

# Utah Valley University Institutional Review Board

## *Investigator's Handbook for Research Involving Human Subjects*



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<sup>1</sup> N.B. Much of this document makes reference to Code of Federal Regulations Title 45, Public Welfare, Part 46, Protection of Human Subjects <<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>>.

# UVU INVESTIGATOR'S HANDBOOK FOR RESEARCH INVOLVING HUMAN SUBJECTS

## I. Introduction

### A. *Mission*

Utah Valley University encourages scholarly research and activities for faculty, students, and relevant staff. The Institutional Review Board furthers the university research mission by:

- Reviewing proposed research involving human participants, in order to protect citizens against potential risks of research participation while promoting high-quality studies that can provide rewards to participants and/or society;
- Educating the larger university community about ethical issues in human participants' research;
- Overseeing compliance with federal, state, and university regulatory requirements for human participant research.

### B. *Board Composition*

The full Institutional Review Board consists of 13 voting members who are staggered at 3 year terms. The board consists of the following:

- IRB Administrator/Chair
- Associate Vice President for Academic Affairs
- 8 experienced faculty researchers from various schools across campus (1 from Business, 1 from Education, 1 from University College, 2 from Humanities, Arts, and Social Sciences; 2 from Science and Health; 1 from Technology and Computing
- 2 community members (one which is unaffiliated), and
- 1 student representative from Student Government

The Executive Board of the IRB consists of 3 members: IRB Administrator/Chair, 2 faculty members serving on the full IRB.

The Director of Institutional Compliance Assistance and Policy Administration, by assignment of the president, serves as a non-voting, administrative liaison and facilitator to the IRB. The Office of the IRB is housed with the Director.

### C. *Overview Information*

1. "Research" means a systematic investigation (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge. For purposes of this policy, activities which meet this definition

constitutes research, whether or not they are conducted or supported under a program which is considered research for other purposes (for example, some demonstration and service programs may include research activities).<sup>2</sup>

2. All research involving human subjects carried out by faculty, staff, or students of Utah Valley University (UVU) is under the review and approval jurisdiction of the Institutional Review Board (IRB). Students, with the assistance of their advisors, are responsible for obtaining the necessary approval for their research. Approval must be obtained before the research is started and must be submitted to the IRB Administrator before the student's research can be approved. The Office of the Associate Vice President for Academic Affairs—Undergraduate Research and International Programs is responsible for administering the program and ensuring compliance with Code of Federal Regulations Title 45, Public Welfare, Part 46, Protection of Human Subjects.
3. It is the responsibility of the Principal Investigator (PI) to submit proposed research for approval. Approval by the IRB does not relieve the PI from the obligation to follow procedures and rules of the institution and any other regulatory body involved in which the research is to be done.
4. The PI should submit the protocol and IRB forms to the IRB Administrator.
5. Normally the IRB will agree to serve as the IRB for research initiated by other institutions only if a UVU faculty or staff member is involved as principal investigator or co-principal investigator on the particular study.

## II. Categories of Research Review

### A. Full Board Review

Research involving moderate or greater risk to subjects requires review by the full board. Full review covers all research not falling into the categories of exempt or expedited review. Normally, all research involving human subjects should be assumed to require full review by the IRB.

### B. Expedited Review<sup>3</sup>

Some types of research require review by the IRB Executive Board. The types of research which may be expedited include

1. Clinical studies of drugs and medical devices only when
  - a. research on drugs for which an investigational new drug application is not required;
  - b. research on medical devices for which
    - i. an investigational device exemption application is not required;
    - ii. the medical device is cleared or approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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<sup>2</sup> Vide Title 45, Part 46 §102d.

<sup>3</sup> Vide Title 45, Code of Regulations Part 46.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - a. from healthy, non-pregnant adults who weigh at least 110 pounds;
  - b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected.
3. Prospective collection of biological specimens for research purposes by noninvasive means. For example
  - a. Hair and nail clippings;
  - b. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
  - c. Permanent teeth if routine patient care indicates a need for extraction;
  - d. Excreta and external excretions (including sweat);
  - e. Saliva;
  - f. Placenta removed at delivery;
  - g. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
  - h. Supra and sub gingival dental plaque and calculus;
  - i. Mucosal and skin cells by buccal scraping or swab, skin swab, or mouth washings;
  - j. Sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. For example
  - a. Physical sensors that are applied either to the surface of the body or at a distance;
  - b. Weighing or testing sensory acuity;
  - c. Magnetic resonance imaging;
  - d. Electrocardiography, ultrasound, etc.;
  - e. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing.
5. Research involving materials that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

### *C. Exempt Research<sup>4</sup>*

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<sup>4</sup> Institutions with DHHS-approved assurances on file will abide by provisions of Title 45 CFR Part 46 §A-D. Some of the other departments and agencies have incorporated all provisions of Title 45 CFR Part 46 into their policies

Research which falls into the “exempt” category requires approval from the IRB Administrator. In order to qualify, research must fall into one of the six federally-defined exempt categories. These categories present the lowest amount of risk to potential subjects because they involve either the collection of anonymous or publicly available data, or conduct of research experiments which are considered less harmful to subjects:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices,<sup>5</sup> such as
  - a. research on regular and special instructional strategies; or
  - b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior unless
  - a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  - b. 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.
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 this section if
  - a. the human subjects are elected or appointed public official or candidates for public office; or
  - b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
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 subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine

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and procedures as well. However, the exemptions at 45 CFR 46 §101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, Subparts B and C. The exemption at 45 CFR 46 §101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, Subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed. (Vide Title 45, Part 46 §101.)

<sup>5</sup> Items 4-9 are from Title 45, Code of Regulations Part 46 §101.

- a. public benefit or service programs, procedures for obtaining benefits or services under those programs;
  - b. possible changes in or alternatives to those programs or procedures; or
  - c. possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies
- a. if wholesome foods without additives are consumed; or
  - b. if a food is consumed that contains food ingredients at or below the level and for a use found to be safe, or agricultural 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.

*D. Non-IRB Regulated Research*

Research which does not involve human subjects, and research which does not give rise to any additional interactions with human subjects due to that research (for example, observing people in a public place without interacting with them) does not require the approval of the IRB Administrator, Executive Board, or the full Board.<sup>6</sup>

### **III. Requirements for IRB Approval**

Before approving research, the IRB shall determine that all of the following requirements are satisfied:

- Risks to subjects are minimized.
- Risks to subjects are reasonable in relation to anticipated benefits.
- *Informed consent* will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by the Code of Federal Regulations, Title 45, Part 46 §116.

*A. General Information*

1. The National Institutes of Health (NIH) requires that all publications derived from work done with federal support must contain reference to federal support and the proportion of work so supported.
2. The UVU IRB meets as needed on Monday afternoon. Contact the IRB Administrator if you are planning on submitting an IRB proposal deemed to need a full board review. Full IRB proposals must be submitted three weeks prior to an IRB meeting to be considered. This lead time allows the Office of the IRB Administrator to prepare and distribute protocols to board members. It also gives the IRB members time to read and review protocols.

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<sup>6</sup> See the Office for Protection from Research Risks (OPRR), "Human Subject Regulations Decision Charts" <<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/decisioncharts.htm>>.

3. If the PI believes the project may be exempt or expedited, he/she should submit the complete protocol package as outlined below.

