INSTITUTIONAL REVIEW BOARD (IRB)

EXPEDITED 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 LDH IRB Chairperson.

1. **Research Application**, completed and signed by the indicated persons.
2. **Letter of 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 is its feasible to conduct the research project at the facility, that the research procedures will be minimally disruptive of facility operations, and that the/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.
3. **University or college students** must also provide documentation that research will be supervised by both a faculty member and a LDH employee and has been approved by the university or college IRB. In addition, the student should also ascertain that the LDH IRB has on file a copy of the university's or college's research policies.
4. **Program Office Administrative Approval**
5. **Researcher's Pledge**
6. **Approvals from any other IRBs with jurisdiction over the project.** PIs are nonetheless encouraged to submit applications to LDH IRB concurrently with other institutions' IRBs. Please note, however, that as the IRB of Record, LDH IRB will require decision letters from all other institutions before it can issue a decision.

Send all application materials and inquiries to:

Email: ldh.irb@la.gov

APPLICATION FOR IRB COMMITTEE EXPEDITED REVIEW

THIS RESEARCH PROPOSAL MEETS THE FOLLOWING REQUIREMENTS FOR EXPEDITED REVIEW:

- ☐ Conducted in established or commonly accepted educational settings, involving normal educational practices.
- ☐ Involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior which does not record identifiers.
- ☐ Involving the collection of study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- ☐ Conducted by or subject to the approval of the Assistant Secretary.
- ☐ Conducted by faculty or students at colleges or universities if 1) university IRB policies and approval of the research is on file; 2) a copy of the full research proposal is documented; 3) written approval of the project by both a faculty advisor and a LDH staff sponsor are included.
- ☐ Approved by an IRB in a 24-hour facility if requested by the CEO of the facility to the LDH IRB Chair.
- ☐ Includes minor changes in research previously approved by the IRB

1. PROJECT INFORMATION

1.1 Project Title

1.2 Principal Investigator (PI)

Name (Last name, First name MI):	Highest Earned Degree:
Mailing Address:	Phone Number:
	Pager or Cell Phone Number:
	Fax:
Organization	Email:
Title	University Department (if applicable):
Occupational Position ☐ Faculty ☐ Staff ☐ Student ☐ Other:	

As Principal Investigator of this study, I assure the IRB that the following statements are true: The information provided in this form is correct. I will seek and obtain prior written approval from the IRB for any substantive modifications in the proposal, including changes in procedures, co-investigators, funding agencies, etc. I will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study. I will report in writing any significant new findings which develop during the course of this study which may affect the risks and benefits to participation. I will not begin my research until I have received written notification of final IRB approval. I will comply with all IRB requests to report on the status of the study. I will maintain records of this research according to the IRB guidelines. The request that I have submitted with this IRB submission accurately and completely reflects what is contained in this application. If these conditions are not met, I understand that approval of this research could be suspended or terminated.	
PI:	Date:

1.3 Department, Division Head, or Dean Information

Please note as the researcher, you are responsible for confirming and following your departmental standards and requirements for research.

Name of Department Head, Division Head or Dean

1.4 Are there additional Co-investigators and Staff?

1.5 Is the PI of this research a student?

Academic Advisor to the Student Investigator	
Advisor's Name (Last name, First name MI):	University Department:
Mailing Address:	Phone Number:
	Email:

2. FUNDING

2.1 Is this research funded by an internal or external agency?

If no, explain how costs of research will be covered:

3. INSTITUTIONAL OVERSIGHT

3.1 Will this research be utilizing Louisiana Department of Health resources or medical records?

3.2 Will this research be utilizing Medicaid data, Office of Public Health data, Vital Records data or any medical records?

3.3 Is this research proposal being reviewed by any other IRB or peer review committee?

(It is the responsibility of the PI to secure the appropriate approval from these committees and document that approval to the LDH IRB. Attach a copy of documentation of approval, and indicate committees below.)

4. CONFLICT OF INTEREST

Federal Guidelines emphasize the importance of assuring there are no conflicts of interest in research projects that could affect the welfare of human subjects. If this study involves or presents a potential conflict of interests, additional information will need to be provided to the IRB. Examples of potential conflicts of interest may include, but are not limited to:

- A researcher or family member participating in research on a technology, process or product owned by a business in which there is a financial interests
- A researcher participating in research on a technology, process or product developed by that researcher
- A researcher or family member serving on the Board of Directors of a business from which that member receives supervised Sponsored Research Support
- A researcher receiving consulting income from a business that funds his or her research

"Immediate Family" means, at a minimum, spouse and each dependent child.
"Financial Interest Related to the Research" means financial interest in the sponsor, product or service being tested.

