
Protocol Title:	Social Networks and Engagement with Science Issues
Protocol Status:	APPROVED
Date Submitted:	07/22/2020
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
Barnidge, Matthew		Assistant Professor

Email	Phone	Fax
mhbarnidge@ua.edu	205-348-7544	

Department Name
Journalism and Creative Media

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.	X	Recruitment	2.	X	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.	X	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.

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
Armstrong, Cory		Faculty, Professor and Department Chair

Email	Phone	Fax
cory.l.armstrong@ua.edu	+1 205 348 9684	

Department Name

Journalism and Creative Media

Human Subjects Training Completed? Y

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?

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.

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* * * Subject Population * * *

Subject Population(s) Checklist

Select All That Apply:

- [X] 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)

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* * * Study Location * * *

Study Location(s) Checklist

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

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

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* * * General Checklist * * *

General Checklist

Select All That Apply :

- [X] Study Eligible for Exempt Review
- [ ] Non-human participants research
- [ ] Collection of Specimens
- [ ] 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
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)

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* * * Funding * * *

Funding Checklist

X NONE

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.

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* * * Exempt Paragraphs(s) * * *

Federal regulations state that certain research is exempt from IRB oversight. However, a research protocol proposing the use of human participants must be submitted to the IRB to determine if it qualifies for exempt status. EXEMPTIONS DO NOT APPLY TO RESEARCH CONDUCTED ON PRISONERS.

45CFR46.101(b) Unless otherwise required by Department or Agency heads, research activities in which the ONLY involvement of human participants will be in one or more of the following categories are exempt from this policy:

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

1. **Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:**

   i) research on regular and special education instructional strategies, or

   ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

   Information Required for Justification

   a) **Explain how the research is part of the commonly accepted educational setting at the research site(s) you listed in Study Locations and how the research involves normal educational practices.**

X 2. **Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:**

   i) information obtained is recorded with identifiers linked to the participants; AND

   ii) disclosure of participants' responses could place participants at risk (e.g., criminal or civil liability, financial standing, employability or reputation).

Information Required for Justification

a) Describe the type of educational test, procedure or observation.

The study will consist of an online survey hosted on the Qualtrics platform, administered to adult volunteer participants recruited by Qualtrics.

b) State how the information will be recorded and indicate any risk: Is information identifiable? If so, could disclosure of responses put participants at risk? If information is identifiable and disclosure of responses could put participants at risk, the study will not qualify as exempt

No identifying information will be collected. Qualtrics collects identifying information in order to compensate participants, but this information is stored on their servers and not included in the dataset available to the researcher. Anonymous Qualtrics IDs will be included in this dataset, but the researcher will remove this information before saving and storing the dataset.

NOTE: Exemption for research involving survey or interview procedures or observation of public behavior does not apply to children as participants except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category two, if:

i) the participants are elected or appointed public officials or candidates for public office; or

ii) Federal statute(s) require(s) without exception that the confidentiality of identifiable information will be maintained permanently.

Information Required for Justification

a) Describe the type of educational test or procedures to be used in research activity.

b) Discuss how the research qualifies for exemption based on item (i) or (ii) above.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

Existing means that the materials are "on the shelf" at the time of IRB approval; prospective collection is not permitted.

Examples of publicly available information: driver's license and court records.

NOTE: Secondary analysis of an anonymous dataset (i.e., data containing no individually-identifiable information) does not meet the definition of human participant research and does not require submission to the IRB.

Information Required for Justification

a) State: type of and source(s). from which data/specimens will be collected, and if they are publicly available.

b) Confirm that materials are existing, (e.g., provide dates) and discuss the method that will be used to record the data to assure that individual participants cannot be linked to the research activity (i.e., no code numbers may be used to link the research data to the participant). Research will not meet the criteria under this category unless it is clearly indicated that no one (including the PI) will be able to link the data to any individual after the information is recorded

as part of the research.

NOTE: Upload a copy of the data collection sheet (e.g., a list or spreadsheet of the questions or data elements to be collected or studied).

5. Research and demonstration projects which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

   i) public benefit or service programs;
   ii) procedures for obtaining benefits or services under those programs;
   iii) possible changes in or alternatives to those programs; or
   iv) possible changes in methods or levels of payment for benefits or services under those programs.