*B. How to Submit a Protocol*

To submit a protocol to the IRB, the PI must supply a copy of the entire protocol package, including the following, in this order:

1. **Form A:** IRB Record of Submission
2. **Form B:** Application for the Approval of the Use of Human Subjects in Research (*Forms A and B can be obtained from the UVU IRB website (<http://UVU.edu/irb>) or the Office of the IRB Administrator.*)
3. **Proposed Consent Form/Letter:** A copy of the proposed consent form/cover letter (on department/center letterhead). Department logo should be on each page of the form/cover letter.
4. **Research Instrument(s):** All questionnaires, surveys, or lists of qualitative interview questions should be submitted. The text containing details of the proposed research should be included in Form B. If a full IRB is expected, a research proposal with added details should be included in the protocol packet.
5. **Organizational Permission** (if appropriate): If you are doing your research in specific organizations, you must attach an email or letter from the primary contact in each organization specifying that the organization agrees to participate. For example, if you are using a random sample of 100 Utah State Department of Health employees and 100 Wal-Mart employees, you need to attach a letter from a decision-maker in each organization confirming agreement to participate in the study and acknowledgment of what is expected of the organization and prospective participants.

When all of the above have been completed, necessary signatures should be obtained and the entire package should be delivered to the Office of the IRB Administrator. Principal Investigators will be notified when protocols have been approved.

## **IV. Other Information about the IRB Process and Protocol Reviews**

*A. IRB*

1. The IRB Administrator serves as Chair of the IRB, appointment is not limited.
2. The Executive Board is comprised of the Chair and two IRB members specifically appointed to serve on the Executive IRB. The position will rotate as IRB members complete terms.
3. The Full Board consists of 12 members. This included the IRB Chair, the Associate Vice President for Academic Affairs, and 8 experienced faculty researchers from various schools across campus (1 from Business, 1 from Education, 1 from General Academics, 2 from Humanities, Arts, and Social Sciences; 2 from Science and Health; and 1 from Technology and

Computing). The 8 faculty members serve for 3 year terms. The remaining 2 board slots are community members at large. Each July 1, three (3) members rotate off the board and are replaced by three (3) new members. Occasionally, a faculty researcher outside the board may be asked to serve as an ad hoc member of the IRB to review a specific proposal in which they have expertise beyond current board members.

4. The IRB meetings will be scheduled on Monday afternoons, as needed. Full IRB protocols must be submitted three (3) weeks prior to a meeting. For full board review, researchers should contact the IRB administrator so an IRB meeting can be scheduled.
5. IRB approvals are for only three years; therefore, the study must be resubmitted after this time period. It is the responsibility of the investigator to notify the IRB when the study has been terminated or when methodology is changed. The IRB Administrator will also do a yearly review of all open research studies.
6. Research protocols will not be closed until all data analyses have been completed. The IRB is to be notified when a study is to be closed. The PI should close an approved study when all data have been entered and all data analyses have been completed. The PI should not allow a protocol to remain open when all activity has been completed.

*B. Investigators*

1. If a UVU student is initiating the research, the student must name a UVU faculty member as the sponsor.
2. If the PI is not a UVU employee, then the PI must obtain the approval of the UVU department chair or program director of the discipline of the proposed research (Form B). As an alternative, if UVU supports the discipline of the proposed subject of the research, then the non-UVU PI must obtain the signature of the Associate Vice President for Academic Affairs—Undergraduate Research and International Programs.
3. If the PI is not a physician and the proposed research includes administration of drugs, medical therapeutic decisions, or diagnostic procedures that may alter medical therapy, a physician must be named as co-investigator.
4. Requests for changes of PI are to be submitted to the IRB in a timely manner, including updated IRB and consent forms.
5. If a study is to be conducted off-campus, a staff member from the off-campus site(s) must be named as a co-investigator.
6. If a PI finds it necessary to deviate in any way from an approved protocol or eligibility requirements, they must submit an amended IRB request in writing to the IRB, with the changes highlighted. If a change affects the approved consent form, it will be necessary to submit a revised consent form with changes highlighted. Usually, major amendments to existing protocols require that new protocol be submitted (usually with a new title) and the old protocol be closed.

7. All consent forms and other communication with the IRB must use the exact (word-for-word) title of the approved protocol as well as the code assigned to the protocol by the IRB Administration.

*C. Informed Consent*

1. Informed Consent letters are to be signed by the subject and the PI. Each signature must have its own date (see Form B and Appendix C).
2. Highest concern must be expressed for obtaining informed consent from subjects who may not understand their medical conditions, rights as a research subject or consequences of the proposed research. Ordinarily, incompetent patients must have an informed consent form signed by the next-of-kin (spouse, parents, children, etc.). Legal guardians should be the last resort and be used only when compelling circumstances require such approval.<sup>7</sup>
3. Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subjects legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
  - a. Basic elements of informed consent. Except as provided in §IV.C.3.c or §IV.C.3.d, in seeking informed consent the following information shall be provided to each subject:
    - i. a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subjects participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
    - ii. a description of any reasonably foreseeable risks or discomforts to the subject;
    - iii. a description of any benefits to the subject or to others which may reasonably be expected from the research;
    - iv. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
    - v. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

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<sup>7</sup> Vide Title 45, Part 46 §116.

- vi. for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and if so, what they consist of, or where further information may be obtained;
  - vii. an explanation of whom to contact for answers to pertinent questions about the research and research subjects rights, and whom to contact in the event of a research related injury to the subject; and
  - viii. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- b. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:
- i. a statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
  - ii. anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subjects consent;
  - iii. any additional costs to the subject that may result from participation in the research;
  - iv. the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
  - v. a statement that significant new findings developed during the course of the research which may relate to the subjects willingness to continue participation will be provided to the subject; and
  - vi. the approximate number of subjects involved in the study.
- c. An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided the IRB finds and documents that:
- i. the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine
    - public benefit or service programs;
    - procedures for obtaining benefits or services under those programs;

- possible changes in or alternatives to those programs or procedures; or
      - possible changes in methods or levels of payment for benefits or services under those programs; and
    - ii. the research could not practicably be carried out without the waiver or alteration.
  - d. An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:
    - i. the research involves no more than minimal risk to the subjects;
    - ii. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
    - iii. the research could not practicably be carried out without the waiver or alteration; and
    - iv. whenever appropriate, the subjects will be provided with additional pertinent information after participation.
  - e. The informed consent requirements in this policy are not intended to preempt. The informed consent requirements in this policy are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.
  - f. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.
4. Documentation of Informed Consent:<sup>8</sup>
- a. Except as provided in §IV.C.3.c, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.
  - b. Except as provided in §IV.C.3.c, the consent form may be either of the following:
    - i. A written consent document that embodies the elements of informed consent required by the previous section. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
    - ii. A short written consent document stating the elements of informed consent required by the previous section have been presented orally to the subject or the subject's legally

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<sup>8</sup> Vide Title 45, Part 46 §117.

authorized representative. When this method is used, there shall also be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

- c. An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either;
  - i. that 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. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subjects wishes will govern; or
  - ii. that 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.

NOTE: In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

*D. Opening a Closed Study*

An investigator may reopen a closed study within one year of closure with a written request to the IRB with updated information. After one year of closure, a protocol must be resubmitted.

*E. Frivolous Research*

The IRB takes the position that research involving human subjects is unethical if it is done to reproduce well-established results, or if the research has no scientific or educational value. Such research will not be approved by the IRB.

