State Of Louisiana

DEPARTMENT OF HEALTH
AND HOSPITALS

INSTITUTIONAL REVIEW BOARD (IRB)

GUIDELINES FOR RESEARCH SUBMISSIONS

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All research proposals involving clients/patients, staff or services in programs/facilities operated or funded by the Department must be reviewed and approved by the DHH Institutional Review Board (hereafter referred to as the DHH IRB). The purpose of the review process is to assure that all research procedures include safeguards to protect clients' rights and welfare and are ethically and professionally sound.

Send all application materials and inquiries to:

DHH Institutional Review Board
Attn: Janet Brown, Director
Post Office Box 3836 Bin#20
Baton Rouge, Louisiana 70821
Phone: (225) 342-1128
Email: dhh.irb@la.gov

1. DEFINING RESEARCH

The distinctions between *Human Subjects Research* and *Public Health Practices* constantly arise in the planning and performance of public health activities.

Public Health Practices are about protecting the public's health. Included are the core health care activities of treatment, payment, and operations. This expands to include epidemiological investigations, surveillance, programmatic evaluations and clinical care for the population. Underlying many of these activities is the collection and analysis of identifiable health data by a public health authority for the purpose of protecting the health of a particular community. It may include:

- Specific legal authorization for conducting the activity as a public health practice at the federal, state, or local levels;
- A corresponding governmental duty to perform the activity to protect the public's health;
- Direct performance or oversight by a governmental public health authority and accountability to the public for its performance;
- Persons who did not specifically volunteer to participate;
- Principles of public health ethics that focus on populations while respecting the dignity and rights of individuals.

Human Subjects Research is conducted for the purpose of creating ***generalizable knowledge*** that benefits those beyond the participating community who bear the risks of participation. Research explores hypotheses, advances current knowledge, and contributes to the welfare of

the persons beyond the study itself.

Generalizable knowledge is new information generated from the project that has relevance beyond the population from which the knowledge was collected. The information learned can be generalized and applied to other populations and primarily benefits society as a whole instead of the pool of participants bearing the risks of participation. If an activity offers no prospect of benefit to the participants, the activity is classified as research. Characteristics include:

- Living individuals
- Data through intervention or interaction with the individual
- Identifiable private health information
- Subjects who are selected and voluntarily participate, absent a waiver of informed consent
- Principles of bioethics that focus on the interests of individuals while balancing the communal value of research.

2. POLICIES

The DHH IRB conducts its research oversight and compliance in accordance with the following rules and regulations:

- The US Code of Federal Regulations (45 CFR 46, Subparts A-D) under the authority of the Office for Human Research Protections (OHRP), an agency of the Federal Department of Health and Human Services (DHHS)
- The Louisiana Administrative Code for the Department of Health and Hospitals, Title 48, Chapter 25: Departmental Research

The DHH IRB looks to the staff attorney for advice on legal issues and to help resolve any conflicts among federal, state, and local laws.

It is the policy of the DHH IRB that all projects involving human beings and/or information (data) collected from human beings must be presented to the IRB Chair to determine whether: (1) the project is human subjects research; (2) the human subjects research project could be given Exempt status under Federal regulations; or (3) the research project must have IRB review, approval and continued oversight. The determination whether a project receives Full Review or Expedited Review is made by the IRB Chair.

3. MEMBERSHIP

The state rule requires that the minimum membership of the DHH IRB be comprised of:

- The DHH Director of Research and Development (Currently the Chief Information Officer) or the Secretary's designee
- A representative of the DHH Office of Aging and Adult Services
- A representative of the DHH Office of Behavioral Health
- A representative of the DHH Office of Citizens with Developmental Disabilities

- A representative of the DHH Bureau of Health Services Financing
- A representative of the DHH Office of Public Health
- A consumer or family advocate
- An ethicist or attorney
- A direct service provider

Members should represent areas of scientific and non-scientific concerns.

The Chair is the an officer appointed by the Secretary of DHH. The IRB Chair performs functions that require official action. The day-to-day conduct and continuous surveillance of the DHH IRB is the responsibility of the IRB Director.

4. REVIEW

The DHH IRB's authority is to review and either: approve, require modifications to secure approval, or disapprove all research activities overseen and conducted by DHH, or with patients, data, services, or within facilities funded by DHH; to suspend or terminate IRB approval of research not being conducted in accordance with the IRB's requirements; or that has been determined to be associated with unexpected serious harm to participants; and to observe the consent process and the conduct of the research.

The DHH IRB will review all research projects involving the use of subjects based on the following requirements:

1. Risks to subjects are minimized by using procedures that are consistent with sound research design.
2. Risks to subjects are reasonable to anticipated benefits and to the importance of any knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable.
4. Research design minimizes possible disruptive effects on organizational operation.
5. Research design is in compliance with accepted ethical standards.
6. Unless waived, informed consent will be sought from each prospective subject or the subject's legally authorized representatives.
7. Informed consent, when required, will be appropriately documented.
8. The research plan provides monitoring of the research and data collection to ensure subjects' safety.
9. Proposal contains requisite safeguards to protect the privacy of subjects and to maintain the confidentiality of the data under HIPAA standards.
10. Proposal has been approved through the appropriate program administrative levels, beginning at the level of the participating program or facility.

Following review of the proposal, the IRB, by majority vote, recommends one of following actions: 1) Full Approval, 2) Approved with stipulation(s), or 3) Disapproved. The researcher

must submit the recommended modifications to the Director of the IRB within 30 days of notification in order for the proposal to be reclassified as Full Approval.

