Checklist for Clinical Investigators: Multi-Center Studies

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The following checklist outlines the steps needed to initiate and conduct a multi-center clinical study through the Clinical Research Division.

1. Review and complete the Start Up Worksheet for Mulitcenter Study.doc. Submit to Jennifer Victory, RN in CRD to start the process. This is not a research application, but an organized way to introduce the study information to Jennifer & CRD/BRI staff. **Jennifer & other BRI staff will assist with the steps outlined below as necessary.**

2. Pre-IRB document collection:
   - ☐ Sponsor Protocol
   - ☐ Contract/Clinical Trial Agreement
   - ☐ Sponsor ICF template
   - ☐ Investigator Brochure (if applicable)

3. Site qualification visit (if necessary). This is done by phone or in person by a sponsor representative.

4. 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/

5. IRB Submission
   - ❖ Prepare & submit IRB application & all required regulatory documents.
   - ❖ 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.

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

Issues to consider for Recruiting Plan:

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. Best way to contact Investigator 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

Post-IRB Approval

7. Study initiation visit – this is done either by web/phone or in person by a sponsor representative. The principal investigator is required to attend a portion of this visit, usually about 30-60 minutes.

8. Ongoing monitoring and study activities:

- Adverse event attribution and assessment
- Case report form signature – This is usually electronic. It provides evidence for investigator oversight and is usually required for payment.
- Study monitor visits – A sponsor representative will visit the site periodically to review the regulatory documents and to confirm participant eligibility, data submission, etc. The frequency of these visits is sponsor dependent. The principal investigator is required to meet with the study monitor to discuss the results of the visit, usually about 15 minutes.