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Protocol Title: Effective Implementation of a Classroom Undergraduate Research Experience (CURE) II

Protocol Status: APPROVED

Date Submitted: 11/01/2018

Approval Period: 12/05/2018-12/04/2019

Important Note: This Print View may not reflect all comments and contingencies for approval. Please check the comments section of the online protocol. Questions that appear to not have been answered may not have been required for this submission. Please see the system application for more details.

* * * Personnel Information * * *

Study Personnel Roles:

- Principal Investigator: accepts responsibility for study, can edit protocol, must submit to IRB
- Administrative Contact: additional study contact, can edit/prepare protocol, may or may not also be member of research team
- Key Personnel (Research Team): University of Alabama member of research team, can view protocol (not edit)
- Non-Alabama Collaborator: member of research team from another institution or organization outside of University of Alabama, has no access to system, must be provided with PDF of protocol.
- Department Chair: Official Department Chair, may or may not also be a member of research team, can view the protocol (not edit). NOTE: a proxy may be listed if the Chair is the PI.

IMPORTANT NOTE: Human Participants Protection Training is mandatory for all research team personnel.

Principal Investigator Mandatory

PI must be University of Alabama affiliate.

Name of Principal Investigator (Faculty, Staff or Student)	Degree (MD/PhD/Other)	Title
Reed, Laura		Associate Professor
Email	Phone	Fax
lreed1@ua.edu	+1 205 348 1345	

Department Name

Biology

Please indicate your status Faculty

Is the (Role) also a Department Chair? N

Human Subjects Training Completed? Y

If you have completed training that is not auto-populated below, upload a copy in the Attachments section.

Research Team Member Duties Picklist

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Recruitment | 2. <input checked="" type="checkbox"/> Obtains consent |
| 3. Determine participant Eligibility for Accrual | 4a. Participant Physical Examinations |
| 4b. Follow-up Visits including physical assessments | 5. <input checked="" type="checkbox"/> Perform study procedures or Specimen Collection |
| 6a. Administer and/or Dispense Study | 6b. Receive, Store, Manipulate or |

- | | | | |
|------|--|-------|--|
| | Drugs, Biologics or Devices | | Account for Study Drugs, Biologics or Devices |
| 7. | Participant Randomization or Registry | 8. | Collection of Participant Data |
| 9. | Report Data (CRFs, e-CRFs, Spreadsheets) | 10. X | Data Analysis |
| 11a. | Review Adverse Events | 11b. | Treat and Classify Adverse Events |
| 12. | Other (Please insert explanation below.) | | |

No training data is available.

Non - Alabama Collaborator

Name of Non - Alabama Collaborator	Degree (MD/PhD/Other)	Title	Department Name
David Loppato	PhD	Professor	Other

Department Chair Mandatory

The official Department Chair should be listed here. If the Department Chair is the PI, a proxy may be listed.

Name of Department Chair	Degree (MD/PhD/Other)	Title
Mortazavi, Behzad		Professor
Email	Phone	Fax
bmortazavi@ua.edu	+1 251 861 2141	+1 251 861 7540

Department Name
Biological Sciences

Human Subjects Training Completed? N

If you have completed training that is not auto-populated below, upload a copy in the Attachments section.

Is Chair a member of the study team? N

Research Team Member Duties Picklist

- | | |
|--|---|
| 1. Recruitment | 2. Obtains consent |
| 3. Determine Participant Eligibility for Accrual | 4a. Participant Physical Examinations |
| 4b. Follow-up Visits including physical assessments | 5. Perform study procedures or Specimen Collection |
| 6a. Administer and/or Dispense Study Drugs, Biologics or Devices | 6b. Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices |
| 7. Participant Randomization or Registry | 8. Collection of Participant Data |

- 9. Report Data (CRFs, e-CRFs, Spreadsheets)
- 10. Data Analysis
- 11a. Review Adverse Events
- 11b. Treat and Classify Adverse Events
- 12. Other (Please insert explanation below.)

No training data is available.

***** Subject Population *****

Subject Population(s) Checklist

Select All That Apply:

- Adult Volunteers
- Cognitively Impaired Participants
- Employees
- Fetuses
- Minors (under 18)
- Pregnant Women
- Prisoners

Students (Note: If students will be compensated extra-credit or course credit for participation in the research, they must be given a non-research alternative for obtaining the same amount of credit, which is of comparable time and effort as is required by the research activity.)

Terminally Ill Participants

Wards of the State (Note: Please consider whether the research population may also be considered "prisoners" or "cognitively impaired." If so, please mark the appropriate corresponding categories in the Subject Population Checklist)

Non-English Speakers (Note: Please provide copies of all correspondence that will be used as a part of the research in English as well as in the native language of participants. Please also attach a copy of the Translator's Declaration.)

Other (any population that is not specified above)

***** Study Location *****

Study Location(s) Checklist

Indicate where the study will be conducted. Select all that apply:

- The University of Alabama
- Another University or College
- VA Center
- Hospital
- Other

see attached list

***** General Checklist *****

General Checklist

Select All That Apply :

- Study Eligible for Exempt Review
- Non-human participants research
- Collection of Specimens

- X Data collection via e-mail or the Internet
 - FDA Approved Device
 - FDA approved drugs, reagents, other chemicals administered to participants (even if they are not being studied), or biologic products
 - Genetic Testing
 - HIV Testing
 - Human blood, cells, tissues, or body fluids
 - Investigational drugs, reagents, chemicals, or biologic products
 - Investigational Device
 - Investigator Initiated Study
 - Medical Records
 - Photography, Video, or Voice-Recording Participants
- X Questionnaires and/or tests
 - Radioisotopes/radiation-producing machines, even if standard of care
 - rDNA/Gene Transfer Therapy
 - Registry or Repository Creation
 - Specimens to be stored for future research projects (must be in consent form)
 - Study of existing data or specimens
 - Other (clarify in text box to the right)

***** Funding *****

Funding Checklist

NONE

Funding - Grants/Contracts

Funding Type	Funded By
Government	National Institute of Health

NOTE: Applicable grant application, contract or subcontract, investigator's brochure, and sponsor's protocol (for all industry sponsored clinical trials) must be attached. Click "Add" to attach the documents.

***** Expedited Review *****

To request an Expedited Review, check the appropriate category(ies) below. Provide justification for your request for Expedited Review.

To qualify for expedited review, research activities must (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories below.

Select one or more of the following paragraph(s):

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - a) Research on drugs for which an investigational new drug application (21 CFR Part 31, 32) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b) Research on medical devices for which
 - i) An investigational device exemption application (21 CFR Part 812) is not required; or
 - ii) The medical device is cleared/approved for marketing and the medical device is being used in

accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
- a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
 - b) From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

Children are "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."

3. Prospective collection of biological specimens for research purposes by non-invasive means.

EXAMPLES: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

EXAMPLES: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participants' privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiology; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes. This category should only be selected if the present research will involve analysis of data that has been previously recorded.

- X 7. 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) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

The research is based on surveys and quizzes for which any personally identifiable information (i.e. subject name) is encrypted so that the researcher cannot recover that information. The purpose of the encrypted identities is to match pre/post quizzes/surveys for given subjects.

8. [FOR IRB use only]. Continuing review of research previously approved by a convened IRB only when condition (a), (b), or (c) is met.
 - a) Previously approved research where
 - (i) The research is permanently closed to the enrollment of new participants;
 - (ii) All participants have completed all research-related interventions; and
 - (iii) The research remains active only for the long term follow-up of participants.
 - b) Previously approved research where no participants have been enrolled and no additional risks have been identified.
 - c) Previously approved research where the remaining research activities are limited to data analysis.
9. [FOR IRB use only]. Continuing review of research not conducted under an investigational new drug application or investigational drug exemption where expedited categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

***** Background , Purpose , Study Procedures *****

Study Title

Effective Implementation of a Classroom Undergraduate Research Experience (CURE) II

Complete Sections 1 - 15. Specify N/A as appropriate. Do not leave any required sections blank.

1) Background

- a) Describe past experimental and/or clinical findings leading to the formulation of the study, if applicable.