The Director will notify the researcher in writing of the IRB's decision on the proposed research. If the proposal is Disapproved, the letter will indicate reasons for disapproval and give the researcher an opportunity to respond in writing to the IRB. Research cannot commence at the facility/program until a Full Approval notification is received from the DHH IRB.

Project directors or principal investigators (PIs) may appeal IRB disapprovals or restrictions on approval to the IRB. If the researchers wish to further challenge any decisions made by the IRB, the researcher must initiate the process through the IRB Director in writing within 30 days of action by the IRB. Disapproval or other decisions by the IRB may be overruled by the Secretary of the Department of Health and Hospitals.

Researchers are invited and encouraged to attend Board meetings at which their proposal is being reviewed in person, but his/her presence is not mandatory for full approval of the proposal. If the researcher cannot be present at the meeting, he/she should be available at an indicated phone number during the time of the review so that he/she can be contacted if necessary.

The DHH IRB does not accept IRB review by other institutions in lieu of the DHH IRB's review. Reciprocity of IRB review is not permitted under the Louisiana Administrative Code. In addition, the DHH IRB is the "IRB of Record," and as such, all other IRBs with jurisdiction over the project must approve the proposal prior to the DHH IRB considering the application. Documentation of the approval of the research project by all other IRBs having jurisdiction over the project must be included in the application to the DHH IRB.

5. PROCESS

All projects must be presented to the IRB Chair for a determination. The DHH IRB performs two types of review: Full Review (convening of the IRB and consideration by the full board) and Expedited Review.

Expedited Review is a procedure by which certain kinds of research may be reviewed and approved without convening a meeting of the IRB, if the research involves no more than minimal risk as defined in the federal regulations. The IRB may also use the expedited review procedure to review minor changes to previously approved research during the period covered by the current approval. The review may be carried out by the IRB Chair or by one or more experienced reviewers designated by the Chair from among IRB members.

Categories listed as Exempt by the federal regulations are submitted through the Expedited Review process. Research that may qualify for expedited review include those projects:

1. Conducted in established or commonly accepted educational settings involving normal educational practices.

2. Involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior if such research does not record information or identifiers that can be linked to individual human subjects.
3. Involving the use of existing data, documents, records, pathological specimens, or diagnostic specimens.
4. Conducted subject to the approval of the DHH Secretary or Assistant Secretaries and are designed to study, evaluate or examine public benefit of services or programs.
5. Conducted by faculty or students at colleges/universities, if
    a. A copy of the university's IRB policies are on file with the DHH IRB;
    b. The university IRB approval is documented;
    c. A copy of the full research proposal is included; and
    d. Student researchers have written approval by a faculty advisor and DHH staff sponsor.
6. Conducted in a 24-hour facility if requested by the CEO of that facility to the DHH IRB chair.
7. Requesting minor changes in research previously approved by the IRB.
8. That constitutes cooperative research that has been approved by the DHH IRB and the head of an agency outside DHH.

5.1 The Full Review Application

The following are the required documents for application. An application is not complete until all of the following documents have been received by the DHH IRB Chairperson.

1. **Research Application,** completed and signed by the indicated persons.
2. **Description of the research**, which must include:
    a. **Project Abstract:** presenting the background, objectives, rationale, significance, and reasons for conducting the research.
    b. **Research Design:** describing procedures to be utilized; a description of all questionnaires, apparatuses, or devices; the number of subjects to be involved and how they will be approached and selected for participation in the research; and the planned data analysis.
    c. **Potential benefits of research.**
    d. **Potential Risks of Physical or Psychological Harm.**
    e. **Discussion of the collection of any Personal Identifying Information.**
    f. **Procedures to protect privacy and maintain confidentiality of the data**
3. **Informed Consent documents** (discussed under requirements for informed consent), unless the research involves only extraction of data from clients' clinical records or the study qualifies for waiver of consent.
4. **Copies of any questionnaires**, survey instruments, or other data collection devices, unless these are in common use and have widespread familiarity.
5. **Letter or Memorandum** of endorsement from the manager of each facility/program where the research is to be conducted and from appropriate administrators in that program's office. The manager's letter should include that he/she has reviewed the

proposal and finds that it is feasible to conduct the research project at the facility, that the research procedures will be minimally disruptive of facility operations, and that he/she will appoint a staff member to coordinate the researcher's activities at the facility during the course of the project. Researchers should contact the facility/program manager early in the planning stages to gain his/her interest and support in the project and initiate a working relationship. Additional approval moving up the chain-of-command in the Program Office must be obtained before the proposal is sent to the DHH IRB. Forms for obtaining necessary approval are included in this package for the applicant's and agency's convenience.

6. **University or college students** must also provide documentation that research will be supervised by both a faculty member of the academic program conducting the research and a DHH employee at the research site and has been approved by the university or college IRB. In addition, the student should also ascertain that the DHH IRB has on file a copy of the university's or college's research policies.
7. **DHH Program Office/Administrative Approval.**
8. **Signed Researcher's Pledge.**
9. **Addendum for Child Subjects (if applicable).**
10. **Approvals from any other IRBs with jurisdiction over the project.**

The DHH IRB meets monthly, on the third Friday of the month unless otherwise specified by the Chairperson. Researchers should contact the Chairperson to confirm the review dates and the status of applications. All application materials must be received by the Chairperson no later than two weeks in advance of the IRB Meeting.

5.2 Expedited Review Application

The following are the required documents for application for Expedited Review by the Chair and/or selected members of the IRB, as determined by the Chair.

