**RESEARCH PROPOSAL APPLICATION**

**UTAH DEPARTMENT OF HEALTH and HUMAN SERVICES**

**Institutional Review Board (IRB)**

Please select applicable DHHS IRB:

[ ] IRB1-Behavioral Research

[ ] IRB2-Health and Biomedical Research

Send application, documents, and all correspondence to dhhs\_irb@utah.gov.

Date of Proposal:Click or tap to enter a date.

Resubmission Date (if this is a resubmission): Click or tap to enter a date.

#  INVESTIGATORS:

Name of Principal Investigator: Click or tap here to enter text.

College/University or other Agency Affiliation: Click or tap here to enter text.

Address: Click or tap here to enter text.

City/State/Zip: Click or tap here to enter text.

Work Phone:Click or tap here to enter text.. Cell Phone: Click or tap here to enter text.

E-mail: Click or tap here to enter text.

Attach Vita of Principal Investigator highlighting academic experience, research experience, experience with proposed procedures and methodology, and experiences with the proposed participant population.

Name of Co-Investigator: Click or tap here to enter text.

College/University or other Agency Affiliation: Click or tap here to enter text.

Address: Click or tap here to enter text.

City/State/Zip: Click or tap here to enter text.

Work Phone: Click or tap here to enter text. Home Phone: Click or tap here to enter text.

E-mail: Click or tap here to enter text.

Attach Vita of Principal Investigator highlighting academic experience, research experience, experience with proposed procedures and methodology, and experiences with the proposed participant population.

(Add other investigators as needed)

DHHS Bureau/Division involved:Click or tap here to enter text.

DHHS Employee Involved:Click or tap here to enter text..

Is a DHHS employee(s) one of the investigators of the research?Choose an item.

**Data Steward** **Approval form or finalized Data Sharing Agreement.** If your project involves utilizing data under the authority of DDHS, contact the administrator of each program, and obtain a letter or ask for the data steward approval support form stating that: (a) the administrator is the person designated to review such proposal for the program; and (b) the administrator has reviewed the proposed research project and has determined that it is in the best interests of the administrator’s program and in the best interests of the clients to approve the research proposal.

Submit a signed data steward approval form with your IRB application while working on your data sharing agreement (s) with the relevant DHHS data steward(s) for your project and determine the feasibility of obtaining the data you are requesting.

The signed Data Steward Approval form must include list of data variables preferably in a table format and the reasoning behind requesting the variables to be used in study. Submit the signed DSA after it is approved to the IRB for our documentation purposes.

Submit letters with this application.

# STUDY INFORMATION:

**Title:** Click or tap here to enter text.

**Brief Description of Study (paragraph overview):**

Click or tap here to enter text.

Anticipated Start Date:Click or tap to enter a date. End Date:Click or tap to enter a date.

Does the research involve:

 Prisoners: Choose an item.

 Children: Choose an item.

 Pregnant Women: Choose an item.

 Wards of the State: Choose an item.

Is the study design (check all that apply):

 Secondary data analysis: [ ]

 Survey data: [ ]

 Recruitment of participants: [ ]

Does the data involve limited/restricted data (names or identifying information, any elements of dates lower than year, any geographic subdivision lower than state)?

 ***PROJECT DESCRIPTION***

1. **Background Information:** Provide a brief literature review with citations that gives enough information for scientists and non-scientists to understand study and objectives.

Click or tap here to enter text.

1. **Objectives:** Explain information that researcher hopes to obtain from the study. If applicable list hypotheses or research aims of study.

Click or tap here to enter text.

1. **Study Design:** Describe experimental design of study including methods of participant selection, use of control groups, etc. If there are multiple parts to the research, the design for each part should be described. Clearly describe what data are to be collected from human subjects; attach questionnaires and data collection forms if these are used. If DHHS datasets are to be used, include a list of specific variables that will be included from each dataset. The IRB is especially concerned about personally identifiable information. So if these are to be collected, a justification should be included as to why these are necessary. For example, if exact date of birth is requested, the investigator must explain why this is needed—e.g., why month and year of birth is not adequate or why a calculated variable show the number of days between birth date and test date is not adequate.

