

INSTRUCTIONS FOR OBTAINING INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL

If your proposed research requires approval from the DHS IRB, the researcher must complete the following steps:

- 1. Letter of Support from the Division.** Contact the designated representative of the appropriate Division of the Department (see list below), and obtain a letter stating that the Division has reviewed the proposed research project and has determined that it is in the best interests of the Division and the Division's clients to approve the research proposal. (See the section above titled "Divisions as Gatekeepers in the Review Process" for the relevant criteria.) Submit this letter to the DHS IRB with the research proposal.

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2. **Letter of Support from Non-DHS Facility Administrator.** If subjects will be drawn from facilities which are not directly under the control of the above-listed Division or Agency, contact the administrator of each facility or program, and obtain a letter stating that: (a) the administrator is the person designated to review such proposal for the facility; and (b) the administrator has reviewed the proposed research project and has determined that it is in the best interests of the administrator's facility or program and in the best interests of the clients to approve the research proposal. Submit this letter to the DHS IRB as part of the research proposal.
3. **Research Agreement.** Review the attached Research Agreement, and submit a signed and dated copy to the DHS IRB as part of the research proposal.
4. **Research Proposal.** Complete the attached Research Proposal form (**including all information requested in Items 1 through 15**), and submit to the DHS Division IRB Representative or the IRB Chair. The Research Proposal may be submitted in hard copy, by e-mail, or by a disk readable in Microsoft Word (preferred) or WordPerfect.
5. **Cover Sheet for the Research Proposal.** Complete the attached Research Proposal cover sheet by providing the **necessary signatures** and relevant documents and submit it to:
DHS Institutional Review Board
Utah Department of Human Services
ATTN: Dr. Navina Forsythe
120 North 200 West, Suite 225
Salt Lake City, Utah 84103

RESEARCH PROPOSAL COVER SHEET
UTAH STATE DEPARTMENT OF HUMAN SERVICES
Institutional Review Board (DHS IRB)

Date of Proposal: _____
 Name of Principal Investigator: _____
 College/University or other Agency Affiliation: _____
 Address: _____
 City/State/Zip: _____
 Work Phone: (____) _____ Home Phone: (____) _____ E-mail: _____
 Anticipated Start Date: _____ End Date: _____

Is this study conducted by DHS employee(s)? _____ Yes _____ No
 Has the appropriate Division reviewed and approved the study? _____ Yes _____ No
 Does this study involve the testing of drugs or biomedical devices? _____ Yes
 _____ No

1. **TITLE:** _____
2. **NATURE OF STUDY:**
3. **RISK LEVEL** (as defined in policy, page 4): Less than minimal risk; Minimal Risk; Greater than minimal risk but with direct benefit to subjects; Greater than minimal risk but no direct benefit to subjects. **(Briefly summarize the facts that support the risk level you have identified. If the study involves greater than minimal risk, identify all direct benefits to the human subjects as well as any additional safeguards.)**
4. **PROTECTION OF RIGHTS AND WELFARE OF HUMAN SUBJECTS:**
 - a. Review and support by Agency and Division (See "Instructions" in preceding section.):
 _____ Letter(s) of support from appropriate Division IRB Representative(s) attached.
 _____ Letter(s) of support from on-site administrator(s) attached.
 - b. Individual Information and Permission. Please attach the following documents:

YES	NO	N/A	ITEMS TO ATTACH TO THIS PROPOSAL
			1. Informational "recruitment statement" that the researcher will distribute to potential subjects.
			2. Informed-consent form that subjects must sign before they participate in the study.
			3. For children, or individuals who are legally incompetent, provide a sample letter requesting written permission of parent or legal guardian.
			4. Debriefing statement that researcher will distribute to the subjects after their participation is completed.
			5. Titles of any questionnaires, surveys or other instruments that the researcher will use in the study.
			6. Signed and dated Research Agreement form.

REQUIRED SIGNATURE

Principal Investigator: _____

ITEMS 1-16 ARE REQUIRED FOR ALL RESEARCH PROJECTS
Please Complete ALL of These Items. If an Item Does Not Apply, Indicate “N/A.”

PROJECT DESCRIPTION

1. **Project Description.**
 - (a) Briefly describe the objectives, methods and *general* procedures of the project. The emphasis should be on the human subject's involvement in the project. For example, describe any physiological or psychological intervention, the means used to administer the intervention, the behavior expected of the subject(s), and the behavior of the investigator during the intervention. Please avoid discussion of theoretical or statistical aspects of the project unless they relate to the protection of human subjects.
 - (b) If questionnaires or testing instruments will be used, describe how they will be administered.
 - (c) If interviews are to be conducted, describe the nature of the interview and how responses will be recorded.
 - (d) The researcher may attach a copy of the project prospectus, if one is available.
2. **Submission of grant proposal.** A copy of any grant proposal or agreement related to the protocol must be submitted with the DHS IRB application.
3. **Outside IRB Review.** If this project is being reviewed by another human subjects research review group (e.g., a hospital institutional review board), attach a copy of the approval of that institution. If the review is still pending, include a statement of the current status of the pending review.

