

DEPARTMENT OF HUMAN SERVICES POLICY AND PROCEDURES		
Reference: 01-10	Effective Date: February 21, 2000 Revision Date: February 24, 2003	Page: 1 of 1
SUBJECT: INSTITUTIONAL REVIEW BOARD, POLICY AND PROCEDURES		
<p>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. This 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.</p>		

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); (2) the Department’s Vision and Mission Statements; (3) the Department’s Code of Ethics; and (4) the policies and procedures contained in this document. To assure that these requirements are met, all research proposals and protocols must be reviewed by an appropriate authority within the Department. That is, depending on the nature and source of the proposed research, the proposal must be reviewed by either: (1) the appropriate Division Director (or the director’s designee); or (2) the appropriate Division Director (or the director designee) and the Department’s Institutional Review Board (DHS IRB) and the Department’s Deputy Director. If the proposed research involves pharmaceuticals or biomedical devices, additional review requirements must be met. The attached Procedures and Instructions provide details about the kind of review required for specific types of research.

These procedures and instructions must be followed *before* the researcher begins any research involving human subjects. In addition, if a researcher proposes to change any research design, procedures or instruments previously approved by the DHS IRB, the researcher must secure approval for such changes *before* implementing them. Ongoing research must be reviewed by the appropriate authority at least once a year.

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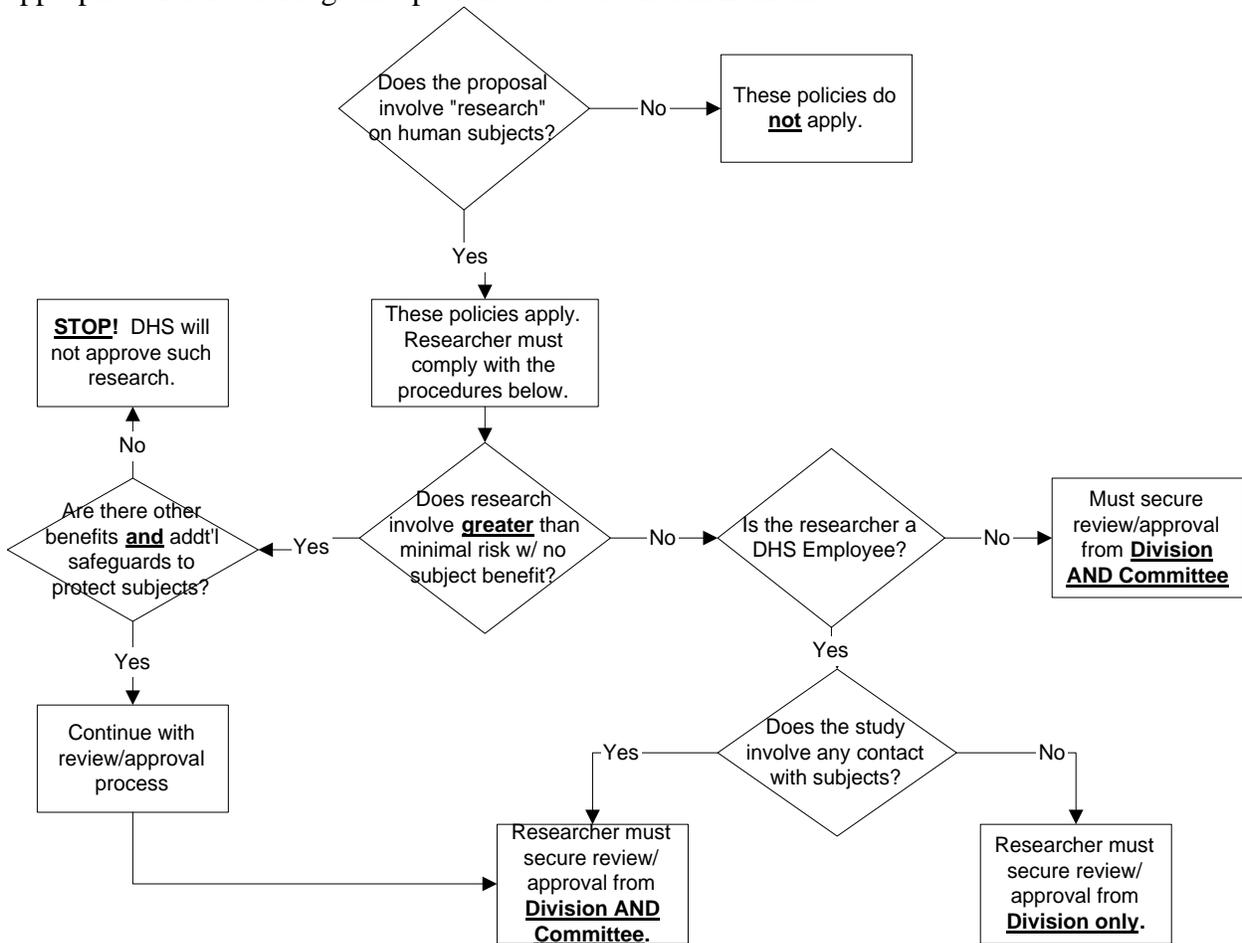
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UTAH STATE DEPARTMENT OF HUMAN SERVICES
DHS Institutional Review Board
 PROCEDURES AND INSTRUCTIONS FOR RESEARCHERS