 Click or tap here to enter text.

1. **Study Procedures:** Describe in chronological order how the study will be conducted. Be sure to include the following:
	1. Participant recruitment and initial contact. The Department of Health and Human Services may not be able to release clients’ names or other identifying information without obtaining prior consent from each client unless the release is allowed under law. Explain how you will initially contact the clients to obtain their consent. Any recruitment materials being used must be included with application.

 Click or tap here to enter text.

* 1. Informed consent processes. The IRB is particularly concerned that potential human subjects recruited for a study understand the research and the potential risks and benefits to them. A checklist of what needs to be included in the Informed Consent form can be found at [2018 Requirements (2018 Common Rule) | HHS.gov](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116). For minor children, instructions for what should be included in an Assent form are also included. Reading level should be appropriate to the study population and can be evaluated using one of the online systems to assess this such as <https://www.online-utility.org/english/readability_test_and_improve.jsp>. The investigator should describe who will be administering informed consent and how documentation of informed consent will be maintained. Include a copy of the Informed Consent (or Assent) form with the IRB submission package.

**Note that you must either provide informed consent or request a waiver of informed consent; a NA or not applicable response is not acceptable**.  If NA or not applicable is entered, the application will be returned for the PI to update to either request a waiver or provide consent.

Click or tap here to enter text..

* + 1. If waiver of informed consent is being requested please specify and explain why informed consent cannot be obtained for this study.

 Waiver of informed consent requested? Choose an item..

 Click or tap here to enter text..

* + 1. If waiver of written informed consent is being requested please specify and explain why written informed consent is not being sought.

 Waiver of written informed consent requested? Choose an item..

 Click or tap here to enter text..

* + 1. If broad consent is being request please explain.

Broad informed consent requested?Choose an item..

Click or tap here to enter text..

* 1. Describe physiological or psychological interventions, the means used to administer the intervention, the behavior expected of the subject(s), and the behavior of the investigator during the intervention

Click or tap here to enter text.

* 1. If questionnaires or testing instruments will be used, describe how they will be administered. If interviews are to be conducted, describe the nature of the interview and how responses will be recorded. Copies of all instruments and interviews must be included with the application.

Click or tap here to enter text.

1. **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.

 Click or tap here to enter text.

1. **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. Even if debriefing isn’t required it may be appropriate for subjects to be informed what their contribution was.

Click or tap here to enter text.

1. **Participant Selection.** Specify the number of the subjects targeted (sample size). Define criteria for age, gender, and other relevant factors. Include specific exclusion criteria. Include power analysis if appropriate. Vulnerable populations - The IRB is especially concerned about vulnerable populations (e.g., infants and children, prisoners, mentally or physically handicapped individuals, pregnant women, disenfranchised populations, etc.) so if these are the focus of the research, a careful explanation of why they are included and how they will be protected should be included.

Click or tap here to enter text.

1. **Methodology, data analysis, and limitations**. Include a brief description of your statistical or qualitative analysis plan. Justify the type of analysis chosen. How will you use it to test your hypothesis and to draw interpretations? List possible limitations to interpretation based on design.

Click or tap here to enter text.

1. **Resources for Study**: List resources available to ensure study can be conducted. This may include personnel, funding, equipment, space etc.

Click or tap here to enter text.

1. **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.

Click or tap here to enter text.

1. **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.

Click or tap here to enter text.

1. **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.

 Click or tap here to enter text.

1. **Information about Risk/Benefit Analysis.**
2. Risk Level (check which applies):
	* 1. [ ] Minimal Risk - the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests;
		2. [ ] Greater than minimal risk but with direct benefit to subjects;
		3. ☐ Greater than minimal risk and without the prospect of direct benefit but likely to yield generalizable knowledge about the subject’s disorder or condition.
3. 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.)

 Click or tap here to enter text.

1. Describe benefits to the human subjects. If the proposed study involves more than minimal risk to the subject, describe any benefit to the subject or others that outweighs this risk.

Click or tap here to enter text.

1. Some research involves neither risks nor discomforts but rather violations of normal expectations (e.g., atypical procedures). Specify whether the proposed study involves any such violations of normal expectations.

