Institutional Review Board

DEPARTMENT OF HEALTH AND HOSPITALS

Purpose

In order to assure that all research involving the public health protects patient welfare and is ethically sound, all research proposals involving clients, patients, staff, or services in programs or facilities operated or funded by the Department of Health and Hospitals must be reviewed and approved by the DHH Institutional Review Board.

Governance

The US Department of Health and Human Services 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. These policies are set in **Louisiana Administrative Code Title 48, Chapter 25: Departmental Research.**

Application

The documents required to apply for consideration to the DHH IRB are:

- ✓ Research application
- ✓ Research Protocol Abstract or Prospectus
- ✓ Letter of Endorsement
- ✓ Approvals from all other IRBs governing the investigators, facilities, or participants in the project.

Depending on the type of research, the following may also be required:

- ✓ Requested Data Description
- ✓ Data Element Table
- ✓ Informed Consent documents
- ✓ Copies of any questionnaires

Membership

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

- ► DHH Chief Information Officer
- ► Aging & Adult Services
- ► Behavioral Health
- ► Developmental Disabilities
- ► Medicaid
- ► Public Health
- ► Consumer/Advocate
- ► Attorney/Ethicist
- ► Service provider

Policies

- All projects 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 DHH IRB before initiation of the project.
- The DHH IRB is the "IRB of Record," and proposals will not be considered until approval has been granted by all other institutions involved in the project.

Process

- The DHH IRB's rules **do not** permit a project to be "exempt" from review. Review of these projects must still be determined by the IRB.
- Applications for Full or Expedited Review are accepted throughout the month. If there are proposals to review, the IRB will meet on the third Friday of the month.
- Proposals are evaluate with a full discussion on the merits of the full protocol, including scientific merit, risk/benefit ratio to subjects, and expertise of the investigators. The board will respond with (1) approved; (2) approved with provisions; and (3) disapproved.
- Project investigators will be notified in written memo of the review of their project.
- All changes to approved protocols must be reviewed and approved by the IRB prior to implementation.

Questions about the IRB or requests for materials should be made to Nell Allbritton, nell.allbritton@la.gov or (225) 342-3716