

Checklist for Clinical Investigators: Investigator-Initiated Studies

Bassett Research Institute Clinical Research Division (CRD)

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The following checklist outlines the steps needed to initiate and conduct an investigator-initiated clinical study as you work with the Clinical Research Division (CRD).

Checklist for Investigators

1. Identify your research questions, methods, and investigator team.
2. Review and complete the [Start Up Worksheet Inv Initiated Study.docx](#). Submit to Jennifer Victory, RN in CRD to start the process. This is not a research application, merely a way to format your ideas prior to meeting with Jennifer & other BRI staff. Jennifer & other BRI staff will assist with the steps outlined below as needed.
3. If necessary, a meeting with the Statistical Center will be arranged to discuss the protocol design, sample size, data management needs and statistical analysis.
4. Explore funding possibilities if needed and prepare grant applications as necessary.
5. IRB Certification (if not already done or not up to date):
 - a. Read MIBH Investigator Handbook (obtain from Heidi Johnson, IRB office)
 - b. Complete all IRB and investigator trainings and provide certificates to Heidi:
 - Bassett specific handbook test (1 time only)
 - NIH Protection of Human Subjects (required yearly)
<https://phrp.nihtraining.com/users/login.php>
 - ICH GCP training (required every 3 years) for studies involving FDA regulated products. <https://globalhealthtrainingcentre.tghn.org/ich-good-clinical-practice/>
6. IRB Submission
 - a. Prepare & submit IRB application & all required regulatory documents.
 - b. If the study requires full board review, you will be expected to attend the IRB meeting and present in person. IRB meetings are the second Tuesday of each month beginning at 4:30 PM. You will be sent an invitation with a presentation time.

7. Recruiting Plan – This is an ongoing process which will be developed in conjunction with CRD/BRI staff.

Issues to consider for recruitment planning:

- a. Recruitment location(s)
- b. List of colleagues who have agreed to allow recruiting of patients
- c. Expectations for recruiting team (availability, time limitations, willingness of patients to participate, etc)
- d. Obtaining consent
- e. Investigator availability to answer questions by study team
- f. Provide sub-investigator(s) who will cover for PI should he/she not be available for questions
- g. identification of potential obstacles for recruiting: use of radiation or invasive procedures, time involved, ability to pay subjects and cover expenses, use of experimental drug or procedure
- h. if applicable, determine how many potential patients in Bassett system diagnosis or diagnoses on interest