*F. Children.*

1. Under Utah law, children are considered “not to have attained legal age” if they are under 18 years old unless a) they are married or b) they are emancipated (living apart from parents with independent means of financial support).
2. Under some other situations, minor children are allowed to give medical consent, but for purposes of research, the IRB will *not* recognize those exceptions.
3. Consent of only one parent is required if the research poses minimal risk to the child. Minimal risk means that the risks of anticipated harm in the

proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

4. Consent of both parents is required if the research involves greater than minimal risk. In these cases, one signature will be acceptable only if one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. Efforts to contact the second parent (e.g. telephone call) should be documented if only one parental signature is obtained.
5. Special considerations are required for research involving children. Protocols in which this population is to be involved must include the following information in addition to the information required in general:
  - a. There should be a full explanation of the rationale and ethical justification for involving children as subjects.
  - b. The investigators must discuss the potential risks and describe the relationship of these risks to the potential benefits or lack of benefits to the child.
  - c. Procedures should be described for obtaining the assent of the child as well as permission of the parent or legal guardian. Assent refers to the child's agreement as distinct from consent, which is legally valid. Assent should be solicited if the child's age is seven years or older. The child should be provided with a fair explanation of what participation will involve and be invited to read and sign the assent form. Assent means a child's affirmative agreement to participate in research. Mere failure to object should not (absent of affirmative agreement) be construed as assent.
  - d. Research involving surgery or interviewing procedures is not exempt if a minor is being questioned. If a parent is being questioned about his/her child, the research may be exempt, if approved by the IRB.

*G. Inclusion of Diverse Study Population*

In order to ensure the widest applicability of collected data, researchers are encouraged to verify that their sample of respondents represents diversities in gender and race/culture, unless the research design requires specific sampling (i.e., a single-gender study).

*H. Adverse Event Reporting*

An Adverse Event (AE) is a negative, unanticipated outcome that affects one or more research participants. An AE report must be filed with the IRB when any of the following happen to a research subject, regardless of whether or not a causal relationship to the study can be determined:

1. Unanticipated negative effect requiring medical treatment
2. Hospitalization (or extensions of hospital stays if subject was already hospitalized or planned to be)
3. Unusual or high frequency/intensity of expected effects

4. Any other suspicious negative effect when, in the opinion of the Lead Investigator, there may be a relationship to the study
5. Birth defect/congenital anomaly following exposure to study procedures prior to conception or during pregnancy
6. The death or hospitalization of a subject is considered serious and must be reported to the IRB by telephone, fax, or e-mail within 24 hours. All other AE reports must be submitted within 14 days of the onset of an adverse event, followed by any appropriate follow-up reports.

*I. Conflict of Interest/Financial Interest*

All researchers are required to disclose any financial interests they may have related to this study. IRB approval will be delayed until each positive has been reviewed for possible conflicts of interest. Financial interest included the following:

1. Significant Financial Interests: With respect to any single entity external to UVU whose business interests are related to the results of this study, researchers are deemed to have significant financial interests if they, their spouses, or their dependent children have any of the following interests:
  - a. Outside income exceeding \$10,000 over the preceding twelve months or anticipated during the forthcoming twelve months (income includes salary, consultant payments, honoraria, royalty payments, dividends, loan, or any other payments or consideration with value).
  - b. Equity in the form of stock, stock options, real estate, loan to, or any other investment or ownership interest exceeding \$10,000 (current market value) or a 5% or greater ownership interest.
  - c. A management position (e.g., director, officer, partner, or trustee) with the interested entity.
  - d. An intellectual property interest, e.g., a patent (actual, planned, or applied for) or a copyright for software.
2. Related Financial Interests: Related interest occurs when the investigator has Significant Financial Interests that would reasonably appear to be affected by the research or in entities whose financial interests would reasonably appear to be affected by the research. Examples include situations where the investigator:
  - a. is conducting a project where the results could be relevant to the development, manufacturing or improvement of the products or services of the entity in which the investigator has a financial interest; or
  - b. has a financial interest in an entity that might manufacture or commercialize a drug, device, procedure, or any other product used in the project or that will predictably result from the project; or
  - c. has consulting income in his/her professional field where the financial interest of the entity or the investigator would reasonably appear to be affected by the project; or
  - d. has a financial interest in an entity and the project proposes to subcontract a portion of the work, or lease property, or make referral of participants to,

or make purchases from the entity, or the entity is part of a consortium or will otherwise participate in the project.

## APPENDIX A

### IRB PROCESS—AT A GLANCE

All research involving human subjects carried out by faculty, staff, or students of Utah Valley University is under the review and approval jurisdiction of the Institutional Review Board (IRB). Approval must be obtained *before* the research (data collection) is started, and specific IRB paperwork must be submitted to the IRB Administrator *before* research can be approved.

Before IRB paperwork is started, the researcher(s) should have been through the preparatory research stages and outlined specific plans and methodologies. This may include (but are not limited to) the development of a problem statement, research purpose, research questions or hypotheses, literature review, research design, population and sample selection, measures/instrumentation, data collection procedures, and data analysis procedures.

After these initial steps are taken, begin filling out the IRB paperwork (if possible, use the Word versions of Forms A and B and type in the information rather than handwriting on the PDF versions):

- 1. FORM A:** Review and begin completing the *RECORD OF IRB SUBMISSION*. This includes the determination of whether the project is to be submitted under an exempt, expedited, or full IRB review (see “Categories of Research” below, and the *UVU Investigator’s Handbook* for further details). In addition, this form provides a checklist of the paperwork that needs to be submitted for IRB approval.
- 2. FORM B:** Complete the *APPLICATION FOR APPROVAL FOR THE USE OF HUMAN SUBJECTS IN RESEARCH*.
- 3. INSTRUMENT:** Attach a blank copy of the final version of the research instrument you are using to gather data.
- 4. INFORMED CONSENT:** Attach a copy of the participant informed consent form or letter you intend to use (this is used to obtain the subject’s permission to willingly participate in your research).
- 5. ORGANIZATION’S PERMISSION:** If you are doing your research in specific organizations, you must attach an email or letter from the primary contact in each organization specifying that the organization agrees to participate. For example, if you are using a random sample of 100 Utah State Department of Health employees and 100 Wal-Mart employees, you need to attach a letter from a decision-maker in each organization confirming agreement to participate in the study and acknowledgment of what is expected of the organization and prospective participants (see *UVU Investigator’s Handbook* for further details).
- 6. COMPLETE PACKET:** Complete Form A by obtaining the appropriate signatures. Next, copies of Form A and B, the instrument, and the letter of informed consent should be sent to the IRB Administrator (Office of the IRB, Mailstop 109) for review. If the research is approved as exempt, then the IRB Administrator will sign Form A and send it back to the Principal Investigator for the record. If the research is categorized as expedited, then the IRB Executive Board will review the proposal. If approved, then the IRB Administrator will sign Form A and send it back to the Principal Investigator for the record. If the research requires full board review, then the IRB will review the proposal. If approved, then the IRB Administrator will sign Form A and send it back to the Principal Investigator for the record.

**7. REQUESTED REVISIONS:** After a packet is submitted, revisions may be requested. If small changes are requested, it is expected that researchers resubmit only the form in question. If minor changes are requested by IRB for expedited and full board review projects, the IRB Administrator can give his/her approval to proceed to data collection without taking the project before the IRB Executive Board or full board for a second time.

**8. DATA COLLECTION:** Once the IRB Administrator has approved your proposal, then you can start your research and begin to collect data!

### CATEGORIES OF RESEARCH

The IRB Administrator, in conjunction with the IRB Executive Board and the full Board, make the final determination of category for review. The following are general definitions for the three levels of research review (see §II of the *UVU Investigator's Handbook* for more details).

***Non-IRB Regulated Research***—This category includes research which does not involve human subjects, and research which does not give rise to any additional interactions with human subjects due to that research (for example, observing people in a public place without interacting with them).