1. **Application for Expedited Review.**
2. **Letter or Memorandum** of endorsement from the manager of each facility/program where the research is to be conducted and from appropriate administrators in that program's office. The manager's letter should include that he/she has reviewed the proposal and finds that it is feasible to conduct the research project at the facility, that the research procedures will be minimally disruptive of facility operations, and that he/she will appoint a staff member to coordinate the researcher's activities at the facility during the course of the project. Researchers should contact the facility/program manager early in the planning stages to gain his/her interest and support in the project and initiate a working relationship. Additional approval moving up the chain-of-command in the Program Office must be obtained before the proposal is sent to the DHH IRB. Forms for obtaining necessary approval are included in this package for the applicant's and agency's convenience.
3. **University or college students** must also provide documentation that research will be supervised by both a faculty member of the academic program conducting the research and a DHH employee at the research site and has been approved by the university or

college IRB. In addition, the student should also ascertain that the DHH IRB has on file a copy of the university's or college's research policies.

4. **DHH Program Office/Administrative Approval.**
5. **Signed Researcher's Pledge.**
6. **Approvals from any other IRBs with jurisdiction over the project.**

5.3 Requirements for Informed Consent

General Requirements:

A written consent form must be signed by each subject in all research involving direct participation of client or staff, unless a waiver of consent is approved. Although informed consent is not required for research involving only extraction of data from clients' clinical records, other procedures for the maintenance of confidentiality of data do apply. In general, the extensiveness of the consent form should be commensurate with the degree of risk to which the subject is exposed. (See Attachment 2, page seven [7] for a sample informed consent form.) The consent form must be written in clear, simple language [at approximately the sixth-grade level] that can be understood by the clients/subjects.

Elements of Informed Consent Must Include:

1) An explanation of the purpose for the research, the procedures involved, the expected duration of client/staff participation, and a stipulation that the project is experimental in nature and not a regular part of the treatment program at the facility.
2) A statement that participation is completely voluntary and that refusing to participate in the project in no way affects the services the client/staff is receiving or will receive; nor does it affect the client/staff's status in the program. In addition, client/staff must be informed that they may cease participation at any time without personal consequence.
3) A full description of both the possible benefits of the research and the possible risks or discomforts related to participation, if any.
4) An explanation of how the privacy of the client and the confidentiality of the information will be assured, including how the information will be used, by whom, and that his/her name will not be used in reporting the results of the research.
5) An assurance that significant new findings developed during the course of the research that may relate to the client/staff's willingness to participate will be provided promptly to the client/staff.
6) An offer to the client/staff to answer any questions that may arise regarding the nature of the research and the client's participation.
7) Signatures of the client/staff, parent or guardian if necessary, the researcher, a witness, and a date.

The procedures for informed consent must be reviewed by the DHH IRB and documented by inclusion of the consent form with the application. A sample consent form, which would meet IRB requirements if properly completed, is included below. The DHH IRB may appoint a consent

auditor to observe the consent process for some projects, particularly those involving minors, special populations, or special procedures. The consent auditor is authorized to suspend research activities pending a report to the DHH IRB in the event a suspected violation of patient rights is observed. The researcher is duly informed of this action and is given the opportunity to respond. The IRB chair or a designee will decide whether to require modification in the consent procedures and/or research protocol. After the research is completed, it is the responsibility of the researcher to remove any confusion, misinformation, stress, discomfort, or concerns that may remain for the client/staff as a result of their participation.

Informed Consent for Minors, Special Populations, and Special Procedures: (See 45 CFR 46, Protection of Human Subjects, Subparts B, C, and D):

When the research subjects are minors or functionally incompetent to provide informed consent, participation must be approved by client/staff's legal representatives (e.g., parents, guardians, family members). The consent form should contain the usual information required for informed consent. In addition, the client/staff, if capable, must verbally agree to participate.

In research involving drugs, the same informed consent procedures are followed, but, in addition, the consent form should indicate the type and dosage of the drugs to be given and the main side effects. The IRB may require other information.

Waiver of Written, Signed Informed Consent:

Some of the elements of informed consent may be waived by the Committee if there is adequate justification, documented by the investigator, which indicates that one or more of the following is applicable.

1) The research or demonstration project is conducted by or subject to approval of state government officials to study or evaluate public impact of benefits or services provided or funded by the Department.
2) The research deals with improving procedures for obtaining benefits or services and/or suggesting appropriate alternatives to such procedures.
3) The research will not involve identifying individual recipients of benefits/services.

The DHH IRB may waive the requirement for the investigator to obtain a signed consent form from some or all of the subjects if it finds either:

1) That the only record linking the subject and research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality. In such cases, each subject will be asked if he/she wants documentation linking him/her with the research, and the subject's wish shall govern; or

2) That the research presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation is waived, the IRB may require the investigator to provide subjects with a written explanation of the research and the waiver.

5.4 Requirements of Periodic Progress Reporting

The Committee will periodically request progress reports on the current status of research projects. It is also the responsibility of the researcher to report immediately to the DHH IRB and Facility Manager any unanticipated adverse reactions/events that occur as a result of the research activities. Significant changes in the research protocol must be reported to the DHH IRB and approved prior to implementation.

A final report of the research findings must be submitted to the DHH IRB and to appropriate persons in the Program Office upon completion of the research. Failure to submit this report will negatively impact future research requests. A presentation of the results of the project to the facility or program staff is strongly encouraged.

