

APPENDIX C

POLICY NUMBER: 0021-98

SUBJECT: Departmental Research

CONTENT: Policy and procedures for the protection of human subjects of research projects conducted in facilities and programs operated or funded by the Department of Health and Hospitals

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DEPARTMENT OF HEALTH AND HOSPITALS
DEPARTMENTAL RESEARCH

I. **PURPOSE**

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).

II. **APPLICABILITY**

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

III. **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 & 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 - refers to 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 the 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.

IV. 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.

V. 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 non scientific areas. If not selected under Section V.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 represent sufficiently 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 by-laws 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 Section V.E. of this document.
7. Informed consent will be appropriately documented, in accordance with and to the extent required by Section V.E.1 - E.5 of this policy.
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 policy 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 non-expedited procedures set forth in Section V.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 this policy, 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 legally 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 Section V.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 CFR 46:201-211), 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 above, 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 impact negatively 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 DHH;
- f. written procedures for the IRB and statements of significant new findings provided to subjects.

- 2. The records required by Section V.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.