

**DEPARTMENT OF HUMAN SERVICES
POLICY AND RESOURCE MANUAL**

Department of Human Services

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Reference: 01-10

Effective date: May 1, 2017

Subject: INSTITUTIONAL REVIEW BOARD, POLICY AND PROCEDURES

RATIONALE: The Utah Department of Human Services (the "Department") is supportive of quality research, especially when such research provides additional insights into the Department's client populations and improves the Department's services. The Department seeks, however, to protect the safety and privacy of any human subjects involved in these research projects. These policy and procedures are intended to assist the Department in reviewing research proposals and protecting individual rights, and complying with federal laws governing research with human subjects.

POLICY ABOUT RESEARCH INVOLVING HUMAN SUBJECTS

It is the Department's policy that any research involving human subjects (including the Department's clients, clients' family members, clients' victims, or employees) shall comply with the following rules and policies: (1) federal regulations about human-subjects research (45 CFR Part 46, 21 CFR 50, 21 CFR 51, 21 CFR 312, 21 CFR 812, 45 CFR 164.508, and 45 CFR 164.512); (2) the Department's Vision and Mission Statements; (3) the Department's Code of Ethics; (4) Utah Administrative Rule R495-820-5-14; and (5) the policies and procedures contained in this document.

This document provides (1) the policies and procedures followed by the Utah Department of Human Services Institutional review board (DHS IRB), and (2) requirements for Department employees or contract agencies that are engaged in research or are approached by researchers.

To assure that these requirements are met, all research proposals and protocols must be reviewed by appropriate authorities within the Department, including the appropriate Division Director (or the director designee) and the DHS IRB.



Ann Williamson, Executive Director
Utah Department of Human Services

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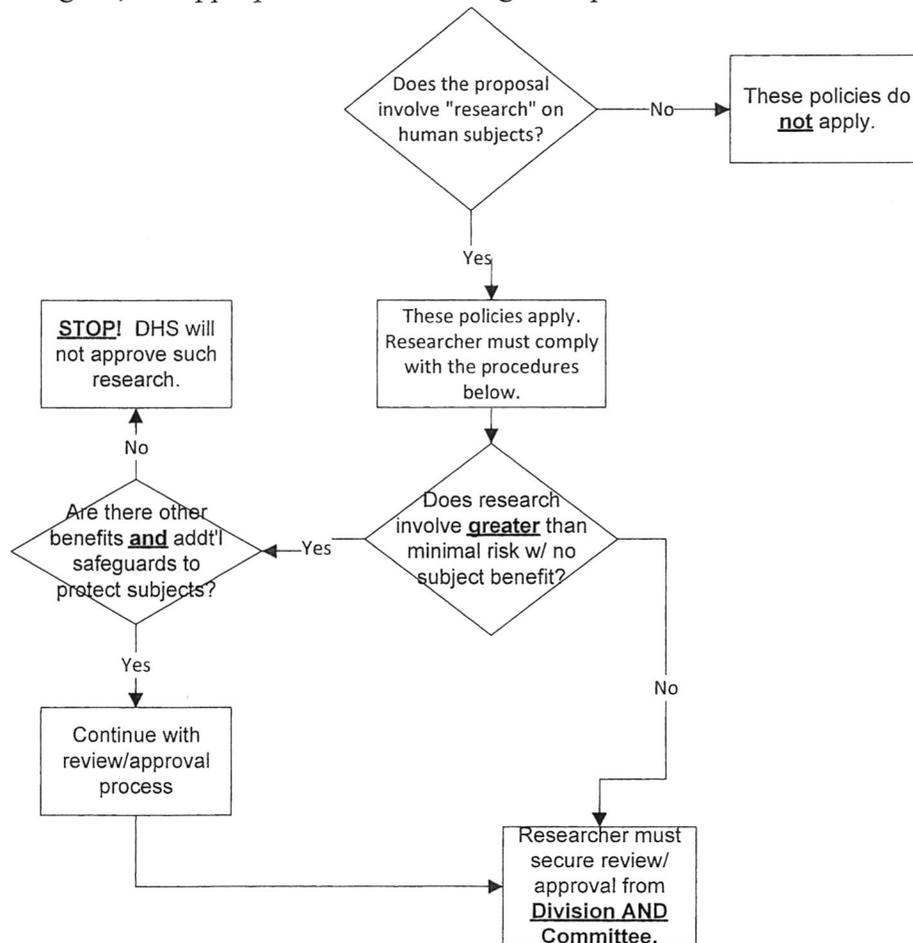
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UTAH STATE DEPARTMENT OF HUMAN SERVICES
DHS Institutional Review Board

