Research projects that involve human participants must be reviewed and approved by the USU IRB Office prior to beginning research. Complete this form if you believe that your project qualifies for an exemption under the federal regulations at 45CFR46.101(b). If the IRB Office determines that your study is not exempt, you will be notified so that a General Application can be submitted. IRB review and approval of exempt research requires up to 2 weeks and research cannot be initiated until IRB approval is granted.

LIMITATIONS TO EXEMPT CATEGORIES (Exempt categories are found beginning on page 3)

1. Exemption #2: If research activities involve children as participants, procedures cannot involve any of the following activities: surveys, interviews, or observation of public behavior where the investigator(s) participate in the activities being observed. However, educational tests may be exempt. Researchers must be aware of FERPA and PPRA regulations.
2. Research involving prisoners cannot be exempt.
3. Research involving use of personal records such as health care information, drug and alcohol treatment records, psychiatric treatment records, educational records, and other records protected by the Federal Privacy Act and other federal and state laws cannot be exempt.
4. Research that qualifies for exemption must be minimal risk. (Minimal risk means where the probability and magnitude of harm or discomfort anticipated in the proposed 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.

Note: USU policy requires that all researchers successfully complete training and certification in the protection of human participants in research. Click the following link to check current IRB certification status. http://www.irb.usu.edu/htm/facultystaff-completed-certifications To complete CITI Certification click the following link for login procedures and instructions https://www.citiprogram.org/default.asp

A. Basic Project Information

<table>
<thead>
<tr>
<th>Project Title:</th>
<th>DATE:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator (USU researchers only):</td>
<td>Email:</td>
</tr>
<tr>
<td>College:</td>
<td>UMC:</td>
</tr>
<tr>
<td>Department:</td>
<td></td>
</tr>
<tr>
<td>Date IRB certification expires:</td>
<td>Click Here to access the IRB certification data base to check expiration date</td>
</tr>
<tr>
<td>Co-PI(s) or student(s):</td>
<td>Email:</td>
</tr>
</tbody>
</table>
Exempt Research Application
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<table>
<thead>
<tr>
<th>Department:</th>
<th>UMC:</th>
<th>Phone:</th>
</tr>
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<tbody>
<tr>
<td>College:</td>
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</tbody>
</table>

**Date IRB certification expires:**
Click Here to access the IRB certification data base to check expiration date

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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 (send copy of signed committee approval page to IRB, see Section F, #5)

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

---

Will this project/protocol be supported by an external funding agency?  Yes [ ]  No [ ]

If yes, name of funding agency or source:

---

Is there a USU Sponsored Program’s Office Grant award number for this project/protocol?  Yes [ ]

No [ ]  List:  (This is found on the SP-01 form)
B. LIST OF EXEMPT CATEGORIES (As listed in Code of Federal Regulations, Title 45, Part 46.101)

Review the 6 categories of exemption listed below before completing this form to determine if your research is exempt. Then proceed and mark the category(ies) that applies to your research.

- Exemption #1: Educational Research Conducted in Educational Settings
  Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (check one)
  - (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.

- Exemption #2: Research Involving Educational Tests, Surveys, Interviews, or Observations
  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 in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation. (Check all that apply)
  - Educational tests (cognitive, diagnostic, aptitude, achievement)
  - Survey procedures
  - Interview procedures
  - Observation of public behavior

(See “Limitation #1 on page 1)

- Exemption #3: Research involving Education Tests, Surveys, Interviews, Observations
  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 exemption #2 above, IF: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

For research in this category, either one of the following must be true: 1) participants are elected or appointed public officials or candidates for public office or 2) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. (Check all that apply).

- Educational tests (cognitive, diagnostic, aptitude, achievement)
- Survey procedures
- Interview procedures
Exempt Research Application
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☐ Observation of public behavior

☐ Exemption #4: Collection or Study of Existing Data
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 subjects cannot be identified, directly or through identifiers linked to the subjects. (Check one).

☐ The sources are publicly available
☐ The investigator records information in such a manner that participants cannot be identified, directly or indirectly, through identifiers linked to the participants

(The IRB may determine that the research can proceed only if the investigator obtains and uses “anonymized” data (codes and other identifiers are permanently removed from the data set before it is sent to the investigator) and the removal is accomplished in such a manner that neither the investigator nor the source maintaining the data set can re-establish participants’ identities. An approval letter is required for obtaining private data sets from organizations or PIs who collected the data).

(See “limitation #3” on page 1)

☐ Exemption #5: Public Benefit or Service Programs
Research and demonstration projects conducted by or subject to the approval of 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 procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

*In addition:* The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act); the research or demonstration project must be conducted pursuant to specific federal statutory authority; there must be no statutory requirement that the project be reviewed by an IRB; the project must not involve significant physical invasions or intrusions upon the privacy of participants; and, the exemption has authorization or concurrence by the funding agency.

Check all that apply:
☐ Public benefit or service programs
☐ Procedures for obtaining benefits or services under those programs
☐ Possible changes in or alternatives to those programs or procedures
☐ Possible changes in methods or levels of payment for benefits or services under those programs

☐ Exemption #6: Taste and Food Evaluation and Consumer Acceptance Studies
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 contaminant 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.

