INSTITUTIONAL REVIEW BOARD (IRB)

Purpose

All human subjects research proposals involving clients, patients, staff, or services in programs or facilities operated or funded by the Louisiana Department of Health (LDH) must be reviewed and approved by the LDH Institutional Review Board (IRB). The purpose of the LDH IRB is to protect the health, safety, and privacy of research subjects and to ensure that proposed research meets ethical and legal standards.

Governance

The U.S. Department of Health and Human Services promulgated 45 CFR Part 46, Protection of Human Subjects, known as the "Common Rule", to govern the operations of IRBs. LDH's research policies, based upon the Common Rule, are set forth in a state rule, Louisiana Administrative Code, Title 48, Part I, Chapter 25: Departmental Research.

Application

The major documents required to apply for LDH IRB consideration are:

- Research application (Full Review or Expedited Review)
- Research Protocol, Abstract, and/or Prospectus
- Administrative Approval from the LDH Program Office affected by the research (form included in the application packet)
- List of requested data elements, questionnaires , or surveys
- Approvals from all other IRBs governing the investigators, facilities, or participants in the research proposal.

For full description of application requirements, including forms, visit http://ldh.la.gov/index.cfm/subhome/38

Membership

The state rule requires that the membership of the LDH IRB include representatives of the following:

- Director of Research and Development
- Each of LDH's major Program Offices (Office of Aging & Adult Services, Office of Behavioral Health, Office of Developmental Disabilities, Office of Public Health and Medicaid)
- Consumer/Advocate (Non-scientific)
- Attorney/Ethicist
- Service Provider
- Non-LDH employee

Policies

All research proposals involving human beings and/or information collected from human beings must be presented to the IRB for a determination. The IRB meets at a minimum of once per quarter, but may meet as often as monthly. Research must be approved by the LDH IRB before initiation of the study.

The LDH IRB must review all proposals within its jurisdiction, and will not do so until approval has been granted by the IRBs of all other institutions involved in the research.

Policies

1. Applications for Full or Expedited Review are accepted throughout the month. If there are proposals requiring Full Review, the IRB will meet on the third Friday of the month.

2. Proposals are evaluated with a full discussion on the merits of the full application, including scientific merit, potential risks and benefits to subjects, and expertise of the investigators. The board will respond with one of the following: (1) Approved; (2) Approved with stipulations; or (3) Disapproved.

3. Principal investigators will be notified in writing of the results of the review of their proposal. Changes to approved protocols must be reviewed and approved by the IRB prior to implementation.

4. A final report of the research findings must be submitted to the LDH IRB upon completion of the study.

Questions about the LDH IRB should be made to: dhh.irb@ la.gov

LOUISIANA DEPARTMENT OF HEALTH

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