6. MODIFICATIONS TO RESEARCH PROJECTS

6.1 Modifications to protocol

Modifications include, but are not limited to:

a. substantive changes in questions asked in surveys or interviews (if unsure whether changes qualify as substantive, check with the IRB Director)
b. changes in personnel conducting the research
c. changes in number or populations of subjects
d. changes in procedures, or
e. addition of instruments

All modifications must be approved by the IRB prior to implementation. The review of the changes may be expedited or may require full board review. The Chair will make that determination. The submission of a modification does not change the expiration date of a project.

The ***Request for Modification of Previously Approved Protocol*** form should be submitted to the IRB Director. A copy of the new consent form with all changes "highlighted" must be submitted and a "non-highlighted" copy of the revised consent form must also be submitted. The IRB cannot consider changes in investigator, sites, amendments, revisions, addendums, investigator brochures, advertisements for subjects, etc. without a memo from the PI that details the impact of those items on the consent form and the conduct of the study.

6.2 Continuations

All research is approved for one year, unless otherwise specified in the original approval letter from the IRB. If the research needs to continue or data analysis is not yet completed, request renewal of approval using the ***IRB Continuation Application***.

7. WHAT MUST BE REPORTED TO THE IRB

7.1 Adverse events:

The DHH IRB considers adverse events (AEs) that are unexpected, related or possibly related to participation in research, and *serious*, to be the most important subset of adverse events representing unanticipated problems because such events always suggest that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized, and routinely warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects.

However, other adverse events which are unexpected and related, or possibly related to participation in the research, but *not* serious, would also be unanticipated problems if they suggest that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized.

The list of problems that need reporting includes:

- Internal adverse events that are unexpected, involve new or increased risks, and are related to the research.
- External adverse events that are unanticipated problems involving risks to participants or others.
- Changes made to the research without prior IRB approval in order to eliminate apparent immediate harm.
- Other unanticipated information that is related to the research and indicates that participants or others might be at increased risk of harm.
- New information that may affect adversely the safety of the participants or the conduct of the clinical trial.
- Any changes significantly affecting the conduct of the clinical trial or increasing the risk to participants.
- Non-compliance by the investigators.

Again, such events routinely warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects or others.

The FDA believes that only the following AEs should be considered as unanticipated problems that must be reported to the IRB:

1. A single occurrence of a serious, unexpected event that is uncommon and strongly associated with drug exposure
2. A single occurrence, or more often a small number of occurrences, of a serious, unexpected event that is not commonly associated with drug exposure, but uncommon in the study population
3. Multiple occurrences of an AE that, based on aggregate analysis, is determined to be an unanticipated problem. There should be a determination that the series of AEs represents a signal that the AEs were not just isolated occurrences and involve risk to human subjects (e.g., a comparison of rates across treatment groups reveals a higher rate in the drug treatment arm than in controls). A summary and analyses supporting the determination must accompany the report.
4. An AE that is described or addressed in the investigator‘s brochure, protocol, or informed consent documents, but occurs at a specificity or severity that is inconsistent with prior observations. For example, if transaminase elevation is listed in the investigator‘s brochure and hepatic necrosis is observed in study subjects, hepatic necrosis would be considered an unanticipated problem involving risk to human subjects. A discussion of the divergence from the expected specificity or severity must accompany the report.
5. A serious AE that is described or addressed in the investigator‘s brochure, protocol, or informed consent documents, but for which the rate of occurrence in the study represents a clinically significant increase in the expected rate of occurrence (ordinarily, reporting would only be triggered if there were a credible baseline rate for comparison). A discussion of the divergence from the expected rate must accompany the report.
6. Any other AE or safety finding (e.g., based on animal or epidemiologic data) that would cause the sponsor to modify the investigator‘s brochure, study protocol, or informed consent documents, or would prompt other action by the IRB to ensure the protection of human subjects.

As suggested by OHRP and the FDA, AEs meeting the previous descriptions must be reported to the IRB in writing.

7.2 Incidents that are unanticipated problems that are not adverse events:

Only a small subset of adverse events occurring in human subjects participating in research will meet the three criteria for an unanticipated problem. However, there are other types of incidents, experiences, and outcomes that occur during the conduct of human subjects research that represent unanticipated problems but are not considered adverse events. For example, some unanticipated problems involve social or economic harm instead of the physical or psychological harm associated with adverse events. In other cases, unanticipated problems place subjects or others at increased risk of harm, but no harm occurs; e.g., the loss of a laptop computer containing health records.

7.3 What information must be included when reporting to the IRB?

The following information should be included when reporting **an adverse event that is unexpected, serious, and possibly related or related, or any other incident, experience, or outcome, as an unanticipated problem** to the IRB:

1. Appropriate identifying information for the research protocol, such as the title, investigators name, and the IRB project number;
2. A detailed description of the adverse event, incident, experience, or outcome;
3. An explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem; and
4. A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.
5. Upon receipt of the report, the IRB Director and the IRB Chair or designee will determine if immediate action must be taken to protect the safety and welfare of past and current subjects. Usually, input from other Board members is solicited to aid in this decision. If immediate action is needed, the Chair or designee may suspend enrollment or take other action until the report can be evaluated by the Full Board.

Examples of corrective actions or substantive changes that might need to be considered by the IRB in response to an unanticipated problem include:

1. Changes to the research protocol which may have been initiated by the investigator prior to obtaining IRB approval to eliminate apparent immediate hazards to subjects;
2. Modification of inclusion or exclusion criteria to mitigate the newly-identified risks;
3. Modification of informed consent documents to include a description of newly-recognized risks;
4. Provision of additional information about newly-recognized risks to previously enrolled and past subjects;
5. Modification of the information disclosed during the consent process;
6. Notification of current participants when such information may relate to participants' willingness to continue to take part in the research;
7. Requiring current participants to re-consent to participation;
8. Implementation of additional procedures for monitoring subjects and the research, and the consent process;
9. Suspension of enrollment of new subjects;
10. Suspension of research procedures in currently enrolled subjects;
11. Modification of the continuing review schedule;
12. Termination of the research; and/or
13. Referral to other organizational entities.