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 and research methodologies 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.” Definitions of research and human subjects are included in that section. 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 in conjunction with the Division Director or designee, the appropriate Division Program Specialist and/or other IRB members.



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 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 make written findings that indicate 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 (see definition of “minimal risk” on page 4);
5. the research methodology is sufficiently sound to yield results that offer a potential benefit 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, including *Utah Code Annotated* § 63-2-202(8) (GRAMA), and the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

If the Division IRB Representative finds that the proposed research satisfies these requirements, the representative shall prepare a written statement to this effect, and shall submit this statement to the Division Director for written approval. If the Division Director or designee approves the research project, the Division IRB Representative sends a copy of the written findings and the Division’s approval to the DHS IRB.

If the proposed research also requires the review and approval of the full DHS IRB, the representative shall also notify the DHS IRB of this requirement, and shall forward the researcher’s application and supporting documentation to the DHS IRB for its review. If the research involves greater-than-minimal risk but no direct benefit to the human subjects, the Division IRB Representative shall notify the researcher and the DHS IRB in writing why the research does or does not qualify for Division approval under the section of these policies that deals with such studies.

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. Federal regulations define “research” as “*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 [of protecting human subjects], whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.” 45 CFR 46.102(d) (emphasis added). In other words, 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.”

This means that 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.

In addition to determining whether an activity constitutes research, it must be determined if “human subjects,” as defined by federal regulations, are involved in the research.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) data through intervention or interaction with the individual, or
- (2) identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. §46.102(f)

As explained in the “Scope of Review” section below, however, 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 Chairperson of the DHS IRB at

(801) 538-4295. If after consulting with the Chairperson, 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.

As a minimum the Department DHS IRB reviews the proposed research to determine that the following requirements are satisfied (§46.111(a)):

1. Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.
5. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

In addition, when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, the review should determine if additional safeguards have been included in the study to protect the rights and welfare of these subjects. 46.111(b).

The DHS IRB reviews only those research studies that involve *human* subjects. Other types of research may need approval from the Division or the Department, but these policies do not apply.

SCOPE OF REVIEW, BASED ON THE TYPE OF PROPOSED RESEARCH.

The scope of review depends on the level of risk involved for the human subject, and whether the study involves pharmaceuticals or biomedical devices and, in part, on whether the research is conducted by a Department employee or by someone other than a Department employee. Each of these factors is discussed in more detail below. All research involving human subjects must be reviewed and approved by either the Division IRB Representative or the full DHS IRB prior to beginning research. The DHS IRB utilizes a system of Division members to the IRB who serve as “gatekeepers.” The Division IRB Representatives review each proposed study to determine which studies will be reviewed by either the full DHS IRB or through an expedited procedure. For more information regarding the “gatekeeper” system and studies reviewed through an expedited procedure, please refer to the section titled “Divisions as Gatekeepers”.

Studies Conducted by Department Employees

If you are a Department employee and your study activity involves human subjects and constitutes “research” as defined above, you must submit your research proposal to the appropriate Division IRB Representative for review. You must obtain prior written approval from that Division IRB representative before your protocol is submitted to the full DHS IRB or before any client contact is made. (For more information about the review process, please refer to the section titled “Divisions as Gatekeepers” and the section on “Mandatory Review Categories.”)

Studies Conducted by Researchers Who Are NOT Department Employees

If you are not a Department employee and you want to conduct a study using Department employees, clients or data, you must first submit your proposal to the appropriate Division IRB representative. (See “Instructions for Obtaining Human Rights Approval”.) If the Division IRB Representative approves the proposed research, the representative will forward the research proposal and a letter of endorsement to the DHS IRB for its review.