The Genomics Education Partnership (GEP) is a collaboration between a growing number of primarily undergraduate institutions and the Biology Depts of Washington University in St. Louis and the University of Alabama. Participating undergraduates learn to take raw sequence data to high quality finished sequence, and to annotate genes and other features, leading to analysis of a question in genomics and research publication. The GEP organizes research projects and provides training/collaboration workshops for PUI faculty and teaching assistants. The advent of genomics technologies has changed the way biomedical scientists study genome organization, regulation of gene expression, and evolution. As such, scientists now analyze massive volumes of data to track events within an entire genome and to compare one genome to another. To keep pace with these developments, undergraduate students in fields related to or contained within the biomedical sciences must be introduced to these new and powerful tools and to this new way of thinking about doing research in these fields early on in their education career. At the same time, it is important that the students maintain an appreciation for and understanding of the biology associated with this massive amount of data. Working scientists construct experiments to answer questions, but too few students are given the opportunity to experience discovery research

too few students are given the opportunity to experience discovery research because of the resource-intensive nature of fundamental research. Incorporating research into an academic year semester-long lab course allows us to provide this experience to more students.

- b) Describe any animal experimentation and findings leading to the formulation of the study, if there is no supporting human data.

N/A

2) Purpose of the study

- a) Provide a brief lay summary of the project in <200 words. The lay summary should be readily understandable to the general public.

We are engaged in providing undergraduates with a research experience in genomics through laboratory courses. The Genomics Education Partnership is a collaboration with faculty from over 100 colleges and universities across the country all engaged in bringing this course-based undergraduate research experience (CURE) to their students. The goals of this proposal are to determine the best instructional practices to optimize this research experience for our undergraduates, and to develop additional instructional materials to make the research experience in genomics more accessible for beginning college/university students.

To assess the efficacy of our practice, we ask students to do a pre-/post-course quiz on genes and genomes, and to respond to a pre-/post survey that asks about their scientific interests and about their course-based research experience. Both the quizzes and the surveys are administered through a web-based site.

Information gained will help us to improve the learning experience for our students, and may aid other faculty interested in designing a course-based research experience for undergraduates using other types of scientific investigations.

- b) List your research objectives (specific aims & hypotheses of the study).

Aim 1: we will further develop the GEP as a research organization, identifying and testing strategies to maximize the effectiveness of a bioinformatics-based CURE, in the process generating a better understanding of how research experiences impact student learning and self-identification as a scientist.

Aim 2: we will develop a modified version of our curriculum and engagement strategy to make bioinformatics-based genome research more accessible to beginning college/university students.

We hypothesize that a bioinformatics-based CURE can be effective at improving student understanding of fundamental concepts in genetics and genomics, and can increase student potential to remain engaged in science disciplines, across diverse undergraduate institution types and diverse implementation strategies.

- c) Describe the study design (e.g., single/double blind, parallel, crossover, control, experimental, observational, etc.)

N/A

Single blind

Double blind

Parallel

Crossover

Control group

Experimental group

Observational

X Other

Correlational, looks for associations between student performance, student perceptions, institution characteristics, and implementation approaches.

d) Provide a timeline for individual participant recruitment and follow-up (analysis for the study is required).

Student recruited at the beginning of the academic term/semester in which they are doing the curriculum when they complete the pre quiz/survey and then conclude their involvement at the end of the term/semester when they complete the post quiz/survey.

e) Will participant be randomized? N

f) If participants will be given placebo, please justify placebo use, and describe contents of the placebo.

N/A

3) Study Procedures

a) Is this project a multicenter study (i.e., same project is conducted elsewhere by a different investigator)? Y

Is University of Alabama acting as a coordinating center for other sites? Y

Will the University of Alabama site be participating in all parts/procedures/arms of the study? Y

If No, explain what University of Alabama will NOT participate in:

b) Describe all the procedures, from screening through end-of-study, that the human participant must undergo in the research project, including study visits, drug treatments, randomization and the procedures that are part of standard of care. Specify which procedures are for research and which are standard of care. If study involves only retrospective record review, describe that review process here, including how records will be selected for review. Please note: The box below is for text only. If you would like to add tables, charts, etc., Click "Add" to attach the documents.

Study participants are the students enrolled in courses taught by GEP faculty. Students are asked to complete the pre-course survey and pre-course quiz during the first week of classes. The purpose of the study is explained by the instructor or a designated representative (e.g. TA), and the various safeguards and opt-out mechanisms are described. In addition, it will be emphasized to the students that whether they participate in this evaluation will in no way impact their grade. At some institutions, time is allowed at the end of class for students to access the website and participate in the survey and quiz, if they choose to do so. Nobody monitors the student activity, so those who choose to opt out can simply continue their lab work, surf the web, or do other work. At other institutions, the students are provided the information to access the pre-survey and pre-quiz in the form of an electronic message (e.g. email) or as a paper hand-out so that they are able to complete the assessments outside of class if they so choose. A similar procedure is used at the end of the semester for the post-course survey and quiz. A student taking the pre-course quiz is randomly assigned to A or B; when they return for the post-course quiz, they are assigned to the other quiz. The instructors have no knowledge or ability to learn whether their students have completed the assessments, nor the nature of the student responses. The data is automatically encrypted and de-identified by the survey/quiz electronic system and then transferred to the external evaluator for analysis. The results are later shared with the GEP faculty (and published) only in aggregate form so specific students, instructors, and institutions cannot be determined. The encrypted data does include an identifier that allows the evaluator to match student responses between pre- and post-quizzes/surveys, and with the institution to allow for aggregate analyses based on publicly available institution metrics (e.g. size, student demographics).

c) Provide stopping rules for the study, If the proposed study is a clinical trial where a drug, vaccine,

device or other treatment is compared to a placebo group or comparison treatment group, what are the guidelines or endpoints by which early decisions regarding efficacy or lack of efficacy can be made? For example, it may be reasonable to stop enrollment on a study when efficacy has already been clearly demonstrated, to avoid unnecessary enrollments of additional participants. Alternatively, it may be reasonable to stop enrollment when it is clear that efficacy will never be demonstrated, given the statistical power of the study as designed. Describe the guidelines that are in place to assist in making these determinations, if relevant to the proposed study.

The study is ongoing and will continue to gather data as long as the curriculum is being used.

- d) Describe how data analysis will be performed (statistical tests, methods of evaluating data) and indicate the smallest group/unit for which separate reporting will occur. For studies involving a questionnaire, if data and reliability information are available, please describe or provide references. (Page numbers from a sponsor's protocol/grant may be referenced in this section).

Except for items that collect demographic or categorical data or that provide text boxes asking for comments, all items across all surveys ask participants to indicate their feelings/responses on a 1-5 scale. We treat these responses as numerical data. All averages are reported as means, and errors are reported as +/- 2 SEM; significance is determined at $p < 0.05$. To compare classroom-based GEP responses with those from control or other groups, we use an independent-groups t test. To test for correlation between institutional characteristics and student learning outcomes (both surveys and quizzes), we apply multiple linear regression. To look for any differences between groups of students with respect to both knowledge and learning gains, we use one-factor analysis of variance (between groups). Text comments are evaluated by looking for common themes and critical words. Quiz answers are scored as correct or incorrect using the rubric supplied by the faculty.

Data is pooled with across all participating schools. The pooled data is from several hundred students and has been shown to be meaningful by several criteria. See Shaffer et al. (2014) CBE-Life Science Education 13: 111-130 for further details (<http://www.lifescied.org/content/13/1/111.full>).

***** Radioisotopes or Radiation Machines *****

4) Radioisotopes or Radiation Machines

Please note: For projects requiring radiation procedures, please contact the UA Environmental Health and Safety Office at 348-6010

- a) If applicable, summarize in lay language the radiographic diagnostic and therapeutic procedures associated with this protocol. (X-ray, fluoroscopy, CT, radioactive materials, nuclear medicine, PET-CT, radiation oncology, accelerator, Cyber Knife procedures, etc.).

- b) Are the radiation procedures being performed a normal part of the clinical management for the medical condition that is under study (Standard of Care), or are the procedures being performed because the research participant is participating in this project (extra CT scans, more fluoroscopy time, additional Nuclear Medicine Studies, etc.) (Not Standard of Care)? If some procedures are Standard of Care and some are Not Standard of Care, check both boxes.

