

APPLICATION FOR APPROVAL FOR THE USE OF HUMAN SUBJECTS IN RESEARCH—Form B

Date Submitted to the IRB:	IRB Tracking # (To be assigned by IRB):
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A. PROJECT AND RESEARCH IDENTIFICATION

1. Proposed Title of Study:

2. Researchers' Information (*A student may be a Principal Investigator (PI) if a faculty or staff advisor is the co-investigator. If the PI is not a UVU employee, the PI must obtain the approval of the department chair/director of the discipline of the proposed research.*):

a. Principal Investigator:

b. Department/Program/Affiliation:

c. Principal Investigator Contact Information (mail code, phone number, e-mail etc.):

Mail Code:	Phone #:	E-mail:
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d. Mailing Address (*if non-UVU PI*):

3. Co-Investigator(s)' Contact Information (*if applicable*):

Name:		
Department Affiliation:		
Mail Code:	Phone #:	E-mail:
Name:		
Department Affiliation:		
Mail Code:	Phone #:	E-mail:
Name:		
Department Affiliation:		
Mail Code:	Phone #:	E-mail:

4. List any other individuals who will assist or view data, including name, phone number and e-mail.

B. PROJECT SPONSORS

1. How will this research be funded (Check all that apply)?

- Internal department funds
- Non-funded research
- Other (Please describe below.)
- Federal grant
- Corporate sponsor or private foundation

C. RESEARCH INFORMATION

1. Abstract/Summary:

NOTE: Use language understood by a person unfamiliar with your area of research. Include the justification, purpose, research questions or hypothesis.

2. Describe the research methods to be used (e.g., measures/instrumentation, procedures for distribution and data collection, plans for minimizing risks to subjects, data analysis procedures, if applicable, etc.):

3. Describe the tasks participants will be asked to complete and approximately how long the participant will be involved in the research (e.g., number of hours, days, months, etc.).

4. DURATION of study:

FROM:	TO:
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(Duration should cover a period of time sufficient for both data collection and data analysis.)

NOTE: By federal regulations, ongoing research protocols must be **reviewed at least annually** by the IRB and re-submitted for additional review every three years. The PI should report the end of the

research to the IRB. If the IRB does not hear from the PI by the date above, it will be assumed the study is termination. Research conducted after the termination will not be considered approved by the IRB and will be in violation of policy and federal regulations.)

5. Is this a multi-center study?

YES NO

a. If yes, please list other institutions participating and attach a page that explains the responsibilities and obligations of each center and/or each investigator.

b. If yes, has this study been, or will it be, reviewed by another IRB?

YES NO

c. If yes (to 5b), give name and address of Board and date of review:

D. DESCRIPTION OF HUMAN SUBJECT AND RECRUITMENT PROCEDURES

1. Subjects:

a. Who will be the human subjects (*be specific*)?

b. Number of subjects:

Male:	Female:	TOTAL:
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c. Age Range: Check all that apply

0-7 (submit parental consent form)

7-17 (submit child's assent form, parental consent form)

18-65 (*Consent document must contain following statement: "Individuals must be 18 years of age or older to participate."*)

d. Location of subjects during research data collection:

e. Vulnerability of Subjects: (If yes on any of the below, explain rationale for selecting vulnerable subjects.)

- | | | |
|--|------------------------------|-----------------------------|
| 1) Are the subjects younger than 18 years of age | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 2) Are the subjects older than 65 years of age? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 3) Are the subjects cognitively impaired? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 4) Are the subjects healthy volunteers? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 5) Are the subjects potentially pregnant? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 6) Are the subjects prisoners? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 7) Are the subjects institutionalized? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| 8) Are the subjects at risk of coercion (e.g., your students)? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |

f. If the research involves any of the groups listed above, please check one of the following:

- Use of such subjects is a necessary part of the research.
 Such subjects may be included incidentally as members of a more general population.

g. By federal regulation, subjects cannot be excluded from research on the basis of race, sex, age, and language or disability status. If research requires the exclusion of subjects, please explain:

h. Does this study involve subjects (or parents or guardians) who are not fluent in English?

