

## Ohio Department of Mental Health

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### Guidelines for Submission of Research Proposals

#### A. Purpose

1. Each year the Ohio Department of Mental Health spends a portion of its monies in the area of research. This document has been prepared to give prospective applicants for these funds a brief outline of the Department of Mental Health research priorities and policies and some necessary information about the proposal review process.
2. Research is a necessary and vital component in our treatment programs. We hope that this document will encourage individuals to apply for research money and that the studies will contribute to improved mental health services.

#### B. Goals of Mental Health Research

There are serious gaps in our knowledge about most facets of mental health and mental illness. In those areas in which some knowledge base exists, there is frequently a lack of consensus among professionals concerning the definitions of the problems as well as the validity of current treatment solutions. Hence, systematic research is imperative for a service organization such as the Department of Mental Health. Research focusing on the fundamental dimensions of mental health, the patterns of mental illness and the needs of consumers of mental health services provides a more firm foundation upon which to construct Departmental programs and priorities. Applied research on strategies of community and hospital treatment and prevention of mental health problems provides a needed base for anticipating future programming and improvements.

#### C. Specific Research Objectives Within the Department of Mental Health

1. The Department of Mental Health does not fund projects in areas of basic sciences. Our research program is directed toward projects of a more applied nature, whose results will have more immediate impact on the problems and needs currently being experienced by consumers of services in the public mental health system.
2. Projects which have the following characteristics will have top priority for funding, if they comply with all other requirements:
  - a. Potential for fairly immediate operational impact on programs in the public mental health system.
  - b. Focus on problems and needs of individuals with the most severe and persistent

mental illness.

3. Areas of special emphasis:

- a. Consumers of mental health services in the public system, including populations of special interest, and family members of consumers.
- b. Mental health service delivery.
- c. Mental health system characteristics and inter-organizational relationships.

For more information concerning the Department's funding priorities, see "Research Priorities, Ohio Department of Mental Health, September 1996", available from the Office of Program Evaluation and Research.

4. Types of research grants awarded:

- a. Regular ODMH Research Grants, as described in this document.
- b. Small Grants for Graduate Research in Applied Mental Health. These grants are designed to provide limited supplemental funds (amounts less than \$5,000) to graduate students who are focusing their research efforts on the immediate and pressing problems associated with providing effective and quality mental health services. Guidelines for applying for these grants are detailed in a separate document available from the Office of Program Evaluation and Research.

D. Early Contact with the Department of Mental Health Regarding Research Topics

1. Prospective researchers are encouraged to contact the Office of Program Evaluation and Research for a mutual discussion of potential topics for study. OPER maintains contact with other Departmental administrators and with individuals in mental health treatment settings who can indicate those problems and issues most in need of research. Whenever possible, our goal is to facilitate the development of projects whose results will have a generalizable impact on the mental health system throughout Ohio.
2. For a preliminary indication of whether a particular topic would be fundable, prospective researchers are encouraged to send a five- to eight-page concept paper to OPER. The concept paper should summarize the problem to be addressed, the methodology contemplated, and the possible outcomes, and must contain a general estimate of the project's budget. Through this mechanism an early dialogue can be set up between potential researchers and the Department's research office, in which we can indicate whether a proposed study would be fundable, whether it might be fundable with certain modifications, or whether it would probably have a very low priority for funding. A positive response to a concept paper should not be interpreted as a commitment to eventual funding, since that decision is made on the basis of the excellence of design of the proposal and the availability of research monies. However, the concept paper mechanism should give potential researchers an indication of the Department's funding priorities before the effort is expended to develop a full-scale proposal. Concept papers are generally reviewed within six to eight weeks.

E. Documentation Required for Research Funding

In order to request funds for a research project, an applicant needs to submit four copies each of two documents. Unless these two documents are provided, the review cannot proceed.

1. A Research Abstract Form (DMH-RES-617). This gives a brief synopsis of the project and includes responses to questions regarding protection of participants as well as the project budget. These forms are available from OPER.

