

State Of Louisiana



INSTITUTIONAL REVIEW BOARD (IRB)

FULL REVIEW APPLICATION MATERIALS

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. **Research Proposal Abstract or Prospectus**, which must include:
 - a. **Project Abstract**: the background, objectives, rationale, significance, and reasons for conducting the research.
 - b. **Research Design**: 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 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.
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 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. 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 and a DHH employee 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. **Addendum for Child Subjects (if applicable)**
8. **Addendum for Prisoners (if applicable)**
9. **Approvals from any other IRBs with jurisdiction over the project**

Send all application materials and inquiries to:

DHH Institutional Review Board
Attn: Coordinator
Post Office Box 3836 Bin #20
Baton Rouge, Louisiana 70821
Phone: (225) 342-3206
Email: dhh.irb@la.gov

APPLICATION TO CONDUCT RESEARCH IN DHH OPERATED OR FUNDED FACILITY/PROGRAM

This application must accompany all research proposals submitted for review by the DHH IRB.
All items must be either completed or indicated as not applicable.

Title of Research Proposal: _____

Principal Investigator: _____

Address, City/State/ZIP: _____

Phone/Email: _____

Affiliations: _____

Education/Qualifications: Attach Vitae

Co-investigators: _____

Address, City/State/Zip: _____

Phone/Email: _____

Affiliations: _____

Education/Qualifications: Attach Vitae (if applicable)

University Faculty Sponsor: Complete if Researcher is a student.

Begin date of Research: _____

End date of Research: _____

DHH Facilities and Locations where research is to be conducted:

1. _____

2. _____

3. _____

4. _____

5. _____

Requirements of research project from DHH

Number of subjects/time required: _____

Program support personnel/space/equipment: _____

Other needs (specify): _____

- (A) Attach abstract of the research proposal.
- (B) Attach brief description of potential benefits of this research.
- (C) Attach brief description of potential risks of physical or psychological harm, or discomfort to participant (if any).
- (D) Attach brief description of procedures to be used to establish informed consent of research participants (if applicable).
- (E) Attach Informed Consent Form immediately after this page. (If a waiver of any aspects of informed consent is requested, a statement of justification is required here.)
- (F) Will client personal-identifying information (e.g., name, address, Medicaid recipient number, Social Security Number, phone number) be collected in the course of this research project? (Yes, no): If **yes**, attach explanation why it is necessary to identify the clients.
- (G) Attach brief description of procedures to be used to protect clients' privacy and to maintain the confidentiality of data

ATTACHMENT A: Project Abstract

ATTACHMENT B: Research Design

ATTACHMENT C: Potential Benefits of Research

ATTACHMENT D: Potential Risks of Physical or Psychological Harm

ATTACHMENT E: Discussion of any Personally Identifying Information

ATTACHMENT F: Procedures to protect privacy and maintain confidentiality of the data

DHH INSTITUTIONAL REVIEW BOARD SAMPLE INFORMED CONSENT FORM
(Or submit samples of all developed informed consent forms, scripts, and protocols)

All Sections Must Be Completed and Fully Explained To Subject. [Responses may be attached]

1. Project Title:
2. Research Location(s):
3. Principal Investigator:
4. Address:
5. Phone Number:
6. Description Of Research Activities (purpose, duration, use of drugs, other applicable components; include here statement that study is experimental and not part of usual services):
7. Benefits to Subjects:
8. Risks to Subjects:
9. Alternatives to Participation in Research:
10. Subject Removal Criteria:
11. Subject's Right to Refuse to Participate or Withdraw: I understand that participation in this study is voluntary and that I may refuse to participate or withdraw at any time without penalty, especially as concerns my status in or services received from this program, either now or in the future. I will also be informed if the research leads to important things which may change my decision to participate.
12. Subject's Right to Privacy: I understand that my privacy will be protected and that neither my name nor any information identifying me will be used under any circumstances.
13. Release of Information: I understand that this form does not authorize the release of any identifying information to any party under any circumstances; nor does it authorize the release of information from my case record.
14. Publication/Distribution of Findings: I understand that the results of this research may be published or otherwise distributed but that the results will not contain any identifying information.
15. Assurances/Signatures: This study has been discussed with me. I have been able to ask questions, and those questions have been answered to my satisfaction. I understand that I can ask other questions of the researcher(s) at any time. I have also been informed that if I have concerns about rights of human subjects of research, I can call the Department of Health and Hospitals, Center for Health Care Innovation and Technology at (225)342-5816. I agree with the terms of this consent form and have been given a copy.