Studies Involving Pharmaceuticals or Biomedical Devices

Regardless of whether the researcher is a Department employee or an outside researcher, any research which involves the use of pharmaceuticals or biomedical devices with human subjects must be reviewed by both the Division IRB Representative and the full DHS IRB, and the researcher must satisfy additional requirements. The researcher should contact the Chairperson of the DHS IRB for more detailed information concerning those requirements.

Phase I or II studies involving investigational pharmaceutical drugs or biomedical devices with Department clients, staff, contractors, or any other human subjects involved with the Department are prohibited by the Department of Human Services. See Appendix A for definitions of the terms "Phase I," "Phase II" and "Phase III."

RESEARCH RISKS AND LEVELS OF REVIEW.

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

“Low-Risk” Research (Less Than “Minimal Risk”¹)

This category refers to research 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. 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.”

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.

Review requirements: Research in the “low-risk” category is exempt from DHS IRB review *if the research is conducted by a Department employee*. Nevertheless, all “low-risk” research requires Division approval and assurances that the researcher has made adequate provisions to safeguard data and to comply with *Utah Code Annotated* § 63-2-202(8), which specifies when the Department may allow access to “private” or “controlled” records for research purposes. The Division may delegate such review and approval authority to its Regional Directors as long as the Regional Directors comply with this policy and determine that the researcher has made adequate provisions to safeguard data. If the “low-risk” research is conducted by an outside researcher (i.e., someone other than a Department employee), the research proposal needs to be approved by both the Division and the DHS IRB. Research involving prisoners, fetuses, pregnant women, or human in vitro fertilization does not qualify for exemption from review. Research involving children does not qualify for exemption from review except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

“Minimal Risk” Research

¹ 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.”

This category refers to research that involves *intervention or interaction* with the human subject when the probability and magnitude of harm or discomfort that the researcher anticipates will be experienced by the human subjects 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. This category may also include research that does not require interaction, such as research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Review requirements: All research in this category requires DHS IRB expedited review as a minimum, and prior *review of methodology* and letter of support from the appropriate Division IRB Representative, regardless of whether the research is conducted by a Department employee or an outside researcher. The researcher has made adequate provisions for soliciting informed consent of human subjects, permission of their parents or guardians, and the informed assent of children or from subjects who suffer from some mental incapacity, when applicable. §46.408. (See “Informed Consent” checklist.)

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.

Review requirements: All research in the “greater-than-minimal risk, but providing some direct benefit to the subjects” category requires full DHS IRB review, and prior *review of methodology* and letter of support from the appropriate Division IRB Representative. The researcher must assure that informed consent requirements are met and that where applicable, informed assent requirements for children are met. (See “Informed Consent”.) The DHS IRB may approve research involving a greater-than-minimal risk **only if** its review finds that:

1. the proposed intervention or procedure holds out the prospect of direct benefit for the individual subject, or the intervention or procedure involves a monitoring procedure that is likely to contribute to the subject's well-being;
2. the risk is justified by the anticipated benefit to the human subjects;
3. the relation of the anticipated benefit to the risk is at least as favorable to the human subjects as that presented by available alternative approaches; and

4. the researcher has made adequate provisions for soliciting informed consent of human subjects, permission of their parents or guardians, and the informed assent of children or from clients who suffer from some mental incapacity, when applicable. §46.408.

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.

Review requirements: All research in the “greater-than-minimal risk” with no direct benefit to subject category requires full DHS IRB review, and prior *review of methodology* and letter of support from the appropriate Division IRB Representative. The researcher must assure that informed consent requirements are met and that where applicable, informed assent requirements for children are met. (See “Informed Consent” checklist.) The DHS IRB may approve research in this category **only if** its review finds that:

1. the risk represents a minor increase over minimal risk;
2. the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations;
3. the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition (except in research involving children) or for the understanding of the programs designed to ameliorate the subjects' disorder or condition;
4. the generalizable and/or program benefits outweigh the risks to subjects; and
5. the researcher has made adequate provisions for soliciting informed consent of human subjects, permission of their parents or guardians, and the informed assent of children or from clients who suffer from some mental incapacity, when applicable. §46.408.

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**, regardless of whether the researcher is a Department employee or an outside researcher.

Research Involving Pharmaceutical or Biomedical Devices

If a research proposal involves pharmaceuticals or biomedical devices, the researcher must satisfy additional requirements. The researcher is directed to contact the Chairperson of the DHS IRB for specific information concerning those requirements.

Phase I or II studies involving investigational pharmaceutical drugs or biomedical devices are prohibited. See Appendix A for definitions of the terms "Phase I," "Phase II" and

PLACEBO STUDIES.

