IMPORTANT NOTES

- Research projects that involve human participants must be reviewed and approved by the USU Institutional Review Board (IRB) **prior to beginning research.**
- IRB review and approval of research using the General Application usually takes **6 - 8 weeks** and research cannot be initiated until IRB approval is granted.
- Your proposal and IRB application must be congruent, however, you should not necessarily cut and paste from the proposal into the application unless it answers the question.
- USU policy requires that all researchers successfully complete **training in human subjects research (CITI Certification)** via on-line modules at [www.citiprogram.org](http://www.citiprogram.org). Successful completion is defined as obtaining a score of 80% or higher. Click the following link to check your current IRB certification status. [http://www.irb.usu.edu/htm/facultystaff-completed-certifications](http://www.irb.usu.edu/htm/facultystaff-completed-certifications) To complete CITI Certification click the following link for login procedures and instructions [www.citiprogram.org](http://www.citiprogram.org).

### A. Basic Project Information

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<td><strong>Project Title:</strong></td>
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<td><strong>Principal Investigator(s) (USU researchers only):</strong></td>
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<td>Date IRB certification expires:</td>
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<td><strong>Co-Principal Investigator(s) (who are not students):</strong></td>
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<td><strong>Student researcher(s):</strong></td>
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Honor Students:
Is this research to complete the requirements for an Honors Thesis?  Yes ☐  No ☐

Graduate Students:
Is this research for:
Plan A (thesis or dissertation)?  Yes ☐  No ☐  Date of committee approval
Plan B (creative project)?  Yes ☐  No ☐  Date of committee approval
Plan C (extra class – no project)?  Yes ☐  No ☐

If Plan A or B, committee must approve prior to IRB submission (attach copy of signed committee approval page to this application,

Anticipated Start Date of Research:  Anticipated End Date of Research:

Will this project be supported by one of the following?  Yes ☐  No ☐
If YES, check which type below and specify the funding agency or source:
☐ External funding agency
☐ Internal funds
☐ AES/Extension

Is there a USU Sponsored Programs control number for this project/protocol?  Yes ☐  No ☐
If YES, provide Control Number:  (This is found on the SP-01 form)

Scientific Validity
The Common Rule (45 CFR 46) requires that for all non-exempt research, “In order to approve research ... the IRB shall determine that ... risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk...”

The requirement to ensure sound research design can be fulfilled through several means at USU. Please CHECK ONE box below to indicate what, if any, review the proposal has undergone to determine its scientific validity.

☐ The proposal has undergone peer review and been selected for funding by an external sponsor.
Identify agency (e.g., NIH, NSF, DOE):
Attach documentation from the agency review. Scientific Validity Review Checklist is not required.
The proposal has been reviewed through an internal (USU) review process (e.g., GEM, SPARC, Ag Experiment Station). Attach documentation from the review and a completed Scientific Validity Review Checklist to this application.

The proposal is for thesis or dissertation research (Plan A). It has been reviewed and has received approval from the student’s committee. Attach documentation of approval (cover sheet signed by committee) and a completed Scientific Validity Review Checklist to this application.

The proposal is a Plan B or Plan C project. It has been reviewed and has received approval from the student’s committee (minimum of 3 faculty members). Attach documentation of this approval (cover sheet signed by committee) and a completed Scientific Validity Review Checklist to this application.

The proposal has not yet been reviewed. The IRB will appoint one of its members, an independent researcher or a qualified consultant to conduct a review, using the Scientific Validity Review Checklist. If you would like to recommend a researcher who would be qualified to review this proposal, please provide their name and contact information here:

B. Study Background/General Information

1. What is the purpose of this research (provide a concise statement of 2-3 sentences):

2. List the research question(s)/hypotheses for this study (do not include your rationale for why you have chosen your research questions):

3. Is this a multi-center study (e.g., research being conducted at two or more separate universities or research being conducted in partnership with community agencies)? Yes [ ] No [ ]
   a. If yes, list other participating institutions/agencies and explain the responsibilities and obligations of each center and/or each investigator:
   b. If yes, has this study been, or will it be reviewed/approved by another IRB? Yes [ ] No [ ] If yes, give the name of the IRB and contact information (include name, address, telephone):

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4. If compensation (e.g., money, gift cards) or incentives (e.g., extra class credit) are offered to participants, provide a description of the amount of money and schedule of payments or type of incentive. *(Type N/A if not applicable)*