2. A detailed project proposal, the contents of which will be discussed in Section V below.

F. Contents of Proposals

1. A documented statement of the problem or question the researcher intends to focus upon.
  - a. An introduction to the problem or question to be studied should contain a review of the relevant literature, with a bibliography of references at the end of the proposal.
  - b. This review plus any experience or data the researcher has to offer should lead to a clear and concise statement of the research problem and why the proposed research could logically address the problem.
2. Goals
  - a. What are the project's goals? What hypotheses will be tested? Clarity and a narrowed focus on objectives are extremely important in this section.
  - b. What new knowledge is expected to come from the study?
  - c. If the proposal is for the research component of a demonstration project, how is the project expected to impact on the problem?
3. Methodology
  - a. What are the dependent and independent variables and how will they be operationalized?
  - b. If participants are to be used, indicate the number, characteristics, and selection criteria, and explain in detail any tests that will be performed. If control group participants are to be used, indicate procedures to be used with these groups.
  - c. What data are to be collected? How?
  - d. What are the data collection instruments? If possible, copies of these instruments should be included, along with reliability and validity information.
  - e. How will the data be analyzed? What statistical tests will be used? How do the results of the statistical analyses relate to the hypotheses or objectives of the study?
  - f. What is the time frame for the project? Explain the phasing of significant segments of the study such as before-and-after measurements, administration of tests, etc.
  - g. Indicate the duties and qualifications of all the staff who will be involved.
4. Protection of Rights of Participants
  - a. If patients or clients or their records are to be involved in the study, what provisions will be taken to assure confidentiality? What provisions will be taken to assure privacy and protection of data, e.g., secure electronic data exchanges, storage and destruction of data?
  - b. If patient or client records from a community agency are to be used, evidence of that agency's approval and cooperation must be included in the proposal. In cases where identifiable individual data will be collected, individual consent is required or a waiver of participant authorization from an IRB/Privacy Board.
  - c. If the research proposal is coming from personnel in one of our BHOs, or if the BHO's

patients or records are to be used, the proposal must contain a statement of approval from the BHO's Chief Executive Officer.

- d. If hospitalized patients are to be used in the research, they must be informed about what their participation will entail, including use of their records, and must sign a consent form. The consent form must also indicate the general use of the data, the possible risks and benefits, and must tell the patient that participation is not required, that a decision to participate or not participate will not affect the treatment that would usually be received, and that he/she can withdraw from the study at any time. In those instances in which only information from patient records will be used, the researcher must utilize a consent form or the study must have a waiver of participant authorization from an IRB/Privacy Board. Participants in non-institutional settings must sign consent forms if the research includes bodily invasive procedures or experimental programs or if the individual's records will be used in an identifying manner. Copies of consent forms to be used must be included in the proposal.
  - e. The chart in Appendix 1 should be used to assist prospective researchers in identifying the kinds of subject protection necessary for all types of research. Prospective researchers should locate the client group and the methodology to be used; subsequent phrases within the appropriate boxes will indicate those factors that must be considered in the design of projects. Where an individual consent form is specified as being needed, subsequent phrases indicate those components which should appear in the form; for example, a statement that the individual's participation is not a requirement.
  - f. It is extremely important that all issues regarding the rights of human subjects in research be addressed in the proposal documentation itself, as this information is used in deciding whether the proposed research would put subjects at substantial risk.
  - g. All proposals submitted to ODMH for funding must have the approval of the IRB at the principal investigator's university or organization. A copy of the IRB approval must be included with the proposal.
5. Applicability
- a. How will the project's findings enhance the state of knowledge in the study area?
  - b. How will the knowledge gained be applicable to improved services to patients and clients under the care of the public mental health system?
  - c. If the project is of a more basic nature and the findings are not expected to be immediately translatable to our system, what might be some avenues of further research leading to more direct application of study results?
  - d. How might the project's findings be disseminated with the mental health system?
6. Proposed Budget
- a. The proposed budget must be listed by line item on the last page of the 617 Form with one- or two-word identifiers, e.g., "Project Director", "Questionnaire printing", etc.
  - b. A justification for each budget line should be included in the body of the proposal, under the heading of "Budget Summary".
  - c. If the project is intended to run across the end of a fiscal year, a separate 617 Form budget page, plus justification, must be included for that segment of the budget

which falls into each fiscal year.