INTRODUCTION AND OVERVIEW

The DHS IRB serves as the Institutional Review Board (IRB) for the Department. Except as otherwise provided below, the DHS IRB reviews all proposed research relating to Department clients, employees, contractors, or any other human subjects involved with the Department.

Please note, however, that these policies and procedures apply only to “research” activities involving human subjects. The section entitled “How to Determine Whether a Project Qualifies as Research” explains in more detail which studies are considered to be “research.” In addition, the following flowchart gives an overview of the decision-making process for determining which type of review is appropriate for a particular research project. In the flowchart, “Division” refers to the Division IRB Representative or gatekeeper in conjunction with the Division Director or designee, the appropriate Division Program Specialist and/or other IRB members.



HOW TO DETERMINE WHETHER A PROJECT QUALIFIES AS “RESEARCH” INVOLVING HUMAN SUBJECTS

These policies and procedures apply only to “research” activities that involve human subjects as defined in 45 CFR 46.102. The label attached to the activity is not the determinative factor; a research study does not cease to be research simply because it is labeled as “treatment” or “program evaluation.” The division gatekeeper, in conjunction with the DHS IRB as needed, will determine if the federal definition of research involving human subjects has been met.

As a general rule, the following activities do not qualify as “research” *when conducted by Department employees*: reviewing client records in order to respond to a client’s complaint; providing standard treatment to a client; or undertaking routine statistical tabulations and program audits for administrative purposes only. Because these activities are not “research” but are part of the usual job activities for Department employees, they do not require approval from either the DHS IRB or from the Division. Program evaluation activities may also be exempt, but determination must be made by division gatekeepers as outlined below.

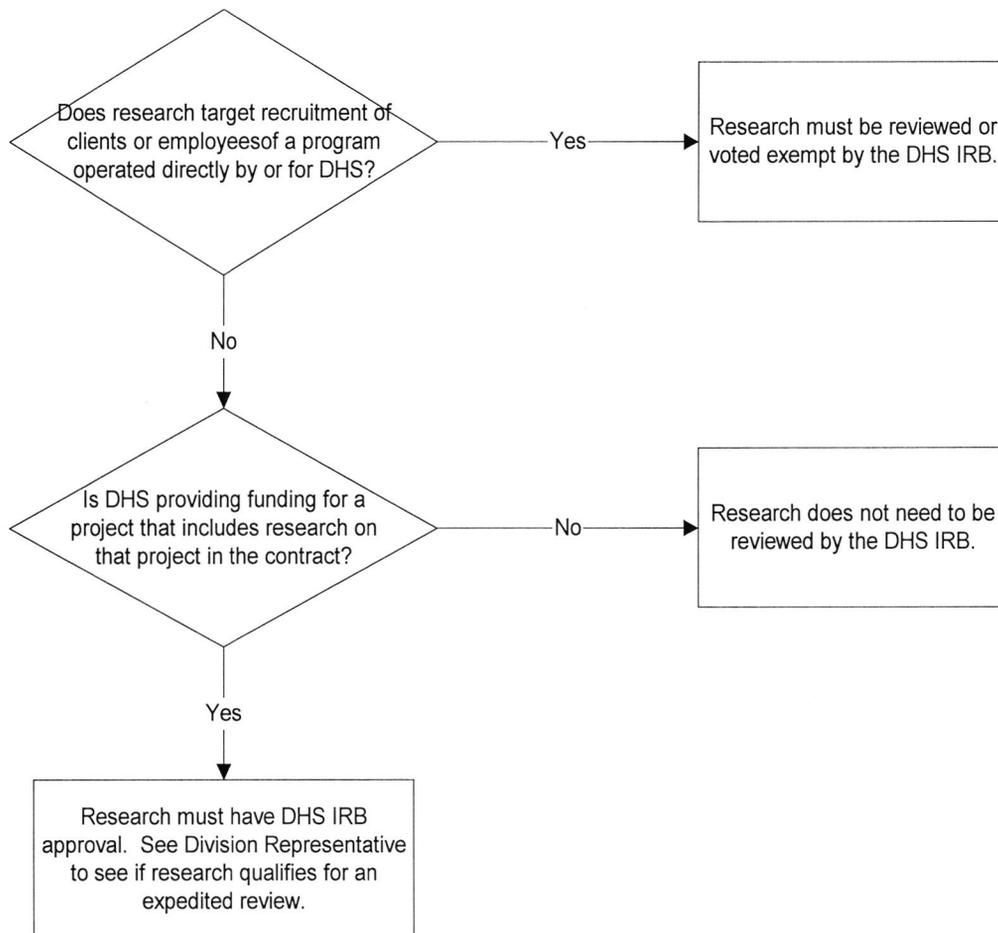
Department employees who engage in “research” involving human subjects do need to submit their research proposals for approval. Department employees who are unsure whether their proposed research must be approved by the DHS IRB, or the Division, or whether the proposed research falls into one of the non-research categories described above should contact the division gatekeeper or DHS IRB chair. If after consulting with the DHS IRB gatekeeper, the employee still has questions about whether the project needs to be reviewed, it is wisest to submit the full proposal to the DHS IRB.