   Information Required for Justification

   a) Is this research subject to approval of Federal Department or Agency heads? Please explain.

   b) Discuss the purpose of the research. Discuss how the study qualifies for exemption based on item (i), (ii), (iii), or (iv) above.

   See Tips Sheet for guidance about whether this exemption category is appropriate for your study.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental containment at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

   Information Required for Justification

   a) Explain the purpose of research.

   b) Discuss how the research qualifies for exemption based on item (i) or (ii) above.

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

Study Title

Social Networks and Engagement with Science Issues

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.

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

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.

The purpose of the research is to understand how the ways that people use social media may affect how they understand scientific and/or environmental issues.

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

The study will explore the connections between demographics, network composition, exposure to science news, and knowledge of scientific issues. The study expects to find that social inequalities will manifest in online social networks, which in turn shape exposure to science news and affects what people learn about science.

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
Other

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

e) Will participant be randomized?

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

3) Study Procedures

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

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

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

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.

This project will involve an online survey that will take approximately 20 minutes for participants
to complete. The survey will include a variety of questions about participants' media habits, and
the types of people they interact with online and offline, as well as a variety of factual questions
about four contemporary science and technology issues - Vaccines, Artificial Intelligence, Climate
Change, and Covid-19. Additional survey items will enable us to collect relevant

data on
participant demographics, political predispositions, and political attitudes.

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.**

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).**

Data analysis will be performed using R statistical software. Statistical tests will include t-tests, linear regression, and structural equation modeling. Results will be reported at the aggregate level.

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* * * 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	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.	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.

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* * * 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.

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* * * 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.

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* * * 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).**

18-99 years

b)	i) Number to be directly solicited for this research.	N/A	2571
	ii) Number to be consented (including withdrawals or screen failures)	N/A	1800
	iii)Number expected to complete the study.		1500
c)	If this is multi-center study, number of participants to complete the study study-wide	X 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.**

NA

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.

Participants will be recruited from Qualtrics' panel of participants.

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

7. Subject Population (continued)

i) Inclusion and Exclusion Criteria.

Identify inclusion criteria.

Qualtrics panelists who are 18+, US residents, and active Facebook users are eligible to participate in the study.

Identify exclusion criteria.

Exclusion criteria include younger than 18, non-US resident, and not an active Facebook user.

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.

Participants will be compensated by Qualtrics in an amount agreed upon by the participants.

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

The researcher will cover all study related costs.

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.

Participation in the survey should take approximately 20 minutes. Data collection will take place over the course of one week in late August 2020. Data analysis will take place in September-December 2020. Paper writing will take place in January-May 2021. Publication of the manuscript(s) should be complete by May 2023.

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* * * 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.

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* * * 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 subjparticipantl 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.

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* * * 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 women 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.

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* * * 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.

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 statue; (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.

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* * * 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.

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

We don't anticipate anything more than minimal risks to participants from participation in this study.

8b. Data Safety Monitoring

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

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)?

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.

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* * * 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.**

There are no direct benefits to participants.

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.**

The alternative is non-participation.

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
- [X] Password access
- [ ] Coded, with a master list kept as a hardcopy or on a secure network (confidential)
- [X] 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))

- [X] 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.

Qualtrics will anonymize all survey responses prior to providing the data to our research team. Anonymous Qualtrics IDs will be included in the dataset, but the researcher will remove these before saving and storing the data. Data will be stored on UABox and accessed via a University-issued, password-protected computer.

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).

NA

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.

NA

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?).

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.

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* * * 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_CoI.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) X 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.

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

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

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* * * 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?

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

Informed Consent

Title	Consent Type	Attached Date
Consent Form	Waiver of Written Consent	07/22/2020

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* * * 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.

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.

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* * * 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?

X 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.**

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* * * 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
Questionnaire/Survey	Science_and_Technology_Survey	07/22/2020	07/22/2020

Other	Barnidge 20-07-3772	08/05/2020	08/05/2020

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* * * 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? N

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.

X **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.

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* * * Event History * * *

Event History

Date	Status	View Attachments	Letters
07/22/2020	NEW FORM CREATED		
07/22/2020	NEW FORM SUBMITTED	Y	
08/03/2020	NEW FORM PANEL ASSIGNED		
08/03/2020	NEW FORM REVIEWER(S) ASSIGNED		
08/05/2020	NEW FORM APPROVED	Y	Y