NOT STANDARD OF CARE

If it is not standard of care, complete the rest of this section. Provide the University of Alabama RSC approval information below.

STANDARD OF CARE

If it is only standard of care, skip the rest of this section.

- c) Are research-related radiation procedures limited to X-rays only?

Yes (Complete X-ray table).

No (Skip X-ray table).

d) Total Radiation Exposure (in mRems) from x-ray procedures:

To calculate radiation exposure from x-rays only, University of Alabama allows use of the Duke University Radiation Safety Committee dose estimate calculator. University of Alabama does not allow use of this website to calculate any other type of radiation exposure.

To determine the dose estimate, click on the appropriate links, below (you will be taken to the Duke University Radiation Safety Committee website). Enter the x-ray procedures into the appropriate fields of the website and click "create statement". Enter the dose estimate from the statement in the table above.

For studies involving adults, please click here.

For pediatric studies, please click here..

e) Please list all radiation procedures (including x-ray) that are research-related (not standard of care). Include the anatomical location and specify the number of times that each procedure will be conducted throughout the entire study.

NOTE: The IRB will determine if this study requires radiation safety review by the Radiation Safety Officer or the Radiation Safety Committee.

For more information on how to submit for radiation safety review, contact the Radiation Safety Officer.

***** Drugs, Reagents, Chemicals, or Biologic Products *****

5. Drugs, Reagents, Chemicals, or Biologic Products

Pilot	Phase I	Phase II
Phase III	Phase IV	Not Phased

- a) Please list in the space below all investigational drugs, reagents or chemicals to be administered to participants during this study.
- b) Please list in the space below all FDA approved drugs, reagents, chemicals to be administered to participants during this study.

Please read the IND Statement 1 and IND Statement 2.

***** Devices *****

6. Devices

- a) Please list in the space below all investigational devices to be used on participants during this study.
- b) Please list in the space below all FDA approved devices to be used on participants during this study.

***** Subject Population(a-h) *****

7. Subject Population - In the space below, please detail the participants that you are requesting to recruit (include description of each group requested)

a) Expected age range of participants. (For example - 19 yrs to 90 yrs).

18 to 24 years old, and at institutions in states that allow 17 year olds to participate in the study without parental permission will also be included.

- b) i) Number to be directly solicited for this research. N/A
- ii) Number to be consented (including withdrawals or screen N/A

failures)

iii) Number expected to complete the study.

c) If this is multi-center study, number of participants to complete the study study-wide N/A

d) If study involves review of medical or other records, number of records to be reviewed. X N/A

e) If women, minorities, or minors are excluded, a clear compelling rationale must be provided unless not applicable. Examples for not including minors: disease does not occur in children; drug or device would interfere with normal growth and development; etc.

f) Describe how potential participants will be identified for recruitment (e.g., chart review, referral from individual's treating physician, those individuals answering an ad). How will potential participants learn about the research, and how will they be recruited (e.g., flyer, e-mail, web posting, telephone, etc.)? State where recruitment materials will be located. Click "Add" to upload recruitment materials document.

Important to remember: Study Activities cannot begin until IRB approval is granted.

The subjects are presented with the study in class by their professors or a designated representative (e.g. TA), and are given the link to go to the website and read the consent form. They are given the option to contact the PI to discuss any questions that they may have.

***** Subject Population(i-l) *****

7. Subject Population (continued)

i) Inclusion and Exclusion Criteria.

Identify inclusion criteria.

Participants are undergraduates who have enrolled in a course taught by a GEP faculty member in which the faculty member uses GEP curriculum materials. These students are most often majoring in biology, biochemistry, or computer science.

Identify exclusion criteria.

j) Compensation. Explain the amount and schedule of compensation, if any, that will be paid for participation in the study. Include provisions for prorating payment.

k) Describe who will cover study related costs. Explain any costs that will be charged to the participant. Include provisions for prorating payment.

l) Estimate the probable duration of the entire study including data analysis and publication. This estimate should include the total time each participant is to be involved and the duration the data about the participant is to be collected. If the study is Investigator-initiated, a timeline for individual participant recruitment, follow-up, total time for participant accrual, and data analysis for the study is required.

This is an ongoing longitudinal study for which we have not determined an end date. Each participant will be participating for about 2 hours twice in 4.5 months (semester).

***** Subject Population(m) *****

Research Involving Children

NOTE: Investigators, please include this information with the e-Protocol application if your research involves children. In Alabama a child is an individual less than 18 years of age unless the child is legally emancipated. If your research involves children with more than one vulnerability (e.g., children who are pregnant, incarcerated, or cognitively impaired) attach the supplementary information for that vulnerable population as well.

Minimal risk means that the probability and magnitude of the harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of a healthy child or during the performance of routine physical or psychological exams or tests.

Section 1.

Select and complete the category that applies to your research.

Category 1 (45 CFR 46.404; 21 CFR 50.51) My research does not involve greater than minimal risk.

a) My research falls under this category because:

b) Describe what provisions will be made for soliciting the assent of the children, and the permission of both parents, or the legal guardian. (Permission from both parents must be obtained unless one parent/guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent/guardian has legal responsibility for the care and custody of the child). Justify reason(s) if seeking permission from only one parent.

Category 2 (45 CFR 46.405; 21 CFR 50.52) My research involves greater than minimal risk but presents the prospect of direct benefit to the individual participants.

a) My research falls under this category because:

b) Justify the risk(s) by explaining the anticipated benefit to the participants:

c) Explain how the relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches:

d) Describe what provisions will be made for soliciting the assent of the children, and the permission of at least one parent/guardian. (Permission from both parents must be obtained unless one parent/guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent/guardian has legal responsibility for the care and custody of the child). Justify reason(s) if seeking permission from only one parent.

Category 3 (45 CFR 46.406; 21 CFR 50.53) My research involves greater than minimal risk, and no prospect of direct benefit to individual participant, but likely to yield generalizable knowledge about the participant's disorder or condition.

a) My research falls under this category because:

b) Describe how the risks for participating in your research represent a minor increase over minimal risk (i.e., the children being recruited have a disorder or condition that would place them in a group other than an average healthy child; therefore, the research qualifies as a minor increment over minimal risk. This risk is slightly more than what the average healthy child would experience, but is reasonable for these participants because it is not more than they would experience or expect given their condition.).

c) Describe how the research intervention(s)/procedure(s) present experiences to participants that are reasonably commensurate to those inherent in their actual or

expected medical, dental, psychological, social, or educational situations:

- d) Explain why the intervention or procedure is likely to yield generalizable knowledge about the participants' disorder or condition, which is of vital importance for the understanding or amelioration of the participants' disorder or condition:

- e) Describe what provisions will be made for soliciting the assent of the children, and the permission of both parents/guardians. (Permission from both parents must be obtained unless one parent/guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent/guardian has legal responsibility for the care and custody of the child). Justify reason(s) for seeking permission from only one parent.

Category 4 (45 CFR 46.407; 21 CFR 50.54) My research does not fall under Category 1, 2, or 3 listed above. However, the research presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

(NOTE: If your research is funded by, or funding has been sought from the Department of Health and Human Services (DHHS), Department of Education, or is FDA regulated, a report must be sent for review to the DHHS Secretary, Secretary of the US Department of Education, or Commissioner of FDA. If this category is applicable, the Office of Research Compliance will prepare and submit a report of IRB review to the appropriate federal official(s)).

- a) My research falls under this category because:

- b) Describe what provisions will be made for soliciting the assent of the children, and the permission of both parents/guardians. (Permission from both parents must be obtained unless one parent/guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent/guardian has legal responsibility for the care and custody of the child). Justify reason(s) if seeking permission from only one parent.

Section 2.

In order to effectively assess and evaluate the risk of your proposed research to children, the IRB requires the following information. Respond to all items.

- a) Provide justification for the participation of children as research participants in your study.

- b) Has this research been conducted in adults?

If yes, is there any indication that the proposed research would benefit, or at least not be harmful to children?

- c) Indicate how many children you propose to enroll in the study and justify this number (whenever possible, involve the fewest number of children necessary to obtain statistically significant data which will contribute to a meaningful analysis relative to the purpose of the study).