INFORMATION ABOUT THE HUMAN SUBJECTS INVOLVED IN PROJECT

4. **Subjects' Number and Characteristics.** Specify the number of the subjects and their relevant characteristics (e.g., police officers, students, random sample of nursing home patients).
5. **Remuneration.** Specify any remuneration that the researcher will give the subjects for their participation (e.g., money, gifts, free treatment). Please explain why this remuneration will not serve as a coercive influence or undermine the subjects' free, informed consent.
6. **Researcher's Relationship with Subjects.** Explain the relationship between the subject(s) and the researcher or investigator (e.g., students, clients, etc.). If there is no relationship prior to the research project, so state.
7. **Recruitment.** Explain how the researcher will identify and recruit the potential subject(s) for participation (e.g., random sample, subject pool). If recruitment involves the use of an intermediary recruiter (such as physicians recruiting their patients), please indicate whether the research is providing any remuneration to the intermediary recruiter (such as the physician), indicate the amount or value of the remuneration, and explain how or why this remuneration will not compromise the interests of the subject and unduly influence the intermediary recruiter's independent judgment about the best interests of the subject (such as the patient).

INFORMATION ABOUT RESEARCH RISKS AND BENEFITS AND RESEARCH PROTOCOLS

8. Information about Risk/Benefit Analysis.

- (a) Describe any risk(s), discomforts or consequences (either negative or positive) to the subject, and specify the level of risks to the subjects. (Risks, discomforts and consequences may be physical, psychological, or social.)
- (b) If the proposed study involves more than minimal risk to the subject, describe any benefit to the subject or others that outweighs this risk. (According to 45 CFR § 46.102 (i), “Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”)
- (c) Some research involves neither risks nor discomforts but rather violations of normal expectations. Specify whether the proposed study involves any such violations of normal expectations.
- (d) Describe the safeguards the researcher will take to minimize any potential risks, effects, or violations.

9. Benefits to Human Subjects and the Department. Identify any potential benefit(s) that the research project will provide to human subjects as well as the Utah Department of Human Services.

10. Questionnaires, Tests, Interviews. Attach copies of all questionnaires, testing instruments, or interview protocols. Include any cover letters or instructions that the researcher will provide to the subjects.

11. Privacy and Confidentiality.

- (a) Identify any personal identifiers or indicators (e.g., name, social security, etc.) that the researcher will record about each subject. (If none, so state.)
- (b) Explain the specific steps the researcher will take to safeguard the anonymity of the subjects or to protect the confidentiality of their responses.
- (c) Specify the procedures for the storage and ultimate disposal of personal information.

12. Initial Client Contact. The Department of Human Services cannot release clients’ names or other identifying information without obtaining prior consent from each client. Explain how you will initially contact the clients to obtain their consent (e.g., arrange initial contact through a specific Department or Division IRB Representative.)

13. Deception. If *deception* is to be used in this project, explain in detail why deception is necessary to accomplish the goals of the research. Care should be taken to distinguish cases in which disclosure would invalidate the research from cases in which disclosure would simply inconvenience the investigators.

14. **Debriefing the Research Subjects.** Describe in *detail* how the researcher will debrief the subjects. (If deception is used, debriefing is required unless the investigator articulates a compelling reason to delay or omit the debriefing.)
15. **Investigators' Qualifications.** Some research procedures may require a certain level of investigator competence and training. Please list the qualifications of each investigator, including the investigator's training, experience and relevant licensure.
16. **Drugs and Biomedical Devices.** Research procedures involving the investigation of new drugs, biomedical devices, or other special interventions require additional information and review. Please consult the Chairperson of the DHS IRB for details.

RESEARCH AGREEMENT

_____ (the “Researcher”) is submitting a research proposal to the Utah Department of Human Services (the “Department”). The Researcher understands and agrees to the following terms and conditions:

- The Researcher has read and shall comply with the Department’s informed-consent policies, which are set forth in Attachment “A” of this Research Agreement
- The Researcher shall use the research records only for the purposes stated in the application and approved by the Department.
- The Researcher shall assure the integrity, confidentiality, and security of the records. The Researcher shall take adequate steps to safeguard anonymity and protect the confidentiality of subjects during all phases of the research project.
- The Researcher shall not disclose any records in an individually-identifiable form except for the purpose of auditing or evaluating the research program or except as provided by the Utah Government Records and Management Act (“GRAMA”). The Researcher shall respect the Department’s classification of its records, and shall comply with GRAMA and any other Utah statutes or regulations that allow or restrict public access to Department records.
- If the Department gives the Researcher access to Department records, the Researcher shall make no subsequent use or disclosure of those Department records without prior written authorization from the Department.
- The Researcher shall follow the procedures and methods described in the application and in any modifications made by the Department’s DHS IRB.
- The Researcher shall notify the Department’s DHS IRB immediately about any proposed changes in the research procedures or methods, and the Researcher shall not implement those changes unless the Committee approves them.
- The Researcher shall notify the DHS IRB immediately about any significant adverse reactions experienced by the subjects as a result of the study.
- If the Researcher only recruits English-speaking participants, the Researcher shall include a statement in any dissemination and/or publication of the results, that the research participants were limited to English-speaking persons.
- The Researcher shall comply with the requirements of the DHS IRB and any institutional review boards of universities, colleges, hospitals or other institutions connected with the research.
- The Researcher shall comply with federal regulations about human-subjects research e.g., (45 CFR Part 46).

- If the Researcher's study involves elementary and secondary school students, the Researcher shall comply with the Utah Family Educational Rights and Privacy Act, *Utah Code Annotated* § 53A-13-301.
- The Researcher shall comply with all state and federal laws, including those that protect the privacy of individuals and research subjects. The Researcher understands that violation of any local, state, or federal law may subject the Researcher to criminal or civil prosecution or other penalties.

Print name of Researcher's principal investigator

Signature of Researcher's principal investigator

Date: _____