****

**Investigator Guidelines for Employees or Students**

**Submitting a Nursing and Allied Health Research Study**

1. Review the guidelines below to determine steps necessary to submit an IRB application for a Nursing and/or Allied Health **research** study.
2. All documents are on [www.bestcare.org](http://www.bestcare.org) and saved under ***IRB Nursing and Allied Health Study Forms.*** Most documents are saved in a word document for ease of typing.(see #1 below in table).
3. All IRB documents must be completed *in their entirety* prior to setting appointment with the Nursing Research and Evidence Based Practice Council (**NREBPC**) Chair or Co-Chair.
4. To ensure the completeness of the IRB application and subsequent documents:
   1. **Students** shall collaborate with their faculty advisor.
      1. Methodist Health System (MHS) employees completing studies as a student or any outside student should contact their faculty advisor for direction and completion of the IRB application.
      2. Faculty advisors are required to be co-investigators on all studies and participate in the student development and submission of the IRB application.
      3. As a co-investigator, the faculty advisor listed has verified the completeness and accuracy of the IRB application.
      4. Students are required to have a clinical partner at the institution where they conduct the study. A clinical partner is an employee of MHS who acts as a liaison and contact person between the investigator and the MHS location of project.
      5. The clinical partner will be a co-investigator on the study.
      6. The clinical partner shall provide the investigator a letter indicating they agree to fulfill the clinical partner role.
      7. Clinical partners are encouraged to participate in dissemination of the project such as being co-authors and/or presenters as *mutually agreed upon.*
   2. **MHS employees (not students)** should collaborate with their clinical partner as assigned by the NREBPC Chair.
5. Once the IRB application is complete, contact Administrative Support for the NREBPC ([sheri.oneel@nmhs.org](mailto:sheri.oneel@nmhs.org)) to set up an appointment with the NREBPC Chair or Co-Chair to review documents prior to IRB submission.
6. For student studies: The NREBPC chair or co-chair will contact the student to email the IRB application and supporting documents for review. If deemed appropriate, the IRB application reviewer may request a meeting with the student(s), clinical partner and faculty prior to submitting the application.
7. For employee initated research studies: The NREBPC chair or co-chair will contact the primary investigator to email the IRB application and supporting documents for review. If deemed appropriate, the IRB application reviewer may request a meeting with the primary investigator and clinical partner prior to submitting the application to the IRB Committee.

The following items provide the investigator with ***expectations*** of IRB application submission and dissemination of studies conducted at Methodist Health System (MHS).

| **Item** | **Expectations/Comments** |
| --- | --- |
| Complete the *IRB Request for Application for Review of a Study* submission form. | Access on [www.bestcare.org](http://www.bestcare.org)  Click on Providers; Resources; IRB; **Nursing and Allied Health Study Forms**  *Sample* support letters and templates are provided as guidelines. |
| 1. Read Methodist Hospital IRB handbook. | Access on [www.bestcare.org](http://www.bestcare.org)  Click on Providers; Resources; IRB; Documents and Forms (not in **Nursing and Allied Health Forms** but located above these forms on Bestcare). |
| 1. Students must submit IRB approval to their school first. Concurrent submission requires prior approval from the NREBPC Chair. |  |
| 1. Complete Collaborative Institutional Training Initiative (CITI) Good Clinical Practice Course, US FDA Focus   Students should complete the CITI training required by school IRB. This school requirement will be accepted in the case it is not the Good Clinical Practice Course.  CITI Web Site Address  <https://about.citiprogram.org/en/homepage/> | * Print *Completion Report/Coursework Transcripts* to include in IRB application prior to submitting. These must be included. * MHS requires CITI training every three years. * Methodist employees will use Nebraska Methodist Hospital as the organization. Do not apply for CEUs (there is a cost for those). |
| 1. IRB Forms and supporting documents are required to be complete for submission. **Submit a hard copy to the NREBPC Chair of all the documents and place them in sequential order: DO NOT submit two sided copy of original. Only one sided.**   *Not all forms are necessary. It is based on the study.*   * IRB Request for Application for Review of Study and Front Cover * CITI Completion Report/Coursework Transcript for each investigator * Letter of support from unit, institution or department * Letter of support for Electronic Health Record (EHR) access (if applicable) – *modify this letter and submit to the compliance officer noted on the letter to obtain permission* * Waiver of Consent and/or HIPAA Authorization Form #6 * Recruitment letter or email (if applicable) * Letter of support from MHS clinical partner to serve in that role (required for students) * Data Collection tool (if applicable) * Survey tool or intervention (if applicable) * IRB approval letter or pending approval at “\_\_” institution (students only) * Evaluation tool (if applicable) * Budget (if applicable) * Other as deemed appropriate | Access forms as noted in #1 – **save on investigator computer.**  **If consent forms are involved for research studies only, KEEP original consent forms and submit to IRB office upon completion of study.**  **Steps for the IRB Application**  **Review Process**   * Reviewed by Nurse Representative on the IRB Committee * Reviewed by Chief Nursing Officer * Reviewed by Chair Methodist Hospital IRB Committee   Always keep a hard copy of the IRB application materials submitted. |
| 1. Email completed documents to the NREBPC Chair or Co-chair **prior** to submission. After review of the NREBPC Chair or Co-chair, they will instruct investigator where to hand in final application for submission | * Contact ([sheri.oneel@nmhs.org](mailto:sheri.oneel@nmhs.org)) 402-354-2519 for NREBPC chair and co-chair email address. |
| 1. Research studies require full review and approval by the Methodist Hospital IRB Committee. |  |
| 1. IRB office will notify investigator via email of study approval.  * Read the entire letter carefully noting the approval to move forward with the study. | Allow 4 – 5 weeks for Methodist Hospital IRB review and approval process. |
| 1. Once the IRB approval is obtained and access to the EHR is needed, follow the directions in the letter submitted in your IRB application from the Compliance Officer. See comments next column. | 1. If investigator is a student and a MHS employee with an existing Cerner username the investigator can use that employee username for the project. When the investigator first signs on, select *Clinical Student* to identify the sign-on relationship rather than Primary Nurse or another option. 2. If investigator is a student with an existing Cerner username the investigator can use that username for the project. When the student first signs on, select *Clinical Student* to identify the sign-on relationship. 3. If investigator is a MHS employee with an existing Cerner username and not a student, but they are doing an IRB project at a MHS affiliate, the employee investigator can access the EHR using their existing Cerner username. When the investigator first signs on, select *Clinical Resource* to identify the sign-on relationship rather than any other option. 4. If investigator is not a MHS employee or student, the approved method to access MHS medical records is through NeHII (Nebraska Health Information Exchange Initiative). Access to NeHII can be obtained via this link. <http://www.hcfms.com/quicklinks/access-request/>. If NeHII access does not meet the needs for the project, the investigator will need to obtain Vice President of Compliance approval for Cerner access. Once this approval is obtained the investigator will need to apply for Access via this link. <http://www.hcfms.com/quicklinks/access-request/> |
| 1. Dissemination – submit abstract for Methodist annual Research Day (poster, podium presentation, etc.). | * Students and staff discuss with clinical partner abstract submission process. |