- d) Describe how assent of a child will be obtained and documented (if applicable). If not applicable, explain why.

I am requesting waiver of the requirement for assent.

Justify:

OR

I have attached an assent form/assent script for IRB review.

- e) Explain what methods will be used for evaluating dissent (i.e., description of behaviors that would indicate child does not want to participate (such as moving away, certain facial expressions, head movements, etc...)).

- f) Describe how parental permission will be obtained. [Note: If you propose to waive the requirement for parental permission (i.e., getting parental permission may be against the best interest of the child, i.e., a study of abused or neglected children), describe what measures will be taken to protect the rights and welfare of the children.]

I am requesting waiver of the requirement for parental permission.

Justify:

OR

I have attached a parental permission form for IRB review.

- g) Describe measures that will be taken to ensure that a parent is present when the child participates in any research interventions or procedures. [Note: If the nature of the research is such that it is not appropriate to have a parent present (i.e., research into sensitive personal issues, physical examinations of teenagers, etc...) please explain why.]

- h) Describe the expertise of the research staff/study personnel for dealing with children at the ages included and whether they are knowledgeable and sensitive to the physical and psychological needs of the children and their families. Describe the appropriateness of facility in which the research will be conducted in relation to environment and/or equipment accommodating to children.

- i) If applicable, provide any additional information that may support your request to involve children in this research.

***** Subject Population(n) *****

Research with cognitively impaired persons

NOTE: Investigators, please include this form with IRB application if your research involves cognitively impaired (decisionally impaired or decisionally challenged) persons. If your research involves people with more than one vulnerability, please complete the supplementary form for that population as well.

The IRB may ask you to designate an impartial observer to monitor the consent process or it may send its own representative to do so.

Section 1.

Note: Check the box next to the category that in your best judgment applies to your research, and provide the information requested in the space provided.

Note: Minimal risk means that the probability and magnitude of the harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily

encountered in daily life or during the performance of routine physical or psychological exams or tests. (i.e., daily life of health persons)

Category 1 My research does not involve greater than minimal risk.

Explain. If appropriate, describe what provisions are in place for allowing a Legally Authorized Representative (LAR) or other person with the participant's best interests at heart to assist the participant in navigating the research process:

Category 2 My research presents greater than minimal risk and prospect of direct benefit to the participants.

Explain. If appropriate, describe what provisions are in place for allowing a Legally Authorized Representative (LAR) or other person with the participant's best interests at heart to assist the participant in navigating the research process.

Category 3 My research presents greater than minimal risk and no prospect of direct benefit to the participants, but likely to yield generalizable knowledge about the participant's disorder or condition, because:

Explain. If appropriate, describe what provisions are in place for allowing a Legally Authorized Representative (LAR) or other person with the participant's best interests at heart to assist the participant in navigating the research process.

Category 4 My research does not fall under Category 1, 2, or 3, listed above.

If you check this category, the IRB determines additional safeguards on a case-by-case basis.

Section 2.

1. Explain why individuals with impaired decision-making capacity are suitable for this research. If the objective(s) of the study allow for inclusion of competent participants, provide compelling justification for inclusion of incompetent participants.
2. Describe who will determine individuals' competency to consent and the criteria to be used in determining competency (e.g., use of standardized measurements, consults with another qualified professional, etc...)
3. It should be recognized that decision-making capacity may fluctuate, requiring ongoing assessment during the course of the research. Is it reasonable to expect that during the course of the research, subjects may lose their capacity to consent or their ability to withdraw?
 - a) Describe what provisions are in place for periodic re-consent. Include the rationale and procedure, the proposed interval, any changes in behavior that might signal the need to re-consent whether or not the proposed interval has elapsed, and any consultative resources that are available for these decisions. Describe the process for re-consent or re-assent, or reassessment of willingness to continue participation.
 - b) Describe what provisions are in place to protect the participants' rights in the event they lose their capacity to consent or their capacity to withdraw during the course of the research. (e.g., power of attorney, consent a caregiver as well as the patient, etc.).
 - c) Describe what provisions are in place for use of additional waiting periods to allow potential participants time to consult with family members about whether or not to participate.

4. Explain how you will identify who is authorized to give legally valid consent on behalf of any individual(s) determined to be incapable of consenting on their own behalf.

5. Explain the criteria you will use for determining when assent is required for participants who are not competent.

6. Explain what methods will be used for evaluating dissent (e.g., description of behaviors that would indicate individual does not want to participate (such as moving away, certain facial expressions, head movements, etc...)).

7. The research protocol should include someone who can be reasonably assumed to have the participant's best interest in mind and can assist the participant in navigating the consent and research process. A person holding durable power of attorney or other legal designee, spouse, close relative who is involved in ongoing care of participant, other person with a personal or blood relationship who is involved in ongoing care of participant, or other close relatives or friends may assume this role. Describe how individuals will be identified to serve in this capacity. If this request is not appropriate for this study, justify why it should be waived.

8. If applicable, describe when and how the individual's health care provider will be consulted prior to participation in the research. NOTE: If the Principal Investigator (PI) is also the individual's health care provider, address how the PI will separate the roles of clinician and researcher.

9. Will the research interfere with current therapy or medications?

If yes, describe what the changes may entail (i.e., if the subparticipant be removed from routine drugs/treatments, wash out periods, etc.) and the potential risks.

10. Does your research involve institutionalized individuals?

a) Justify the use of institutionalized individuals and explain why non-institutionalized individuals can not be substituted.

Section 3.

Complete this section if your research involves individuals from the Department of Veterans Affairs (VA).

1. Address procedures you will use to ensure the participant's representative is informed regarding his/her role and obligation to protect the incompetent participant or person with impaired decision-making capacity.

2. Address procedures you will use to ensure the participant's representative has been told of his/her obligation to try to determine what the prospective participant would do if competent, or if the prospective participant's wishes cannot be determined, what the participant's representative thinks is in the incompetent person's best interests:

3. The VA has specific requirements and procedures for determining and documenting in the person's medical record that an individual is incompetent or decisionally-impaired.

There are additional requirements if the lack of decision-making capacity is based on diagnoses of mental illness. These requirements are outlined in the Veterans Health Administration (VHA) Handbook 1200.5, Section II. Have you reviewed these requirements and included them in your procedures?

4. Justify that the research involves no significant risks, or if the research presents probability of harm, justify that there is at least a greater probability of direct benefit to the participant:

Note:[Veterans Health Administration Handbook 1200.5, July 15, 2003, Section 11 - Research Involving Human participants with Surrogate Consent, and Appendix D Vulnerable Populations, Section 6(c)]

Section 4.

For research involving cognitively impaired persons outside the state of Alabama, also complete this section.

- a) Provide information regarding the state definition of legally authorized representative, child, decisionally-impaired, or guardian, as applicable to the research and to the federal definitions. [If the research is to be conducted in more than one state outside of Alabama, provide this information for each state.]

Definitions:

Assent - is defined as a child's or decisionally-challenged individual's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Competence "Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice." [OHRP Institutional Review Board Guidebook, Chapter VI, Section D]

Permission is defined as the agreement of parent(s) or guardian to the participation of their child or ward in research or clinical investigation. Permission includes the element of consent set forth in federal regulations and outlined in the informed consent template included in the IRB expedited and full review applications.

In Alabama child/children refers to all individuals less than 18 years of age unless the individual(s) is/are legally emancipated. (See Guidance: Alabama Law on Children, Minors, Consent, and Other Research-Related Topics. Individuals less than 18 years of age who are not emancipated meet the federal definition for "child" (e.g., Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), and U.S. Department of Education).

Legally authorized representative (LAR) is an individual who has the authority to make research participation decisions on behalf of another. Alabama law does not specify who may make such decisions. UA legal counsel recommends the following in this order of preference: A legally appointed guardian, a health care proxy or person authorized to make medical decisions in conjunction with a durable power of attorney, a spouse, an adult child, next of kin, or a person or agency acting in loco parentis.

NOTE: Consent from a legally authorized representative involves all the ethical and regulatory concerns that apply to consent from the prospective participant.