Signature of Subject _____ Date _____

Signature of Witness _____ Date _____

Signature of Investigator _____ Date _____

Reader Attests:

The subject has informed me that she/he is unable to read. I hereby certify that I have read this consent form to the subject and have explained that by signing above, she/he agrees to participate.

Signature of Reader _____ Date _____

Children and/or Subjects Unable To Give Informed Consent:

The subject is _____, a child or person unable to give informed consent, and I certify that I am the subject's legal guardian and do give my consent for his/her participation.

Legal Guardian's Name/Signature _____ Date _____

Subject's Name _____ Age _____

Subject's Signature _____ Date _____

LETTER OR MEMORANDUM OF ENDORSEMENT FROM FACILITY OR PROGRAM

DATE:

M E M O R A N D U M

TO: Chairperson, DHH Institutional Review Board

FROM: _____
Facility/Program Manager's printed name and signature required

Facility/Program Name Location

RE: _____
Title of Research Proposal

I have reviewed the above-entitled research proposal. The research procedures appear to be minimally disruptive to clinical and facility operations. I agree to provide the necessary support requested in the application and hereby designate a staff member,

_____, who will be responsible for monitoring these research activities. I understand that any modifications to the research protocol must be approved by the DHH IRB prior to implementation. I agree to suspend research activities and to report to the DHH IRB any unauthorized research modifications or instances in which client rights appear to be violated. I understand that the researcher is not authorized to begin research activities at this facility until written authorization from the Secretary or designee is received.

Send c/o:

**DHH Institutional Review Board
Attn: Coordinator
Post Office Box 3836 Bin #20 Baton
Rouge, Louisiana 70821 Phone:
(225) 342-3206
Email: dhh.irb@la.gov**

UNIVERSITY FACULTY SPONSORSHIP

(Complete For Student Researchers Only)

I have reviewed this research application and proposal and find that the research design and planned data analyses are appropriate to the research objectives and that there are safeguards to protect the rights and welfare of the research participants. I hereby assume responsibility for supervision of this/these students' research activities during the course of the project.

Signature of faculty member _____ Date _____

College/University Location _____

Attach University IRB Approval after this page.

PROGRAM OFFICE ADMINISTRATIVE APPROVAL

I hereby certify that this proposal has been reviewed and approved by this Office/Bureau. Our review finds that the research is ethically appropriate, does not unduly disrupt the organization/agency/program, and is compatible with the agency’s research agenda; i.e., it will benefit the patient and/or service delivery system.

(Obtain appropriate signatures for Offices)

Regional Manager _____ Date _____
(For region-based projects)

Division Director _____ Date _____
(For region-based/program-based projects)

Assistant Secretary _____ Date _____
(For statewide projects)

RESEARCHER’S PLEDGE

I am applying to conduct the research project entitled above at the indicated DHH facilities/programs. I agree to conduct this research in an ethical and responsible manner and as stipulated by the proposal and this application. I agree to secure the approval of the DHH IRB for any modifications to the research protocol. I understand that I have an ethical and legal responsibility not to divulge the identity of any clients or any information about them as identifiable individuals, nor will the final compilation of results of this project contain any client identification information. As soon as the project is complete, all client-identifying information collected will be destroyed. I agree to keep the DHH IRB informed periodically of the progress of the project, and I will submit a report of the final results to the IRB and facilities/programs involved.

Signature of principal investigator

Date

Signature of Co-Investigator(s)

Date

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