**Amendment, Renewal, Adverse Event, and Termination of Research Proposal Form**

**UTAH DEPARTMENT OF HEALTH and HUMAN SERVICES**

Institutional Review Board (IRB)

DHHS\_IRB@utah.gov

288 North 1460 West, Salt Lake City, UT 84116

Please select applicable DHHS IRB:

[ ] IRB1-Behavioral Research

[ ] IRB2-Health and Biomedical Research

Date of Submission:Click or tap to enter a date. UDOH IRB #: Click here to enter text.

Researcher’s Name: Click here to enter text.

Street Address: Click here to enter text. E-mail: Click here to enter text.

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

Start Date: Click here to enter a date.

Anticipated End Date: Click here to enter a date.

**NOTE:** *All research projects must be reviewed by the Department's IRB no less than annually. All renewals and amendments must include the most recent protocol, survey, and informed consent documents. If the Researcher plans to make* ***any*** *changes to the research design, instruments, or surveys, the Researcher must submit the documents with the changes highlighted for review, and obtain approval* ***before*** *the changes are implemented. See item #5.*

1. **TITLE:** Click here to enter text.
2. **BRIEF STUDY DESCRIPTION:**

 Click here to enter text.

3. **STUDY STATUS:** *(Check one)*

**[ ]  NO CHANGES** have been made to the study protocol or instruments since the IRB last approved the study.  ***Please enter a response to the three question below then complete #4. Update of the Study Status.***

* Has study progressed to the point that it only involved data analysis? Choose an item.
* Does the study team have access to identifiable information? Choose an item.

Identifiable data is defined as follows:

Names; Any geographic subdivisions smaller than a State; Any elements of dates lower than a year for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89; Telephone numbers; FAX numbers; Electronic mail addresses; Social security numbers; Medical record numbers; Health plan beneficiary numbers; Account numbers Certificate/license numbers; Vehicle identifiers and serial numbers; license plate numbers; Device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; Biometric identifiers; Full face photographic images and any comparable images, Any other unique identifying number, characteristic, or code.

* Has study progressed to the point that it is only accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care? Choose an item.

**[ ]  CHANGES ARE PROPOSED** for the study protocol and instruments since the IRB last approved the study. ***Please attach a list that itemizes each change proposed for the protocol or instruments. Attach copies of all proposed protocol changes and all new or modified survey instruments or questionnaires. Complete update of the study status (#4 below)***

**[ ]  STUDY TERMINATED. *Please attach a copy of the final report.***

4. **UPDATE OF STUDY STATUS:** *(Please attach additional pages as necessary*)

* + The # of subjects accrued: Click here to enter text.
	+ Adverse events. Provide detailed and complete explanation of the adverse event that occurred, what action was taken (if any), and outcomes: Click here to enter text.
	+ Unanticipated problems involving risks to subjects or others, subject withdrawals, or complaints about the research since last IRB review: Click here to enter text.
	+ Summary of preliminary findings, relevant recent literature, multi-center trial reports: Click here to enter text.
	+ Attach a copy of informed consent document used for most recent subject enrollment
	+ Other relevant information, especially about risks associated with the research. Click or tap here to enter text.

5.  **ATTACH MOST RECENT VERSIONS:** *(Please attach most recent versions of the following, changes from previously approved version should either show as tracked changes or be highlighted.*)

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

* Research protocol
* Informed consent or assent documents
* Recruitment Flyers, Emails, Letters, Advertisements
* Questionnaires, testing instruments, interview or focus group questions
* Current Data User Agreement or Data Steward Approval form

**REQUIRED SIGNATURE:**

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_