***** Subject Population(o) *****

Pregnant Women, Fetuses and Neonates

NOTE: Investigators, please include this information with the e-Protocol application. Check the box that best fits your research and address the issues that immediately follow as they apply to your research. If your research involves women with more than one vulnerability (e.g. , pregnant women who are children under Alabama law or

pregnant women who are cognitively impaired), attach the supplementary application form for that population as well.

Note: Definition of Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological exams or tests.

Research Involving Pregnant Women or Fetuses [45 CFR 46.204]

A. Explain why the proposed research is scientifically appropriate, including descriptions of any pre-clinical studies on pregnant animals and any clinical studies conducted on non-pregnant women that have provided data for assessing potential risks to pregnant women and fetuses.

B. Check the box next to the item that best describes the anticipated risk to the fetus:

1. Not greater than minimal
2. Greater than minimal risk and the risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus.

C. Provide a rationale for the anticipated risk:

D. Explain why any risk is the least possible for achieving the objectives of the research:

E. Check the appropriate box as it applies to this research:

1. This research holds out the prospect of a direct benefit to the pregnant woman.
2. This research holds out the prospect of direct benefit both to the pregnant woman and the fetus.
3. This research does not hold out the prospect of a direct benefit for the woman or the fetus, but the risk to the fetus is not greater than minimal, and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

Note: If "Yes" to any of the above in "E", informed consent must be obtained from the pregnant woman or her legally authorized representative (LAR) as required in 45 CFR 46.116 & 117, but consent from the father is not required. The informed consent process should include a clear explanation of the reasonably foreseeable impact of the research on the fetus.

4. This research holds out the prospect of a direct benefit solely to the fetus.

Note: If "yes", informed consent must be obtained from the pregnant woman and the father as required in 45 CFR 46.116 & 117. The informed consent process should include a clear explanation regarding the reasonably foreseeable impact of the research on the fetus. NOTE: The father's informed consent need not be obtained if he is unable to consent because of non-availability, incompetence or temporary incapacity or if the pregnancy resulted from rape or incest.

5. This research will involve individuals under the age of 19 who are pregnant and are not considered emancipated minors.

Note: If "Yes", assent from the pregnant child and permission from her parent or legal guardian must be obtained in accordance with the provisions of 45 CFR 46, Subpart D.

6. Will there be any inducements, monetary or otherwise, offered to terminate a pregnancy?

7. Will individuals performing research procedures have any part in any decisions

as to the timing, method, or procedures used to terminate a pregnancy?

8. Will individuals performing research procedures have any part in determining the viability of a fetus?

Note: "Yes" answers to 6-8 mean that the research cannot be approved.

Section 2. Research Involving Neonates [§ 46.205]

- A. Neonates of Uncertain Viability AND Nonviable Neonates - Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by 45 CFR 46 Subpart B unless the IRB determines that the following conditions are met.

1. Explain why the proposed research is scientifically appropriate and provide a description of any pre-clinical and clinical studies that have been conducted which provide data for assessing potential risks to neonates.

2. Will individuals engaged in the research have any part in determining the viability of a neonate?

Note: A "Yes" answer means that the research cannot be approved. Individuals engaged in the research may have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

3. Is any inducement, monetary or otherwise, offered to terminate a pregnancy?

Note: A "Yes" answer means that the research cannot be approved. No inducements, monetary or otherwise, may be offered to terminate a pregnancy.

- B. Neonates of Uncertain Viability - Additional Requirements. Check if applicable.

1. The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, AND any risk is the least possible for achieving that objective, or
2. The research has the main purpose of the development of important biomedical knowledge, which cannot be obtained by other means AND there will be no added risk to the neonate resulting from the research.
3. Explain the procedures that will be used to obtain legally effective informed consent of either parent of the neonate.

NOTE: If neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's LAR will be obtained as required by 45 CFR 46.116 & 117. These procedures must assure that each individual providing informed consent will be fully informed regarding the reasonably foreseeable impact of the research on the neonate. The father's informed consent need not be obtained if he is unable to consent because of non-availability, incompetence or temporary incapacity or if the pregnancy resulted from rape or incest.

- C. Nonviable Neonates - Additional Requirements. After delivery a nonviable neonate may not be involved in research covered by 45 CFR 46 Subpart B unless the IRB determines that the following additional conditions are met. Please check if applicable to your research.

1. Will the vital functions of the neonate be artificially maintained?
2. Does the research include procedures to terminate the heartbeat or respiration of the neonate?
3. Will there be any added risk to the neonate from this research?

"Yes" answers to 1-3 mean that the research cannot be approved.

4. Is the sole purpose of the research for the development of important biomedical knowledge that cannot be obtained by other means?

If "Yes", please explain:

- 5. Explain the procedures that will be used to obtain legally effective informed consent of both parents of the neonate.

Note: If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice. The consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will NOT suffice. These procedures must assure that each individual providing informed consent will be fully informed regarding the reasonably foreseeable impact of the research on the neonate.

- D. **Viable Neonates - A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accordance with the requirement of 45 CFR 46 Subparts A and D. The neonate is now a child. Please follow policies and consenting process for research with children and attach FORM: APPLICATION FOR RESEARCH WITH CHILDREN.**

Section 3. Research Involving After Delivery, The Placenta, The Dead Fetus, or Fetal Material [§ 46.206]

- A. This research proposes to use the following: (Check all that apply)

Placenta

The dead fetus

Macerated fetal material

Cells excised from dead fetus

Tissue excised from dead fetus

Organs excised from dead fetus

Other(Describe)

Note: The use of any of the above must be conducted in accordance with any applicable Federal, State, or local laws, regulations, and institutional policies regarding such activities.

- B. Will any information associated with the above material be recorded for research purposes in such a manner that living individuals can be identified directly or through identifiers linked to those individuals?

If "Yes", provide a rationale for the recording of identifiable information.

Note: These individuals are considered to be research participants and all pertinent human participant regulations are applicable to their participation.

Section 4. Research Not Otherwise Approvable Which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem Affecting the Health or Welfare of Pregnant Women, Human Fetuses, or Neonates [§ 46.207, § 46.208, §46.209, § 46.210]

- A. If the study is Department of Health and Human Services (HHS) funded, or if funding by HHS is sought, review by the Secretary of HHS and posting in the Federal Register for public comments and review is required. If this category is applicable, the Research Compliance Office will prepare and submit a report of IRB review to the appropriate HHS institutional official.

***** Subject Population(p) *****

Research Involving Prisoners

NOTE: Investigators, please include this information with the e-Protocol application if your research involves prisoners. This includes studies of known prisoners and studies recruiting participants at risk of becoming involuntary prisoners, such as participants with histories of substance abuse. Remember that persons involuntarily committed to mental health facilities (Taylor Hardin Secure Mental Health Facility, Mary Starke

Harper, etc.) by the courts are also prisoners.

If participants unexpectedly become prisoners, go directly to SECTION FOUR of this form.

If your research involves prisoners with more than one vulnerability (i.e., prisoners who are also children or pregnant, are involuntarily committed to mental health facilities), attach the supplementary form for that vulnerable population as well.

Regardless of the category of your research, be sure that your application makes clear why the research must be done on prisoners.

Indicate the category that best represents your research by checking the applicable box below, and explain in the space provided for that category why your research meets the criteria.

Note: For research involving prisoners, the definition of minimal risk refers to the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental or psychological examination of healthy persons.

Category 1 (45 CFR 46.306(a)(2)(i))

My research involves the study of possible causes, effects, processes of incarceration, and of criminal behavior. (Processes of incarceration can be interpreted broadly to include substance abuse research, half-way houses, counseling techniques, criminal behavior, etc.)

Justify how the research presents no more than minimal risk and no more than inconvenience to the participants:

Category 2 (45 CFR 46.306(a)(2)(ii))

My research involves the study of prisons as institutional structures, or of prisoners as incarcerated persons. (This category is usually used fairly narrowly as when looking at prisoner diet and conditions of prison life.)

Justify how the research presents no more than minimal risk and no more than inconvenience to the participants

Category 3 (45 CFR 46.306(a)(2)(iii))

My research involves the study of conditions particularly affecting prisoners as a class. (This category is less frequently used than the previous ones and refers to such research as vaccine trials, research on hepatitis, and social and psychological problems such as alcoholism, drug addiction, and sexual assaults. Minimal risk studies should not go under this category.) For DHHS-funded research, OHRP has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of its intent to approve such research.