7.4 Investigator Compliance

Non-compliance is defined as any deviation from approved protocol specifications by an investigator or study team member. Protocol deviations place study subjects at increased risk. Non-compliance that is neither serious nor continuing is handled by the IRB Director through corrective instructions, agreements and review of practices and documentation. For more

serious deviations from approved protocol, the IRB Chair and DHH will act promptly to halt the research, assure remedial action regarding any breach of human subjects protection requirements, and address the investigator's fitness to conduct further research.

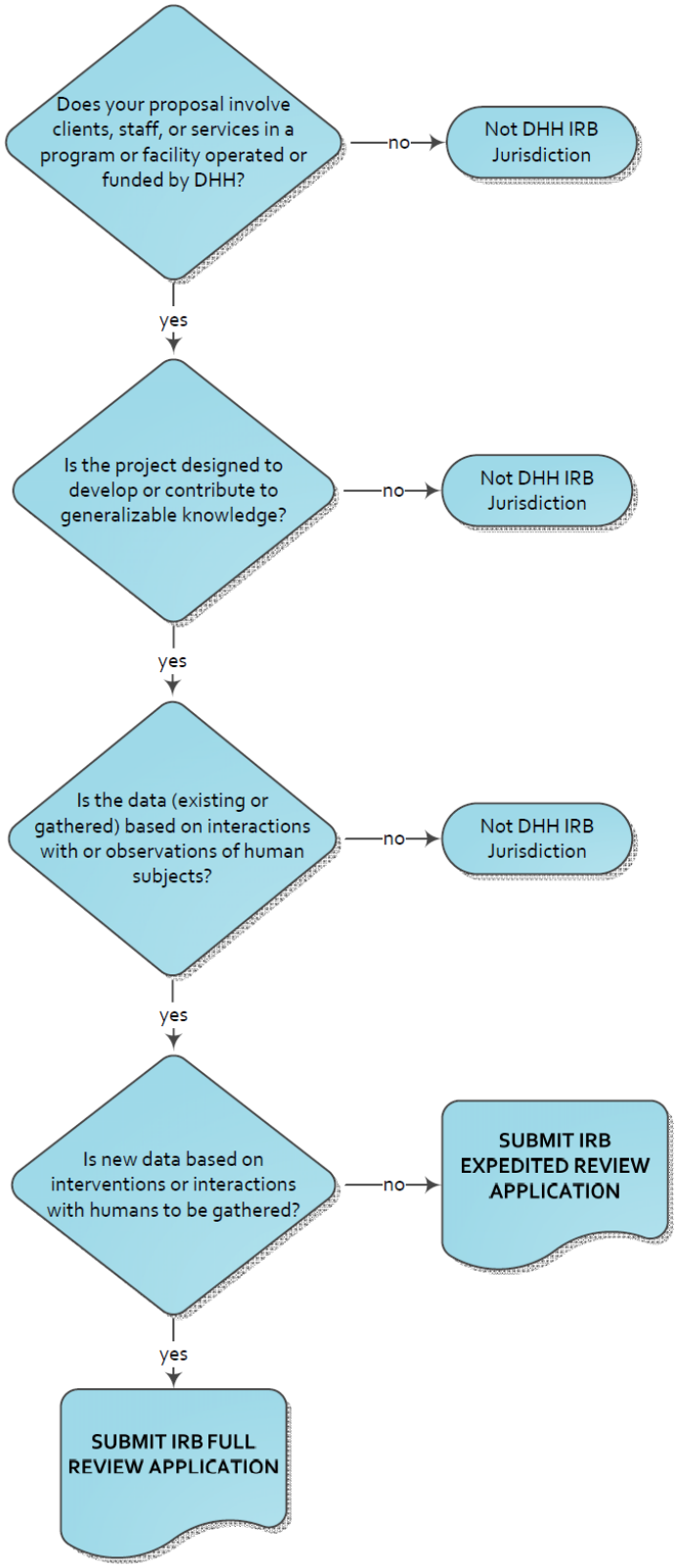
8. CONFIDENTIALITY OF DATA AND HIPAA PRIVACY RULE

When the research involves collection of data that might be harmful to subjects if disclosed to third parties in an individually-identifiable form, the investigator must be attentive to the adequacy of provisions to protect the confidentiality of data. The investigator must limit the collection of personal information to that which is essential for the research. Depending upon the degree of sensitivity of the data, the methods for protecting the confidentiality of data may include coding or removal of identifiers as soon as possible, limitation of access to data to the investigator and authorized staff, the use of locked file cabinets, the use of password-protected computers and computer servers, encryption of data on computers, and plans for the ultimate disposition of data.

The investigator should be aware of the extensive vulnerability of research data to subpoena, particularly in studies that collect data that would put subjects in legal jeopardy if disclosed. The subject names should be recorded only when necessary and subjects must be informed that their identity can be protected only to the extent allowed by law. The investigator should also be aware when and where possible Certificates of Confidentiality should be requested for investigator-initiated studies including projects establishing data and tissue repositories where personal identifiers or codes to identifiers are maintained. See OHRP guidance on Certificates of Confidentiality at http://www.hhs.gov/ohrp/policy/certconf.html and the Certificate of Confidentiality Kiosk on the National Institutes of Health website http://grants.nih.gov/grants/policy/coc/index.htm.

