the IRB receives the institutional approval letter.

*** 6. Where will participation take place (e.g., UNL, at home, in a community building, schools, hospitals, clinics, prisons, unions, etc)? Please specify and give location if not already listed above.**

UNL

*** 7. Briefly describe the facilities available for the research (e.g., there will be a quiet room in the school to conduct interviews, a secure lab space is available, etc).**

Subject screening interviews will take place in a private room on campus. During the intervention, subjects will pick up treatment foods in a classroom on campus. Stool collection will take place at the subjects' homes. Blood collection will take place at the student health center on campus.

Project Information

*** 8. Present/Proposed Funding Source:**

Agricultural Research Division

*** 9. Project Start Date:**

(Start date is dependant upon IRB approval)

01/01/2015

*** 10. Project End Date:**

08/31/2017

Description of Multi-Institutional Study Coordination

*** 11. Is this a Multi-Institutional Study?**

No

Project Information (Continued)

*** 1. Does the research involve prisoners?**

No

*** 2. Will the research only be conducted in schools or educational settings?**

No

*** 3. Does the research involve only the use of educational tests, survey procedures, interview procedures, or observation of public behavior?**

No

*** 4. Does the research involve only the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens?**

No

*** 5. Does the research involve only studying, evaluating or examining public benefit or service programs?**

No

*** 6. Does the research involve only a taste and food quality evaluation or food consumer acceptance study?**

No

*** * 7. Does the research present more than minimal risk to human subjects?**

No

For each category, please mark if it is a part of the project:

- ☐ **Clinical studies of drugs and/or medical devices.**
- ☒ **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.**
- ☒ **Prospective collection of biological specimens for research purposes by noninvasive means.**
- ☒ **Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.**
- ☐ **Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).**
- ☐ **Collection of data from voice, video, digital, or image recordings made for research purposes.**
- ☐ **Research on individual or group characteristics or behavior (including but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior).**
- ☐ **Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.**

*** 7.a. Does the research involve only procedures included in the previous 8 categories?**

No

*** 7.b. Could identification of subjects put them at risk of criminal or civil liability, or be socially or economically damaging?**

No

Description of Participants

* 1. In the chart below, please indicate the estimated number of participants per category.

	Male	Female	Unspecified	Totals
Adults			100	
Children				
Totals				

* 2. Please indicate what special groups will be utilized/recruited for your study. Check all that apply.

- ☒ **Adults, Non Students**
- ☐ **Language Impaired**

☒	**UNL Students**	☐	**Persons with HIV/AIDS**
☐	**Children (under age 19)**	☐	**Prisoners**
☐	**Decisionally Impaired**	☐	**Persons with Psychological Impairment**
☐	**Institutionalized Persons**	☐	**Persons with Mental Retardation**
☐	**Students**	☐	**Adults w/ Legal Representatives**
☐	**Pregnant Women/Fetuses/Neonates**	☐	**Handicapped**
☐	**Persons with Neurological Impairment**	☐	**Employees**
☐	**Persons with Limited Civil Freedom**	☐	**Other**

Inclusion Criteria

*** 3. Will participants of both sexes/genders be recruited?**

Yes

*** 4. Will participation be limited to certain racial or ethnic groups?**

No

*** 5. Describe the participant population to be included in this research and how they are selected, including any special characteristics targeted for inclusion.**

120 obese men and women (body mass index, BMI, 30 kg/m2) who are free of known gastrointestinal disease, do not take supplements, participate in less than 1 h of exercise per week, have not taken antibiotics in the last six months, have a low typical intake of fruits, vegetables, and whole grains, are willing to adhere to intervention instructions (either consume 5 servings of fruits and vegetables per day or 3 servings of whole grain foods per day will), are willing to provide 2 stool samples and 2 blood samples to study personnel, and willing to complete 2 diet history questionnaires online, will be recruited from the University of Nebraska-Lincoln and the surrounding community using paper and online advertisements.