Note: Contact the Office of Research Compliance at (205) (348-8461 for more information

Explain what condition(s) will be studied and provide rationale for each:

Category 4 (45 CFR 46.306(a)(2)(iv))

My research involves the study of practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. (Note: It is rare for research involving placebo or control groups to fall in this category because of the difficulty in justifying improvement of the health or well-being of the participant being given placebo or in a control group.) For DHHS-funded research which requires the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after OHRP has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of its intent to approve such research.

Note: Contact the Office of Research Compliance at (205) 348-8461 for more information.

information.

Explain the research practices that will be used in this study and how they are intended to improve the health and well-being of the participants:

Section 2. [45 CFR 46.305]

Note: When an IRB is reviewing a protocol in which a prisoner will be a participant, the IRB must find and document justification that six additional conditions are met. Describe in the space provided how each condition applies to your research.

1. Advantages acquired through participation in the research, when compared to the prisoners' current situation, are not so great that they impair their ability to weigh risks.

Describe the possible advantages that can be expected for prisoner participants:

2. Risks are the same as those that would be accepted by non-prisoners.

Describe the possible risks that can be expected for prisoner participants and justify that they are the same as for non-prisoners:

3. Procedures for selection are fair to all prisoners and are immune from intervention by prison authorities in prisons; control participants must be randomly selected.

a) **Describe how prisoners will be selected for participation:**

b) **Describe what measures will be taken to prevent intervention by prison authorities in the selection process:**

4. Parole boards cannot take into consideration a prisoner's participation in research. Informed consent must state participation will not affect length of sentence or parole.

5. For studies that require follow-up, provisions are made including consideration for the length of individual sentences; informed consent must reflect provisions for follow-up.

Describe what provisions have been made for follow-up and how this information will be relayed to the prisoner participants:

6. Information about the study is presented in a language understandable to prisoners.

Describe what efforts have been made to present information about the study in a language that is understandable to the prisoner population. This may mean a non-English language or an appropriate reading level in whatever language the prisoner uses.:

Section 3. Only complete if applicable: Epidemiologic Research Involving Prisoners and Funded by the Department of Health and Human Services (DHHS)

Note: Effective June 20, 2003, DHHS adopted policy that allows waiver of the requirement for documenting applicability of a 45 CFR 306(a)(2) category (as found in Section 1 of this form) for certain epidemiologic research involving prisoners. This waiver applies to DHHS conducted or supported epidemiologic research on prisoners that presents no more than minimal risk and no more than inconvenience to the prisoner-participants.

Check the box below if your research meets the listed criteria, then provide justification in the space provided.

1. My research is funded by HHS and I request a waiver for meeting the category

conditions under Section 1 of this form.

2. My research involves epidemiologic research intended to describe the prevalence/incidence of a disease by identifying all cases, or to study potential risk factor associations for a disease; and
3. Prisoners are not the sole focus of my research.

Justify how the research presents no more than minimal risk and no more than inconvenience to the participants:

Section 4. Complete if applicable:

Prisoners are not the targeted population

Note: Although prisoners may not be the target population for your research, a participant could become a prisoner during the course of the study (particularly if studying a subject population at high-risk of incarceration).

Note: If you did not receive IRB approval for involvement of prisoners, and a participant becomes a prisoner during the study, all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated participant must cease until IRB approval has been issued for their continuation in the research. If you need IRB approval for a prisoner participant to continue participation in your research, select and complete the applicable category from Section 1, complete section 2 and this section, then submit for IRB review.

In special circumstances in which the Principal Investigator asserts that it is in the best interest of the participant to remain in the research study while incarcerated, the IRB Chairperson may determine that the participant may continue to participate in the research prior to satisfying the requirements of Subpart C. However, subsequent IRB review and approval of this completed form, documenting that the requirements of Subpart C are met, is required.

Prisoners are not a target population for my research, but a participant became a prisoner during the study and I am seeking IRB approval so the participant can continue participation in the research.

Explain the importance of continuing to intervene, interact, or collect identifiable private information during the participant's incarceration:

Note: Prisoner: An individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism,) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution [45 CFR 46.303(c)]. Note: Persons on Probation and parole are usually NOT considered to be prisoners.

If you will receive or are seeking Department of Health and Human Services (HHS) funding for this study, a certification letter must be submitted to the Office for Human Research Protections (OHRP). The research cannot be initiated until OHRP issues approval. The Office of Research Compliance (ORC) will prepare and submit the certification report to OHRP. Contact the Director for the Office of Research Compliance at 205-348-8461 8641 for more information.

***** Risks *****

8. Risks

There is no research that can be considered totally risk free (e.g., a potential risk of breach of confidentiality). Therefore, when describing the risk, the lowest level of risk is "no more than minimal risk".

- a) For the following categories include a scientific estimate of the frequency, severity, and reversibility of potential risks. Wherever possible, include statistical incidence of complications and the mortality rate of proposed procedures. Where there has been insufficient time to accumulate significant data on risk, a statement to this effect should be included. (In describing these risks in the consent form to the participant, it is helpful to use comparisons which are meaningful to persons unfamiliar with medical terminology).

Address any risks related to (input N/A if not applicable):

1. Use of investigational drugs. Please include the clinical adverse events (AEs) associated with each of the drugs with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with placebos or washout periods that participants may experience while in the study.

na

2. Use of investigational devices. Please include the clinical adverse events (AEs) associated with each of the devices with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with procedures that participants may experience while in the study.

na

3. Use of FDA approved drugs, reagents, chemicals, or biologic products. Please include the clinical adverse events (AEs) associated with each of the drugs with an indication of frequency, severity and reversibility. This information can often be found in the package insert provided by the manufacturer. NOTE: Include any likely adverse effects associated with placebos or washout periods that participants may experience while in the study.

na

4. Use of FDA approved devices. Please include the clinical adverse events (AEs) associated with each of the devices with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with procedures that participants may experience while in the study.

na

5. Describe any risks related to performing study procedures. Please include all investigational, non-investigational, and non-invasive procedures (e.g., surgery, blood draws, treadmill tests).

na

6. Describe any risks related to the use of radioisotopes/radiation-producing machines (e.g., X-rays, CT scans, fluoroscopy).

na

7. For clinical studies (of a drug, vaccine, device or treatment), describe any alternative procedure(s) or course(s) of treatment. List important risks and benefits of these alternatives in order to compare to study procedure(s) or course(s) of treatment. This information MUST be included here. Any standard treatment that is being withheld must be disclosed and the information must be included in the consent form.

na

- 8a. Describe any other physical, psychological, social or legal risks the participant may experience.

There is no expectation of risk associated with participation. The personal identification code provided by the student is converted into a hashed identification code using a cryptographic hash function (SHA256). This conversion is done on the client-side (i.e. on the web browser using the JavaScript jquery.sha256 library:

<https://github.com/alexweber/jquery.sha256>) prior to data transmission to the Washington University in St. Louis Biology Department servers. Hence the original name or ID provided by the student is not part of the submitted data. However, each unique identification code provided by the student will produce a unique digest, which allow us to match the pre and post course data. Surveys and quizzes will continue to be hosted on the Washington University in St. Louis servers as the study is transferred to the University of Alabama.

8b. Data Safety Monitoring

Is there a Data Monitoring Committee (DMC) or Board (DSMB)? N/A

If yes, describe its role, if it is independent of the sponsor or research team, the make-up of the Board and their qualifications, and how often the Board will meet.

If no, please justify why not.

Is there a Data Safety Monitoring Plan (DSMP)? N

If yes, describe the data and safety monitoring plan developed to ensure the safety of participants and the validity and integrity of research data. Monitoring should be commensurate with risks and with the size and complexity of the trials. As such, state that SAEs will be reviewed by a qualified MD in real time and indicate how often aggregate data will be reviewed for safety trends.

If no, please justify why not.

There is no complexity and minimal risk involved in this study.

***** Benefits/Alternatives, Procedures to Maintain Confidentiality *****

9. Benefits/Alternatives

- a) **Benefits.** Describe the potential benefit(s) to be gained by the participants and how the results of the study may benefit future participants and/or society in general. Indicate if there is no direct benefit to the participants.