- d. The percentage of time based on a 40-hour work week must be included for each position (e.g., if the researcher will average 30 hours per week for the duration of the project, the percentage should be entered in the appropriate space on the 617 Form as 75%).
- e. "Salary", on the 617 Form, is the total money to be paid to the individual, from all sources, for the purpose of doing the project. This figure should exclude fringe benefits.
- f. If fiscal arrangements for a project are handled through a research foundation, overhead costs are permissible. The rate of overhead costs cannot exceed 15 percent of the salary and wage costs.

#### G. General Policies

1. Research funds are to be used for studies from which new knowledge is expected to emerge. Research funds are not to be used for ongoing operations or regular agency functions such as program evaluation.
2. Projects can be funded for periods either shorter or longer than one year. However, if the intended duration is longer, initial funding will be granted for one fiscal year only. Continued funding is contingent upon a re-application which outlines the project design, discusses findings and progress during the first year or portion thereof, and indicates justification for continuation of the project.
3. There are no specific calendar deadlines, but research applications need to be submitted a minimum of four months prior to the projected starting date in order to allow for the necessary review.

#### H. The Proposal Review Process

1. The major review of a proposal is by the Office of Program Evaluation and Research. We review the proposal for subject matter, applicability, research design and methods, ethical considerations, human subject protections, and budget.
2. As part of this process, we generally secure reviews by one or more individuals outside OPER. These individuals may be either within or outside the Department, depending on the nature of the proposal, and are selected because of their expertise in the content area of the proposed research.
3. Based on the reviews, OPER staff will correspond with the proposers and in addition may request a meeting to clarify any further questions or discuss necessary proposal revisions.
4. When a proposal has successfully completed both the technical and ethical review procedures and has received an approval letter from OPER, a formal grant agreement is drawn up for signature by the agency conducting the research, the Chief of OPER, and the Deputy Director, and the research is thereby approved by the Department of Mental Health.

#### I. Responsibilities of Researchers

1. Once a project is approved, researchers are responsible to OPER for carrying out the project as specified in their original proposal, including all design changes or amendments specified during the review process.
2. Fiscal management and grant services for active projects are handled by OPER. Payments generally are made on an annual basis but may be adjusted depending upon the nature of a particular project.

3. Researchers are responsible for submitting quarterly project progress reports to OPER. Agency fiscal officers are responsible for submitting quarterly fiscal reports on the project to OPER. (Forms and time lines for both of these reports will be sent to researchers when projects are approved.) Any major deviations (e.g., time frame, instrumentation, methodology) in procedures from the original proposal should be reported and are subject to renegotiation with OPER. Final fiscal reports are due within 30 days after the completion of the project.
4. Researchers are responsible for submitting written project abstracts for "New Research in Mental Health", published biennially by OPER.
5. Researchers are responsible for working with OPER to disseminate results. Dissemination costs are a permissible budget item when justified by a dissemination plan.
6. Researchers are responsible for submitting to OPER four copies of a detailed final report on the research, outlining statement of problem, methodology and findings within 30 days after the completion of the project.
7. Researchers are responsible for carrying out all procedures with human subjects as originally specified in the proposal or as amended in response to requests by OPER.
8. If results of research are published in a professional journal, presented at professional meetings or given other media coverage, the Ohio Department of Mental Health should be given appropriate credit as the funding source. OPER should be supplied with reprints of any publications based upon funded research.

J. Contact

Any questions about these procedures should be addressed to the Office of Program Evaluation and Research, Ohio Department of Mental Health, Suite 1170, 30 East Broad Street, Columbus, Ohio, 43266-0414. E-mail: [rothd@mhmail.mh.state.oh.us](mailto:rothd@mhmail.mh.state.oh.us) or telephone: 614.466.8651. Further information is available on the OPER World Wide Web home page: <http://www.mh.oh.state.us/oper.html>

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Dee Roth, Chief  
Office of Program Evaluation and Research

