

WCHO	<i>Policy and Procedure</i>		
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Policy Number 04.002	Effective Date	Revision Date	Approval Date 4/12/06
Administrative/Board of Directors Sign Off			
Administrative Signature:		Date:	
Board of Directors Signature:		Date:	

Washtenaw Community Health Organization is frequently approached by individuals, groups and organizations desiring to conduct research, investigative activities and/or utilize experimental intervention methods that will involve, as a subject, a recipient of services, staff member, contractor, student, volunteer, or Board member.

WCHO encourages proposals that encourage and stimulate research and/or investigative efforts in mental illness, developmental disabilities and substance abuse.

WCHO has established a standing committee, known as the Institutional Review Board (IRB), whose function is to review and evaluate the merits and potential effects of all experimental intervention methods. The IRB monitors all approved projects in conjunction with the Recipient Rights Office and that Program's Deputy Director to assure compliance to relevant agency policy and to insure the rights, benefits, and privileges under law to all participants.

I. PURPOSE

To establish policies, standards and procedures governing the conduct of research, investigative activities and/or utilization of experimental intervention methods at Washtenaw Community Health Organization .

II. APPLICATION

- A. Any individual, group, or organization desiring to conduct research, investigative activity and/or utilize experimental intervention methods or medications that will involve, as a subject, a recipient of services, staff member, contractor, student, volunteer, or Board member.

- B. Any individual, group, or organization desiring to utilize for research and/or investigative activity data collected by Washtenaw County Community Mental Health pertaining to recipients of service, staff members, contractors, students, volunteer or Board members.

III. DEFINITIONS

None

IV. POLICY

- A. All research proposals and requests to conduct investigative activities shall be reviewed and approval received prior to initiation. Experimental medications are not permitted as a topic of research.
- B. The agency will establish and maintain a standing committee, known as the Institutional Review Board, with the charge:
 - 1. To encourage and stimulate research and/or investigative efforts in mental illness, developmental disabilities and substance abuse.
 - 2. To participate in research and/or investigative activity which will explore new or improved methods of prevention, diagnosis, treatment and service delivery.
 - 3. To review and evaluate the merits of and the potential effect of any research, investigative activity and/or use of experimental intervention methods for subjects and/or agency operations.
 - 4. To monitor the conduct of research, investigative activity and/or use of experimental intervention methods or medication, which have been approved, for adherence to agency standards and/or relevant policies.
 - 5. To insure the rights, benefits and privileges guaranteed by law and/or applicable policies and/or regulations of entities governing such for participants in research, investigative activities or the utilization of experimental intervention methods or medication.
- C. Institutional Review Board
 - 1. The Institutional Review Board members shall be appointed or designated

by the Director's Office. The Director will appoint a Convener.

- a. The membership shall be composed of at least five persons with varying backgrounds and professional experience and expertise to ascertain the acceptability of proposals in terms of, but not limited to:
 1. organizational commitments and policies
 2. applicable law and regulations
 3. standards of professional conduct and practice
 4. community attitudes
- b. Individuals who are not formally associated with the agency will be asked to serve as volunteer community members of the committee.
- c. The membership of the committee shall not be restricted to those with permanent appointments. Members may be added to the committee on an ad hoc basis because of a particular area of expertise, experience, knowledge or advocacy activities to assist in review of a proposal in that area.
- d. The members designated as the Review Panel shall not have any direct association with the proposal under consideration.