*** 6. Describe your access to the population that will allow recruitment of the necessary number of participants.**

Fliers will be placed in the unions on city and east campus and at the dairy store. These establishments are frequented by many people throughout the day. Online advertisements will also be posted to the Food Science Facebook page and departmental website.

*** 7. The research plan should have adequate provisions to protect the privacy interests of participants. Explain provisions to protect privacy interests of participants. This refers to how investigators will access private information from or about participants during and after their involvement in the research (e.g., time, place, etc of research procedures).**

Data will be stored on two computers belonging to the principal investigator and the graduate student on the project. These computers are kept in locked offices when not in use and have single users. Only 1 file will contain subjects' names and contact information. All other documents will contain only coded names of subjects. If files need to be shared among collaborating investigators, only the files containing coded names will be used.

*** 8. Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions.**

Potential participants will meet with study personnel. Study personnel will inform subjects of all procedures and requirements. Subjects will provide written informed consent to participate.

Exclusion Criteria

*** 9. If not already described above, will any groups or categories of participants be excluded from this research?**

No

*** 10. Will some or all subjects likely be vulnerable to coercion or undue influence?**

No

Unique Research Methodology or Data Sources

*** 1. Will your project involve audio taping?**

No

*** 2. Is this project web-based research?**

Yes

*** 2.a. For web-based studies, how will the data be handled? Will the data be sent to a secure server? Will the data be encrypted while in transit? Will you be collecting IP addresses?**

Potential subjects will complete a diet history questionnaire online. Each subject will receive the log in web address (https://riskfactor.cancer.gov/dhq2.html) and a unique ID and password. Subjects' ID will be their 3-digit code number used for identification purposes. Subject responses will be collected using a unique web address for the research personnel only. This web address will only be available to the research personnel listed on this IRB form. This web address requires a username and password log in. The site is hosted by the National Cancer Institute. No IP addresses will be collected.

*** 3. Is this study utilizing Protected Health Information (PHI; e.g., information obtained from a hospital, clinic, or treatment facility)?**

No

*** 4. Does this project involve genetic data, sampling, or analysis?**

No

*** 5. Does this project ask questions about illegal drug use or criminal activity that places the participant at risk for legal action?**

No

*** 6. Does this project involve photography?**

No

*** 7. Does this project involve videotaping?**

No

*** 8. Does this project involve archival or secondary data analysis?**

No

*** 9. Does this project involve biological samples?**

Yes

*** 9.a. Where are you getting your samples from? What are the samples?**

All subjects will provide blood and stool samples 2 times during the study.

Blood will be collected using standard venipuncture techniques by a licensed technician at the University Health Center room 205. Blood samples will be centrifuged and the plasma will be aliquoted into multiple tubes, labeled with the subjects' 3-digit ID code and the date of collection (no name) and then snap frozen in liquid nitrogen. Plasma will be

transported back to the lab (252 FIC) on dry ice. Once samples are received in the lab, they will be stored in freezer boxes at -80 C until analysis.

Stools will be collected using a stool collection pan that fits on the toilet seat in the privacy of the subjects' homes or in the restroom at the University Health Center. Stool samples will be transferred to a specimen bag, labeled with the subjects' 3-digit ID code and the date of collection (no name) and then snap frozen in liquid nitrogen. The samples will then be handled as described for blood.

*** 10. Does this project ask participants to perform physical tasks?**

No

Research Purpose of Project

*** 1. What is the significance/purpose of the study? (Please provide a brief 1-2 paragraph explanation in lay terms, to include a brief literature justification.)**

This project will provide new evidence in support of whole wheat in the diet for prevention of inflammation and reduction of risk factors of many of the very diseases that have been implicated in wheat-based diets. This project could lead to improved understanding of how whole wheat mediates an anti-inflammatory effect, allowing health professionals to offer better suggestions to individuals on how to make the most positive impact on health through diet. Due to the rising problems associated with consumer health, this project has the potential to have a positive impact on the well-being of many individuals.