In addition to the requirements set forth in federal law and regulation, and elsewhere in Department of Human Services (DHS) policy, research protocols that involve the use of a pharmaceutical or medical placebo, must meet the conditions outlined below, in order to assure the safety of human subjects. This policy applies to individuals who receive services that are either partially or fully funded by monies allocated through the Department of Human Services (DHS):

1. The following individuals are prohibited from inclusion in any placebo studies: an individual having any pending legal or criminal charge or action, or who has pending or a reasonable potential for court involvement, or a person who is incarcerated or is in detention, or who is pending or having completed a competency evaluation or commitment procedure. However, if the individual has entered the study prior to involvement with the legal system, the courts, or the beginning of civil or criminal legal proceedings, and subsequently becomes involved in any such action, a referral will then be made to the agency or entity that has assumed guardianship or responsibility for that person, if any, and to the appropriate court to determine whether continued participation in the study is appropriate.
2. No minor who is under the guardianship or custody of the Department of Human Services (DHS), the Division of Child and Family Services (DCFS), the Division of Substance Abuse and Mental Health (DSAMH), the Division of Youth Corrections (DYC), or the Division of Services for People with Disabilities (DSPD) may be recruited, enrolled, or participate in any research study that involves the use of a placebo. If a child has previously entered a study involving placebos prior to entrance into state guardianship or custody, then a referral will be made to the DHS agency or entity that has guardianship or custody, to determine whether the child's continued participation in the study is appropriate. That determination shall be consistent with existing DHS policy, and state and federal law, taking into consideration the opinions of

medical and psychological experts who have provided care for the child prior to and during the study. In addition, the child's Guardian ad Litem (GAL), if one has been appointed, shall be notified by telephone, as well as by certified mail, and a copy of that letter shall be kept with the child's DHS records, and be sent to the DHS IRB. In every case, it must be determined that the biological or custodial parent(s), prior to the child's entrance into state custody or guardianship, had agreed to and signed an informed consent to the study prior to the child's participation in the study.

3. The research participant (human subject) must give written informed consent, and shall have been determined to be competent to grant that consent. Where children or disabled adults are involved as human subjects, adequate provisions must be made for obtaining the assent of the children or disabled adults, in addition to permission via written informed consent of their parents, guardians or legally authorized representatives, in accordance with federal law. (See, 45 CFR § 46.408.)
4. If a proven or known effective standard of care or treatment exists (whether or not the standard of care has been subjected to empirical testing), that treatment shall not be withheld, and placebos shall not be used. Placebos may only be used in studies where no proven or known effective standard of care, prophylactic, diagnostic or therapeutic method exists.
5. Recruitment for the study shall not be limited exclusively to subjects who are receiving services that are either partially or fully funded by monies allocated through the Department of Human Services (DHS).
6. Remuneration for participation in the study must not be coercive, or have the appearance or effect of being coercive; or, be offered to entice individuals to participate in the study rather than receive traditional treatment. Compensation to research participants who are enrolled in placebo studies must be restricted to fair and reasonable remuneration. Only the Institutional Review Board (IRB) at a convened meeting, with a quorum of its members present, may assess and determine a compensation that is fair and equitable.
7. If the child or adult has a current DSM-IV diagnosis of major mental illness at the beginning of a proposed study, the individual will be excluded from participation in placebo studies. Major mental illness will be defined as Major Depression, Manic Depression, Schizophrenia, Disassociative Disorder, other psychotic illnesses, Attention-Deficit Hyperactivity Disorder, Post Traumatic Stress Disorder, Borderline Personality Disorder, Reactive Attachment Disorder, and Panic Disorder.
8. Frequent and close clinical monitoring (as dictated by the medical need of each client) is required in order to assure the ongoing safety and well-being of each human subject. That monitoring shall be documented by the research/medical personnel in each client's clinical record.

9. Any individual with homicidal or suicidal ideations, or who poses a clear threat to themselves or others, is prohibited from participation in any study that involves the use of a placebo.

RESEARCH THAT NEEDS TO BE REVIEWED ONLY BY THE DIVISION IRB REPRESENTATIVE.

