XIII. Other Important Information

Research and Evaluation Protocols:

Jurisdiction of the DMHAS OOC Institutional Review Board (IRB)

The DMHAS OOC IRB must review and approve activities categorized as research involving human subjects when DMHAS is engaged in the research. DMHAS is engaged in research when the research is conducted by an employee of DMHAS, by an investigator who is an agent (contractor) of DMHAS, or by a non-DMHAS investigator at a State-operated facility, including Local Mental Health Authorities.

Note: Proposals for research conducted at the Connecticut Mental Health Center (CMHC) are reviewed and approved by the Yale Human Investigations Committee because CMHC is jointly operated by both DMHAS and Yale University, unless the research will also be conducted at another DMHAS facility.

Definitions

Research is defined by the regulations (45 CFR 46.102 (d)) as a "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

Human subject is defined by the regulations (45 CFR 46.102 (f) (1), (2)) as "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."

IRB Application is the document that the DMHAS OOC IRB uses as the research protocol. It describes, in detail, the purpose of the study and the detailed plan for conducting the study.

Note: The Federal Office of Human Resear ch Protections recommends that, because of the potential for conflict of interest, investigators not be given the authority to make an independent determination that a human subjects research activity is exempt from the regulations. Similarly, an investigator should not make an independent determination that a study does not meet the definition of human subjects research. In these cases, the investigator should contact the DMHAS IRB Chair, Janet Storey, at janet.storey@ct.gov or (860) 418-6823.

DMHAS IRB Review Process

Any qualified individual who proposes to conduct research at a DMHAS facility should review the *DMHAS IRB Policy* and the *Guidelines for Investigators*, which can be accessed on the DMHAS IRB Website, along with all necessary forms. The application package must include:

- Funding application
- Informed consent form or application for waiver of consent requirements
- Recruitment material such as posters, flyers, letters, information sheet public announcements, etc.
- All questionnaires or data collection instruments
- General outline or focus of interview/interaction where interaction will be semi structured, if applicable
- Scripts to guide interviews or presentations of verbal information
- Release of information form, if applicable
- HIPAA Authorization form, if applicable

XIII. Other Important Information

The IRB chair conducts a preliminary review within two weeks of receiving the application package and sends an email to the investigator if any clarification or revisions are needed. The study will then undergo expedited or full board review.

Research Not Sponsored or Conducted by DMHAS Involving DMHAS Facilities, Records, Clients, or Staff

Research originating outside DMHAS involving DMHAS facilities, records, clients, or staff is subject to a Commissioner's Review. This includes research proposed by university, hospital or other organization-based investigators who:

- Are not affiliated with DMHAS;
- Are not under contract with DMHAS to conduct research;
- Have not otherwise obtained OOC endorsement for the research; or
- Are graduate students or other whose research is related to educational requirements; or
- Are student employees of DMHAS whose research is related to educational requirements.

The following process applies to such research.

1. DMHAS Facility Approval

    a. The investigator submits a detailed written research proposal to the research committee and/or the head of each state-operated facility where the proposed research activity will occur. The proposal may be submitted using the DMHAS Application for IRB Approval, but use of the application is not required at this point in the approval process.

    b. The head of each facility must consider the burden to DMHAS of participating in the research (e.g. amount of staff hours, days of client care, or other DMHAS resources to be devoted to the research over-and-above what would be used in the absence of the proposed research, as well as any resources to be gained by DMHAS in exchange for participating in the proposed research). Therefore, the investigator should provide information to the head of the facility about expectations of the facility. The facility heads will take the findings of this review into account when deciding whether to endorse the research proposal.

    c. The investigator must submit documentation that the research has been approved by the investigator's institution human subject protection committee.

    d. If the proposed research includes obtaining access to confidential information, then the proposal must clearly indicate who will have access to such information in sufficient detail for a reader to be able to assess whether the request falls within state statutes and complies with HIPAA regulations.

    e. If, following review, the proposed research is approved at the facility level, the head of the facility will forward a letter of endorsement to the DMHAS Research Director and the OOC IRB Chair. If the facility is part of a Local Mental Health Authority, the LMHA Director should forward a letter of endorsement to the DMHAS Research Director.

2. OOC IRB Review

After obtaining facility endorsement, the investigator then submits an Application for IRB Approval to the OOC IRB for its review.

3. DMHAS Research Director Review

Upon receipt of both the letter of endorsement and the IRB Application, the DMHAS Research Director finalizes the Commissioner's Review, which comprises review of scientific merit.

4. Commissioner Approval

Final approval by the Commissioner will be based upon a favorable assessment related to scientific merit, administrative impact, benefit of research to DMHAS, and IRB approval. The Commissioner or his designee will notify the relevant parties as to the Commissioner's decision. Such approval must be received prior to participation by