We will focus on wheat in this project for several reasons. First, this is a requirement of the funding agency. Second, our previous research suggests that the indigestible components of wheat are particularly important in butyrate, and anti-inflammatory microbial metabolite, that we hypothesize plays a role in the health benefits of whole grain diets.. Third, wheat is an important commodity in Nebraska. Research supporting wheat consumption would be beneficial for Nebraska wheat producers.

Methods and Procedures

*** 2. Describe the data collection procedures and what participants will have to do.**

During recruitment, potential subjects will complete a diet history questionnaire online as part of the screening process. This questionnaire takes about 1 h and can be filled out at any time on any computer that is connected to the internet. Subjects will also be screened in a phone or personal interview. During this interview, subjects will be inquired as to whether they meet all of the inclusion criteria or not. This includes:
-Have no known gastrointestinal diseases
-If a student, you will not graduate before Aug 2015
-Be 19 years of age or older
-Have not taken antibiotics within the last 6 months
-Participate in less than 1 hour of structured exercise per week
-Have a low typical intake of fruits, vegetables, and whole grains (this will be assessed by the diet history questionnaire and should be <1 serving/d for each food group)
Have no known allergies to fruits, vegetables, or grains
Have a body mass index above 30
Be willing to adhere to intervention instructions (either consume 5 servings of fruits and vegetables per day or 3 servings of whole grain foods per day)
Be willing to provide 2 stool samples and 2 blood samples to study personnel
Be willing to complete 2 diet history questionnaires online
Be willing to fill out a gastrointestinal symptom questionnaire weekly during the study
Be willing to keep track of consumption of test foods on a daily basis

Enrolled subjects will be required to visit the study facility 6 times (weeks -1, 0, 1, 2, 3, and 4). At the study facility visit subjects will collect and turn in diet records and GI symptom questionnaires and order and pick up food items. At weeks -1 and 3, subjects will also receive stool collection kits to turn in at the clinical facility visits (described in the next paragraph). Each study visit will take about 20 min. During this 20 min, subjects will turn in diet records and GI symptom questionnaires. They will also pick up food items ordered the previous week and order food items for the next week. They will also have a chance to speak with the study personnel about any concerns. On visits -1 and 3, subjects will also receive stool collections kits with instructions on how to use them.

Subjects will be required to visit the clinical facility 2 times (weeks 0 and 4). At the clinical facility visit, subjects will be fasted (12 h fast) and a blood sample will be taken by a licensed phlebotomist using standard venipuncture techniques. Weight and height will be recorded. Subjects will give their stool sample to the study personnel either already collected or collected at the facility. If the subjects is unable to defecate at either of these times, they will be instructed to contact the study personnel as soon as possible after the visit to have the stool sample picked up.

The food diary requires writing down all of the fruits, vegetables, and whole grain products consumed everyday. There is a form supplied to help with this. For fruits and vegetables, subjects should write down the form (whole, peeled, juice, cooked, raw, etc.) that they were consumed in addition to the amount. For whole grains, subjects should write down the type of food and brand as well as the amount consumed.

*** 3. How long will these procedures take the participants to complete? Please describe the duration of the session, the number of sessions, over what period of time, etc.**

The blood and stool collection will take 20-30 min each session. The diet history record takes about 1 hour to complete. Each subject will complete these sessions at the beginning and the end of the study. During the study, subjects will be required to incorporate 3 servings of whole grain per day; 5 servings of fruits and vegetables per day; or noting (control) into their normal diets. This will take minimal extra time.

Total estimated time for participation in this study is 6 hours over the course of 5 weeks (six 20 minute study facility visits; two 30 minute clinical facility visits; two 60 minute diet history questionnaires; 60 minutes cumulative time filling out dietary records and GI symptom questionnaires).