Where appropriate, all studies must adhere to regulations concerning privacy at 45 CFR Parts 160 and 164 (Standards for Privacy of Individually-Identifiable Health Information or **HIPAA Privacy Rule**.) If HIPAA Authorization is required of subjects, the signed authorization document must be maintained with the signed informed consent document for the study (attach these two documents together). In addition, a HIPAA compliant Notice of Privacy Practices must be provided to all subjects enrolled into a study in which HIPAA Authorization is required. Acknowledgement procedures must be followed and documented as described on the website of the DHHS, Office for Civil Rights-HIPAA at http://www.hhs.gov/ocr/privacy/.

IRB Jurisdiction Flow Chart



Chapter 25. Departmental Research

§2501. Purpose

A. These policies are designed to assure the protection of the rights of human subjects of research conducted in programs or facilities operated or funded by the Department of Health and Hospitals (DHH).

AUTHORITY NOTE: Promulgated in accordance with 56 FR 28002.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 24:449 (March 1998).

§2503. Applicability

A. These policies apply to all research conducted in programs/facilities operated or funded by the DHH.

AUTHORITY NOTE: Promulgated in accordance with 56 FR 28002.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 24:449 (March 1998).

§2505. Definitions

Cognitively Impaired—having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders), an organic impairment (e.g., dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgement and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps may also be compromised in their ability to make decisions in their best interests.

Competence—technically, a legal term used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (See also: Incompetence, Incapacity.) Competence may fluctuate as a function of the natural course of a mental illness, response to treatment, effects of medication, general physical health, and other factors. Therefore, mental status should be re-evaluated periodically. As a designation of legal status, competence or incompetence pertains to an adjudication in court proceedings that a person's abilities are so diminished that his or her decisions or actions should have no legal effect. Such adjudications are often determined by inability to manage business or monetary affairs and do not necessarily reflect a person's ability to function in other situations.

DHH—Department of Health and Hospitals (Louisiana).

DHHS—U.S. Department of Health and Human Services. This federal agency promulgated 45 CFR, Part 46, Protection of Human Subjects, revised June 18, 1991, effective August 19, 1991. DHH's research policies are based upon 45 CFR, Part 46.

Human Subject—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.

Identifiable Private Information—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 (e.g., a medical record). Private information must be individually identifiable (i.e., the identification 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.

Incapacity—a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence.

Incompetence—technically, a legal term meaning inability to manage one's affairs. Often used as a synonym for incapacity.

IRB Approval—the determination of the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other state and federal requirements.

Institutional Review Board (IRB)—the DHH committee with responsibility for reviewing and recommending approval/disapproval of all research proposals.

Interaction—includes communication or interpersonal contact between investigator and subject.

Intervention—includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or his/her environment that are performed for research purposes.

Investigator—the person conducting research.

Minimal Risk—the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests.

Programmatic Offices—the major programmatic offices in DHH are: Bureau of Health Services Financing (BHSF), Office of Alcohol and Drug Abuse (OADA), Office for Citizens with Developmental Disabilities (OCDD), Office of Mental Health (OMH), and Office of Public Health (OPH).

Research—systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

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§2507. Statement of Principles

A. The DHH believes that research involving human subjects must be based upon the principles of respect for persons, beneficence, and justice.

1. Respect for persons involves a recognition of personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.

2. Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.

3. Justice requires that benefits and burdens of research be distributed fairly.

B. DHH also recognizes that many consumers of its services may be cognitively impaired and therefore deserve special consideration as potential research subjects. The predominant ethical concern in research involving persons with psychiatric, cognitive, developmental, or chemical dependency disorders is that their conditions may compromise their capacity to understand the information presented and their ability to make a reasoned decision about participation. Consequently, approval of proposals to use these individuals as research subjects will be conditioned upon the researcher demonstrating that:

1. such individuals comprise the only appropriate subject population;

2. the research question focuses on an issue unique to these subjects;

3. the research involves no more than minimal risk, except when the purpose of the research is therapeutic for these individual subjects and the risk is commensurate with the degree of expected benefit.

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§2509. Policies and Procedures

A. Policy Basis. Research conducted and authorized by the DHH will meet all applicable federal and state laws and regulations, accreditation standards, and professional codes of ethics. These policies derive primarily from 45 CFR, Part 46, Protection of Human Subjects and are also consonant with 21 CFR, Parts 50 and 56, adopted by the Food and Drug Administration. (Both sets of regulations were effective on August 19, 1991.) 45 CFR, Part 46 is

applicable to other DHHS components, including the Health Care Financing Authority (Medical Assistance Programs).

B. Establishment of Institutional Review Board (IRB). There is hereby established a DHH IRB to review and evaluate all proposed research projects.

1. Twenty-four hour facilities may either utilize these policies as written or amend them to provide for an in-house IRB for initial assessment of research projects prior to submission to the DHH IRB for final review.

2. All research involving DHH consumers, employees, or services in the community and in institutions will be reviewed by the DHH IRB before it is submitted to the secretary or designee for final approval.