5. Provide a description of procedures already being performed on the participants for non-research purposes that may be related to this study. Examples may include existing therapy or treatment, educational programs or physical activity programs. *(Type N/A if not applicable)*

**C. Participant Information**

1. Describe your research population:
   a. What age or age range(s) will the participants be?
   b. List the inclusion criteria for participants including the source of subjects, i.e. public school, clinic, general population, university students, etc.:
   c. List the exclusion criteria for participants:
   d. Does this study involve participants (or parents, guardians, or wards) who are not fluent in English? **Yes** □ **No** □  *If yes, you will be asked to submit a translation of the consent document in the appropriate language(s), after the contents of the English version have been finalized and approved. Participants (or parents, guardians, or wards) who do not read and/or speak English must have the consent form written and/or read to them in their native language. They must sign a form indicating that the informed consent has been explained to them in their native language, and that all of their questions have been answered. **Participants may not be excluded from research based solely on language ability**
   e. Will the researcher be asking about individuals other than those from whom informed consent has been received? **Yes** □ **No** □  
      If yes, explain:
      If yes, can these people be identified? **Yes** □ **No** □

2. Number of anticipated participants by gender
   a. How many subjects will be invited to participate?
      Male: Female: Total:
   b. How many do you anticipate will participate or complete the study?
      Male: Female: Total:
Provide justification for your sample size. *The number of participants must be sufficient to appropriately answer the research question(s). Small scale designs are acceptable if such designs adequately answer the research question(s):*

3. Explain how participants will be identified/recruited:
   Will recruitment materials be used? **Yes** **No**
   Click Here to access IRB Advertising Guidelines. Please submit a draft copy of advertising or recruitment materials for review.

**D. Vulnerability of Participants**

*Participants who are vulnerable are often included in research even though they are in protected categories. If you answer YES to any of the items below, explain your rationale for selecting vulnerable participants and indicate whether the use of such participants is a necessary part of the research or if such participants are included incidentally as members of a more general population. If vulnerable participants are necessary, provide an explanation.*

1. Are participants younger than 18 years of age? **Yes** **No**
   - If yes, is this necessary **or** incidental **?**
   - If necessary, explain:

2. Are participants older than 65 years of age? **Yes** **No**
   - If yes, is this necessary **or** incidental **?**
   - If necessary, explain:

3. Are participants cognitively impaired? **Yes** **No**
   - If yes, is this necessary **or** incidental **?**
   - If necessary, explain:

4. Do participants have a known physical or mental illness or condition that impairs their ability to consent? **Yes** **No**
   - If yes, is this necessary **or** incidental **?**
   - If necessary, explain:
5. Are participants potentially pregnant (most females over age 10 and under age 55 may be potentially pregnant)? Yes □ No □
   - If yes, is this necessary □ or incidental □?
   - If necessary, explain:

6. Are participants prisoners? Yes □ No □
   - If yes, explain:

7. Are participants institutionalized or adjudicated (in a detention center, hospital, or other residential setting)? Yes □ No □
   - If yes, is this necessary □ or incidental □?
   - If necessary, explain:

8. Are participants at risk for coercion (e.g. students in your class, employees, etc.)? Yes □ No □
   - If yes, is this necessary □ or incidental □?
   - If yes, explain how you will minimize the perception of coercion:
     Coercion Guidelines

If you answered YES to any of questions C1-C8 above, and participation is necessary and not incidental, describe any additional safeguards and to demonstrate that risks have been minimized to protect the rights and welfare of the vulnerable participants, (e.g., a process for obtaining informed consent and a monitoring process, a data safety monitoring plan).

E. Waiver or Alteration of Informed Consent Requirements
Written documentation of informed consent that embodies all the required elements of informed consent, as described in 45 CFR 46.116, is required for all research subjects. With sufficient justification, the IRB may approve a consent process that does not include, or which alters, some or all of the elements of informed consent provided that it finds and documents specific requirements.

- If you are NOT requesting a waiver or alteration of informed consent requirements, SKIP to Section F.
- If you would like to request a waiver or alteration of informed consent requirements, choose EITHER Option 1 or 2 below and complete that section, then Skip to Section G.
1. If requesting a waiver or alteration of the requirements to obtain informed consent, justify such in accordance with each of the following four criteria established under 45 CFR 46.116(d) (1-4).

   a. The research involves no more than minimal risk* to the subjects
   b. The waiver or alteration will not adversely affect the rights and welfare of the subjects
   c. The research could not practicably** be carried out without the waiver or alteration; AND
   d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

2. If requesting a waiver or alteration from the requirements for written documentation of informed consent, justify such in accordance with at least one of the criteria established under 45 CFR 46.117(c) (1 or 2).

   a. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. In this case, each subject will be asked whether s/he wants documentation linking the subject with the research, and the subject’s wishes will govern; OR
   b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

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

** Practicable refers to instances in which the additional cost would make the research prohibitively expensive, or where the identification and contact of thousands of potential subjects would not be feasible for the anticipated results of the study. Practicable would not mean an inconvenience or increase in time or expense to the investigator or the research.

3. If requesting a waiver of the documentation of consent, attach a draft Letter of Information using the template. Describe how the Letter of Information will be provided to participants (in person, mailed with questionnaire, sent to home, etc.). (If not applicable, type NA)

4. Describe procedures that are in place other than the translation of the Letter of Information to allow research staff to communicate with non-English speaking participants in a language the participants can understand. (If not applicable, type NA)

Skip to Section G.

F. Informed Consent (Informed Consent Checklist) Informed Consent Template
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1. **How** will informed consent be obtained (e.g., verbally for phone interview, via use of video tape, in person, via consent sent to home and returned, etc.)? Clearly describe the process that will be used:

2. **Who will obtain** informed consent (e.g., PI, research assistant, teacher, counselor)?
   
   Individuals who carry out the consent process in person or verbally with participants must have completed CITI training:

3. **Who will provide** consent or permission (e.g., participant, parent(s), or legally authorized representative):

4. What is the waiting time, if any, between informing the prospective participant about the study and obtaining consent:

5. What procedures are in place other than the translation of the consent document to allow research staff to communicate with non-English speaking participants in a language the participants can understand:

**G. Procedures**

1. Explain what participants will be asked to do as part of your research (written or on-line survey, interview, treadmill test, blood test, assessments, etc.). Provide a step by step explanation of the study procedures:

2. How long will participants be involved in this research (e.g., one session, multiple sessions, minutes, hours, days, etc.):

3. What is the proposed duration of this study (time needed for all research activities to be completed):

4. Provide a description of the setting in which the research will be conducted:

**H. Risks and Benefits (Both risks and benefits must be addressed)**
1. **Investigator Assessment of Risk**

   Please indicate the level of risk to participants you feel is associated with participation in this study (check only one box):
   - 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 examinations or tests.
   - Minor increase over minimal risk *(Note: this level is only applicable to some research involving children as participants)*
   - Greater than minor increase over minimal risk

2. If the research involves more than minimal risk to participants, describe the provisions for monitoring the data collected to ensure the safety of participants (e.g. Data and Safety Monitoring Plan involving ongoing review of participant profiles as they are enrolled and study data as they are collected to identify unexpected outcomes and to ensure participant safety. See IRB Handbook, Chapter 6, page 24).

3. What are the risks or discomforts to the participant(s)? *All research has some risk, even if it is minimal. Risks may include loss of confidentiality, anonymity, economic, social, or psychological or physical harm.* Please describe all potential risks related to your research:

   a. What measures will be taken to minimize each of the risks?

4. If applicable, what decision rules will be considered in determining whether a participant should continue in the study or be withdrawn by the PI? *(Type N/A if not applicable)*

5. How will unexpected harms be detected promptly (i.e. periodic record review, observation and reporting by staff or PI)?

6. What are the potential benefits to be gained from this study? *Research involving human participants is unethical if it has no educational or scientific value:*

   **I. Privacy Interests, Privacy and Confidentiality**
Privacy interests refer to how much a participant has control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) within the research. Confidentiality refers to the protection of study data collected from participants, including personal identifying information.

Efforts should be made to separate identifying information from study data. Participants are identifiable when:

- The researcher or colleague maintains a coded list that could be used to match names and codes.
- Addresses or social security numbers or birth dates or other relatively specific information is collected.
- In a state, unit or area with a small population, it may be possible to identify participants through a combination of demographic or other personal characteristics (i.e. grade level or major in school, years of employment, etc.). To minimize the risk of identification of participants for this reason, it is suggested that researchers combine categories/responses where the number of participants in a cell of a table is less than 10.

1. If applicable, provide a description of provisions to protect the privacy interests of participants during the research (i.e. during in-person interviews, when completing written or online questionnaires, during physical or psychological assessments). If not applicable, please explain.

2. If the recruitment process will involve approaching participants who have been referred to the study by an outside source, how will you protect privacy interests of the prospective participants? (Type N/A if not applicable)

3. If data or specimens are collected during a screening process, explain what will be done with those data or materials if the participant declines or is not eligible/selected to participate in the research. (Type N/A if not applicable)

4. If the research is within a specific culture, describe any feelings about privacy within the culture that relate to the research and provisions to protect the privacy interests of participants based on those feelings. (Type N/A if not applicable)

5. Will the research participants be identifiable to the researchers?  Yes ☐  No ☐
• If yes, explain how they will be identifiable and how long identifying information will be kept:

6. What measures will be taken to protect the confidentiality of participant data:

7. How and where will data be stored (e.g., locked file cabinet in locked room, secured computer, etc.)

8. Who will have access to the data:

9. Will any video or photo images or audio records be made?  
   Yes ☐ No ☐  (If yes, this information must be included in the informed consent)
   • If yes, list types:
   • If yes, what measures will be taken to ensure confidentiality of these records:
   • If yes, when will the images or audio records be destroyed?  
     (Timeline for destruction of these records must be included in the informed consent)

J. Reporting

1. Is it possible you will discover a participant’s previous unknown condition (e.g., disease, suicidal thoughts, etc.) as a result of the study procedures?  Yes ☐ No ☐
   • If yes, explain how you will deal with this:

2. Is it possible you will discover a participant engaging in illegal activities (e.g., child abuse, use of illegal drugs)?  Yes ☐ No ☐
   • If yes, explain how you will deal with this:

3. Is it possible you will discover that a participant is a victim of abuse?  Yes ☐ No ☐
   • If yes, explain how you will deal with this:

K. Deception  (Deception Research Checklist)

1. Does this project involve giving false or misleading information to participants or withholding information from them such that their “informed” consent is in question?  Yes ☐ No ☐
• If deception is being used, attach to this application a copy of the debriefing/disclosure statement to be read to the participant(s) upon conclusion of the study.

L. Health Records – (HIPAA Checklist) (Additional Reading)

1. Will any of the data you collect or record consist of existing health records (e.g., medical case notes, evaluations, etc.): Yes ☐ No ☐
   • If yes:
     a. Are there any personal identifiers on the data (e.g., names, birth dates, social security numbers, medical chart numbers, etc.) Yes ☐ No ☐ If yes, please explain:
     b. Will participants authorize use of the data as part of the informed consent process for this study? Yes ☐ No ☐ If yes, please explain:

M. Biological Specimens (Tissue Banking)

1. Will the research involve the collection of biological specimens (e.g., blood, saliva, urine, skin cells, etc.)? Yes ☐ No ☐
   • If yes, will these specimens be stored for future studies after completion of the current research? Yes ☐ No ☐
     o If stored for future studies, explain where they will be stored and how long they will be kept:

N. Conflict of Interest (Definition)

This section pertains to the Principal Investigator and all other Key Personnel involved with this project. The term ‘you’ in these questions refers to the respondent or any of the respondent’s first degree relatives (spouse, children, parents, siblings) or in-laws.

1. Do you have a significant financial interest in or serve as a director or officer in a commercial organization:
   a. that could be involved in this study? Yes ☐ No ☐ If Yes, please explain:
   b. whose business is substantially related to subject matter of this study? Yes ☐ No ☐ If Yes, please explain:
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2. Do you plan to use University facilities or personnel in the conduct of work for your outside interest that will be related to this study?  
Yes ☐  No ☐  If Yes, please explain:

3. Have you or do you expect to receive gifts of $100 or more from a commercial entity that is connected to this study?  
Yes ☐  No ☐  If Yes, please explain:

4. Do you supervise any students or other personnel who will be working on this study and who also work for your outside interest?  
Yes ☐  No ☐  If Yes, please explain:

5. Is this study related to subject matter in which you are aware that another sponsor or entity has a claim to ownership or any rights granted by USU/USURF?  
Yes ☐  No ☐  If Yes, please explain:

"Significant Financial Interest" (SFI) means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g. stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term SFI does NOT include:

(1) salary, royalties, or other remuneration from the institution (Note: royalties paid to an investigator on behalf of Utah State University are not considered reportable SFIs);
(2) income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
(3) income from service on advisory committees or review panels for public or nonprofit entities; or
(4) an equity interest that when aggregated for you meets both the following tests: is less than $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and is less than a five percent ownership interest in any single entity; or
(5) salary, royalties or other payments that when aggregated for you over the next twelve months, are not expected to exceed $10,000.