The research involves taste and food quality evaluation or is a consumer acceptance study if EITHER of the following is true: (check one)

- Wholesome foods without additives are consumed.
- Food contains a food ingredient or an agricultural chemical or environmental contaminant, that is at or below the level and for a use found to be safe by any one of the following (check one):
  - The Food and Drug Administration
  - The Environmental Protection Agency
  - The Food Safety and Inspection Service of the U.S. Department of Agriculture

C. Project Details

1. State the purpose of this research and your research questions:

2. Will your research only involve the analysis of existing data?

   Yes (If yes, answer a, b, c, d immediately below then skip to the last 3 questions in this section)

   No (If no, proceed to question 3)

   a. Briefly describe the type(s) of data that will be analyzed (i.e. documents/records, specimens, survey or clinical data). If specific forms or survey data will be analyzed, please submit a copy of the survey instrument or forms with this application

   b. Where is the data currently held, or who is the custodian of the data?

   c. Were the data collected under an IRB-reviewed/approved protocol? Yes □ No □ If yes, please submit a copy of the IRB approval or determination of exempt status with this application

   d. How many records will be included in the analyses (or, what is the sample size of the data set)?

3. Describe your research population (e.g., children ages 9-12, adults, etc.) and include any inclusion/exclusion criteria for participants:

4. Number of anticipated participants by gender Male: Female: Total:
Provide justification for your sample size:  

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).

5. How will subjects be recruited? (Attach a copy of any recruitment materials to be used – see section F)

6. Explain what the participants will be asked to do:

7. If compensation (e.g., money, gift cards) or incentives (e.g., extra class credit) are offered to participants, provide a description of the amount and scheduled payment(s) or type of incentive:  
(type N/A if not applicable)

8. Will electronic records be made (e.g., audio/video tapes, photographs, DVD CD, spreadsheets, etc)?
   Yes ☐ No ☐  If yes, list all that apply:  
   (If you are only using existing data, you will not be creating any new electronic records, except for, possibly, spreadsheets. If this does not apply, type N/A)
   
   • What measures will be taken to ensure confidentiality of these records?
   
   • When will these records be destroyed?

9. Explain how anonymity, privacy and/or confidentiality will be maintained:  
   (If you are only using existing data, explain how the pre-existing records will be safeguarded.)

10. Provide a description of provisions to protect the privacy interests of participants. (Privacy interests refer to how much a participant has control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others:  
   (If you are only using existing data, this may not apply. If so, type N/A)

   *Note – Unanticipated problems must be reported to the IRB Office.  Click here for the form.

D. Conflict of Interest Statement

The following conflict of interest 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 member 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:
c. which has requested rights to USU/USURF intellectual property?  Yes ☐  No ☐  If yes, please explain:

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.

E. Investigator’s Assurance

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

• The information provided in this application is accurate to the best of my knowledge.
• Adequate provisions are available to carry out this research and ensure participants’ safety.

v10  9/13/2011
• All named individuals on this project have read and understand the procedures outlined in the application.
• All experiments and procedures involving human participants will be performed under my supervision or that of another qualified professional listed on this protocol as Co-Principal Investigator.

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/are identical in principle to that contained in this application. I will submit modifications and/or changes to the IRB as necessary to ensure these are identical.

I and all the co-investigators and research personnel agree to comply with all applicable requirements for the protection of human participants 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 Institutional Review Board; and
• Promptly providing the IRB with any information requested relative to the project; and;
• Promptly reporting the premature completion of a study;
• Promptly and completely complying with an IRB decision to suspend or withdraw its approval for the project; and
• Obtaining continuing review approval 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.
• I understand that the report of an unanticipated problem may require me to inform participants

I assume responsibility for ensuring the competence, integrity and ethical conduct of the student researcher(s). I certify that any student researcher(s) is/are fully competent to accomplish the goals and techniques stated in this application and supporting documents, and that all researchers (faculty and student) have current IRB certifications.

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

Proceed to Section F on next page
F. 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 may be returned to you as “not reviewable”:

1. Proposal – (e.g., thesis, dissertation, grant) OR a summary of the methods and objectives
2. Data collection forms / instruments / measures
3. Draft Informed Consent / Letter of Information. *Format the letter of information using our template (this does not apply to applications seeking approval to use existing data)*
4. Recruitment materials (fliers, advertisements) – applicable? **Yes**  **No**  If yes, attach recruitment materials to your application *(this does not apply to applications seeking approval to use existing data)*
5. Approval letter or determination of exempt status (if seeking approval to analyze existing data)
6. Signed committee approval page – applicable? **Yes**  **No**  If Yes, mailed, faxed or delivered to the IRB? **Yes**  **No**

Once this application is complete, email it and all pertinent documents [listed above] to the **IRB Office**

**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
9530 Old Main Hill
Logan, UT 84322
(435) 797-1821
(435) 797-3769 (fax)
true.rubal@usu.edu
nancy.sassano@usu.edu
janet.roberts@usu.edu

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**For IRB Review Only:**

The following criteria have been used to determine whether research is consistent with USU’s ethical standards:

- [ ] 1. The research holds out no more than minimal risk to participants.
- [ ] 2. Selection of participants is equitable.
- [ ] 3. If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.

v10 9/13/2011
4. If there are interactions with participants:
   (a) There will be a consent process or documentation such as Letter of Information that will disclose such information including that the activities involve research; the procedures to be performed; that participation is voluntary; the name and contact information of the investigator.

5. There are adequate provisions to maintain the privacy interests of participants. *(Privacy interests refer to how much a participant has control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others).*

6. This application is exempt under category number: