



A Healthcare Service Agency

STATE OF CONNECTICUT
Department of Mental Health & Addiction Services

Commissioner's Policy Statement and Implementing Procedures

Table with 2 columns: Label (SUBJECT, P & P NUMBER, APPROVED, EFFECTIVE DATE, REVISED, REFERENCES, FORMS AND ATTACHMENTS) and Content (Review of Proposals for Research within DMHAS, Chapter 8.2, Miriam Delphin-Rittmon, Commissioner, Date: 10/15/2015, October 15, 2015, 1/1/2011, Replaced Policy #17: Policy on Research Personnel Not Employees of DMH in DMH Facilities, dated September 9, 1965 and Policy #20: Research Utilizing Human Subjects or Data Obtained from Records, dated March 20, 1975, DMHAS Institutional Review Board Policy dated 10-1-10)

STATEMENT OF PURPOSE: Outlines procedures staff and external researchers are to follow with regard to the review of research proposals and participation in research activities. The purpose of these procedures is to ensure that research undertaken at DMHAS by internal and external researchers meets standards of ethical treatment of human subjects in compliance with federal regulations regarding the protection of human subjects; has a scientific value as great as the burden on DMHAS staff and consumers; and where needed, meets business standards.

POLICY: Before research may be conducted at DMHAS facilities, it must undergo a review to determine whether the research question warrants DMHAS involvement, the impact it will have on the DMHAS system of care, and whether the risks, benefits, and protections for clients are acceptable. In order for research to commence, the facility where the proposed research will take place must review and endorse the research; and the DMHAS Institutional Review Board (IRB) and the DMHAS Commissioner must review and approve the proposed research.

Except for research initiated at the Office of the Commissioner, facilities shall not allow research to be conducted at a DMHAS-operated facility without prior written approval of the DMHAS Commissioner.

**NOTE ON EXCEPTION:** Because the Connecticut Mental Health Center (CMHC) is jointly operated by both DMHAS and Yale University, proposals for research to be conducted at CMHC are exempt from these procedures, unless the research will also be conducted at another DMHAS facility.

**PROCEDURE:** The following procedures apply to research proposals originating outside of DMHAS (research conducted by student employees of DMHAS, whose research is related to educational requirements, is considered to originate outside of DMHAS).

- a) A written proposal of the research project must be submitted to the head of the DMHAS facility proposed as a recruitment or study site, along with documentation that the proposed research has been approved by the applicant's human subject's protection committee. The proposal should outline the goals and potential benefits of the study and provide full details regarding the proposed research procedures (i.e., access to confidential data, access to non-confidential data, access to and interaction with clients of DMHAS-operated services, access to and interaction with staff members, etc.). The proposal may be submitted using the DMHAS IRB application which can be found at DMHAS IRB (on DMHAS website); however use of the IRB application is not required at this point in the approval process.
- b) The project budget should also be clearly presented to the head of the DMHAS facility for review by the participating facility's chief fiscal officer. This facility-based review must also include estimates of the DMHAS resources that will be required in order to participate in the research, e.g., number of staff, number of staff hours, days of patient care, allocation of office space, or other DMHAS resources, such as IT equipment, access to charts or electronic data, to be devoted to the proposed project beyond 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. The head of the facility should take these factors into account when deciding whether to endorse the research proposal.
- c) If the facility is a sub-unit of a Local Mental Health Authority, the Director of the LMHA must also indicate his/her endorsement of the proposal before it can be considered further.
- d) Once a proposal has received the above-mentioned endorsement(s) the facility or LMHA Director should forward a letter of endorsement to the DMHAS Director of Research. In addition, the researcher must now submit an IRB Application to the DMHAS IRB. Upon receipt of both the letter of endorsement and the IRB Application, the DMHAS Director of Research will initiate the Commissioner's review process. This process involves a review of scientific merit, staff and client burden; a review of administrative requirements upon DMHAS, and a review of human subject's protections as per the DMHAS IRB Policy. Final approval by the Commissioner will be based upon a favorable assessment related to scientific merit, usefulness of research to DMHAS, administrative impact and IRB approval
- e) Upon notice of Commissioner approval, the DMHAS IRB will forward notice of

IRB approval to any involved DMHAS-operated facility(ies).

- f) The Commissioner or her/his designee will notify the relevant parties as to the Commissioner's decision. The Commissioner's approval must be received prior to participation by DMHAS in any such research projects.
- 1) For proposals originating within DMHAS facilities, but not within the Office of the Commissioner, procedures outlined in steps a-f noted above should be followed.
  - 2) Research proposals originating within the Office of the Commissioner. Most research proposals originating within OOC are approved by the Commissioner at the onset of planning. In such cases:
    - a) Once a research proposal is forwarded to the DMHAS IRB, the review will proceed without the need for a letter of endorsement by the facility or LMHA Director(s). However internal researchers should obtain the support of affected LMHA directors prior to grant submission and/or protocol development whenever possible.
    - b) Upon DMHAS IRB approval, the IRB will forward notice to the researcher and involved DMHAS-operated facility(ies) and the study may commence.
  - 3) For research proposals originating at the OOC level where the Commissioner has not been apprised of the research plan and has not granted approval, the following procedures should be followed:
    - a) When the proposal involves staff resources from other DMHAS facilities, the researcher should confer with the appropriate facility Director(s) so that the administrative impact can be assessed.
    - b) The researcher will submit an IRB application to the DMHAS IRB.
    - c) The IRB will forward a copy of the IRB application to the DMHAS Director of Research who will coordinate the Commissioner's review.
    - d) Following IRB and Commissioner approval the IRB will then forward notice of IRB approval to the researcher and involved DMHAS-operated facility(ies) and the study may commence.

Questions regarding this policy should be directed to the DMHAS Director of Research