- YES NO

NOTE: If yes, please submit both the English consent form and translation in the appropriate language(s). Participants who do not read and/or speak English must have the consent form written in and/or read to them in their native language, they must sign a form indicating that the informed consent has been explained to them, and that all questions regarding it have been answered, in their native language.

1. Recruitment: Explain how subjects will be recruited (e.g., advertisement, referred by someone, etc.) and if they will be compensated in any way (e.g., extra credit, money, coupon, gift certificate, etc.).

E. RISKS AND BENEFITS OF THE RESEARCH

1. What are the potential benefits to the subjects and/or to generalized knowledge to be gained from the study?

2. What are the risks to the subject(s) and what measures will be taken to minimize the risks?

F. INFORMED CONSENT

1. What method will be used to obtain informed consent (e.g., consent letter/form, script for phone interview, parental form, etc.), by whom will it be obtained (PI, student researcher, professor) and where will it be obtained (in-person, by phone, in a classroom, in the workplace)?

G. CONFIDENTIALITY OF DATA

1. Will the research subjects be identifiable to the researchers?

YES NO

2. Does the researcher or the researcher's representative interact with subjects to obtain the data?

YES NO

3. What measures will be taken to ensure participants' confidentiality in data collection, if applicable, and in resulting publication and/or presentation?

4. In what secured environment will the documents be stored (e.g., locked cabinet) and who will have access to the documents?

5. Will audio/videotapes, photographs, DVD, or other electronic records be made?

YES NO

6. How long will identifying information (if any) be kept before being destroyed?

7. Secondary Research Subjects:

- a. Will the investigator be asking about individuals other than those from whom informed consent has been received?

YES NO

- b. If yes, can these people be identified (e.g., asking a parent about a child's behavior or a spouse about the other spouse)?

YES NO

- c. If "YES", please explain.

H. EXISTING DATA AND INTENT TO PUBLISH OR PRESENT

1. Existing Data

- a. Has the data already been collected for another purpose?

YES NO

- b. If "YES", please specify (*e.g., existing data, census data, experimental data previously collected for a different purpose*) :

- c. If "YES", will there be any personally identifiable information attached to the data whereby the researcher may be able to identify individuals?

- d. Where will the results be published, presented, or displayed (*e.g., textbooks, training videos, theses, dissertations, journals, internet*)?

I. ASSURANCE STATEMENTS AND SIGNATURES

I understand the institution's policy concerning research involving human participants and I agree:

- To obtain voluntary and written informed consent of subjects who are to participate in this project (when required, as explained previously).
- To report to the IRB any unanticipated effects on subjects which become apparent during the course of, or as a result of the research, and I will report what actions I have taken.
- To cooperate with members of the Board charged with the continuing review of this project, and therefore furnish relevant information when requested.
- To obtain prior approval from the Board before amending or altering the scope of the project or implementing changes in the approved consent form.
- To maintain documentation of consent forms and progress reports as required by the IRB.
- To protect confidentiality of research subjects and the data collected.
- To be responsible for the ethical conduct of this project, and for protecting the rights and welfare of the subjects.
- To follow through with what is explained on the informed consent.
- To provide amended procedures to the board as these occur.

Principal Investigator:

Signature: _____ Date: _____ CITI No. _____

Co-Investigator(s) or Other Researcher(s):

Signature: _____ Date: _____ CITI No. _____

Signature: _____	Date: _____	CITI No. _____
Signature: _____	Date: _____	CITI No. _____
Department Chair/Program Director:		
Signature: _____	Date: _____	CITI No. _____
Dean (Dean must sign only if full IRB review is necessary)		
Signature: _____	Date: _____	CITI No. _____

Submit completed packet to the following:

On-Campus:

Office of the IRB
Mailstop: 272
Office: BA 203d

Off-Campus:

Utah Valley University
Office of the IRB
800 West University Parkway, MS 272
Orem, UT 84058-5999