***Exempt Review***—The exempt category is determined by the federal regulatory agencies and include research of negligible risks in the following situations:

- The study of some educational practices
- Survey interviews of adult subjects or public figures (non-sensitive topic areas, only)
- Observation of non-institutionalized adults, and minors under some circumstances
- Archival or secondary use of data or specimens with no identifiable information
- Demonstration or service projects under the “Social Security Act”

***Expedited Review***—Expedited review covers research that involves only minimal risk procedures such as those involving the drawing of small amounts of blood, removal of dental plaque, moderate exercise by normal volunteers, the study of individual or group behavior where the behavior is not manipulated and the subjects are not exposed to any stressful situation. Expedited review categories are designated by federal regulatory agencies.

***Full Board Review***—Research involving moderate or greater risk to subjects requires review by the full board. Full review covers all research not falling into the categories of exempt or expedited review.

## APPENDIX B – Application Forms RECORD OF IRB SUBMISSION—Form A

Date Submitted to the IRB: \_\_\_\_\_

1. **Proposed Title of Study:** \_\_\_\_\_  
\_\_\_\_\_

2. **Principal Investigator:** \_\_\_\_\_

Principal Investigator’s UVU Status:     \_\_\_ Faculty \_\_\_ Staff \_\_\_ Student \_\_\_ Other

**Co-Investigator (if applicable):** \_\_\_\_\_

Co-Investigator’s UVU Status:     \_\_\_ Faculty \_\_\_ Staff \_\_\_ Student \_\_\_ Other

**Student Researcher(s) (if applicable):** \_\_\_\_\_

*(A student can 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.)*

3. **Proposed category of research review** (check one - see *UVU IRB Handbook*):  
       \_\_\_ Exempt Review                   \_\_\_ Expedited Review                   \_\_\_ Full IRB Review

4. **Paperwork submitted:**  
       \_\_\_ Form A – Record of IRB Submission  
       \_\_\_ Form B – Application for Approval for the Use of Human Subjects in Research  
       \_\_\_ Research Instrument  
       \_\_\_ Participant Consent Form or Letter (*blank copy*)  
       \_\_\_ Organizational Letter(s) of agreement to participate (*if applicable*)

5. **Signatures:**  
*I have reviewed this packet for completeness and accuracy:*

Principal Investigator (PI): \_\_\_\_\_ Date: \_\_\_\_\_

Co-Investigator (Co-PI): \_\_\_\_\_ Date: \_\_\_\_\_

Department Head: \_\_\_\_\_ Date: \_\_\_\_\_

*Dean must sign only if full IRB review is necessary:*

Dean: \_\_\_\_\_ Date: \_\_\_\_\_

FOR OFFICE USE ONLY IRB Action ( <i>to be completed by the IRB Administrator</i> ): <input type="checkbox"/> <i>Exempt Determination:</i> This research has been approved and data collection can begin. <input type="checkbox"/> <i>Expedited Review Approval:</i> This research has been approved and data collection can begin. <input type="checkbox"/> <i>Full IRB Review Approval:</i> This research has been approved and data collection can begin.	Date Received: _____   Date: _____  IRB Code: _____
_____ ( <i>Signature of the IRB Administrator</i> )	

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

Date Submitted to the IRB: \_\_\_\_\_ Code # \_\_\_\_\_ (To be assigned by IRB)

**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: \_\_\_\_\_  
 Department/Program/Affiliation: \_\_\_\_\_  
 Mail Code: \_\_\_\_\_ Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_  
 Mailing Address *(if non-UVU PI)*: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_
  
  - b. Co-Investigator(s) *(if applicable)*:  
 Name: \_\_\_\_\_ Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_  
 Name: \_\_\_\_\_ Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_
  
  - c. List any other individuals who will assist or view data: \_\_\_\_\_  
 \_\_\_\_\_

**B. PROJECT SPONSORS**

- How will this research be funded?
- |   |   |
|---|---|
| <input type="checkbox"/> Internal department funds<br><input type="checkbox"/> Non-funded research<br><input type="checkbox"/> Other, please describe _____ | <input type="checkbox"/> Federal grant<br><input type="checkbox"/> Corporate sponsor/private foundation |
|---|---|

**C. RESEARCH INFORMATION**

1. Abstract/Summary *(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 \_\_\_\_\_  
*(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/institutional 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 SUBJECTS AND RECRUITMENT PROCEDURES**

1. Subjects:
  - a. Who will be the human subjects (*be specific*)?
  
  - b. Number: Male \_\_\_\_\_ Female \_\_\_\_\_ Total \_\_\_\_\_
  
  - 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                     YES     NO
    2. Are the subjects older than 65 years of age?                     YES     NO

- 3. Are the subjects cognitively impaired?  YES  NO
- 4. Are the subjects physically impaired or ill?  YES  NO
- 5. Are the subjects potentially pregnant?  YES  NO
- 6. Are the subjects prisoners?  YES  NO
- 7. Are the subjects institutionalized?  YES  NO
- 8. Are the subjects at risk of coercion (e.g., your students)?  YES  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

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.

- 2. 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***

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?
  
2. 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.
- To provide my CITI human subject research certification number.

**Principal Investigator:**

Signature: \_\_\_\_\_ Date: \_\_\_\_\_ CITI Cert # \_\_\_\_\_

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

Signature: \_\_\_\_\_ Date: \_\_\_\_\_ CITI Cert # \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_ CITI Cert # \_\_\_\_\_

**Department Chair/Program Director:**

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Submit completed packet to the following:**


***On-Campus:***

Office of the IRB  
 IRB Administrator  
 Mailcode: 272  
 Office: BA 004

***Off-Campus:***

UVU—Office of the IRB  
 IRB Administrator  
 800 West University Parkway, MC 272  
 Orem, UT 84058-5999

(For OHRPP use only) UVU IRB Protocol #	
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	<b>Institutional Review Board</b> <i>Office for</i> <b>Human Research Protection</b> BA 004 (801) 863-8156 Fax: (801) 863-8590 E-Mail: irb@uvu.edu
<b>Request for Exemption from IRB Review</b>	

<b>I. Study Title:</b> <i>(if funded, must match the sponsored title)</i>	
--	--

<b>II. Principal Investigator Information</b>
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A. Name of Principal Investigator	CITI Certification#:	B. Are You...? <i>(Please check ONLY 1 box below.)</i>
C. Mailing Address:		<input type="checkbox"/> Staff
D. Department:		<input type="checkbox"/> Faculty
E. E-mail Address:		<input type="checkbox"/> Undergrad Student
		<input type="checkbox"/> Graduate Student
		<input type="checkbox"/> Other
F. Primary Phone Number:	G. Alternate Phone:	
H. Name of Faculty Advisor	I. Faculty Phone:	
	J. Faculty E-mail:	

<b>III. Funding</b>
---------------------

A. <input type="checkbox"/> None <i>(Answer item below, then go on to Section IV.)</i> Do you plan to apply for funding in the future? <input type="checkbox"/> Yes <input type="checkbox"/> No Please explain: B. <input type="checkbox"/> University Funded: List Source: C. <input type="checkbox"/> External: List source and grant number: D. <input type="checkbox"/> Federal: List agency, department and grant number: E. Is UVU the primary awardee for the grant? <input type="checkbox"/> Yes <input type="checkbox"/> No If No, please list Primary Awardee: F. Are there subcontracts? <input type="checkbox"/> Yes <input type="checkbox"/> No Please list sub-contractors:
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<b>IV: Study Information</b>
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Research must be <b>“minimal risk”</b> in order to qualify for an Exemption. 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 test (45 CFR 46).
<b>A. Risk Level:</b> Does this research pose more than minimal risk to participants? <input type="checkbox"/> Yes* <input type="checkbox"/> No *Greater than min. risk research must be reviewed by at least 2 Board members. <b><u>Please complete an IRB Application.</u></b>
<b>B. Prisoners:</b> Does this research involve interaction with Prisoners or prisoner’s private information? <input type="checkbox"/> Yes* <input type="checkbox"/> No *Please explain: *All prisoner research must be reviewed by the Full Board. <b><u>Please complete an IRB Application.</u></b>
<b>C. Public Data:</b> Will the study utilize archived data, documents, records or biological specimens? <input type="checkbox"/> Yes* <input type="checkbox"/> No *Provide Source: *When were these data collected:

**D. Exempt Categories (45 CFR 46.101(b))** *Check One Category below that best describes the study:*

(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.