3. The IRB is a permanent standing committee which meets quarterly or as needed.

4. The membership shall consist of at least seven members, appointed by the secretary, partly from recommendations by the assistant secretaries and the director of the BHSF:

a. the director of research and development or his/her designee shall serve as permanent chairperson of the IRB. In the event of an extended absence from duty of the permanent chair, the secretary shall appoint a temporary replacement to serve during that period;

b. each office and the BHSF shall have at least one member;

c. relevant professional disciplines shall be represented in the membership;

d. at least one member shall be a direct service provider;

e. one member shall not be employed by the DHH. If possible, this member should be an ethicist (specialist in ethics) or an attorney;

f. at least one member shall be either a primary consumer, or a family member, or an advocate;

g. at least one member's primary concerns shall be in science areas and at least one member's primary concerns shall be in nonscientific areas. If not selected under §2509.B.4.e, an attorney or ethicist should fill the latter slot;

5. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available to the IRB. Such individuals shall not vote with the IRB.

6. IRB members should have appropriate research training, experience or interest. Membership should also sufficiently represent the cultural, ethnic, and gender diversity of the state and be sensitive to diverse community attitudes.

7. Except for the chair, members shall be appointed for one-year terms and may be reappointed.

8. No IRB member may participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

9. Once constituted, the IRB shall adopt written bylaws and guidelines/application materials for conducting research in DHH operated/funded programs or facilities.

10. Research approved by the Office of Public Health's (OPH) IRB prior to the adoption of these policies does not require DHH IRB approval. However, copies of proposals approved by the OPH IRB shall be provided to the chair of the DHH IRB.

C. IRB Review Process. Prior to authorization and initiation of research, an IRB meeting shall be convened to conduct a detailed review of the project in order to determine that all of the following requirements are met.

1. Proposal incorporates procedures designed to minimize the risk to participants. Risks to subjects are minimized by using procedures which are consistent with sound research design and do not unnecessarily expose subjects to risk and, whenever appropriate, by using procedures already being performed on subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits and the importance of any 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 (e.g., possible effects of research on public policy) as among those research risks that fall within its purview.

3. Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes and setting of the research. It should be particularly cognizant of special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Research design minimizes possible disruptive effects of project on organizational operation.

5. Research design is in compliance with accepted ethical standards.

6. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required in §2509.E.

7. Informed consent will be appropriately documented, in accordance with and to the extent required by §2509.E.1-5 of these rules.

8. When appropriate, the research plan provides monitoring of the data collected to ensure subjects' safety.

9. Research proposal contains requisite safeguards to protect the privacy of subjects and to maintain the confidentiality of data.

10. Research proposal has been approved at the appropriate program administrative level, beginning with the program/facility.

D. IRB Recommendations and Notification

1. Researchers should be either present at the IRB meeting which considers their proposals or available for questioning at an indicated phone number during that time.

2. Following detailed review, the IRB by majority vote approves (fully or provisionally) or disapproves the research proposal.

a. Provisional approval means that minor modifications, specified in writing by the IRB, must be received by the chair within 30 days in order to recommend full approval.

b. Proposals receiving full approval are sent to the secretary or designee for authorization to begin research.

3. The secretary or the director of research and development will notify the researcher in writing of the IRB's decision to approve or disapprove the proposed research within 10 working days.

a. If the proposal is not approved, the letter will indicate reasons for disapproval and give the researcher an opportunity to respond in writing to the IRB.

b. There are no appeals for research proposals disapproved on the basis of ethical shortcomings or potential harm to subjects.

c. No research, subject to IRB review, can begin until written authorization from the secretary or designee is received.

d. Research approved by the IRB may be subject to further administrative review and approval or disapproval. However, no administrator can approve research which has not been approved by the IRB.

e. After approval, the IRB shall review the research in progress at appropriate intervals, but not less than once per year.

f. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected harm to subjects. Any suspension or termination of approval shall be in writing, include the reasons for this action, and be reported promptly to the investigator, appropriate agency officials, and the secretary.

g. Cooperative research refers to those projects covered by this Chapter which involve more than one institution or agency. In the conduct of cooperative research projects, each institution or agency is responsible for

safeguarding the rights and welfare of human subjects and for complying with 45 CFR, Part 46. With the approval of the DHH or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

4. Expedited Review Procedure

a. Research that involves no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the IRB through an expedited review procedure. Under this procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chair from among IRB members. In reviewing the research, the reviewers may exercise all of the authority of the IRB except that they may not disapprove the research. Research may be disapproved only after review in accordance with the nonexpedited procedures set forth in §2509.C. A report of all research approved by expedited review will be presented by the chair to the full IRB at its next regularly scheduled meeting. Categories of research which may qualify for expedited review include:

i. research conducted in established or commonly accepted educational settings, involving normal educational practices (e.g., research on special education instructional strategies);

ii. research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior if such research does not record information or identifiers which can be linked to individual human subjects;

iii. research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens;

iv. research and demonstration projects which are conducted by or subject to the approval of the secretary or heads of programmatic offices and are designed to study, evaluate, or otherwise examine public benefit of services or programs;

v. research conducted by faculty or students at colleges/universities if all of the following conditions are met:

(a). a copy of the university's IRB policies is on file with the DHH IRB;

(b). university IRB's approval of the research is documented;

(c). a copy of the full research proposal is included;

(d). for student research, written approval of the project by both a faculty advisor and a DHH staff sponsor must be provided;

vi. research approved by an IRB in 24-hour facilities if requested via the chief executive officer of the facility to the DHH IRB chair;

vii. requests from investigators for minor changes in research approved less than one year prior to such request;

viii. cooperative research which has been approved by the IRB and head of an agency outside of DHH.

b. The secretary or agency heads may restrict, suspend, terminate, or choose not to authorize use of the expedited review procedure.

