UTAH DEPARTMENT OF HEALTH AND HUMAN SERVICES POLICY AND PROCEDURES	
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INSTITUTIONAL REVIEW BOARD AND HUMAN RESEARCH PROTECTIONS	
RATIONALE: The Utah Department of Health & Human Services is supportive of quality Research. The department seeks to protect the safety and privacy of any human subjects involved in these research projects. This policy is intended to assist the department in reviewing research proposals and protecting individual rights and complying with federal laws governing research with human subjects. *Related Policies, Applicable Standards, Statutes: DHS IRB Policy and Procedure Reference No 01-10, UDOH IRB and Human Research Protections Reference No 01.20, 45 CFR Part 46 (also known as the "Common Rule") DHHS Federal wide Assurance, 45 CFR §§ 160 and 164 - Health Insurance Portability and Accountability Act (HIPAA) FERPA 20 U.S.C. § 1232g; 34 CFR Part 99 42 CFR Part 2, FDA- 21 CFR 50,21 CFR 51, 21 CFR 3T2 & 21 CFR 812, Utah Medical Examiner Act U.C.A. 26-4-17 (4)(d).*	

Original Effective: **September 1, 2022**	**Revision:**	**Next Review Due:** **September 1, 2028**

I. DESCRIPTION

This policy guides how DHHS may operate the Institutional Review Boards in accordance with the federal regulations. This policy supersedes any previous policy governing these awards. It does not supplant any existing state or department policies to which the department must adhere.

II. DEFINITIONS

The following terms are defined for this policy as

A. **Conflict of Interest:** Any situation where an IRB member has financial, economic, social, political, familial, legal, professional, or other interests which interfere with or have the potential to interfere with their judgment in connection with the outcome of the research being reviewed.
B. **DHHS or Department:** The Utah Department of Health and Human Services and collectively all its operational units.
C. **DHHS OHRP:** U.S. Department of Health and Human Services, Office of Human Research Protections

D. **Engagement in Research:** When one or more of the following apply:
    A. DHHS sponsors the research;
    B. DHHS receives a direct federal award from U.S. DHHS through a grant, contract, or cooperative agreement to conduct human subject research, even where all of the human subjects activities will be carried out by another organization;
    C. The research is conducted, in whole or in part, by DHHS employees or agents acting in their DHHS capacity regardless of the location of the activity, either at DHHS or elsewhere in the world.
    D. See other guidance here: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html
E. **Human Subject or Participant:** A living individual about whom an investigator conducting research obtains either (1) data through intervention or interaction with the individual; or (2) identifiable private information.
F. **Human Subject Research** - projects that meet the definitions of both "research" and "human subject".
G. **IRB** - Institutional Review Board
H. **Principal Investigator** - a person designated as the individual responsible for the administrative and programmatic aspects of the proposed project.
I. **Research** – a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities, which meet this definition, constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes.
J. **Researcher** - anyone seeking to access data or recruit clients or employees of DHHS for research purposes, and anyone proposing or conducting research activities.

III. POLICY

A. The Department shall operate two Institutional Review Boards (IRBs)- (a) Behavioral Research & (b) Health and Biomedical Research in accordance with the requirements of its Federal Wide Assurance. These IRBs are established by DHHS to review research proposals that provide for the protection, rights, and wellbeing of persons who participate or are subjects in research sponsored or conducted by DHHS.
B. This policy applies to DHHS employees engaged in research, required to request IRB review, and/or request an ethical review of a project.
C. Except as otherwise provided below, the DHHS IRBs review all proposed research relating to Department clients, employees, and contractors involved with the Department.
D. Review by one of the DHHS IRBs is required for all research by individuals or agencies gaining access to Department employees or clients for research studies.

E. Contract agencies may not conduct research involving human subjects without an IRB approval, who are employees of DHHS or individuals receiving services (whether direct or contracted) from DHHS, or where the Department has provided funding for a project that includes research in the contract.