*** 4. Will there be any follow-up or will reminders be sent?**

Yes

*** 4.a. Please explain.**

Email and phone calls will be used to update patients.

*** 5. Differentiate any procedure being done solely for research purposes from procedures being done anyway.**

Not applicable.

*** 6. Describe the time you have available to conduct and complete the research (ex. the time from initiation of the research to completion of data analysis).**

Sufficient time will be allotted to complete this project. If sufficient subjects are not initially available, we will use a rolling enrollment to obtain the number of subjects required.

Recruiting Procedures

*** 1. How will the names and contact information for participants be obtained?**

Personal interview, email, or phone conversation.

*** 2. How will participants be approached about participating in the study?**

Paper and online advertisements.

Benefits and Risks

*** 3. Explain the benefits to participants or to others.**

The study is designed to have participants meet the recommended intakes of fruits and vegetables and whole grains during the intervention periods. Any benefits arising from meeting the USDAs recommended servings of these foods may be realized in this study.

You will also receive a copy of your dietary analysis along with the findings from the blood tests at the end of the study. This will show intake of nutrients and food groups. You can also request the findings from your blood tests, which include fasting blood glucose, cholesterol, LDL cholesterol (bad cholesterol), HDL cholesterol (good cholesterol), triglycerides, and the inflammatory markers IL-6, C-reactive protein, and lipopolysaccharide binding protein. These results of the tests and analysis should be interpreted by your primary care physician.

Benefits to others include new evidence in support of whole wheat in the diet for prevention of inflammation and reduction of risk factors of many of the very diseases that have been implicated in wheat-based diets. This project could lead to improved understanding of how whole wheat mediates an anti-inflammatory effect, allowing health professionals to offer better suggestions to individuals on how to make the most positive impact on health through diet. Due to the rising problems associated with consumer health, this project has the potential to have a positive impact on the well-being of many individuals.

*** 4. Explain the risks to participants. What will be done to minimize the risks? If there are no known risks, this should be stated.**

Participants may experience gastrointestinal discomfort from consuming fruits and vegetables or whole grains if they are not used to consuming these products normally. This will be monitored through gastrointestinal symptom diaries that will be filled out by participants. Typically, the discomfort subsides within days. If discomfort persists for longer than this the individual will be invited to withdraw, but given the option to remain in the study.

Participants may also experience some discomfort during blood draw. Additional risks during blood draw include bruising, infection, and dizziness. Standard procedures will be used to minimize discomfort. Participants will be well-informed that this will be required for inclusion in the study.

Participants may experience some embarrassment when providing a stool sample. Stools will be collected privately by the participant using a stool collection kit that fits on the toilet seat. This kit contains a removable opaque container with a lid, so the specimen can be transported discretely.

If the participants are concerned about any physical distress they are experiencing during the study, they will be referred to their medical provider.

*** 5. Describe the availability of medical or psychological resources that participants might require as a consequence of the research.**

None.

Compensation

*** 6. Will compensation (including money, gift certificates, extra credit, etc.) be provided to participants?**

Yes

*** 6.a. Please describe the amount and type of compensation.**

During screening, subjects will complete a diet history questionnaire. They will receive $5 for completing this questionnaire. Of the subjects enrolled in the study, if a participant begins the study but withdraws, they will receive $20. Upon completion of the study, subjects will receive $75. When subjects receive payment of $75, a research participant disclosure form with social security number will be collected. If compensation is $5 or $20 no social security number will be collected. Receipts from compensation will be kept in a locked drawer during the study and then returned to the bursar's office for storage for 7 years as required by law.

Subjects will not be required to purchase test foods. These will be provided by the study personnel. Other foods consumed during the study period will be purchase by the subjects.

Informed Consent Process

*** 1. How will informed consent/assent be obtained?**

Paper signature following a personal meeting/interview with study personnel.

*** 2. Who will conduct the consent interview?**

Study personnel

*** 3. Who will provide consent or permission?**

The subject.