4.1 Do any of the investigators or personnel listed on this research have a business interest or a financial interest of $10,000 or more associated with this study when aggregated for their immediate family?

If yes, identify the individual(s) and complete section 4.3:

4.2 Do any of the investigators or personnel (when aggregated for their immediate family) listed on this research have:

Ownership interests less than $10,000 when the value of interest could be affected by the outcome of the research.

Do ownership interests exceed 5% interests in any one single entity when aggregated for the immediate family?

Compensation less than $10,000 when the value of the compensation could be affected by the outcome of the research.

If yes, identify the individual(s) and complete section 4.3:

4.3 Has the potential conflict of interest been disclosed and managed?

Final IRB approval cannot be granted until all potential conflict matters are settled. The IRB requires a recommendation regarding disclosure to subjects and management of the conflict. The full IRB committee determines what disclosure language should be in the consent form.

5. USE OF PROTECTED HEALTH INFORMATION (PHI): HIPAA REQUIREMENTS

5.1 As part of this study, do you:

a. **Collect protected health information (PHI)* from subjects in the course of providing treatment/experimental care; OR**
b. **Have access to PHI* in the subjects' records?**

Please read the definition of PHI below before answering.

*PHI is defined under HIPAA as health information transmitted or maintained in any form or medium that:

1. identifies or could be used to identify an individual;
2. is created or received by a healthcare provider, health plan, employer or healthcare clearinghouse; and
3. relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of healthcare to an individual.

The following records ARE EXEMPTED from the definition of PHI even though they may contain health-related information: student records maintained by an educational institution and employment records maintained by an employer related to employment status. If your study uses these kinds of records, it is not subject to HIPAA. However, existing IRB rules on informed consent and confidentiality still apply**.**

Health-related information is considered PHI if (any of the following are true):

1. The researcher obtains it directly from a provider, health plan, health clearinghouse or employer (other than records relating solely to employment status);
2. The records were created by any of the entities in "1" and the researcher obtains the records from an intermediate source which is NOT a school record or an employer record related solely to employment status; OR
3. The researcher obtains it directly from the study subject in the course of providing treatment to the subject.

Health-related information is not considered PHI if the researcher obtains it from:

1. Student records maintained by a school;
2. Employee records maintained by an employer related to employment status; OR
3. The research subject directly, if the research does NOT involve treatment

6. SUMMARY OF ACTIVITIES

6.1 Briefly state what is your research question.

6.2 Describe the source of the records; medical, educational, employment, existing data set, or pathological specimens. (A list of data elements may be attached.)

6.3 Number of records or specimens to be used:

6.4 How long do you anticipate this research study will last from the time you are determined to meet the criteria for exempt research? *This LDH IRB routinely inactivates exempt applications after one year from the time it was determined to meet the exempt criteria.*

6.5 Is the data you are gathering publicly available?

6.6 Do you already have permissible access to the records or specimens (i.e. through a job, volunteer work, internship etc.)

6.7 Will the records you receive be stripped of all identifiers and a link that would make it possible for you to identify a subject?

6.8 Confirm that the data/specimens you wish to review already exist:

6.9 Choose whether or not the data is identified and/or recorded:

6.10 Describe the identifying information to which you will have access to prior to recording de-identified data:

6.11 Describe the de-identified information you will record:

7. CONFIDENTIALITY

7.1 Describe provisions to maintain confidentiality of data:

7.2 Describe the security plan for data including how and where stored and duration of storage (i.e., password protection, encrypted data, etc.):

7.3 Will identifiable data be made available to anyone other than the PI?

If yes, explain who and why they will have access to the identifiable data:

This regulation does not apply to FDA regulated research.

You have reached the end of this form. Please make sure that you have responded to every question on this application (even if your response is "not applicable"). Forward the complete Application for Expedited Review to LDH IRB: ldh.irb@la.gov

LETTER OR MEMORANDUM OF ENDORSEMENT

DATE:

M E M O R A N D U M

TO: Chairperson, LDH 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 LDH 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:

Email: ldh.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 LDH 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 LDH 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, not 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 LDH 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