**This applies only to Normal educational research in regular educational settings.**

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observations 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.

**This exemption does not apply to children or prisoners.**

(3) Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, 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.

**This applies only to elected official, not official appointed via a regular hiring process.**

(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 subjects cannot be identified, directly or through identifiers linked to the subjects. **All data must exist when the application is submitted (if data will be used that is collected or will be collected for clinical purposes, complete the IRB Review Form).**

(5) Research and demonstration projects which are 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;
- (iv) possible changes in methods or levels of payment for benefits or services under those programs.

This applies only to research and demonstration projects under the Federal Social Security Act. **This does not apply to state or local public service projects that are not pursuant to the Social Security Act.**

(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 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.

**E. Categories of Sensitive Information** (generally not eligible for exemption)

1. Information relating to sexual attitudes, preferences, or practice.
2. Information relating to the use of alcohol, drugs or other addictive products.
3. Information pertaining to illegal conduct.
4. Information that if release could reasonably damage an individuals financial standing, employability, or reputation within the community.
5. Information that would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination.
6. Information pertaining to an individual's psychological well-being or mental health.

7. Genetic information.  
 Does the study include collection of any sensitive information?  Yes\*  No \*Specify the category of sensitive information:

**F. Special Subject Populations** (generally not eligible for exemption, unless the study qualified for an educational exemption)

1. Minors (under 18 years of age). Not applicable to educational research
2. Fetuses or products of labor and delivery
3. Pregnant women (in studies that may influence maternal health)
4. Prisoners
5. Individuals with a diminished capacity to give informed consent

Does the study include any special subject populations?  Yes\*  No  
 \*Indicate population, and why their participation is incidental or needed:

**G. Research Summary:**  
 Please attach a brief (1-2 page) Research Summary that includes the following items, labeled and presented in this order:

1. Introduction
2. Start and End Dates
3. Specific Aims of research
4. Methods of data collection and analysis (qualitative and/or quantitative)
5. Description of the subject population, research setting, subject recruitment procedures
6. Informed consent procedures (if consent is needed)
7. Provisions for subjects and data confidentiality
8. Statement of potential research risks to subjects (e.g., breach of confidentiality, treatment complications)
9. Statement of potential research benefits to subjects (monetary compensation is not a benefit of participation)

**Attach any research instruments that will be used for the study** (interviews, questionnaires, advertisements). If the study is designed to develop instruments and test the instrument's validity, state this in the Research Summary. Provide a copy of the materials to the IRB once developed using an Action Request Form.

<b>SIGNATURES</b>		
<b>SIGNATURE OF PRINCIPAL INVESTIGATOR</b>		
The undersigned accept(s) responsibility for the study, including adherence to the ethical guidelines set forth in the Belmont Report, Declaration of Helsinki, the Nuremberg Code, the ethical principles of your discipline, the Common Rule and UVU policies regarding protection of the rights and welfare of human subjects participating in this study. In the case of student protocols, the faculty supervisor and the student share responsibility for adherence to policies.		
Print Name of PI	Signature of PI	Enter Date signed above.
<b>SIGNATURE OF FACULTY SUPERVISOR – REQUIRED FOR STUDENT RESEARCH</b>		
By signing this form, the faculty research supervisor attests that (s)he has read the attached protocol submitted for IRB review, and agrees to provide appropriate education and supervision of the student investigator, above and share the above Principal Investigator responsibilities.		
Print Faculty Supervisor Name	Supervisor's Signature	Enter Date signed above.
<b>SIGNATURE OF DEPART. CHAIR/DEAN – REQUIRED FOR FACULTY RESEARCH</b>		
Your signature below affirms you have been informed of the research.		

Print Name of Chair/Dean	Signature of Chair/Dean	Enter Date signed above.

For OHRPP Use Only			
1. Reviewer		2. Date	
3. Summarize the research proposed:			
<p>4. Exemption Category:</p> <p><input type="checkbox"/> 45 CFR 46.101(b)(1)            Is the research in a normal educational setting? <input type="checkbox"/> Yes <input type="checkbox"/> No            Does the research examine normal educational topics? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> 45 CFR 46.101(b)(2)            Does the research include minors (under the age of 18 years)? <input type="checkbox"/> Yes* <input type="checkbox"/> No            *If yes, the research requires IRB review. Defer for IRB review.</p> <p><input type="checkbox"/> 45 CFR 46.101(b)(3)            Are only elected officials included in the research? <input type="checkbox"/> Yes <input type="checkbox"/> No*            * If no, the research requires IRB review. Defer for IRB review.</p> <p><input type="checkbox"/> 45 CFR 46.101(b)(4)            Does all data exist at the time of application? <input type="checkbox"/> Yes <input type="checkbox"/> No*            *If no, the research requires IRB review. Defer for IRB review.</p> <p><input type="checkbox"/> 45 CFR 46.101(b)(5)            Is this a research or demonstration project under the Social Security Act? <input type="checkbox"/> Yes <input type="checkbox"/> No*            If no, the research requires IRB review. Defer for IRB review</p> <p><input type="checkbox"/> 45 CFR 46.101(b)(1)</p>			
<p><b>Recommendation:</b></p> <p><input type="checkbox"/> Exempt</p> <p><input type="checkbox"/> Defer for Expedited Review</p> <p><input type="checkbox"/> Defer for Full Board Review</p> <p><input type="checkbox"/> Not Research with Human subjects or personally identifiable private information</p>			
Additional Comments:			

## APPENDIX C

### ACTION REQUEST

Date Submitted: \_\_\_\_\_

1. **Title of Study:** \_\_\_\_\_  
\_\_\_\_\_

2. **IRB Code:** \_\_\_\_\_

3. **Principle Investigator:** \_\_\_\_\_

4. **Action Requested:**

\_\_\_ Research Study Completed: *(Check if you are finished with the data collection and analysis phases of your research study and would like to close your file)*

\_\_\_ Research Methodology Change Request: *(check if you have a change in any part of a study that has already been approved: e.g., sample number or composition, new distribution, research instrument change, new title, addition of new researchers or assistants who will see confidential data, and so forth)*

\_\_\_ Research Extension Request: *(check if you would like to request an extension on an already approved research study)*

\_\_\_ Other Action Request: *(use this for any other action requested for a previously approved research study)*

5. **Description:** *(Describe the methodology change, reasons and new date for extension request, or other action request)*

6. **IRB Administrator Approval**

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

*Send form via email to [irb@UVU.edu](mailto:irb@UVU.edu) or intercampus mail to IRB at MC*

## APPENDIX D

### ELEMENTS OF INFORMED CONSENT

NOTE: This template attempts to address 11 possible situations. Therefore, some statements may not apply to your protocol. There are instances in which research cannot be conducted with the complete knowledge and consent of the subjects. When these circumstances arise, the IRB will assist the researcher in ensuring that human subjects will be protected. Please contact the Office of the IRB Administrator for procedures in handling these special cases.

