MultiCare Institute for Research & Innovation
BetterConnected

Reference Sheet- IRB Submission for Expanded Access/Compassionate Use

Submitting to MHS IRB for Expanded Access/Compassionate Use:

- Expanded access, also known as compassionate use, is the use of an investigational product (including drugs and medical devices) outside of a clinical trial. Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), a patient may seek individual patient expanded access to investigational products for the diagnosis, monitoring, or treatment of a serious disease or condition if the following conditions are met:
  - The patient and a licensed physician are both willing to participate.
  - The patient's physician determines that there is no comparable or satisfactory therapy available.
  - That the probable risk to the person from the investigational product is not greater than the probable risk from the disease or condition.
  - The FDA determines that there is sufficient evidence of the safety and effectiveness of the investigational product to support its use in the particular circumstance.
  - FDA determines that providing the investigational product will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval.
  - The sponsor or the clinical investigator submits a clinical protocol that is consistent with FDA's statute and applicable regulations for INDs or investigational device exemption applications (IDEs), describing the use of the investigational product.
  - The patient is unable to obtain the investigational drug under another IND or to participate in a clinical trial.

- The purpose of this document is to provide background and a checklist for Investigators and/or Study Coordinators to quickly and efficiently gather all applicable documents and information for regulatory review and IRB approval.

- For MHS IRB to approve a proposed compassionate use of an Investigational Drug or Device the above conditions must be met and the following information/documents must be provided:
  - Registration in Mentor, MultiCare Health System's IRB Software portal, by contacting MHS IRB coordinator at IRB@multicare.org or calling 253-403-3877
  - Investigator Application
  - All documents laid out in the below checklists, which are also located within Mentor.

- The following forms should be utilized and all documents sent to MIRI Regulatory staff for review and submission to MHS IRB.
  - IND Checklist is for investigational study medication
  - Device Checklist is for investigational devices

Reference Sheet- IRB Submission for Expanded Access/Compassionate Use

IND Checklist

Protocol: _____ **Sponsor:** _____ **PI:** _____

Name of Drug: _____ **IND Number:** _____

- ☐ **MultiCare Health System IRB Handbook** *(accessed within Mentor software under "Create New Study" button)*
  - ☐ **IRB Handbook Confirmation and Assurance Form** *(located under MHS Forms within Mentor software)*
- ☐ **IRB Internal Review Memorandum** *(located under MHS Forms within Mentor software)*
- ☐ **IRB Primary Investigator (PI) Application** *(located under MHS Forms within Mentor software)*
  - ☐ CV (only required if current copy is not on file)
  - ☐ Medical License – if applicable (only required if current copy is not on file)
  - ☐ Proof of human subjects training (only required if copy is not on file)
- ☐ **IRB Consent Form Checklist** *(located under MHS Forms within Mentor software)*
- ☐ Assent Form(s) and/or Informed Consent form(s)
- ☐ Protocol or detailed study plan
- ☐ Recruitment plan – including advertisements and/or web postings
- ☐ Interview scripts, letters, questionnaires, subject diary, etc.
- ☐ Relevant correspondence with the FDA and related agencies – if applicable

Location of Treatment (i.e., hospital or clinic address): _____

Anticipated Start Date: Click here to enter a date.

Category of Expanded Access (check one):

☐ Expanded access for individual patients, including for emergency use

☐ Expanded access for intermediate-size patient populations (generally smaller than those typical of a treatment IND or treatment protocol — a treatment protocol is submitted as a protocol to an existing IND by the sponsor of the existing IND)

☐ Expanded access for widespread treatment use through a treatment IND or treatment protocol (designed for use in larger patient populations)

Per the PI, state why alternative therapies are unsatisfactory and why the probable risk of using the investigational drug is no greater than the probable risk from the disease or condition: _____

