

Systematic Treatment Enhancement Program – Bipolar Disorder (STEP-BD)

Ancillary Studies Guidelines

PURPOSE

To provide a procedure for review of ancillary study applications to the STEP-BD clinical trial. To provide NIMH the STEP-BD Scientific Advisory Board (SAB) recommendations for the ancillary study. To provide the ancillary study applicant the SAB's decision; and, if recommended, provide the applicant with information regarding potential funding sources.

SCOPE

These guidelines cover the ancillary study application process, STEP-BD Scientific Advisory Board activities and reporting requirements to/from STEP-BD and NIMH.

PROCEDURES

Investigators interested in applying as an ancillary study to STEP-BD will be provided the appropriate STEP-BD Ancillary Study Application Procedures. The completed Application will be circulated to key members of the STEP-BD Scientific Advisory Board, who will review the application based on the merits outlined below. These key members will make their recommendations to the full board. The result of this full committee recommendation will be provided to NIMH on a timely basis.

Investigators may propose ancillary studies to be conducted in one or more of the Research Network sites or Affiliated sites.

An ancillary study is an investigation which, although not part of the core STEP-BD trial, will yield additional information related to study objectives.

An ancillary study is not funded by STEP-BD contract funds. Ancillary studies may include all or a subgroup of the cohort at a given center and may involve additional interviews or examinations of study participants as well as analysis of blood or tissue samples, tapes, or images collected previously. Participation in ancillary studies will be contingent upon successful and up-to-date fulfillment and completion of the main study contract requirements and deliverables, including participant recruitment, follow-up report development, and analysis and publication activities.

Ancillary studies are subject to the same policies and reviews and approvals as the core protocol. Ancillary studies requiring additional participant burden will require OMB clearance. Investigators proposing ancillary studies will also prepare a request for clearance for the ancillary study, or as appropriate, a request for exemption from OMB review. The investigator comply with the funding agency requirements (e.g., DSMB approval or Clinical Exemption).

Ancillary study data, collected under a grant mechanism are not required to become part of the public use data set; however.

Investigators conducting ancillary studies are to be viewed as collaborating investigators of the primary study, but with limited access to the full data set.

Ancillary studies will be reviewed by the STEP-BD Scientific Advisory Board with regard to the following:

Highest priority will be assigned to studies which have

- 1) The highest scientific merit
- 2) Do not interfere with the main study objectives
- 3) Produce the least burden on the study participants
- 4) Have objectives directly related to the study, and
- 5) Require the unique characteristics of the study cohort

For all ancillary studies, the Applicant shall define the hypotheses to be investigated and the methodology to be used and should estimate the cost and burden on the study participants. Study data collection must not interfere with the conduct of the core examination. All ancillary studies may be proposed before and/or after contract award as scientific opportunities arise. All ancillary studies must be approved by the STEP-BD Scientific Advisory Board and NIMH project officer before initiation.

REPORTING

The PI of ancillary study must submit an annual progress report to the SAB. This report can be a duplicate of the one submitted to the funding agency and should describe progress, difficulties, and future directions for the research. Publications developed from an ancillary study must include acknowledgement that the study is an ancillary study of STEP. A STEP-BD publications guideline is available by request.