University Hospitals
Clinical Research Center

IRB ADMINISTRATION OFFICE
11100 Euclid Avenue, Lakeside 1400
Cleveland, Ohio 44106
Phone: (216) 844-1529

FAQs for Research Mentors

1) How do I get IRB help?

   Call 216-844-1529 or visit the IRB Administration Office during Office Hours. It is also recommended that you sign up for CRC newsletter and news feed by emailing ResearchCompliance@uhhospitals.org

2) What training do I need as a mentor?

   The "For Researchers" page of the UH Clinical Research section of the website is a helpful place to search for information about the research process at UH and also required trainings. If not already completed, you will need CREC Certification (by taking CITI BASIC) and Investigator Training prior to submitting anything to the IRB. As you likely know, NIH-funded projects require GCP training (ICH – GCP Guidelines). A free option is available within the CITI Program (https://www.citiprogram.org)

3) What training does my resident or fellow need?

   The same training as a mentor in the answer above (in fact *everyone* listed on the study personnel table needs to be CREC certified.)

4) What training does my medical student need?

   Even if he/she has access to the AEMR or UHCare via clerkships, students are not UH employees and must be Research Credentialed in order to access UH PHI. The research credentialing page of the website details the credentialing process and you can contact the Research Credentialing office at UHResearchCredentialing@UHhospitals.org for help as needed.

5) What is SpartaIRB and how do I access it?

   SpartaIRB is the new electronic IRB submission system. If you do not have an account, there are instructions on the log in page for how to request. You will sign in with either your UH or Case credentials.

   There are 2 main tabs: "**My Inbox**" and "**IRB**". If you go to "IRB," then to "Library" and then to the "General" tab you will find the Investigators Manual for IRB Submissions (HRP-103 - UH Investigator Manual) which has all of the IRB policies in a single document. Use the *[Ctrl] F* "Find" feature to find information on whatever topic you would like to peruse.

   The Investigators Manual for IRB Submissions is also available on the IRB Policies webpage.

6) How do I get help in SpartaIRB?

   Go to "IRB," then to "Help Center," and then to "Guides." There you will find guides for submitting a new protocol, continuing reviews, adding personnel, etc.

7) What do I actually submit in SpartaIRB?

   You will submit your protocol on a template. These templates (protocols, consents, and assents) can be found in the Templates section in the SpartaIRB Library and are REQUIRED for submissions. Note that there are both CWRU and UH templates – wherever there is the option, please choose the UH templates. You are required to submit the templated protocol, any informed consent and/or assent forms, and all "patient-facing" materials (advertising, letters, surveys, etc). You will likely need to submit your data collection forms also (and linking log if using one - ask if unsure).

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8) What is the difference between an Expedited study and an Exempt one?

In general, Exempt studies have to clearly fit into one of the specific Exempt categories and would go on the Exempt protocol template (HRP-503EXEMPT). Exempt studies need to meet certain criteria, and generally if the data being collected is either sensitive or identifiable, the Expedited review is more appropriate.

Expedited studies include surveys, interview studies, chart reviews, and other not greater than minimal risk studies. An excellent summary can be found on this website. Expedited studies are often submitted on a chart review (HRP-503DATA) or a Social, Behavioral and Educational Research template (HRP-503SBER), but please review the descriptions to be sure you use the correct template.

9) Does Quality Improvement work need to be submitted to the IRB?

The IRB always recommends that you submit proposed QI work for a determination of Not Human Research on HRP-503NHR. There may be components of the QI that are research and it can be difficult to see this clearly in your own work. Having a determination ahead of time can ensure you are on the right track.

10) Do Case Reports need to be submitted to the IRB?

These also should be submitted for a determination of NHR. For 3 cases or less, the NHR submission is correct; if >3 cases (a case series) please submit as Expedited. You will obtain permission from the subject(s) of the case report but not informed consent – this is not an IRB specification but is almost always a requirement of journals.

The most important message is: **PLEASE CALL THE IRB AT 216-844-1529 AND COLLABORATE WITH AN IRB SPECIALIST BEFORE SUBMISSION**.

The specialists can help you with many aspects of submissions and planning. Please identify your statistics person and collaborate with him/her to complete a sample size calculation and analysis before submitting.