iMedRIS IRB Instructions (includes amendment instructions on pg. 3)

In order to get access to the Beaumont iMedRIS IRB application, you'll need to complete Beaumont CITI training as well as the annual Conflict of Interest (COI) Survey. Once CITI is complete, you should request iMedRIS registration by using the following link: . Access as well as the link to the COI survey will be sent in approximately 3-5 business days. Once you have access, you'll log on to hic.beaumont.edu and you'll see an option that says "Create a new study." Or if you're being added to an existing study, you'll need to request access as a "study contact" from the study's research nurse. Please check with your mentor for that person's information.

For questions regarding iMedRIS registration, please contact Raquel Celani or Patricia Walker. For information regarding the COI survey, please contact Danielle Khella.

*Before filling out the IRB, you need to make sure that ALL key personnel have current CITI training as well as a current COI (CITI – click on completion report/KPR and COI – List of submitted disclosures):

Filling out the IRB

The IRB application package is comprised of approximately seven sections. This number will increase depending on the number of research-related components involved, i.e., face to face interaction, consenting, etc.

Section 2.0 Application –

- Please refer to the sample application for specific instructions.

Section 3.0 = COI Smart Information

- For this section, you'll need to upload your CV as well as CVs for any key personnel on your project who has not previously conducted research at Beaumont.
- FYI, you do NOT need to upload proof of your COI.
- Please be sure ALL key personnel have completed both CITI and COI. You can do this by clicking on the orange "Help" button in iMedRIS (upper right). From here, you can check by clicking on the highlighted links below:

- Section 4.0 – Embark Project
  - For this section, you will need to upload a blank document as placeholder so that you can continue and complete all following sections. The Director of Research (or course director) will provide this form after conducting a pre-review of your materials.

- Section 5.0 – Data Collection Tool
  - This section refers to either your variable list (for chart reviews) or some other type of data collection tool, such as a survey. If using a Qualtrics survey, you will need to export from Qualtrics to either a word document or PDF and upload here.

- Section 6.0 – Other Study Documents

- This section refers to your HealthStream transcript. You should complete the following modules in HealthStream https://providers.beaumont.org/homepage-navigation/education--research/annualeducation and once finished, create a PDF of your transcript and upload here.

- Section 7.0 – Clinical Trials Office/Research Department Selection
  - For this section, please indicate the department you'll be working with. If your department is not listed or you're not sure, please choose "Outcomes Research."

At this point, you've completed the IRB package. Your application can now be uploaded to OpenCaseware for your mentor to review. Once that's complete, one of the OUWB directors will receive notification to conduct your pre-review. Once you've satisfied all the questions from the pre review, you'll receive an "OUWB IRB Pre-Review Assurance Form," that should be uploaded to the "Embark Project" section of the IRB.

Once the Assurance Form is uploaded, follow the routing instructions provided in the email. All new submissions must go to (materials are sent to the PI automatically):

1. Beaumont Pre-review – Barb Higgins
2. Research Nurse Manager (please refer to list using "Help" button.
3. Department Chair (please refer to list using "Help" button.

Instructions for Amendments/Embark

Students will need access as "study contacts" – this does not require IRB approval. (can be added by logging on to iMedRIS and adding the individual under "study management," "key personnel," "study contacts"). This is typically done by the research nurse but any key personnel on the study can add study contacts.

Students should fill out the application for an amendment request (under the submissions tab).

Most will follow this format:

2.5 Is this protocol closed to enrollment/recruitment?

- ○ Yes
- ◉ No
- ○ N/A - Study involves chart review or other data collection activities that do not involve enrollment

2.6 Amendment originates from:

○ Sponsor
◉ Principal Investigator

2.7 Will any of the changes affect the budget?

○ Yes ◉ No

2.8 Does this change involve greater than minimal risk?

Minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater in and
examinations or tests.

