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OHIO DEPARTMENT OF MENTAL HEALTH

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Guidelines for the Institutional Review Board

- A. Purpose:  
The Institutional Review Board (IRB) of The Ohio Department of Mental Health (ODMH) operates under the US Department of Health and Human Services regulations for the Protection of Humans Research Subjects: Title 45 of the Code of Federal Regulations, Part 46 (CFR 46). The IRB also is guided by the ethical principles regarding all research involving humans as subjects as set forth in the April 18, 1979, report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled: "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," commonly referred to as The Belmont Report.
- The mission of the ODMH IRB is to ensure that vital, department research can be conducted in full compliance with both the letter and spirit of regulations designed to protect the rights and welfare of human subjects. The IRB also monitors research to ensure that human subjects are protected from undue risk and from deprivation of personal rights and dignity. This protection is assured by consideration of three principles that are the basis of ethical research:

1. That voluntary participation by the subjects, indicated by free and informed consent, is assured by the investigators;
2. That an appropriate balance exists between potential benefits of the research to the subject or to society and the risks assumed by the subject; and
3. That there are fair procedures and outcomes in the selection of research subjects.

The IRB Chair and Committee share authority over all IRB policy and procedure in collaboration with the Chief of the Office of Research and Evaluation.

B. Procedure:

All offices, hospitals, including CSN programs, and workforce members of the Ohio Department of Mental Health are directed to follow all applicable policies and procedures found in the ODMH IRB Requirements, Policies and Procedures Manual maintained at each Regional Psychiatric Hospital (RPH), at OSS, and in Central Office. Failure to comply with this internal management rule and its referenced document, the ODMH IRB Requirements, Policies and Procedures Manual, may result in disciplinary sanctions as defined in Policy # 01-55, Guidelines for Disciplinary Action, effective 08/01/01, as it may be amended.

Promulgated under:  
Authorized by:  
Implements:

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Tracy Plouck, Director  
Department of Mental Health

Date \_\_\_\_\_