D. Review Criteria

1. The Institutional Review Board, in reviewing a proposal, shall give particular attention to the following:
 - a. potential risks and benefits to subjects
 - b. qualifications and credentials of individual responsible for as well as others involved with the proposal
 - c. completeness of the proposal, particularly the adequacy of the methodology and procedures
 - d. conformance of proposed methodology and procedures with accepted standards of appropriate regulatory bodies and agency procedures
 - e. potential disruptive effects, as well as benefits, to the agency
 - f. process for obtaining informed consent from subjects which includes benefits, discomforts, alternative services, full explanation of procedures and right to refuse participation without compromising access to other services and minimizing harm and risk.
 - g. procedures for detecting and responding to any potentially harmful effects that may occur during the course of carrying out the project

C. Review Process

1. The proposal is submitted to the Institutional Review Board with due regard to the lead time required by the Committee to complete the review.
2. The Convener will assign the proposal to members to review.
3. The reviewers will make a recommendation in one of the following categories:
 - a. Approved with no modification
 - b. Approved with minor modification
 - c. Approved with major modifications
 - d. Disapproved
 - e. Withdrawn by applicant

The recommendation shall include an evaluation of the following areas:

- a. rights and welfare of the subjects
 - b. appropriateness and adequacy of methods used to obtain informed consent
 - c. potential risks and/or discomfort for subjects
 - d. benefits of the proposal to the subjects, as well as the long term benefits to the field ethical issues
 - e. alternative services available to the subjects
 - f. right of the subjects to refuse to participate in any research project without compromising their access to agency services
4. The Convener, as a representative of the Director's Office, shall communicate the recommendation in writing to the applicant and place a copy of all pertinent materials in the Institutional Review Board file for reference.
 5. Proposal modifications will be negotiated with the applicant by the Convener, as a representative of the Director's office, or a designee.
 6. The course of the implementation of the proposal will be monitored by the Program Administrator of the Unit in which the activity is occurring. The Recipient Rights Officer will assist in the monitoring with particular emphasis on the areas of obtaining consent and process for terminating participation.

V. EXHIBITS

None

VI. REFERENCES

None

VII. PROCEDURES

WHO

DOES WHAT

Applicant	<ol style="list-style-type: none">1. Prepares general narrative outline of research proposal, investigative activity or request to use experimental intervention method.2. Submits narrative outline to Program Administrator in whose Unit the activity will occur. If uncertain as to the appropriate Unit, may submit to the Director.
Deputy Director	<ol style="list-style-type: none">1. Refers narrative outline to Convener of the Institutional Review Board.
Convener	<ol style="list-style-type: none">1. Evaluates narrative outline to determine its general eligibility as a research proposal, investigative activity or experimental intervention.
Institutional Review Board	<ol style="list-style-type: none">1. Returns narrative outline to applicant with recommendation for correction of deficiencies or reasons for non acceptability, as appropriate, if outline is not acceptable.2. Confers with applicant as necessary to facilitate preparation of formal proposal.
Applicant	<ol style="list-style-type: none">1. Completes formal proposal.2. Submits formal proposal to Convener.
Convener	<ol style="list-style-type: none">1. Review proposal for completeness. If incomplete, returns proposal to applicant for completion and resubmission.2. Establishes date on which the Institutional Review Board will meet and informs members of meeting.3. Informs applicant of date.4. Convenes Institutional Review Board meeting.
Institutional Review Board	<ol style="list-style-type: none">1. Discusses and evaluates proposal.2. Submits recommendation to Director's Office.

WHO

DOES WHAT

Convener	<ol style="list-style-type: none">1. Communicates in writing the committee's recommendation.2. Includes requests for modification for correction of deficiencies or reasons for rejection, as appropriate.3. Notifies Program Administrator and Recipient Rights Officer of the approval and the date of implementation
Deputy Director	<ol style="list-style-type: none">1. Monitors the course of implementation of proposal.
Recipient Rights Officer	<ol style="list-style-type: none">1. Notifies Convener of any proposed changes in major objectives, design risk level, schedule for completion or change in personnel.
Applicant	<ol style="list-style-type: none">1. Submits a report of project results to Convener to be filed.
Convener	<ol style="list-style-type: none">1. Disseminates report to WCHO-WCCMH Program Management Team, Quality Improvement Team, and appropriate staff members.

10/5/00