If a *Department employee* proposes to engage in the following research activities, the employee must secure prior approval from the appropriate Division IRB Representative, but review by the DHS full IRB is *not* required unless the research also falls into one of the “mandatory review” categories listed in the next section:

1. Research that involves the review of existing case logs or other client-identifiable records maintained by the Department or a Division if:
 - a) the employee normally has access to such logs or records to carry out his or her job responsibilities, or
 - b) the employee does not normally have access to such logs or records, but the director of the Division which maintains such logs or records has reviewed the proposed research and has authorized the employee to have access for that purpose;
2. Conducting client-satisfaction surveys or administering similar questionnaires to the Department’s clients and their families, or to the Department’s employees, consumers, contract providers or collateral contacts, as long as:
 - a) the questions focus on programs or services provided by the Department or a Division;
 - b) the questions do not intrude on the survey respondent’s personal privacy by asking for information (such as sexual history or substance-abuse history) of the kind that most respondents would prefer to keep confidential; *and*
 - c) the survey or questionnaire is administered only to potential subjects who can make an informed choice about whether to participate in the survey or study. (For example, some individuals in the following categories may be *unable* to make such an informed choice and may need the consent of parents, guardians and/or treating physicians: children; clients who are mentally incompetent; clients whose developmental disabilities or serious mental illnesses appear to impair their judgment about whether to participate in the study.)
3. Conducting routine quality assurance reviews or audits for the Department or Division.

For example, Department employees do not need DHS IRB approval for the following routine activities: research studies involving the analysis of existing records or information normally maintained as part of the agency's services or functions; needs-assessment studies; customer/employee satisfaction surveys; service delivery assessments; in-house program evaluations or audits; and interviews/surveys of clients, employees, contract providers or service partners such as the courts.

As noted above, however, prior approval for such research studies is always required from the Division itself. In addition, any research done by an "outside researcher" (i.e., a researcher who is not a Department employee) requires review and approval by both the Division and the DHS IRB, even if that research is the type discussed in this section.

MANDATORY IRB REVIEW CATEGORIES.

Prior review and approval by both the Division IRB Representative and the full DHS IRB is required before a researcher (including a Department employee) may conduct any of the following types of research studies or before the researcher may contact the Department's clients, employees, or subjects:

Research Involving More-Than-Minimal Risk to Human Subjects

Review by the DHS IRB is required for any research that poses more than minimal risk to employees, clients or their families, regardless of whether the research is conducted by Department employees or others.

Federally-Funded Research

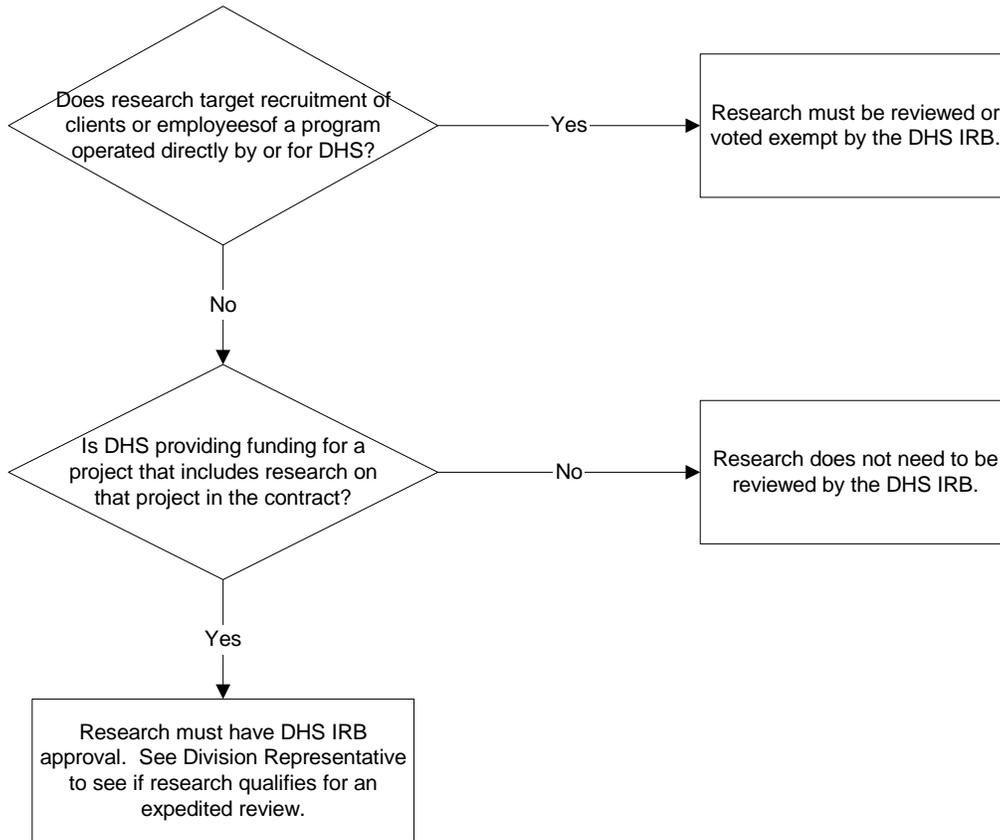
Review by the DHS IRB is required for *all* federally-funded research, regardless of whether the research is conducted by Department employees or others.