If any answer to the above questions is ‘yes’ or if you have existing conflicts of interest in relation to previously awarded projects that have not been resolved through the Office of Compliance Assistance, you should contact the Federal Compliance Manager at (435) 797-8305.
O. Investigator’s Assurance: Please read the entire statement below and place your initials as indicated at the end of this section.

“As Principal Investigator, I have ultimate responsibility for the performance of this study, the protection of the rights and welfare of the human subjects, and strict adherence by all co-investigators and research personnel to all Institutional Review Board (IRB) requirements, federal regulations, and state statutes for human subjects research. I hereby assure the following:

- The information provided in this application is accurate to the best of my knowledge.
- Adequate resources are available to carry out this research and ensure participants’ safety
- All named individuals on this project have read and understand the procedures outlined in the application.
- All experiments and procedures involving human subjects will be performed under my supervision or that of another qualified professional listed on this protocol.

I understand that, should I use the project described in this application as a basis for a proposal for research funding (either intramural or extramural), it is my responsibility to ensure that the description of human research used in the funding proposal(s) is identical in principle to that contained in this application.

I and all the co-investigators and research personnel agree to comply with all applicable requirements for the protection of human subjects in research including but not limited to, the following:

- Making no changes to the approved protocol without first having submitted those changes for review and approval by the IRB; and
- Promptly providing the IRB with any information requested relative to the project; and
- Promptly reporting the premature completion of a study; and
- Promptly and completely complying with an IRB decision to suspend or withdraw its approval for the project; and
- Obtaining continuing review prior to the expiration of approval. I understand if I fail to apply for continuing review, approval for the study will automatically expire, and study activity must cease until current IRB approval is obtained.
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I understand that the report of an unanticipated problem may require me to inform participants of the problem.

I assume responsibility for ensuring the competence, integrity and ethical conduct of student researcher(s). I certify that any student researcher(s) is/are fully competent to accomplish the goals and techniques stated in the attached proposal, and that all researchers (faculty and students) have current IRB (CITI) certification.

As PI, I have read and accept the Investigator’s Assurance
(Type initials in box)

P. Are you Ready to Submit Your Application?

Your application MUST be accompanied by the supporting documents (listed below) at the time of submission or the application will be returned to you as “not reviewable.”

1. Proposal (e.g., thesis, dissertation, grant) OR a summary of the purpose, methods and objectives of the study *(Your proposal and IRB application must be congruent, however, you should not necessarily cut and paste from the proposal into the application unless it answers the question.)*
2. Data collection forms, study instruments and/or measures (see section G #1, Procedures).
3. Draft Informed Consent / Letter of Information (see Section F, Informed Consent). Format the informed consent using the current IRB template
4. Recruitment materials (fliers, advertisements) – applicable? Yes□ No□ (See Section C #3, Participant Information)
5. Description of the additional safeguards to protect rights and welfare of vulnerable participants – applicable? Yes □ No□ (See Section D, Vulnerability of Participants)
6. Data and safety monitoring plan – applicable? Yes □ No □ (see Section H, #2, Risks and Benefits)
7. Debriefing/disclosure statement (deception research) – applicable? Yes □ No □ (See Section K, #1, Deception)
8. Signed committee approval page – applicable? Yes □ No □ (See Section A, Graduate Students)
9. Scientific Validity Review Checklist – applicable? Yes □ No □ (see Section A, Scientific Validity)
10. Approval letter(s) from participating IRB(s) – applicable? Yes □ No □ (see Section B, #3, Study Background)

Once the application is complete, email all components (this application and the above supporting documents) to the IRB by clicking here

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Give Feedback to the IRB:

The IRB encourages investigators and research staff to provide feedback regarding the IRB review process and provide suggestions that will improve USU’s Human Research Protection Program. To leave comments and suggestions, click here

Institutional Review Board
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Logan, UT 84322
(435) 797-1821
(435) 797-3769 (fax)
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nancy.sassano@usu.edu
janet.roberts@usu.edu