IV. PROCEDURE

A. The IRBs are established in accordance with 45 CFR 46.107.
B. Role of DHHS IRBs
    1. Conduct reviews of human subjects research under 45 CFR 46 in which DHHS is considered engaged. (see definitions of research, human subjects, and engagement in research)
        A) DHHS employees shall submit a proposal to the IRBs for review and determination of projects for which human subjects research classification under this policy is not known.
    2. Conduct review of research proposals that are not human subjects research under 45 CFR 46 and are not subject to oversight by OHRP. This includes
        A) Releases of restricted datasets for research that are not part of human subjects research in which DHHS is engaged, are not covered by an alternate IRB, or existing MOA, and are permitted under state law.
C. The IRBs shall refer any politically sensitive issues to the Executive Director's Office for consideration.
D. IRBs Composition
    1. The IRBs shall be composed of at least the following members:
        A) A minimum of five members with varying backgrounds to promote a complete and adequate review of research activities commonly conducted or supported by DHHS with broad representation from across the agency;
        B) At least one member has primary concerns in scientific areas;
        C) At least one member has primary concerns in nonscientific areas;
        D) At least one "community" member who is not otherwise affiliated with DHHS and who is not part of the immediate family of a person who is affiliated with DHHS;
        E) At least one member represents prisoners if reviewing a protocol (§46.304) that involves prisoner participants; and
        F) At least one non-voting member to serve as legal counsel.
        G) Consultants/Subject matter experts: As needed and at their discretion, the DHHS IRBs may request consultants or subject matter experts in order to ensure a protocol is properly reviewed and understood. This consultant/subject matter expert may review all documentation related to the protocol and offer information and

recommendations, but may not vote on the final decision on the protocol.

H) The DHHS IRBs will fulfill membership requirements established in 45 CFR 46.107. IRB meetings are suspended any time the number of members present is less than a majority, or if there is no non-scientist present.

2. Selection and Appointment
    A) The Executive Director or designee shall appoint individuals to the IRBs. The members serve until they are replaced or resign.
    B) Members may resign at any time by submitting a letter of resignation to the IRB Chairs. IRB Chairs may remove members from the committee if the member is not able to complete his/her responsibilities as an IRB member.
3. Chair
    A) The Executive Director shall appoint individuals to serve as the IRB Chairs. The IRB Chairs must be DHHS employees. There is no specified time limit for serving as an IRB Chair.
    B) The Executive Director may remove an IRB Chair from the committee if he/she is not able to complete their responsibilities as an IRB Chair.

E. IRB member responsibilities include but are not limited to:
    1. Attending IRB meetings (generally occurring monthly)
    2. Reviewing protocols by completing a checklist form for reviews that will be discussed at the convened meetings.
    3. Being prepared to discuss issues related to human subjects research
    4. Serving as a designated reviewer/subject matter expert at the request of IRB Chairs.
    5. Working with principal investigators (PIs) to resolve issues related to IRB review.
    6. Fulfilling all training requirements.
    7. Staying informed about relevant regulations and any changes or current state of the human subjects research program(s).
    8. A full list of requirements for members is outlined in the IRB Standard Operating Procedures document.
F. Compensation of non-DHHS IRB members
    1. Non-DHHS IRB members are not compensated for service on the IRBs.
G. Conflicts of Interest
    1. Conflicts of interest will be declared by IRB members. IRB members, including the Chairs, cannot vote on protocols in which they have a conflict of interest, such as protocols in which they are serving as Principal Investigator or Co-Principal Investigator. They may offer information to the other voting members and answer any questions related to the protocol, but they may

not participate in voting and they must recuse themselves from the meeting during the final discussion and voting.