Device Checklist

Protocol: _____ **Sponsor:** _____ **PI:** _____

Name of Device: _____ **IDE (Investigational Device Exemption) Number:** _____

- ☐ **MultiCare Health System IRB Handbook** *(accessed within Mentor software under "Create New Study" button)*
  - ☐ **IRB Handbook Confirmation and Assurance Form** *(located under MHS Forms within Mentor software)*
- ☐ **IRB Internal Review Memorandum** *(located under MHS Forms within Mentor software)*
- ☐ **IRB Primary Investigator (PI) Application** *(located under MHS Forms within Mentor software)*
  - ☐ Signed/dated CV (only required if current copy is not on file)
  - ☐ Medical License – if applicable (only required if current copy is not on file)
  - ☐ Proof of human subjects training (only required if copy is not on file)
- ☐ **IRB Consent Form Checklist** *(located under MHS Forms within Mentor software)*
- ☐ FDA Approval Letter with HDE (Humanitarian Device Exemption) number
- ☐ Assent Form(s) and/or Informed Consent form(s)
- ☐ Protocol or detailed study plan
- ☐ Humanitarian Use Device (HUD) product labeling, clinical brochure and/or other pertinent manufacturer informational materials
- ☐ Recruitment plan – including advertisements and/or web postings
- ☐ Interview scripts, letters, questionnaires, subject diary, etc.
- ☐ Relevant correspondence with the FDA and related agencies – if applicable

Location of Treatment (i.e., hospital or clinic address): _____

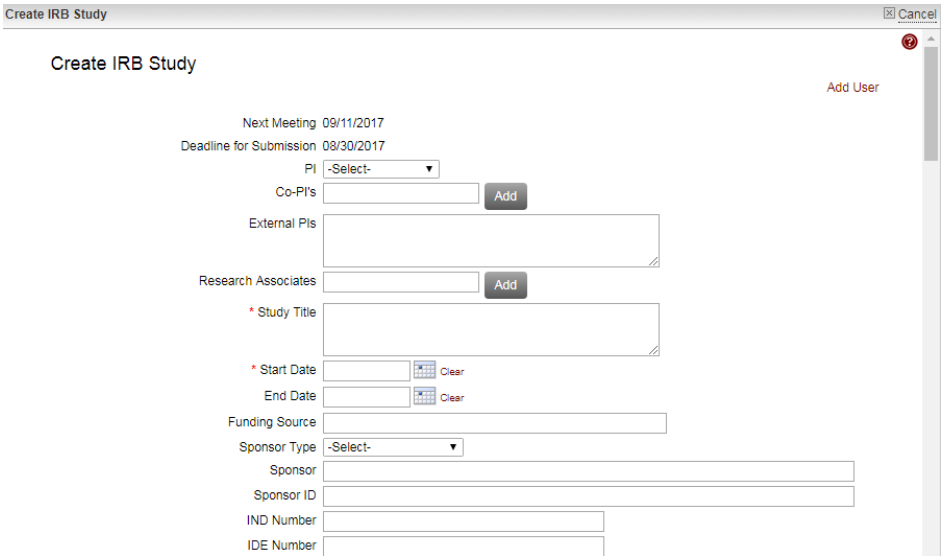
Anticipated Start Date: Click here to enter a date.

Per the PI, state why alternative therapies are unsatisfactory and why the probable risk of using the investigational device is no greater than the probable risk from the disease or condition: _____

- ❖ **Once Mentor access is received, the following steps must be completed:**
  - Log into Mentor at https://www.axiommentor.com/ Navigate to the IRB tab and click on My Studies on the left hand menu.

  - Click on the Create New Study button.

- This will open the new study application page:



- Complete the upper portion, or at least the items that have a red asterisk (*). Those are required to save the initial form, you can always go back in and make any changes/updates as necessary until you are ready to submit.
- Under the "Review Type" choose "Humanitarian Use Device Requested" or "Emergency Use Requested" as appropriate for the request.

- Complete the questionnaire and upload any additional documents needed. Please provide comment FDA Individual Access IND application has been/is currently being submitted to FDA and upload the FDA Form 3926 as a reference document for MHS IRB.
- Please use the above Submission Checklist to ensure you are submitting all required documents. If you have questions at any time regarding your submission, please contact the IRB Coordinator at 253-403-3877 or irb@multicare.org.