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 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



Non-Routine Research by Department Employees

Review by the DHS IRB is required for any research studies prepared and conducted by Department employees if the research involves human subjects (including the Department's employees, clients or their families) *and* the research is outside the scope of the employees' usual case management activities or quality assurance activities.

For example, review by the DHS IRB *is* required if a Department employee proposes to conduct the following research studies:

1. pharmaceutical research or research about biomedical devices;
2. research involving any invasive or painful medical or therapeutic procedures, including blood draws;
3. research that compares the efficacies of certain therapies, *and* involves the use of control groups or the withholding of certain therapies from a client;
4. except as provided in paragraph (2) of the preceding section ("Research That Needs To Be Reviewed *Only* By The Division"), research that requires the subject to respond to a questionnaire or survey;
5. research by Department employees for personal or academic reasons rather than as a part of their normal job duties in the Department.

VOLUNTEERS, STUDENTS, INTERNS, OR INDIVIDUALS SERVING FIELD PRACTICUMS.

Volunteers, college and/or university students, interns, temporary staff, or individuals serving a field practicum with the Department are subject to this policy. Therefore, if such individuals plan to conduct research accessing or otherwise using DHS employees, clients or their data, they must submit a proposal for applicable DHS IRB and/or Division review. If the volume of research from such individuals becomes too great for the Divisions and/or the DHS IRB to adequately process, the Divisions and/or the DHS IRB reserve the right to deny these study requests based on administrative burden. If individuals are conducting literature reviews or presenting reports on topics related to their internship or practicum without using or accessing employees, clients or client data, they are not subject to this policy.

TIMING FOR SUBMITTING PROPOSALS TO THE DHS IRB.

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 by the last day of the month will be reviewed during the second week of the following month. After reviewing the research proposals, the DHS IRB submits a letter to the Department's Deputy Director, recommending either that the research proposal be given final approval or that the research proposal be denied.

CONFLICTS OF INTEREST.

Conflicts of interest will be declared by IRB members; they will then leave the room, and not participate in the discussion or voting.

EXEMPTIONS.

Research proposals may be voted as exempt by the DHS IRB if they meet the criteria in the regulations at 45 CFR 46.101. 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. 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.

APPEALS PROCESS.

If the DHS IRB decides to disapprove a research activity, it shall include in its written notification to the Researcher, a statement of the reasons for its decision and give the Researcher an opportunity to respond in writing and in person.

DHS IRB approved research may be subject to further appropriate review and approval or disapproval by the DHS Director or Deputy Director. However, the DHS Director or Deputy Director may not approve federally-funded research if it has not been approved by the IRB (45 CFR 46.112). The Director and/or Deputy may appoint an appeals board composed of both medical and non-medical IRB representatives and appropriate representatives from the DHS executive staff to make a recommendation to him/her regarding an appeal. If the study is covered by federal regulations, the DHS Director or Deputy cannot reverse a decision to disapprove a study made by the appeals board.

MANDATORY REPORTING LANGUAGE.

Utah statute requires everyone to report actual or suspected abuse, neglect, or exploitation of a child, or disabled or elderly adult. In order to protect potential research subjects right to be informed of all foreseeable risks related to participating in a research study, the DHS IRB requires that all informed consent or permission forms include language informing the signatory of the mandatory reporting requirements.

The Department of Human Services requires disclosure language in every consent form for the protection of potential human research subjects. The language, which reflects requirements of *Utah Code Annotated* §§ 62A-3-301, 305, 306 and 76-5-111, is as follows:

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.

RESEARCH MISCONDUCT.

The handling of allegations of research misconduct is outside the purview of the DHS IRB. Allegations should be brought to the attention of the Deputy Director.

INSTRUCTIONS FOR OBTAINING INSTITUTIONAL REVIEW BOARD 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.

