

| | | |
|-------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------|
| Form B: APPLICATION FOR EXPEDITED OR FULL IRB REVIEW FOR RESEARCH INVOLVING HUMAN SUBJECTS | For IRB Use Only: | |
| | IRB No. | Click here to enter text. |
| | Date Submitted | Click here to enter text. |
| | Date Approved/Disapproved | Click here to enter text. |

Investigator's Assurance: By submitting this protocol, I attest that I am aware of the applicable principles, policies, regulations, and laws governing the protection of human subjects in research and that I will be guided by them in the conduct of this research.

Provide the required information in the space available. If additional space is needed, attach a separate sheet or expand that section of the form. Both scanned original signatures and typed electronic signatures are acceptable. Please submit any research instruments (including questionnaires, surveys, and consent forms) at the same time as the application. Incomplete submissions will be returned to the applicant without review.

All forms and research instruments should be submitted by email to kraig.knudsen@mh.ohio.gov or you may mail them to: Kraig Knudsen, Ph.D., Ohio Department of Mental Health, 30 East Broad Street, 8th Floor, Columbus, Ohio 43214-3430.

TYPE OF REVIEW REQUESTED:

- Expedited Application
 Full Board Application
 Annual Review
 Report of Major Changes

| | |
|---------------------------|---------------------------|
| TITLE OF RESEARCH: | Click here to enter text. |
|---------------------------|---------------------------|

| | | DEPT | EMAIL |
|-------------------------------|---------------------------|---------------------------|---------------------------|
| Principal Investigator | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Other Investigator | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Other Investigator | Click here to enter text. | Click here to enter text. | Click here to enter text. |

| | |
|------------------------------------------------------------------------------------------------|---------------------------|
| Funding Agency (if applicable) and ID Number | Click here to enter text. |
| Grant Submission Deadline | Click here to enter text. |
| Estimated Start Date <i>(Cannot begin until IRB approval granted)</i> | Click here to enter text. |
| Estimated Completion Date <i>(Include all aspects of research and final reports)</i> | Click here to enter text. |

FOR STUDENT RESEARCH:

| FACULTY SPONSOR | DEPT | MAIL CODE | PHONE |
|--------------------------------------------------------------------------------|---------------------------|---------------------------|---------------------------|
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Student Address | Click here to enter text. | | |
| Type of Research <i>(Dissertation, Thesis, Class Project, Other)</i> | Click here to enter text. | | |

Purpose/Objectives of Research: (Briefly state, in non-technical language, the purpose of the research and the problem to be investigated. When possible, state specific hypotheses to be tested or specific research questions to be answered. For pilot or exploratory studies, discuss the way in which the information obtained will be used in future studies so that the long term benefits can be assessed.)

Relevant Background and Rational for the Research: (This section should present the context of the work by explaining the relation of the proposed research to previous investigations in the field.)

Subject Population: (List the size of population to be used, and check if any of the populations listed below apply to the study. Discuss criteria for selection or exclusion, population from which they will be selected, and duration of involvement. *NOTE: Federal guidelines require selection of subjects be equitable within the exclusions; and subjects meeting the criteria cannot be discriminated against for gender, race, social or financial status, or any other reason.*)

| | | |
|---------------------------------------------------------------|----------------------------------------|--------------------------|
| Describe sample: Click here to enter text. | | |
| Approximate No. of Subjects: Click here to enter text. | | |
| Subjects Include (Check if applicable): | Minors (under 18) | <input type="checkbox"/> |
| | Involuntarily institutionalized | <input type="checkbox"/> |
| | Mentally handicapped | <input type="checkbox"/> |
| | Health Care Data/ Information | <input type="checkbox"/> |

IF YOU HAVE CHECKED THE BOX PERTAINING TO HEALTH CARE DATA, BE SURE YOU HAVE COMPLETED ANY NECESSARY **HIPAA FORMS** AS WELL.

Methods/Procedures: Briefly discuss, in non-technical language, the research methods which directly involve use of human subjects. List any potential risks, or lack of such, to subjects and any protection measures. Discuss how the methods employed will allow the investigator to address his/her hypotheses and/or research question(s). Explain how anonymity of names and confidentiality of materials with names and/or data will be obtained and maintained. List the names of individuals who will have access to names and/or data.)

Incentives: What incentives will be offered, if any? (Indicate whether or not subjects are to be paid, how and when they will be paid, amount, and the rationale for payment. The proposed payment should be commensurate with the time required for participation, travel expenses, and/or inconvenience assumed by the subject, but should not be so great as to constitute undue influence on an individual to assume risks of study participation that would not otherwise be undertaken.)

Risks/Benefits to Participants and Precautions to be Taken: (This section should discuss all possible risks and discomforts from participation in the study, indicating both severity and likelihood of occurrence for each. Risks may range from the physical to the psychological. Inconvenience, travel, or boredom may also be considered risks of participation in the study. The methods that will be used to minimize these risks should also be discussed. Many studies hold the potential for loss of privacy and confidentiality. These concerns should be noted in this section. If subjects are vulnerable populations, or if risks are more than minimal, please describe what additional safeguards will be taken.)

In your opinion, do benefits outweigh risks? Yes No

Privacy/Confidentiality: (Please describe whether the research would involve observation in situations where subjects have a reasonable expectation of privacy. If identifiable existing records are to be

examined, has appropriate permission been sought, i.e. from institutions, subjects, and physicians? What provision has been made to protect the confidentiality of sensitive information about individuals? Are research records anonymous? If not, there should be discussion of how records will be coded, and where and how they will be stored. It should also note where and how signed consent forms will be maintained. If video or audio tapes will be made as part of the study, disposition of these tapes should be addressed. In general, the IRB recommends that research tapes be destroyed as soon as the needed data are transcribed, and that the only restricted study personnel be allowed access to the tapes. If other procedures are proposed [for example, retaining tapes for future use, allowing individuals other than study investigators access to the tapes] justification should be presented and separate.)

| SIGNATURES: | |
|---------------------------------------------------------------------------------|------------------------------------------|
| <u>Click here to enter text.</u> Principal Investigator or Student | <u>Click here to enter text.</u> Date |
| <u>Click here to enter text.</u> Faculty Advisor (<i>for student apps</i>) | <u>Click here to enter text.</u> Date |

| IRB APPROVED: | |
|------------------------------|-------------|
| <u>IRB Chair or Designee</u> | <u>Date</u> |