Hazelden Betty Ford Foundation

Butler Center for Research
RESEARCH ACTION TEAM AND PRIVACY BOARD RESEARCH REQUEST AND SUBMISSION GUIDELINES

Thank you for your interest in working with the Hazelden Betty Ford Foundation!

In order to use any patient data or information from the Hazelden Betty Ford Foundation (HBFF), or to collaborate on a research project with HBFF staff, principal investigators must submit a proposal including the following items. Please use this form, and keep it under 3 pages to expedite the review process. You can also append any additional information you like. **Important: This review process does not constitute Institutional Review Board (IRB) approval, and documentation of IRB approval will be required for final proposal approval by the Research Action Team and Privacy Board (RAT/PB).**

Background Information

Title of Research Project: *What is the name of your proposal?*

Briefly describe your research topic and its value: *This section should clearly explain the basis for your research questions and/or hypotheses.*

Briefly describe prior research on this topic and how your study will advance knowledge in the research area: *Include a brief literature review that supports your rationale for conducting this research. Describe any preliminary studies and findings that led you to develop this research, and confirm that you are not duplicating any previous efforts. This section should provide rationale for your study design and variables. Be sure to include citations (they can be included as an appendix to save space on this document).*

How will you protect HBFF patient confidentiality? *Guidelines for protecting patient confidentiality should be based on federal regulations for human subjects' protection (45 CFR 46). Information on HBFF policies regarding patient confidentiality can be found in the BCR Research Policy Manual (sections 4.4 and 5.2).*

What is your funding source and approximate budget? *An overall project budget is sufficient – no need for detailed information here.*

How will your findings be disseminated? *Include brief description of HBFF dissemination plan required in the Researcher Collaboration Agreement (detailed in the BCR Policy Manual, section 5.2 "Dissemination of results").*

Please describe your research experience and capability (if you are a student, who is your research advisor?): *Include degrees, certifications, past research experience, and other qualifications for this research. Information for the principal investigator must be included; information for other key research personnel is optional.*

Description of Research Methods to Be Used

Briefly describe the study design: *State the type of research design in one to two sentences. A list of research design definitions is available from the Department of Health and Human Services IRB Guidebook at* http://www.hhs.gov/ohrp/archive/irb/irb_chapter4.htm

Hazelden Betty Ford Foundation

What is your desired sample size? *Include number of subjects, and any a priori power analyses conducted to estimate necessary sample size for statistical significance.*

Briefly describe your planned sampling procedures: *Include pertinent sample demographics and explain how the sample will be selected to accurately reflect the population under study.*

How will data be collected, and who will collect it? *Briefly list what variables will be collected, how they will be collected (electronically, pen and paper, etc.), and which members will be collecting it (roles or specific members). Briefly explain how the integrity of the data will be monitored/maintained during data collection procedures. If specific members of the study team are listed, make sure they are also included on the Study Team Roster submitted with this proposal.*

How much time will it take each patient to participate in this project? *Remember to include time required for study briefing, consenting, and debriefing (if necessary).*

Submission Document Checklist

- ☐ Study proposal
- ☐ Sample consent form
- ☐ Any data collection instruments to be used (questionnaires, tests, etc.)
- ☐ Research Confidentiality Agreement (for all members of the study team)
- ☐ Study Team Roster (can use the BCR Study Team Roster form, or use study team list from study protocol)

All proposals and submission documents should be sent electronically to Dr. Bethany Ranes, RAT/PB Chairperson, at BRanes@hazeldenbettyford.org. Additionally, proposals and submission documents can be mailed to:

Bethany Ranes, Ph.D.
RAT/PB Chairperson
Butler Center for Research
Hazelden Betty Ford Foundation
P.O. Box 11
Center City, MN 55012

NOTE: Upon RAT/PB approval of the research proposal, the principal investigator will be asked to sign a Researcher Collaboration Agreement and/or a Data Use Agreement before any research procedures can begin.