The headings in the left column on this sample consent must be shown as bolded headings in your letter of informed consent.

<b>Topic</b>	<b>Sample Text</b>
Introduction/Purpose (Who is PI)	<b>Professor _____ in the Department of _____ at Utah Valley University is conducting a research study to find out more about...There will be approximately _____ participants at this site. (Also, a statement must be included that this study involves “research”.)</b>
Procedures (What will happen? Duration?)	If you agree to be in this study, the following will happen to you. (Make clear which procedure(s) or treatments(s) are expectations, and the duration of the subjects’ involvement in the study. Include the number and frequency of tests, the amount of blood (in teaspoons or tablespoons) to be taken if appropriate, and the frequency of follow-up visits. Describe any visits which may be time-consuming. (State how much time is required for these visits. 1. 2. 3. (Any questionnaires, diaries, surveys, etc. should be provided to the IRB for review at the time of initial submission.)
New Findings	During the course of this study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research, or new alternatives to participation which might cause you to change your mind about continuing in the study. If new information is obtained that is relevant or useful to you, or if the procedures and/or methods change at any time throughout this study, your consent to continue participating in this study will be obtained again.

<p>Risks (reasonably to be expected)</p>	<p>Participation in this study may involve some added risks or discomforts. These include:</p> <ol style="list-style-type: none"> <li>1.</li> <li>2.</li> <li>3.</li> </ol> <p>(For studies involving experimental therapies, there should be a statement that unforeseen risks could occur. For studies involving sensitive issues (i.e., AIDS, drugs use, alcohol abuse, criminal activity, etc.) there should be a statement that describes the risk of that information being released through legal methods.)</p>
<p>Unforeseeable Risks</p>	<p>State if there are ANY risks involved. If there are no risks involved, write a statement saying that “there is minimal risk”. <i>There is no such thing as “no risk.”</i> (Explain what measures have been taken to minimize risk.)</p>
<p>Benefits (reasonably to be expected)</p>	<p>There may or may not be any direct benefit to you from these procedures. The investigator, however, may learn more about...(this section should include a description of possible benefits, major or minor, directly to the research subjects or to others which may be reasonably expected to result from the proposed research. If no benefits to the subject are expected, it should be stated as such. A statement should be included that the information gained from this study may benefit medical knowledge and others in the future.)</p>
<p>Explanations &amp; Offer to Answer Questions</p>	<p>_____ has explained this study to you and answered your questions. If you have any other questions or research-related problems, you may reach Professor _____ at extension _____.</p>
<p>Extra Cost(s)</p>	<p>Specify if there will be any additional costs in participating.</p>
<p>Payment (If this applies, include this statement)</p>	<p>You will be paid \$_____ at the end of this study for your participation. (Clearly state what costs the subject is responsible for. If there is no cost to the subject, it should be stated here. The conditions for obtaining the compensation must be stated. If they withdraw from the study, then explain that compensation may be void.)</p>
<p>Voluntary nature of participation and right to withdraw without consequence</p>	<p>Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without consequence or loss of benefits. (Add alternative procedures which might be beneficial here.) You may be withdrawn from this study without your consent by the investigator (list the circumstances under which participation may be terminated by the investigator without the subject’s consent.)</p>

Confidentiality (extent to which)	Research records will be kept confidential consistent with federal and state regulations. (If it is an investigational drug/device study, the FDA has maintained the right to review the records and a statement MUST be stated here.) Only the investigator and _____ will have access to the data, and it will be kept for three months and then destroyed (or kept indefinitely). If your study involves videotaping or voice recordings, explain if it will be destroyed in a certain period of time or kept indefinitely.								
Care if Harmed	In the event that you sustain injury resulting from your participation in this research project, Utah Valley University can reimburse you for emergency and temporary medical treatment not otherwise covered by your own insurance. If you believe that you have sustained an injury as a result of your participation in this research program, please contact the Vice President for Academic Affairs.								
IRB Approval Statement	The Institutional Review Board (IRB) for the protection of human subjects at Utah Valley University has reviewed and approved this research project.								
Copy of Consent (to be given to subject)	You/I have been given two copies of this Informed Consent. Please sign both copies and retain one copy for your files.								
Investigator Statement	“I certify that the research study had been explained to the individual, by me or my research staff, and that the individual understands the nature and purpose, the possible risks and benefits associated with taking part in this research study. Any questions that have been raised have been answered.”								
Signature of PI & Student or Co-PI	<table border="0" style="width: 100%;"> <tr> <td style="width: 50%; text-align: center;">_____</td> <td style="width: 50%; text-align: center;">_____</td> </tr> <tr> <td style="text-align: center;">(Signature of PI)</td> <td style="text-align: center;">(Signature of Student/Co-PI)</td> </tr> <tr> <td style="width: 50%; text-align: center;">_____</td> <td style="width: 50%; text-align: center;">_____</td> </tr> <tr> <td style="text-align: center;">(Phone number)</td> <td style="text-align: center;">(Phone number)</td> </tr> </table> <p>(Provide signature lines for witness, translator, parent(s)/guardian and child assent if applicable.)</p> <p>By signing below, you agree to participate.</p>	_____	_____	(Signature of PI)	(Signature of Student/Co-PI)	_____	_____	(Phone number)	(Phone number)
_____	_____								
(Signature of PI)	(Signature of Student/Co-PI)								
_____	_____								
(Phone number)	(Phone number)								
Signature of Subject(s)	<table border="0" style="width: 100%;"> <tr> <td style="width: 50%; text-align: center;">_____</td> <td style="width: 50%; text-align: center;">_____</td> </tr> <tr> <td style="text-align: center;">Subject’s Signature</td> <td style="text-align: center;">Date</td> </tr> </table> <p>(If the study will enroll subjects who may be unable to provide their own consent, add a signature line for “Duly Authorized Representative” and an additional line for “Relationship to the Patient”.)</p>	_____	_____	Subject’s Signature	Date				
_____	_____								
Subject’s Signature	Date								



## **APPENDIX E**

### **SAMPLE INFORMED CONSENT LETTER**

Regarding the formatting of the letter:

- Each page of the consent should be printed on department/program letterhead
- Number each page and include date
- Center 'INFORMED CONSENT' in the top of the header of each page; place title of Study below it

Example header:

INFORMED CONSENT  
Assessing Flow Experiences Amongst Rock Climbers

Example footer:

April 28, 2004  
Page 2

Title of Study:

Principal Investigator:

Name

Department

Address

Phone

E-mail

Background:

You are being invited to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please take the time to read the following information carefully. Please ask the researcher if there is anything that is not clear or if you need more information.

The purpose of this study is:

Study Procedure:

Your expected time commitment for this study is: (time)

Explain procedure.

Risks:

The risks of this study are minimal. These risks are similar to those you experience when disclosing work-related information to others. The topics in the survey may upset some respondents. You may decline to answer any or all questions and you may terminate your involvement at any time if you choose.

Benefits:

There will be no direct benefit to you for your participation in this study. However, we hope that the information obtained from this study may.... (list possible benefits)

Alternative Procedures:

If you do not want to be in the study, you may choose not to participate and leave your answers blank, or you may read quietly at your desk (for in-class survey research).

Confidentiality:

Please do not write any identifying information on your questionnaire. Your responses will be anonymous.