RESEARCH BY INDIVIDUALS AND AGENCIES OUTSIDE THE DEPARTMENT

Review by the DHS IRB is required for *all* research by individuals or agencies outside the Department if the researcher is requesting or gaining access to Department data or Department employees or clients for research studies. (Please note that if the researcher is outside the Department, the DHS IRB’s review is required regardless of whether the Department or a Department agency has requested or contracted for outside assistance in the study, and regardless of whether the study involves Department clients served by private contract providers. In other words, companies and individuals that contract with the Department to provide services to the Department’s clients and consumers are considered to be “outside the Department.”)

Contract agencies may not conduct research involving human subjects, who are employees of DHS or individuals receiving services (whether direct or contracted) from DHS, or where the Department has provided funding for a project that includes research in the contract.” A decision tree is included below:

Decision Tree for Contract Agency Research



DIVISIONS AS “GATEKEEPERS” IN THE REVIEW PROCESS

Each Division in the Department shall designate a representative to serve on the DHS IRB and to serve as a “gatekeeper” to review any proposed research study that involves the Division’s employees, clients, or resources. Each research proposal must be reviewed by the Division IRB Representative in the appropriate Division, regardless of whether the research must also be reviewed later by the DHS IRB. The Division’s IRB Representative shall review the proposed research and determine whether:

1. the research is in the best interests of the Division and the Division's clients;
2. the researcher has made adequate provision for obtaining informed consent from the subjects, permission from the subjects' parents or legal guardian, and where applicable, informed assent from children or from clients who suffer from some mental incapacity;
3. the research protocols and procedures are designed to protect individual privacy and ensure confidentiality, respect, and ethical treatment during the researcher's gathering of the data, storage and retrieval of the data, and publication of the data,
4. the research study involves no more than minimal risk to subjects, or if the risk is more than minimal, that the direct benefits to the human subjects outweigh the risks;
5. the research methodology is sufficiently sound to yield clear results to the Department or the Division; and,
6. the research protocol protects individual privacy rights, and complies with the Department's Vision and Mission Statements, the Department Code of Ethics and any applicable rules or statutes.
7. The research proposal is complete and contains all required documentation.

If the Division IRB Representative finds that the proposed research satisfies these requirements, the representative shall submit the proposal to the DHS IRB chair for processing and/or scheduling the review.

