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**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. ***It is important that staff or students wishing to complete a research study at Methodist contact the Nursing Research and Evidence Based Practice Council (NREBPC***) ***Chair or Co-Chair prior to beginning developing the study.*** To do so, contact Administrative Support for the NREBPC (sheri.oneel@nmhs.org) who will notify the Chair or Co-chair to contact staff member.
2. The NREBPC Chair or Co-Chari will assign a clinical partner.
	1. 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.
		1. The clinical partner will be a co-investigator on the study
		2. Clinical partners are encouraged to participate in dissemination of the project such as being co-authors and/or presenters as *mutually agreed upon*
3. 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.
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. Students must submit IRB approval to their school first. Concurrent submission requires prior approval from the NREBPC Chair.
		3. Faculty advisors are required to be co-investigators on all studies and participate in the student development and submission of the IRB application.
		4. Students should also collaborate with their clinical partner at the institution where they conduct the study.
	2. **MHS employees (not students)** should collaborate with their clinical partner as assigned by the NREBPC Chair.
5. Once the IRB materials are complete, contact Administrative Support for the NREBPC (sheri.oneel@nmhs.org) to set up an appointment to submit application.

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** |
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| 1. Contact the ***Nursing Research and Evidence Based Practice Council (NREBPC***) ***Chair or Co-Chair*** to be assigned a clinical partner
 | Contact Administrative Support for the NREBPC (sheri.oneel@nmhs.org) |
| 1. Read Methodist Hospital IRB handbook.
 | Access on [www.bestcare.org](http://www.bestcare.org)Click on Providers; Resources; IRB; **Research Documents and Forms**  |
| 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).
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| 1. IRB Forms and supporting documents are required to be complete for submission.
* *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 from MHS clinical partner to serve in that role (required for students)
* Letter of support for Electronic Health Record (EHR) access (if applicable)
* Waiver of Consent and/or HIPAA Authorization Form #6
* Recruitment letter or email (if applicable)
* Data Collection tool (if applicable)
* Survey tool or intervention (if applicable)
* Evaluation tool (if applicable)
* Budget (if applicable)
* Other as deemed appropriate
* IRB approval letter from school IRB (students only)
 | Click on Providers; Resources; IRB; **Nursing and Allied Health Study Forms****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. **Once application and all forms are complete, submit a hard copy to Sheri O”Neel. Place all documents in sequential order: DO NOT submit two sided copy of original. Only one sided.**
 | * Contact (sheri.oneel@nmhs.org) 402-354-2519 for NREBPC chair and co-chair email address.
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| 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. Dissemination – submit abstract for Methodist annual Research Day (poster, podium presentation, etc.).
 | * Employee and student to discuss with clinical partner abstract submission process.
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