E. Informed Consent of Research Subjects. Except as provided elsewhere in Chapter 25, no investigator may involve a human being as a subject in research unless the investigator obtains the legally effective informed consent of the subject or the subject's authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or representative shall be in language easily understandable to the subject or representative. No informed consent document may include any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights or the investigator, the sponsor, or the agency and its agents are/appear to be released from liability for negligence.

1. Basic Elements of Informed Consent. Except as provided below, the investigator shall provide each subject the following information:

a. a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

b. a description of any reasonably foreseeable risks or discomforts to the subject;

c. a description of any benefits to the subject or to others which may reasonably be expected from the research;

d. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

e. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

f. for research involving more than minimal risk, explanations as to whether any compensation and medical treatment are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

g. an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research related injury to the subject;

h. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

2. Additional Elements of Informed Consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

a. a statement that the particular treatment or procedure may involve risk that is currently unforeseeable;

b. anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

c. any additional costs to the subject that may result from research participation;

d. the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

e. a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;

f. the approximate number of subjects involved in the study.

3. Waiver of Informed Consent. The IRB may waive the requirement to obtain informed consent provided that the IRB finds and documents that:

a. the research or demonstration project is to be conducted by or subject to the approval of state government officials and is designed to study or evaluate public benefit of services provided or funded by DHH;

b. such project deals with improving procedures for obtaining benefits/services under those programs and/or suggesting possible changes in or alternatives to those programs/procedures or in the methods/levels of payment for benefits or services under those programs; and

c. such research or projects shall not involve identifying individual recipients of services/benefits.

4. Documentation of Informed Consent

a. Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

b. The written consent document must embody the elements of informed consent required in §2509.E.1. This form may be read to the subject or the subject's legally authorized representative but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed. An IRB recommended informed consent document will be included in the guidelines/application materials for conducting research in DHH operated/funded programs or facilities.

c. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

i. that the only record linking the subject and the research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality. Each subject will be asked if he/she wants documentation linking him/her with the research, and the subject's wish shall govern; or

ii. that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

d. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

5. The IRB shall demand additional protection and informed consent rights if the research involves fetuses, pregnant women and human in-vitro fertilization (45 CFR46:201-211), prisoners (45 CFR 46:301-306), or children (45 CFR 46:401-409).

F. Responsibilities of Research Investigators. In addition to all of the requirements detailed in §2509, researchers shall be responsible for the following.

1. Research investigators shall prepare and submit a protocol giving a complete description of the proposed research.

a. The protocol shall include provisions for adequate protection of the rights and welfare of prospective research subjects and ensure that pertinent laws and regulations are observed.

b. Samples of proposed informed consent forms shall be included with the protocol.

c. A completed DHH Application to Conduct Research must be submitted with the protocol.

2. Research investigators shall obtain and document appropriate administrative approval (beginning at the program/facility level) to conduct research before the proposal is submitted to the DHH IRB.

3. Prior to the beginning of the research, the investigator shall communicate to impacted staff the purpose and nature of the research.

4. Upon completion of the research, the principal investigator shall attempt to remove any confusion, misinformation, stress, physical discomfort, or other harmful consequences, however unlikely, that may have arisen with respect to subjects as a result of the research.

5. Within 30 working days of the completion of the research, the principal investigator shall communicate the outcome(s) and practical or theoretical implications of the research project to the program administrator and, when appropriate, program staff in a manner that they can understand.

6. The researcher shall submit progress reports as requested by the IRB (at least annually). As soon as practicable after completion of the research, but in no case longer than 90 working days later, the research investigator shall submit to the IRB a written report, which, at a minimum, shall include:

a. a firm date on which a full, final report of research findings will be submitted;

b. a succinct exposition of the hypotheses of the research, the research design and methodologies, and main findings of the research;

c. an estimate of the validity of conclusions reached and some indication of areas requiring additional research; and

d. specific plans for publishing results of the research.

7. A final report of the research as well as copies of any publications based upon the research will be submitted to the IRB as soon as possible. The state owns the final report, but prior permission of the IRB for the investigator to publish results of the research is not required. The publication is the property of the researcher and/or the medium in which it is published. However, failure to provide the IRB with required periodic and final reports or publications based on the research shall negatively impact that researchers's future research shall negatively impact that researcher's future requests to conduct research in DHH operated/funded programs or facilities.

G. Initiation of the Research Review Process

1. The first contact in the process should be by the research investigator with the manager of the program or facility from which subjects will be drawn.

2. If the manager agrees that the research is feasible and desirable, the researcher will obtain his/her written authorization and send the protocol to appropriate staff at headquarters for consideration and approval by the assistant secretaries or the director of BHSF.

3. The assistant secretaries or the director of BHSF, in approving the research proposal, will certify that:

a. the research design is adequate and meets acceptable scientific standards;

b. appropriate ethical considerations have been identified and discussed;

c. the proposal contains provisions to minimize possible disruptive effects of the project on organization's operation;

d. the research will potentially benefit the participants directly or improve the service system; and

e. the research topic is compatible with the agency's research agenda.

4. The assistant secretaries or the director of BHSF, after approval of the research, will submit the proposal to the IRB for further consideration.

H. IRB Records

1. The IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

a. copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects;

b. minutes of IRB meetings in sufficient detail to show attendance at the meeting; actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution;

c. records of continuing review activities;

d. copies of all correspondence between the IRB and investigators;

e. a list of IRB members identified by name; earned degrees; representative capacity; indications of experience sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the DHH;

f. written procedures for the IRB and statements of significant new findings provided to subjects.

2. The records required by §2509.H shall be retained for at least three years, and records relating to research which is conducted shall be retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of DHHS or the agency at reasonable times and in a reasonable manner.

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