Click or tap here to enter text.

1. Describe the safeguards the researcher will take to minimize any potential risks, effects, or violations.

 Click or tap here to enter text.

1. **Benefits to the Department.** Identify any potential benefit(s) that the research project will provide to the Utah Department of Health and Human Services. This may include anticipated products of the research including publications, reports, presentations, etc.\

Click or tap here to enter text.

1. **Privacy and Confidentiality.**
2. Identify any personal identifiers or indicators (e.g., name, social security, etc.) that the researcher will record about each subject. (If none, so state.)

 Click or tap here to enter text.

1. Explain the specific steps the researcher will take to safeguard the anonymity of the subjects or to protect the confidentiality of their responses. Maintaining high levels of security of DHHS data resources is very important to the IRB. Therefore, make a clear explanation of how the data collected will be physically and electronically protected from viewing by persons other than the investigators including: physical location of the data, password protection methods, list of persons who will have access to the data, etc.

 Click or tap here to enter text.

1. Specify the procedures for the storage and ultimate disposal of personal information. The IRB requests that investigators estimate how long they will need the data to complete their investigation. After that date, the investigators should describe disposition of the data. If all identifiers are to be stripped and a de-identified dataset is to be retained after the study termination date, the investigator should describe in detail the identifiers that have been removed and the re-numbering system used.

Additionally, if research includes identifiable information, specify a timeframe (usually no longer than seven years) after which all data containing identifiable information will be destroyed.

 Click or tap here to enter text.

1. **Funding source(s) of the research –** Describe any funding sources for the project.

Click or tap here to enter text.

1. **Conflict of Interest-** Describe any conflicts of interest that the IRB needs to be aware of. A "Conflict of Interest" means any situation where the researcher has financial, economic, social, political, familial, legal or other interests which interfere with, or have the potential to interfere with, their judgment in connection with the research. Recipient must attest in writing to the Department any and all real or potential conflicts of interest of both the Recipient and any and all listed data users in this agreement which could have an impact on the planning, conduct or the interpretation of the project. In addition to the attestation of any and all real or potential conflicts of interests, Recipient must supply the Department with a conflict of interest management plan, outlining how the conflicts will be mitigated. By signing this agreementClick or tap here to enter text., Recipient acknowledges this Conflict of Interest statement and will fully abide by its requirements.

**ATTACHMENTS**:

**List names of all attachments. Please name attachments clearly using the following naming convention documenttype\_piname\_projectname\_version date. For example parentconsent\_smith\_agencyevaulation\_6-4-2013.**

1. Curriculum Vitae for Principal Investigator and Co-Investigators

 Click or tap here to enter text.

1. Recruitment Flyers, Emails, Letters, Advertisements

 Click or tap here to enter text.

1. Informed Consent and Assent Documents

 Click or tap here to enter text.

1. Questionnaires, testing instruments, interview or focus group questions

 Click or tap here to enter text.

1. IRB applications submitted to other IRBs

 Click or tap here to enter text.

1. Letter(s) of support from on-site administrator(s) attached.

 Click or tap here to enter text.

1. Flow Chart. If your proposal has multiple objectives or has complicated objectives and analysis, please include a flow chart detailing the objectives, data sources, types of methods or models used for analysis, and/or outcomes to assist the reviewers understand the protocol request. (This may only apply to applications submitted to the DHHS IRB 2- Health and Biomedical Research.)
2. Signed and dated Research Agreement (below)

RESEARCH AGREEMENT

[Researcher Name] (the “Researcher”) is submitting a research proposal to the Utah Department of Health and 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 follow this Research Agreement.
* The Researcher shall adhere to the ethical standards of respect of persons, beneficence, and justice as outlined in the Belmont Report.
* 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 as allowed under law.
* 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 IRB.
* The Researcher shall notify the Department’s 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 IRB immediately about any significant adverse reactions or events 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 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).
* 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. Researcher also agrees to comply with Utah DHHS Misconduct policy.
* The researcher agrees to provide a copy of study results to the IRB.

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Print name of Researcher’s principal investigator

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

Signature of Researcher’s principal investigator