○ Yes ◉ No

And then proposed changes:

3.1 Choose the proposed changes which apply to this Amendment. Check ALL that apply.

- ☐ Change in Study Protocol
- ☑ Change to Key Personnel
- ☐ Recruiting/Advertising Materials
- ☐ Revised Investigator Brochures/Package Inserts/Instructions For Use
- ☐ Revision/addition to the Consent, Assent and/or Information Sheet
- ☐ Report from Sponsor (e.g., DSMB report, Safety Monitoring report, sponsor's Annual Report)

And then section 4.0 – Key personnel:

4.0 Key Personnel

Please review your approved Key Personnel list, found under the Study Management tab. Using this list answ

4.2 Briefly describe Key Personnel change:

Student name is a second year medical student at OUWB being added to this IRB to fufill his/her Embark requirement.

4.3 Update Key Personnel below for the project to reflect the changes(include deletions and additions)
After the IRB has approved the Key Personnel, request should be sent to SharePoint site access to Derrick

If applicable, please add the new Principal Investigator for the Study:

If applicable, please select the new Research Staff personnel:

A) Additional Investigators

Student name
Co-Investigator

B) Research Staff

If applicable, please add any new Study Contact:

The Project Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The proj
themselves).

If applicable, please select any existing Personnel you wish to remove:

4.4 If adding Key Personnel, will they be obtaining verbal or written consent?

Upon final HIC approval, the Principal Investigator assumes sole responsibility for the conduct of this project. Key Personn
does not constitute any acceptance or responsibility for the conduct of the project. Medicolegal responsibility must remain
reserves the option of auditing records and reviewing its approval at any time.

○ Yes ◉ No

If Yes, list consent provider name & credentials below:
Please note that non-Research Institute employees who are not physicians must complete consent (or in
RN Barbara.Higgins@beaumont.org to schedule a session.

4.5 **The COI- Smart Annual Research Questionnaire has replaced the previously used paper conflict of interes Competitive Extramural Research Grants form). Accounts were set up in COI Smart for most current rese listed on the study. Check the List of Submitted Disclosures for Key Personnel posted daily in iMedRIS lis Procedures or iMedRIS Help.**

Please click the link provided to access COI Smart:
https://www.healthstream.com/hlc/beaumonthealth

If you are new to research, if you are an OUWB student who will be working on a new project or if you ha or Karen Sherer at (248) 551-3322 or Karen.sherer@beaumont.org.

Version	Title	Category
No Document(s) have been attached to this form.		

4.6 **Do you have any curriculum vitae(s) (CV) to attach?**

Any individuals on the Key Personnel and Delegation of Authority roster *new to research* at Beaumont mu

If the study requires full compliance with ICH-GCP, CV's are required.

◉ Yes ○ No

If Yes, attach:

Version	Title	Category
1.0	CV Student	Curriculum Vitae

4.7 **Are you adding any students, residents or fellows?**

◉ Yes ○ No

Section 5.0 – Identification of Students…

5.0 Identification of Students, Residents & Fellow

5.1 **Complete the Education Requirement Table below: Be sure to list the duties in the table for each students**

Student/Trainee Name	Program
Student Name	○ Residency ○ Fellowship ◉ Medical Student ○ Anesthesia ○ Nursing ○ Pharmacy ○ PT/OT/Rehab ○ Health Administration ○ Other

5.2 Is this Key Personnel addition to fulfill a Embark/Capstone project for the Oakland University William Bea

◉ Yes ○ No

If Yes, attach Director's Assurance Form, Mentor's Scientific Review form and Embark/Capstone Director's Scientific Revie

Please include Tracy Wunderlich-Barillas and Michelle Jankowski as Key Personnel for the study

Version	Title	Category
1.0	Embark Assurance 2021	Capstone Project - Required Attachme
1.0	Healthstream Report as of 8:20:20	Other Study Documents
1.0	OUWB Embark Project Proposal	Capstone Project - Required Attachme

5.3 Is this new student, resident or fellow taking a lead role in the research (i.e., PI or co-investigator)? Be s

(●) Yes ( ) No

If Yes, who is the mentor?
Mentor must be included as key personnel.

Dr. Mentor, MD

5.4 Will student have face to face interaction with participants?

( ) Yes (●) No

All amendments need to routed (automatically goes to PI) – Barb Higgins and the CRM (list of CRMs can be found under the orange "help" button).