OR

For the purposes of this research project your comments will not be anonymous unless you request that they be. You may request that all or part of your responses be kept anonymous at any time.

Every effort will be made by the researcher to preserve your confidentiality including the following:

Assigning code names/numbers for participants that will be used on all researcher notes and documents.

- Notes, interview transcriptions, and transcribed notes and any other identifying participant information will be kept in a locked file cabinet in the personal possession of the researcher. When no longer necessary for research, all materials will be destroyed.
- The researcher and the members of the researcher's committee will review the researcher's collected data. Information from this research will be used solely for the purpose of this study and any publications that may result from this study. Any final publication will contain the names of the public figures that have consented to participate in this study (unless a public figure participant has requested anonymity): all other participants involved in this study will not be identified and their anonymity will be maintained.
- Each participant has the opportunity to obtain a transcribed copy of their interview. Participants should tell the researcher if a copy of the interview is desired.

(Modify as needed for each protocol)

Participant data will be kept confidential except in cases where the researcher is legally obligated to report specific incidents. These incidents include, but may not be limited to, incidents of abuse

and suicide risk.

Person To Contact:

Should you have any questions about the research or any related matters, please contact the researcher at (your email address or telephone number).

Institutional Review Board:

If you have questions regarding your rights as a research subject, or if problems arise which you do not feel you can discuss with the Investigator, please contact the Institutional Review Board Office at (801) 863-8455.

Voluntary Participation:

Your participation in this study is voluntary. It is up to you to decide whether or not to take part in this study. If you do decide to take part in this study, you will be asked to sign a consent form. If you decide to take part in this study, you are still free to withdraw at any time and without giving a reason. You are free to not answer any question or questions if you choose. This will not affect the relationship you have with the researcher.

Unforeseeable Risks:

There may be risks that are not anticipated. However every effort will be made to minimize any risks.

Costs To Subject:

There are no costs to you for your participation in this study

Compensation:

There is no monetary compensation to you for your participation in this study.

Consent:

By signing this consent form, I confirm that I have read and understood the information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

Signature \_\_\_\_\_

Date \_\_\_\_\_

**APPENDIX F**  
**INFORMED CONSENT CHECKLIST – OFFICE OF HUMAN RESEARCH**  
**PROTECTION (OHRP)**

**§46.116 - Informed Consent Checklist - Basic and Additional Elements**

	A statement that the study involves research
	An explanation of the purposes of the research
	The expected duration of the subject's participation
	A description of the procedures to be followed
	Identification of any procedures which are experimental
	A description of any reasonably foreseeable risks or discomforts to the subject
	A description of any benefits to the subject or to others which may reasonably be expected from the research
	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
	For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
( ) Research Qs	An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
( ) Rights Qs	
( ) Injury Qs	
	A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
<b>Additional elements, as appropriate</b>	
	A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable

	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
	Any additional costs to the subject that may result from participation in the research
	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
	A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
	The approximate number of subjects involved in the study

**§46.117 Documentation of Informed Consent Checklist**

<p>a. Except as provided in paragraph "c" of this section, informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.</p>	
<b>WRITTEN</b>	<p>The consent form may be either of the following:</p> <ol style="list-style-type: none"> <li>1. A <b>written consent</b> document that embodies the elements of informed consent required by <a href="#">§46.116</a>. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.</li> </ol>
<b>DONE ORALLY</b>	<ol style="list-style-type: none"> <li>2. A <b>short form written consent</b> document, stating that the elements of informed consent required by <a href="#">§46.116</a> have been presented <b>orally</b> to the subject or the subject's legally authorized representative. When this method is used, there shall be a <b>witness</b> to the oral presentation. Also, the IRB shall approve a <b>written summary</b> of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.</li> </ol>
<b>WAIVER of requirement for signed form</b>	<p>c. An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:</p> <ol style="list-style-type: none"> <li>1. That the only record linking the subject and the research would be the consent document, and the <b>principal risk</b> would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants</li> </ol>

	<p>documentation linking the subject with the research, and the subject's wishes will govern; or</p> <p>2. That the research presents <b>no more than minimal risk</b> of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context.</p> <p>In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.</p>
--	---

**IRB Latitude to Approve a Consent Procedure that Alters or Waives some or all of the Elements of Consent**

**§ 46.116** - An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

	<p><b>C:</b> 1. The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials, and is 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; and</p>
	<p><b>C:</b> 2. The research could not practicably be carried out without the waiver or alteration.</p>
	<p><b>D:</b> 1. The research involves no more than minimal risk to the subjects;</p>
	<p><b>D:</b> 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;</p>
	<p><b>D:</b> 3. The research could not practicably be carried out without the waiver or alteration; and</p>
	<p><b>D:</b> 4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.</p>

<b>Special Requirements - 45 CFR 46 Subpart D - Additional DHHS Protections for Children Involved as Subjects in Research</b>	
Assent/ Waiver	The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted, or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children, and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances, in which consent may be waived in accord with <a href="#">§46.116</a> of Subpart A.
Parents	The IRB may find that the permission of <b>one</b> parent is sufficient for research to be conducted under <a href="#">§46.404</a> or <a href="#">§46.405</a> .
	Where research is covered by <a href="#">§46.406</a> and <a href="#">§46.407</a> , and permission is to be obtained from parents, <b>both parents must give their permission</b> , unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
	If the IRB determines that a research protocol is designed for conditions or for a subject population, for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law.

09/30/98

## **APPENDIX G**

### **ADDITIONAL INFORMED CONSENT RESOURCES**

#### **What are the basic elements of informed consent?**

Answer:

The basic requirements of informed consent can be found in the HHS regulations at 45 CFR 46.116(a). OHRP also has a tips sheet for informed consent at <http://www.hhs.gov/ohrp/humansubjects/guidance/ictips.htm>.

The regulations require that the following information must be conveyed to each subject:

1. a statement that the study involves research, an explanation of the purpose of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. a description of any reasonably foreseeable risks or discomforts to the subject;
3. a description of any benefits to the subject or to others which may reasonably be expected from the research;
4. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where information may be obtained;
7. an explanation of whom to contact for answers to pertinent questions about the research (the principal investigator) and research subjects' rights (the IRB), and whom to contact in the event of a research-related injury to the subject; and
8. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional elements are described in 45 CFR 46.116(b) and must be provided as part of the informed consent process whenever appropriate.

## INFORMED CONSENT

Be sure the language on the consent form is at the level of the least educated participant that will be contacted. A sixth grade language level is appropriate if a general adult population is used and the education level is not known. Obtaining consent is a process of providing meaningful information and not merely the signing of the consent form.

The consent form should be written in second person, except for the final consent statement that is written in first person.

The consent should use the headings that appear on the sample below. These headings are for convenience in reading and to guide the subjects through the document.

### **Elements of Informed Consent and Sample Basic Consent Form:**

1. Title: The title of the consent form must include the words "research subject."
2. Introduction: What is being studied, why participants were selected, how the treatment differs from normal treatment (if applicable), and the names of the investigator(s).
3. Procedures: Inform subjects what would happen to them if they participate that would not otherwise occur. Subjects should know exactly what is expected of them, where they need to go, and the amount of time they will be asked to give, as well as the duration of their participation (i.e., data collected all at one time, data collected three times once a month, etc.).
4. Risks and/or Discomforts: This section should include potential legal, economic, psychological, emotional and physical risks. Very few studies have no risks. Most have minimal risks. If there are minimal risks then this should be stated. All potential risks must be specifically stated.
5. Benefits: The benefits section should contain an unbiased statement that discusses personal and/or societal benefits. It should not read like an advertisement. If there are no benefits to the individual that should be stated and societal benefits listed. If there are no benefits to society, then the value of the research may be negligible and may not be approved.
6. Alternatives: (if applicable) This section should discuss the therapeutic or treatment options open in lieu of participation in this study. If there are none, then leave this section out.
7. Confidentiality: There needs to be a statement that information will remain confidential and will be reported as a group and not as data identifiable to a specific person, unless the research subject has specifically agreed to be identified.