DHS IRB MEMBERSHIP

The DHS IRB will fulfill membership requirements established in 45 CFR 46.107. The meeting is suspended any time the number of members present is less than a majority, or if there is no nonscientist present. The National Committee for Quality Assurance (NCQA) has provided guidance regarding who may be considered a nonscientist. NCQA defines a nonscientist as a member without scientific training or experience, such as lawyers, clergy and ethicists. Retired scientists, by NCQA definition, are not considered nonscientific members. Further, scientific members include physicians, dentists, Ph.D. scientists, pharmacists, nurses, veterinarians and others with scientific training and experience. Members with a combination of both scientific and nonscientific backgrounds should not be appointed to satisfy the nonscientist requirement. The member representing prisoners must be present at any meeting considering research involving prisoners (§46.304). For all biomedical protocols, the DHS IRB uses a nonvoting member who is a physician. The physician must be present for, and an active participant in, the review of all biomedical protocols.

DHS IRB REVIEW

The DHS IRB will review research in accordance with federal regulations about human-subjects research (45 CFR Part 46, 21 CFR 50, 21 CFR 51, 21 CFR 312, 21 CFR 812, 45 CFR 164.508, and 45 CFR 164.512) and Utah Administrative Rule R495-820-5.

The division gatekeeper will determine with the DHS IRB chair if research is exempt from DHS IRB in accordance with 45 CFR 46.101(b). If there are questions regarding if the proposal is exempt it may be taken to the full board. The DHS IRB may vote to conditionally exempt a research proposal pending minor changes to the proposal. Exemptions will be documented in the meeting minutes or agendas. A letter will be sent out notifying the researcher that the study was voted exempt. The Division representative will then be responsible for keeping track of the research and obtaining a copy of the final report

The division gatekeeper will determine with the DHS IRB chair if research is eligible for expedited review in accordance with 45 CFR 46.110 or if the proposal requires full review. Expedited reviews will be documented in the meeting minutes or agendas for the other DHS IRB members to see.

The Divisions and the DHS IRB will use the following risk categories to determine the appropriate level of review:

Less Than “Minimal Risk”

Minimal risk is defined in 45 CFR 46.102. This category refers to research, including but not limited to, proposals in which the researcher will not contact the human subject in person, but may request access to client or employee data maintained by the Department or its contractors, and the risk of harm or discomfort to the human subject is less than minimal. The following research may be considered “low-risk”: (a) the researcher reviews client or employee data, databases or aggregate data that contain no information by which an individual subject can be identified; or (b) the researcher reviews client or employee data or databases that contain the clients’ or employees’ names or other identifying information. Research in this category may be eligible for exemption or expedited review in accordance with 45 CFR 46.101 or 45 CFR 46.110

“Minimal Risk” Research

Minimal risk is defined in 45 CFR 46.102. All research in this category requires DHS IRB expedited review at a minimum.

Research Involving Greater Than Minimal Risk to the Human Subjects, But Providing Some Direct Benefit to the Subjects

This category refers to research that involves *intervention/interaction* with the human subject for treatment or survey purposes when the subject’s anticipated harm or discomfort involves a greater-than-minimal risk and when the intervention presents the prospect of direct benefit to the individual subject. All research in the “greater-than-minimal risk, but providing

some direct benefit to the subjects” category requires full DHS IRB review. The DHS IRB will review in accordance with 45 CFR 46.405

Research Involving “Greater-Than-Minimal Risk” and No Direct Benefit to the Human Subjects, but Likely to Yield Generalizable Knowledge about the Subject's Disorder or Condition

This category refers to research that involves a greater-than-minimal risk by an intervention or procedure that does not hold out the prospect of direct benefit to the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, but is likely to yield generalizable knowledge about the subject's disorder, condition, or the programs designed to assist or ameliorate the subject's disorder or condition. All research in the “greater-than-minimal risk” with no direct benefit to subject category requires full DHS IRB review. The DHS IRB will review in accordance with 45 CFR 46.406

Studies Involving Greater-Than-Minimal Risk, with No Benefit to the Human Subject, nor Generalizable or Program Knowledge

If the proposed research study involves more than minimal risk to the human subject, with no prospect of direct benefit to the individual subjects, and the study is not likely to yield generalizable knowledge about the subject's disorder or condition or the programs designed to serve the subject population, **the Department will not review nor approve the study.**

MONTHLY MEETINGS

The DHS IRB meets monthly to review research proposals that affect the Department’s employees, clients or other human subjects related to the Department. All completed proposals received, reviewed, and approved by the division gatekeeper, by the last day of the month will be reviewed during the following month. A majority of members, including one nonscientist, must be present for a quorum. The monthly meeting may be cancelled due to lack of quorum, or lack of agenda items. The DHS IRB chair will distribute protocols for review by the Friday prior to the meeting.