Mary Caputo, M.P.A., Chair of DHS IRB,

Bureau of Internal Review & Audit (BIRA) 538-4295

Brenda Ahlemann, M.B.A.,

Division of Substance Abuse and Mental Health (DSAMH) 538-9868

Kelly Colopy, M.A.,

Executive Directors Office (EDO) 538-4275

John DeWitt, Ph.D.,

Division of Youth Corrections (DYC) 538-4330

Mary Jane Ciccarello, J.D.,

Division of Aging & Adults Services (DAAS) 538-4641

Navina Forsythe, M.P.A.,

Division of Child & Family Services (DCFS) 538-4045

Dennis Geertsen, Ph.D.,

Division of Substance Abuse and Mental Health (DSAMH) 538-9879

Paul Day,

Division of Services for People with Disabilities (DSPD) 538-4118

George Kelner, Ph.D.,

Division of Services for People with Disabilities (DSPD) 538-4208,
Alternate for Paul Day

- 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 of the Research Agreement 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 the Research Proposal 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:
Chairperson, Institutional Review Board
Utah Department of Human Services
c/o Executive Director's Office
120 North 200 West, Suite 319
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.
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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: _____

Attachment “A” to the Research Agreement

DHS INFORMED CONSENT POLICIES

Where informed consent is required, the Researcher shall obtain the legally effective informed consent of the subject or the subject’s legally authorized representative. If the subject is a child or an adult with a legally authorized representative or guardian, but the subject is nevertheless capable of consenting to the research project, the Researcher must also obtain the informed assent of that child or adult. (As used in the following provisions of this policy, the term “subject” includes both the subject and the subject’s legally authorized representative, if any.)

The Researcher shall give each subject a written informed-consent form that explains the study in simple, easily-understood language and easy-to-read type. The Researcher shall give each subject a reasonable opportunity to read the form and ask questions before signing the form.

At a minimum, the informed-consent form shall comply with the following requirements:

- A. The informed-consent form shall not include any exculpatory language that requires or appears to require the subject to waive any of the subject’s legal rights, nor may the form release or appear to release the Researcher, investigator, sponsor, the institution or their agents from liability for negligent or intentional harm.
- B. The Researcher shall provide the subject with sufficient information and opportunity to consider whether or not to participate in the study.
- C. The Researcher shall ensure that the possibility of coercion or undue influence is minimized.
- D. The Researcher shall give the subject a written statement that clearly explains the following:
 - 1. That the study involves research
 - 2. The purposes of the research
 - 3. How long the subject’s participation will last
 - 4. The procedures that the Researcher will use
 - 5. Whether any of procedures the Researcher plans to use are experimental, and if so, which ones
 - 6. The approximate number of subjects who will be involved in the study.
 - 7. That participation in the research study is voluntary, and that refusal to participate in the study will not result in any penalty or loss of benefits to which the subject is otherwise entitled; and
 - 8. That the subject may withdraw from the study at any time without penalty and without loss of any benefits to which the subject is otherwise entitled.

- E. The Researcher shall give the subject a written description of any reasonably foreseeable risks, discomforts or consequences that the subject might experience as a result of participating in the study.
- F. For research involving more than minimum risk, the Researcher shall give the subject a written explanation of:
 - 1. Whether the subject may obtain compensation for any injuries or damages arising out of such risk;
 - 2. Whether any medical treatment is available for such injuries or damages, and if so, what those treatments are and whether the Researcher will provided them free of charge to the subject; and
 - 3. Whom the subject should contact to obtain further information about the risk of injury or damage or about compensation or treatment.
- G. The Researcher shall give the subject a written description of any additional costs that the subject may incur as the result of participating in the research study.
- H. The Researcher shall give the subject a written description of any benefits that the research project will provide to the subject or others.
- I. The Researcher shall give the subject a written disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the subject.
- J. If any of the Researcher's treatments or procedures poses currently unforeseeable risks to the subject or to an embryo or fetus if the subject becomes pregnant, the Researcher shall notify the subject in writing about this risk. (The Department will not approve any studies that involve foreseeable risk to a pregnant subject or to the subject's embryo or fetus.)
- K. The Researcher shall give the subject a written statement describing the extent to which the Researcher will maintain confidentiality of records.
- L. The Researcher shall notify the subject in writing whom the subject should contact if the subject has questions about the research or the subject's rights, including the DHS IRB contact.
- M. The Researcher shall give the subject a written statement listing the anticipated circumstances in which the Researcher may terminate the subject's participation in the research study.