H. IRB Standard Operating Procedure
    1. The IRBs shall maintain an operations manual and ensure documentation of required processes are complete and adhere to 45 CFR part 46.
        A) The Standards Operations Manual shall include
            1) IRB Member Composition and Responsibilities
            2) IRB operational procedures for
                (A) Convened Meetings and Minutes;
                (B) Records and Recordkeeping;
                (C) Submissions and Reviews;
                (D) Approval, Renewal, and Notification;
                (E) Informed Consent and Waiver of Informed Consent;
                (F) Unanticipated Problems and Adverse Events;
                (G) Noncompliance, Suspension, and Termination; and
                (H) The appeal of IRB Action.
            3) Biological Specimens in Research

I. Instructions for Researchers
    1. The IRBs shall develop and maintain instructions for researchers to submit applications to the IRBs for review.
    2. All researchers must obtain an IRB approval or exemption prior to initiating human subjects' research in accordance with the DHHS Standard Operating Procedure.
    3. All researchers must accept responsibility for protecting the rights and welfare of human subjects and comply with applicable DHHS IRB policies and procedures, and federal regulations and guidelines.
    4. Ensure that the research is conducted according to the IRB-approved Protocol and any conditions set forth by the IRBs when approval was given.
    5. Department employees who engage in "research" involving human subjects will ensure research activities are documented and reported to the IRBs as necessary. This includes maintaining files of all approved study documents such as
        A) The most recent application form that can be found on the DHHS IRB website
        B) Data Sharing Agreement/Data Steward Approval document
        C) Informed consent documents
        D) Recruitment materials including advertisements intended to be seen or heard by potential subjects
        E) Any relevant grant application(s), as per §46.103(f)
        F) The investigator's brochure (if one exists)

G) Study materials and tools (i.e. interview questions, surveys, etc.) to which potential subjects will be exposed
H) Principal Investigator qualifications
I) Associated study correspondence (with the IRBs, stakeholders, universities, and regulatory Authorities)

6. Department employees who are unsure whether their proposed research must be approved by the DHHS IRBs, should contact the DHHS IRB Chairs.
7. Researchers that are relying on DHHS data are responsible for working with the appropriate data steward to obtain approval for data use. The applicable signed data sharing agreement (DSA), or the Data Steward Approval Form if the DSA is still pending, shall be included as part of the application submitted to the IRBs for review. A signed DSA does not guarantee IRB approval of a protocol.
8. Researchers must submit an IRB application to the DHHS IRBs by the due date listed on the DHHS IRB website prior to a meeting date to be considered for the agenda of that meeting.
9. Researchers must report all of the following to the IRBs:
    A) Any proposed changes to research activity, personnel, or study documents including, but not limited to, proposed modifications to the protocol, data variables, informed consent, recruitment materials, and study materials and tools.
    B) Study progress reports in the form of annual renewals if required per federal regulations.
    C) Unanticipated problems or adverse events involving risks to subjects or others in accordance with federal regulations.
    D) Noncompliance with federal regulations, IRB approval, IRB stipulations, and IRB standard operating procedures.
    E) Copies of any study monitoring or audit reports received by the researcher, if available.
    F) Closure information once the human subjects research study is completed.
10. Researchers conducting human subjects' research are responsible for addressing concerns or issues that arise during the conduct of the study.

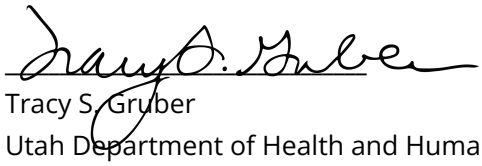
J. The DHHS IRBs reserves the right to conduct audits of active research protocols.

K. Utah law requires reporting of any suspected or actual abuse, neglect, or exploitation of a child, an adult 65 or older, or an adult who has a mental or physical impairment, which affects that person's ability to provide for or protect themselves. If the researcher has reason to believe that such abuse, neglect, or exploitation has occurred, the researcher will report this to Child Protective Services (CPS), Adult Protective Services (APS), or the nearest law enforcement agency. The mandatory reporting language will be included in informed consent documents verbatim whenever possible or will be included in language understandable to the signatory

including the spirit of the required statement. For informed assent documents, the language may be simplified so that a child can understand the reporting requirements.

v. EXCEPTIONS

A. EDO may make exceptions to this policy as allowed.



September 1, 2022

Tracy S. Gruber — Date

Utah Department of Health and Human Services Executive Director