Special meetings may be called between monthly meetings when the monthly meeting falls after an important deadline date or there is a quorum issue. An important deadline date may include a funding submission deadline or an approval expiration date for either DHS or any other institutional IRB. If the nonvoting physician member and/or prisoner representative cannot attend a monthly meeting at which they are needed, a special convened meeting may be called to accommodate their schedules to review the protocol. The regularly scheduled monthly meeting will be held as scheduled to review all other protocols.

In the event a special meeting is necessary, the IRB Chair, or designee, contacts every IRB member by phone or email to determine availability and to ensure a proper quorum for the convened meeting. Following assurance of a quorum, the IRB Chair, or designee, notifies each

member of the time, date, and place for the meeting. The protocol(s) to be reviewed will be distributed to ensure sufficient time for review by every member.

The minutes of each convened meeting are recorded and prepared by the Chair, or a designee, in accordance with §46.115(a)(2). Waiver or alteration of informed consent or documentation of informed consent will comply with 45 CFR 46.116(d) and 45 CFR 46.117 (c) the determinations will be documented in the meeting minutes. The IRB will determine which protocols require continuing review more often than annually, as appropriate to the degree of risk (§46.103(b)(4) and §46.109(e)). The minutes of IRB meetings will clearly reflect these determinations regarding risk and any approval period (review interval) of less than one year. Draft minutes are emailed to all members for review. Additions or corrections may be sent to the chair.

Utah's Open Meetings Law

The DHS IRB is subject to the Utah Open and Public Meetings Law (U.C.A. § 52-4-1 through 7). Notice of regularly scheduled meetings are publicized through posting on the DHS website, or the Utah Open Meeting website. Notice of regular meetings is provided at least once per year, specifying the date, time, and place of the meeting.

Meeting Minutes are kept along with a recording of the proceedings and posted to the DHS website.

CONFLICTS OF INTEREST

Conflicts of interest will be declared by IRB members. Members with a conflict of interest cannot participate in initial or ongoing review in accordance with 45 CFR 46.107(e).

RESEARCH REVIEW MATERIALS

Initial Review Materials

In conducting the initial review of proposed research, the IRB must obtain information in sufficient detail to make the determinations required under §46.111. Materials should include the full proposal any other applicable items including but not limited to: a proposed informed consent document, any relevant grant application(s), as per §46.103(f), the investigator's brochure (if one exists), any surveys, questionnaires or other materials to which potential subjects will be exposed, and any recruitment materials, including advertisements intended to be seen or heard by potential subjects. Furthermore, for US Department of Health and Human Services (DHHS)-supported multicenter clinical trials, the IRB should receive and review a copy of the DHHS-approved sample informed consent document and the complete DHHS-approved protocol, if they exist. Researchers will include the most recent application form which can be found on the DHS IRB website.

Continuing Review Materials

Continuing review of research must be substantive and meaningful. The IRB will ensure that the criteria set forth by §46.111 are satisfied at the time of continuing review. In conducting continuing review of research the IRB members conducting the review will at least receive and review a protocol summary and a status report on the progress of the research, including:

- the number of subjects accrued;
- a summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
- a summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
- any relevant multi-center trial reports;
- any other relevant information, especially information about risks associated with the research; and
- a copy of the current informed consent document and any newly proposed consent document.

Upon request, any IRB members also should have access to the complete IRB protocol file and relevant IRB minutes prior to or during the convened IRB meeting.

VULNERABLE POPULATIONS

The Division IRB Representative reviews the protocol to identify the proposed populations to be studied and to determine if protected or vulnerable populations are involved. The determination is based on the elements of 45 CFR 46 subparts B, C, and D, as well as protected populations under Utah state laws, and any other classes of human subjects that may be considered vulnerable in the context of the protocol under review.

PLACEBO STUDIES

Review of placebo studies will be in accordance with Utah Administrative Rule 495-820-6.

MANDATORY REPORTING LANGUAGE

Utah law requires us to report 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 him/herself. 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 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.