- N. The Researcher shall give the subject a written description of the consequences of a subject's decision to withdraw from the research study, and a description of the procedures for orderly termination of the subject's participation in the study.
- O. The Researcher shall give the subject a written statement indicating that if the Researcher makes significant new research findings which relate to the subject's willingness to continue participation in the research project, the Researcher will notify the subject about those findings during the study.
- P. The Researcher shall give the subject a written statement indicating that if the subject discloses any actual or suspected abuse, neglect or exploitation of a child, disabled adult or elder adult, the Researcher must report this abuse to the authorities, as required by federal and state laws.
- Q. If the subject is a child and the State has guardianship over the child, the Researcher shall give the subject a written statement indicating that the child is represented by the Office of the Guardian Ad Litem. To facilitate access to the Guardian Ad Litem, the statement shall also include the Guardian Ad Litem's phone number: (801) 578-3962.
- R. The informed consent must disclose if the research is being conducted to fulfill the requirements for a master's thesis or doctoral dissertation.

Change, Ongoing, or Annual Resubmission of Research Proposal

UTAH DEPARTMENT OF HUMAN SERVICES

Institutional Review Board (IRB), Mary Caputo, Chairperson (801-538-4295)

120 North 200 West, Room 221, Salt Lake City, Utah 84103

Date of Submission: _____ DHS IRB #: _____

Researcher's Name: _____

Street Address: _____ E-mail: _____

Work Phone: _____ Home Phone: _____ FAX: _____

Start Date: _____ Anticipated End Date: _____

NOTE: All research projects must be reviewed by the Department's IRB no less than annually. If the Researcher plans to make **any** changes to the research design, instruments, or surveys, the Researcher must submit those changes for review, and obtain approval **before** the changes are implemented.

1. **TITLE OF STUDY:** _____

2. **NATURE OF STUDY:**

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

_____ **NO CHANGES** have been made to the study protocol or instruments since the DHS IRB last approved the study. *Please provide an update of the study status including a copy of consent document used for most recent subject enrollment (see #3 below).*

_____ **CHANGES ARE PROPOSED** for the study protocol and instruments since the DHS 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. Include an update of the study status as requested #3 below.*

_____ **STUDY COMPLETED.** *Please attach a copy of the final report.*

4. **UPDATE OF STUDY STATUS:** (*Please attach additional pages as necessary. At a minimum, include the number of subjects accrued; adverse events, subject withdrawals, or complaints; summary of preliminary findings, relevant recent literature, multi-center trial reports; copy of informed consent document, other relevant information, especially about risks associated with the research.*)

5. **REQUIRED SIGNATURE:**

Principal Investigator: _____

Checklist for Division-Level Approval of Research Proposal
UTAH DEPARTMENT OF HUMAN SERVICES

(This form may be used as the Division’s Letter of Support of a Research Proposal being submitted for DHS IRB review and/or may be used for Division approval of research only requiring only Division review and approval.) If a study involves more than minimal risk and no direct benefit to the subject, attach a separate justification statement. *A copy of the completed form must also go to the DHS IRB Chair.*

Date of Review: _____
Researcher’s Name: _____
Street Address: _____ E-mail: _____
Work Phone: _____ Home Phone: _____ FAX: _____
Start Date: _____ Anticipated End Date: _____

1. TITLE AND NATURE OF STUDY:

2. REVIEWED FOR THE FOLLOWING:

- _____ (a) the research is in the best interests of the Division and the Division’s clients;
- _____ (b) the researcher has made adequate provision for obtaining all required informed consents and informed assents;
- _____ (c) 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;
- _____ (d) the research study involves no more than minimal risk* to subjects, or the direct benefits to the subjects outweigh the risks;
- _____ (e) the research methodology is sufficiently sound to yield results that offer a potential benefit to the Department or the Division; and
- _____ (f) 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, including UCA § 63-2-202 (8).

3. RECOMMENDATION FOR APPROVAL: Yes _____ No _____

Division IRB Representative: _____ Date: _____

Division Director: _____ Date: _____

¹ 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.”

APPENDIX A

Definitions of the Terms "Phase I Study," "Phase II Study" and "Phase III Study"

As used in these policies and procedures on "Protecting the Rights of Human Research Subjects," the terms "Phase I Study," "Phase II Study," and "Phase III Study" have the following meanings, which are taken from definitions in the Code of Federal Regulations:

Phase I Study: A "Phase I study" refers to the initial introduction of an investigational new drug into humans. Phase I studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase I, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase II studies. The total number of subjects and patients included in Phase I studies varies with the drug, but is generally in the range of 20 to 80. Phase I studies also include studies of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.

Phase II Study: The term "Phase II study" refers to controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase II studies are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects.

Phase III Study: "Phase III studies" are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase III studies usually include from several hundred to several thousand subjects.

See 21 CFR 312.21.

NOTE: The Utah Department of Human Services does not approve Phase I or Phase II studies.