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Date

Appendix 1

Methodology or Type of Research	General Public	Agency Consumer/Outpatient	Hospitalized Patient
Mail-out or hand-out questionnaires	Subject told: Outline type of confidentiality (Return implies consent)	Subject told: Outline general use of data Outline type of confidentiality Specify feedback/non-feedback to agency (Return implies consent) Agency consent necessary	Subject told: Outline general use of data Outline type of confidentiality Specify feedback/non-feedback to BHO/ hospital Specify participation not required/withdraw at any time (Return implies consent) BHO/Hospital-consent necessary
Interviewing	Subject told: Outline type of confidentiality (Continuing interview implies consent)	Subject told: Outline general use of data Outline type of confidentiality Specify participation not required/withdraw at any time (Consent form recommended) Agency consent necessary	Subject told: Outline general use of data Outline type of confidentiality Specify participation not required/withdraw at any time (Consent form recommended) BHO/Hospital consent necessary
Use of individual patient or client records	Guarantee of overall confidentiality Agency consent necessary  Individual consent form, or IRB/Privacy Board waiver of participant authorization Outline general use of data Outline type of confidentiality	Guarantee of overall confidentiality Agency consent necessary  Individual consent form, or IRB/Privacy Board waiver of participant authorization Outline general use of data Outline type of confidentiality Specify participation not required/ withdraw at any time Participation or refusal will not affect treatment	Guarantee of overall confidentiality BHO/Hospital consent necessary  Individual consent form or IRB/Privacy Board waiver of participant authorization Outline general use of data Outline type of confidentiality Specify participation not required/withdraw at any time Participation or refusal will not affect treatment
Follow-up studies	Special provisions for seeking out subjects Prior consent if possible Privacy safeguards (e.g., plain envelopes for letters)	Special provisions for seeking out subjects Prior consent if possible Staff brokers consent Privacy safeguards (e.g., plain envelopes for letters) Agency consent necessary	Special provisions for seeking out subjects Prior consent if possible Staff brokers consent Privacy safeguards (e.g. plain envelopes for letters) BHO/Hospital consent necessary
Use of excreta, blood samples, etc., not originally collected for research	Outline type of confidentiality Agency consent necessary	Outline type of confidentiality Agency consent necessary	Outline type of confidentiality BHO/Hospital consent necessary
Taking additional blood or excreta for research purposes	Individual consent form: Indicate general purpose, risks Outline type of confidentiality Agency consent necessary	Individual consent form: Indicate general purpose, risks Outline type of confidentiality Specify participation not required/withdraw at any time Participation or refusal will not affect treatment Agency consent necessary	Individual consent form: Indicate general purpose, risks Outline type of confidentiality Specify participation not required/withdraw at any time Participation or refusal will not affect treatment BHO/Hospital consent necessary
New interventions or programs (no bodily invasions)	Individual consent form or IRB/Privacy Board waiver of participant authorization Indicate experimental and general purpose Possible risks Experimental/control if applicable (Participation implies consent)	Individual consent form: Indicate experimental and general purpose Possible risks, benefits Experimental/control if applicable Specify participation not required/withdraw at any time Agency consent necessary	Individual consent form: Indicate experimental and general purpose Possible risks, benefits Experimental/control if applicable Specify participation not required/withdraw at any time BHO/Hospital consent necessary
Bodily invasions	Individual consent form: Indicate experimental and general purpose Known discomfort and possible side effects Possible risks, benefits Known alternatives	Individual consent form: Indicate experimental and general purpose Known discomfort and possible side effects Possible risks, benefits Known alternatives Specify participation not required/withdraw at any time Participation or refusal will not affect treatment	Individual consent form: Indicate experimental and general purpose Known discomfort and possible side effects Possible risks, benefits Known alternatives Specify participation not required/withdraw at any time Participation or refusal will not affect treatment
New drugs	Individual consent form: Indicate experimental and general purpose Known discomfort and possible side effects Possible risks, benefits Experimental/control if applicable	Individual consent form: Indicate experimental and general purpose Known discomfort and possible side effects Possible risks, benefits Experimental/control if applicable Specify participation not required/withdraw at any time Participation or refusal will not affect treatment	Individual consent form: Indicate experimental and general purpose Known discomfort and possible side effects Possible risks, benefits Experimental/control if applicable Specify participation not required/withdraw at any time Participation or refusal will not affect treatment Hospital consent necessary

		Agency consent necessary	
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