8. Compensation: (if applicable). If money is offered in exchange for research participation it should not be disproportionate nor reflect payment for acceptance of risk. Extra credit, drawings, vouchers, etc. are also described in this section.

9. Participation: Include these statements verbatim: "Participation in this research study is voluntary. You have the right to withdraw at any time or refuse to participate entirely without jeopardy to (your class status, grade or standing with the university, etc.). "

10. Questions about the Research: Subjects have the right to be able to contact the investigator if any questions come up. This must be visible on the consent form. Please include name, phone number, address and/or email.

11. Questions about your Rights as Research Participants: There needs to be a person not involved with the study who can answer questions about the rights of a research subject. This person is typically the Chair of the IRB. This must be visible on the consent form. Please include name, phone number, address and email.

12. Signatures: There should be a consent statement in first person indicating that the participant understands and has received a copy of the consent form and agrees to participate in the research. When using a signed consent form, all participants over the age of 18, unless cognitively impaired, must sign a consent form written in language they can understand. See "Vulnerable participants" for other instructions if you are using individuals who fall within these population groups. The forms must be witnessed.

Please use the **following example** as a guide in preparing an appropriate informed consent document.

## **SAMPLE of an Consent to be a Research Subject Form**

### Introduction

This research study is being conducted by Drs. T.V. Protein and P. Milk at Utah Valley University to determine how parental food storage relates to personal views and habits on food storage. You were selected to participate because you are currently taking a 100 level community Health class.

### Procedures

You will be asked to complete a questionnaire in LA213. The questionnaire consists of 35 questions and will take approximately 30 minutes. Questions will include details about your food storage (how, what, where, how much, etc.), demographics including family size, and your own personal views about and feelings toward food storage. Participants may volunteer to be part of a focus group. Researchers will contact those who volunteer with more information regarding the time and place. The focus group will last for approximately 60 minutes and consist of more in-depth questions similar to those of the questionnaire. It will be tape-recorded and then transcribed.

### Risks and/or Discomforts

There are minimal risks for participation in this study. However, you may feel emotional discomfort when answering questions about personal beliefs. When participating in the focus group, it is possible that you may feel embarrassed when talking in front of others. The moderator will be sensitive to those who may become uncomfortable.

### Benefits

There are no direct benefits to subjects. However, it is hoped that through your participation researchers will learn more about food storage practice and belief and be able to assist the Department of Homeland Security in improving their emergency preparedness education program.

### Confidentiality

All information provided will remain confidential and will only be reported as group data with no identifying information. All data, including questionnaires, tapes and/or transcriptions from the focus group, will be kept in a locked storage cabinet and only those directly involved with the research will have access to them. After the research is completed, the questionnaires, tapes and transcripts will be destroyed.

### Questions about your Rights as Research Participants

If you have questions you do not feel comfortable asking the researcher, you may contact Dr. Genan Anderson, IRB Chair, Utah Valley University, 800 West University Parkway, Orem, Utah 84058, andersge@UVU.edu.

I have read, understood, and received a copy of the above consent and desire of my own free will to participate in this study.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

### **Request for Waiver or Modification of Consent**

A request for modification of consent, if approved by the IRB, allows the researcher to modify some elements of consent (i.e. signed document, etc), in certain limited circumstances. The researcher must still provide the IRB a script explaining the research to potential research participants. Use the "exempt" sample at the bottom of this page as a guide for the script.

### **Exempt Protocols**

"Exempt" research means a lower level of review, not that it is "exempt" from IRB review.

Categories of Exempt research:

1. Research conducted in established educational settings involving normal educational practices such as (i) instructional strategies, or (ii) effectiveness or comparison of instructional techniques.

2. Research involving educational testing where subjects cannot be identified or release of information would not be harmful to the subjects.
3. Research involving the use of surveys or interviews or observation of public behavior for which subjects cannot be identified or release of information would not be harmful to the subjects. Research may not include children.
4. Research involving a study of existing data, if the data is 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 subject.
5. Taste and food quality evaluations.

Any project involving sensitive topics cannot be reviewed through exempt procedures and requires a higher level of review. The following list is not inclusive but is meant to offer a general idea: sexual orientation or abuse, substance use or abuse, eating disorders or behaviors, questions dealing with mental and emotional health, religious views, and protocols involving deception. Projects involving vulnerable populations (children, prisoners, pregnant women or focusing on one group) raise the level of review.

#### Classroom Projects:

Coursework involving surveys, interviews or observational studies which don't involve sensitive topics or vulnerable populations and where the information will be kept exclusively in the classroom, can be reviewed by the teacher. Information must be recorded anonymously and if the information became known it would not be damaging or embarrassing to the individual. This does not include research done for publication outside of the college (journals, white papers, conference presentations, graduate theses or dissertations, etc.).

### **SAMPLE of an "Informed Consent Statement" for an "Exempt" research survey:**

This survey is being conducted by UVU Students to determine...(purpose or objectives). Participants will be chosen randomly from the UVU student body...(how you will choose your participants). You must be 18 years or older to participate. The survey consists of eight (number of) questions and will take five minutes (amount of time) to answer...(how long it is). There are minimal risks or and/or benefits to your participation in this study...(risks vs. benefits). Involvement in this research project is voluntary. You may withdraw at any time without penalty or refuse to participate entirely. There will be no reference to your identification at any point in the research.

If you have questions regarding this study you may contact Dr. XYZ Researcher at (801) 863-xxxx.

If you have questions regarding your rights as a participant in research projects, for which you do not feel comfortable asking the researcher, you may contact the Institutional Review Board at 801-863-8156 or by e-mail at [irb@uvu.edu](mailto:irb@uvu.edu).

## **APPENDIX H WAIVER OF CONSENT - SAMPLE LETTER**

### **Debriefing Template**

Thank you for participating in our study. In (insert the type of research), it is sometimes necessary to conceal our hypotheses because when people know what is being studied they often alter their (insert behavior, answers, etc). However, we do not want you to leave misinformed, so we will now tell you what we were actually studying.

The purpose of this study is to (insert true purpose of the study).

In order to test these hypotheses, (insert how this was accomplished in the study).

We apologize that we could not reveal our true hypotheses to you up front, but we hope you can see why it was necessary to keep this information from you. When people know exactly what the researcher is studying, they often change their behavior, thus making their responses unusable for drawing conclusions about human nature and experiences. For this reason, we ask that you please not discuss this study with other subjects who might participate anytime in the (insert next week, next semester, next year, etc.). Thank you for your cooperation.

If your participation in this study has in any way upset you, please feel free to set up an appointment with one of UVU's licensed psychologists or counselors. Counseling services are provided by the Student Health Services which is located on the second floor of the Sorensen Student Center. Student Health Services can be reached at (801) 863-8876.

If you have any questions about this study, feel free to ask the researcher (insert phone number and email). Thank you for your help today.

Now that you know the true purpose of this study, please check the box below if you would like your data to be excluded from our study:

- Remove my data from the study.

---

Signature of Participant or Participant #

---

Date