Participant Benefits for students:

1. Gain experience with bioinformatics tools, genomic analysis, working with large data sets;
2. Develop analytical skills while gaining a better understanding of genes and genomes;
3. Gain a sense of how research is accomplished, how new knowledge is created in this field;
4. See oneself as a scientist, have greater confidence in asking questions, exploring the unknown;
5. For those returning completed projects, become a co-author on a genomics research paper

The GEP is already making important contributions to the science education literature, providing evidence that a CURE in genomics can have the same impact in developing an understanding of how science is done as a summer research experience (Lopatto et al. 2008, Science 322: 684; Shaffer et al. 2014, CBE-Life Sci Edu, 13: 111-130). Capitalizing on the diversity of partners and implementation approaches in the GEP, we will identify and test "best practices" that help students "think like scientists" and self-identify as members of a scientific community. Lessons learned should contribute to our foundational knowledge on how to help our students to acquire the intellectual habits and self-confidence that lead to success in the sciences.

- b) Alternatives. Describe any alternative treatments and procedures available to the participants should they choose not to participate in the study. If no such alternatives exist, please state that the alternative is nonparticipation. For some studies, such as record reviews, a description of alternatives would not be applicable.

na

10. Procedures to Maintain Confidentiality

Federal regulations require that study data and consent documents be kept for a minimum of three (3) years, and HIPAA documents be kept for a minimum of six (6) years after the completion of the study by the PI. For longitudinal or sponsored projects, the PI may be required to keep the data and documents for a longer time period.

Data Security

Please indicate how information will be secured. All information must be stored using at least two of the following safeguards and must be kept in accordance with the University of Alabama Information Security Policies. (If you are using both electronic data and hard copy data, you will need two safeguards for each type).

- a) Electronic Data: (mark all that apply - at least 2 - or indicate not applicable)

Not applicable

Password access

Coded, with a master list kept as a hardcopy or on a secure network (confidential)

Data collected anonymously

Secure network (e.g., firewall)

Data are de-identified by PI or research team

Other

Please specify:

- b) Hardcopy Data: (mark all that apply - at least 2 - or indicate not applicable))

Not applicable

Locked suite

Locked office

Locked file cabinet

Coded, with a master list secured and kept separately (confidential)

Data collected anonymously

24 hour personnel supervision

Data are de-identified by PI or research team

Other

Please specify:

- c) Describe measures employed to protect the identity of the participants, their responses, and any data that you obtain from private records (e.g., identifiers will be stripped so data cannot be linked to participants, or code numbers will be used, etc.). If data will be coded, specify the procedures for coding the data so that confidentiality of individual participants is protected. If you will keep a master list linking study codes to participant identifiers, explain why this is necessary, how and where you will secure the master list, and how long it will be kept.

The personal identification code provided by the student (based on their name as it appears on their diver's license) is converted into a hashed identification code using a cryptographic hash function (SHA256). This conversion is done on the client-side (i.e. on

the web browser using the JavaScript jquery.sha256 library: <https://github.com/alexweber/jquery.sha256>) prior to data transmission to the Washington University in St. Louis Biology Department servers. Hence the original name or ID provided by the student is not part of the submitted data. However, each unique identification code provided by the student will produce a unique digest, which allow us to match the pre and post course data. Surveys and quizzes will continue to be hosted on the Washington University in St. Louis servers as the study is transferred to the University of Alabama.

The computer software to administer the survey/quiz data is Qualtrics.

- d) If data or specimens are being shared outside of the research team, indicate who will receive the material and specifically what they will receive (data or specimens).

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- e) If samples or data will be provided from an outside source, indicate whether you will have access to identifiers, and, if so, how identifiable information is protected. Please provide a letter from the appropriate persons indicating that data will be provided in a de-identified manner.

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- f) If data will be collected via e-mail or the internet, how will anonymity or confidentiality be protected? Describe how data will be protected during electronic transmission and how data will be recorded (i.e., will internet protocol (IP) address and/or e-mail addresses be removed from data?).

In order to match the pre and post course results, students are asked to provide a personal identification code when they participate in the surveys and quizzes. Confidentiality is maintained by applying a cryptographic hash function (SHA256) to this identification code prior to data transmission. The application of the cryptographic hash function means that it is computationally infeasible for the GEP staff to determine the original identification code based on the hashed identification code (i.e. digest). Only the hashed identification code is stored with the survey data. Both the GEP surveys and quizzes are hosted on a Washington University Biology Department server (biology4.wustl.edu) that is maintained by Frances Thuet (thuet@wustl.edu), the Senior Computer Systems Manager of the Biology Department. The survey data are stored on the same server. GEP staff members do not have physical or remote access to this system. Surveys and quizzes will continue to be hosted on the Washington University in St. Louis servers as the study is transferred to the University of Alabama.

- g) If you will be audio/video recording or photographing participants, provide a rationale for recording/photographing. Describe confidentiality procedures, including the final disposition of the recordings/photos (destruction, archiving, etc.) and a reasonable timeline by which this disposition will occur.

***** Potential Conflict of Interest *****

11) Potential Conflict of Interest

Federal regulations and UA policy require all investigators to disclose their significant financial interests to allow a review of potential conflicts of interest. If a potential conflict of interest is identified, a formal plan must be developed and implemented to manage, reduce, or eliminate the conflict.

Examples of significant financial interests include receipt of income, honoraria, and stock or stock options from a public or private entity sponsoring the research. They may also include a consulting arrangement or membership on an advisory board of the entity. Significant financial interests are reported on the UA Statement of Financial Interest.

All members of the research team who are involved in the design, conduct, or reporting of research (i.e., senior/key personnel) should have a current Statement of Financial Interest and conflict of interest training on file prior to submitting the IRB protocol. Please refer to the Office for Research Compliance website for additional information regarding the financial conflict of interest requirements, as well as links to the disclosure form and training at (http://osp.ua.edu/site/RC_Col.html).

The Statement of Financial Interest must be submitted annually and within 30 days of discovering or acquiring a new or increased financial interest. Conflict of interest training must be completed once every four years.

If such a relationship as described above exists between a member of the research team and the sponsor of the research, the investigator is also required to disclose this relationship and identify the entity involved on the informed consent form. For questions regarding Conflict of Interest consult the Conflict of Interest in Research Policy.

Check one of the following:

- 1) No Financial Interest or Financial interest less than or equal to \$5K
- 2) Financial Interest exceeding \$5K but not exceeding \$25K, and/or more than 5 percent equity interest in aggregate
- 3) Financial Interest exceeding \$25K

Check all those that apply:

Consulting

Speaking Fees or Honoraria

Gifts

Patent

Copyright

Licensing agreement or royalty income

Equity interests, (including stock, stock options, warrants, partnership or equitable ownership interests), or serving on a scientific advisory board or board of directors

Other fees/compensation

Describe financial interests(s) and indicate specific amounts for each subcategory checked. Be sure to describe how these financial interests relate to the protocol being submitted.

Note to Investigator(s) Reporting a Potential Conflict of Interest

Investigator(s) must have:

- 1) Current, up-to-date Conflict of Interest Disclosure Form on file with the University of Alabama Conflict of Interest Committee (COIC) that describes any financial relationship indicated above.
This information must be disclosed on the University of Alabama confidential Conflict of Interest Disclosure Form for review by the COIC before accruing research participants in this study. If your current Disclosure Form does not contain this information, you are required to submit an updated Disclosure Form to the COIC.
- 2) Financial disclosure statement incorporated into the consent document. Please see Model Consent for suggested language.
- 3) You may not begin your study until your disclosure form has been reviewed and any required management plan has been approved by the COIC.

Does any member of the study team, members' spouses, or members' dependent children have any significant financial interests related to the work to be conducted as part of the above-referenced project?

N

Name of Personnel with Financial Conflict of Interest

Other research staff that may have a conflict. Please specify below.

[Empty text box]

Any member of the study team who answers in the affirmative must be listed in the box below.

[Empty text box]

A staff person will contact any researcher listed above to obtain additional information regarding the specific financial interest(s).