*** 4. What is the waiting period, if any, between informing the prospective participant and obtaining consent?**

There is no waiting period.

*** 5. What steps will be taken to minimize the possibility of coercion or undue influence?**

If participants are given a oral invitation to participate, this will only be done once.

*** 6. What is the spoken language used by those obtaining consent?**

English

*** 7. What is the language understood by the prospective participant or the legally authorized representative?**

English

*** 8. Will any subjects be decisionally impaired so that they may not have the capacity to give consent?**

No

*** 9. In certain cases for children over the age of 14, such as UNL students who are 17 or 18, waivers of informed consent can be granted. Would you like to request a waiver of consent?**

No

Confidentiality

*** 1. The research plan should make adequate provisions to maintain the confidentiality of the data. How will confidentiality of records be maintained?**

Subjects will receive a 3 digit code number at the beginning of the study and will be identified by this number throughout the study. This code will be used to identify sample both in the online data (diet history questionnaire) and the biological sample data. Only 1 file will contain the names and contact information of individuals with corresponding code number. This will be maintained by one of the study personnel on a computer that is property of the University and has a single user. The computer log-in as well as the file containing names will be password protected.

*** 2. Will individuals be identified during data collection or in the results?**

Yes

*** 2.a. Will the participants be identifiable during data collection? How long will individuals be identifiable? At what point will the identities be removed (if ever)?**

Participants will only be identifiable in one key file containing personal information for contact purposes. This file will be password protected and kept on a computer with a single user that is also password protected. All other files will only contain the participant's ID number. Once data collection and verification is complete, the file with names and personal information will be destroyed.

*** 2.b. If the data is coded, will there be a list linking names and codes? If so, how long will this list be kept and where?**

The file linking names with codes will be kept on a private computer maintained by one of the study personnel for a period of 5 years.

*** 3. How long will records be kept?**

5 years.

*** 4. Where will records be stored?**

In locked offices on private computers.

*** 5. Who has access to the records/data?**

The project director and the graduate student on the project. Collaborators will only have access to coded data (not containing names or contact information.

*** 6. How will data be reported (e.g., in a dissertation or thesis, in scientific journals, at conferences, etc)?**

Dissertation, conferences, and in scientific journals. Data will be reported in a summarized format (not individually).

Data Monitoring

*** 7. Does this research involve more than minimal risk to participants?**

No

Questionnaires, Surveys, and Testing Instruments

*** Please list all questionnaires, surveys, and/or assessment instruments/measures used in the project.**

Diet history questionnaire (online; a demo can be found here: http://appliedresearch.cancer.gov/dhq2/webquest/demos.html)

Uploaded Attachments

Please submit copies of the following:

- **Funding application**
- **Institutional Approval letters**
- **Recruitment flyers, ads, phone scripts, emails, etc.**
- **Informed Consent Forms, emails, and/or letters**
- **If transcriptions are required, Confidentiality Agreement that transcriptionists will sign**
- **If this is a study utilizing PHI, Release of Authorization that will be used to obtain permission from the participant for the agency/institution to release protected health information for project purposes or a letter from the agency/institution documenting agreement to provide protected health information for project purposes**
- **All Instruments/Measures used in the project**

Please upload all documents that would include the IRB approval stamp as a PDF. These documents could include recruitment materials AND informed consent/assent forms.

☒Wheat proposal v4.pdf
☒Approval letter.pdf
☒Instructions for completing diet history questionnaire.pdf
☒Project amendment and approval.pdf
☒dhq2_pastmonth.pdf
☒Food diary.pdf
☒GI symptom diary.pdf
☒Participant contact script.pdf
☒Participant reminder.pdf
☒Compensation document less than 50 dollars.pdf
☒Compensation document more than 50 dollars.pdf
☒Informed Consent Form.pdf
☒Participant enrollment script.pdf
☒Recruitment flier.pdf