I certify that all members of the study team have answered the financial interests question and only those individuals listed in the box above have disclosed any financial interest related to this study. Y

*** Informed Consent ***

12 Informed Consent

Federal regulations require that informed consent be obtained from individuals prior to their participation in research unless the IRB grants a waiver of consent. Answer the questions, below, then click Add to provide the necessary consent documents and information regarding participant consent. Multiple consents/waivers may be added, but they must be uploaded one at a time.

NOTE: You may refer to the University of Alabama IRB Guidance for Obtaining Informed Consent for considerations regarding the consent/assent process.

State N/A if not applicable.

1) How is consent being obtained? When and where will the discussion take place?

The professor or their representative (e.g. TA) will describe the study to students in class and provide in the data collection website link and login information. Students will then have the option to complete the survey quiz on their own time. Students will read the consent documents on the survey/quiz landing page when they log into the website. By clicking to continue to the assessment instrument they will indicate their consent.

2) Explain how risks, benefits, and alternatives will be discussed.

The students will be told that their identifiable information will be immediately encrypted and unavailable to their course instructor. Their data will be kept confidential. It will be explained that there are no expected direct benefits to participation in the study other than further self-exploration and that the alternative is to not participate.

Informed Consent

Title	Consent Type	Attached Date
Pre_Survey	Consent	12/04/2018
Pre_Quiz	Consent	12/04/2018
Post_Survey	Consent	12/04/2018
Post_Quiz	Consent	12/04/2018

*** Assent ***

13 Assent

Complete this section if your study includes minors. An assent document should be used if participants are 6 to 18 years of age. The Assent Form Template provides guidelines for writing assent documents.

1) Will minors be asked to give assent? If not, please justify.

[Empty text box]

Note: For studies that require a discussion about reproductive risks, note that the conversation with the minor should take place separately from the parents. Also, if a minor will reach adulthood (18 in Missouri) during the course of the study, they will need to be asked to

consent as an adult at that time to continue in the study.

***** HIPAA *****

14 HIPAA

Studies that receive or create protected health information (PHI) are subject to HIPAA regulations. PHI is health information with one or more personal identifiers. For more information see: <http://www.ua.edu/research/index.html> If you are working with UMC, then a separate IRB approval is required. This must be obtained prior to IRB submission and attached.

1) Will health information be accessed, received or collected?

No health information. HIPAA does not apply.

Yes (continue to question 2).

2) Which personal identifiers will be accessed, received or collected?

No identifiers. I certify that no identifiers from the list below will be received or collected and linked to health information. HIPAA does not apply (skip remainder of page).

Names

Social Security numbers

Telephone numbers

Linkable code or any other unique identifying number (note this does not mean the unique code assigned by the Investigator(s) to code the research data)

All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000

All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

Fax numbers

Electronic mail addresses

Medical record numbers

Health plan beneficiary numbers

Account numbers

Certificate/license numbers

Vehicle identifiers and serial numbers, including license plate numbers

Device identifiers and serial numbers

Web Universal Resource Locations (URLs)

Internet Protocol (IP) address numbers

Biometric identifiers, including finger and voice prints

Full face photographic images and any comparable images

If you are receiving or collecting health information and at least one personal identifier, HIPAA applies to your study. Please continue to complete the sections, below.

3) Sources of Protected Health Information:

Hospital/medical records for in or out patients
Physician/clinic records
Laboratory, pathology and/or radiology results
Biological samples
Interviews or questionnaires/health histories
Mental health records
Data previously collected for research purposes
Billing records
Other Please describe:

- 4) If data will be shared outside the research team and the study involves PHI indicate how the research team will share the information. Contact the University of Alabama Privacy Officer for guidance on the proper procedures for sharing of protected health information. <http://hipaa.ua.edu/>

Not applicable (continue to question 5).

Only linkable code that can link data to the identity of the participant. A code access agreement or business associate agreement may be needed when data are shared with other non-University of Alabama entities. If necessary, the agreement can be added and uploaded in item #5, below.

Limited identifiers: Zip codes, dates of birth, or other dates only. The study qualifies as a Limited Data Set. A data use agreement may be needed when data are shared with other non-AlaUniversity of Alabamatities. If necessary, the agreement can be added and uploaded in item #5, below.

With unlimited identifiers. The consent document and HIPAA Authorization form must describe how the information will be disclosed.

- 5) A HIPAA Authorization Form or Waiver of HIPAA Authorization is required for this study. Use the table below to add HIPAA Documents for your study. If you are accessing medical records, or other health records that include PHI, you must complete a waiver of HIPAA authorization.

***** Attachments *****

15) Attachments

In this section, please upload additional documents associated with your protocol. Failure to attach files associated with the protocol may result in the protocol being returned to you.

Possible documents for this protocol could include:

Bibliography
Cooperating Institution's IRB Approval
Data Collection Sheet
Debriefing Script
Device Information/Documentation
Grant Proposal/Sub-Contract
Human Participants Training Certificate/Proof of Training
IND Application Letter
Information Sheet/Brochure
Interview/Focus Group Questions
Investigator's Brochure
Letter of Agreement/Cooperation
Package Insert

- Patient Diary Form
- Phone Script
- Questionnaire/Survey
- Recruitment Material (e.g., flyers, ads, e-mail text)
- Recruitment Statement (if there is no waiver of written consent)
- Scientific/PPC Review
- Sponsor's Protocol
- Sponsor's Protocol Amendment
- Study Design Chart/Table
- Waiver Request

Other files associated with the protocol (most standard formats accepted: pdf, jpg, tif, mp3, wmv, etc.)

To update or revise any attachments, please delete the existing attachment and upload the revised document to replace it.

Document Type	Document Name	Attached Date	Submitted Date
Other	GEP_active_institutions_state	11/01/2018	11/01/2018
Questionnaire/Survey	GEP_quiz_B_revised_08_05_2015	11/01/2018	11/01/2018
Questionnaire/Survey	GEP_quiz_A_revised_08_14_2015	11/01/2018	11/01/2018
Human Subjects Training Certificate/Proof of Training	citiCompletionReport1307389	11/19/2018	11/30/2018
Questionnaire/Survey	Pre_Course_Survey_2018_lkr_2	12/04/2018	12/04/2018
Questionnaire/Survey	Post_Course_Survey_2018_lkr_2	12/04/2018	12/04/2018
Other	Reed 18-OR-448	12/07/2018	12/07/2018

***** PI Obligations *****

PI Obligations

By clicking the box below, you indicate that you accept responsibility for and will follow the ethical guidelines.

1) Have you completed the annual Statement of Financial Interest (i.e., disclosure)? Y

NOTE: An annual disclosure must be completed by all faculty, staff, and students who are identified as senior/key personnel receiving federal funding for research. The disclosure can be completed online at <https://www.formstack.com/forms/index.php?1338617-e6Kw9EILFS>.

2) Have your financial interests changed significantly since you completed the annual disclosure form? Y

According to the UA policy on conflict of interest, it is the PI's responsibility to inform co-investigators, staff, or students involved in the design, conduct, or reporting of federally sponsored research of their requirement to complete the Statement of Financial Interest.

I accept this responsibility.

By submitting this form, the PRINCIPAL INVESTIGATOR certifies that he/she has read the UA policy on conflict of interest and has a current Statement of Financial Interest on file. In

addition, the PI certifies that, to the best of his/her knowledge, no person working on this project at UA has a conflict of interest or, if a conflict of interest does exist, an appropriate management plan is in place.

X The Principal Investigator has read and agrees to abide by the above obligations.

The Department Chair has read and agrees to abide by the above obligations.

The Faculty Sponsor / Mentor has read and agrees to abide by the above obligations.

***** Event History *****

Event History

Date	Status	View Attachments	Letters
10/23/2018	NEW FORM CREATED		
11/01/2018	NEW FORM SUBMITTED	Y	
11/09/2018	NEW FORM RETURNED		
11/30/2018	NEW FORM RESUBMITTED	Y	
11/30/2018	NEW FORM RETURNED		
12/04/2018	NEW FORM RESUBMITTED	Y	
12/04/2018	NEW FORM PANEL ASSIGNED		
12/04/2018	NEW FORM REVIEWER(S) ASSIGNED		
12/07/2018	NEW FORM APPROVED	Y	Y