Scholarly Activity

(assistance with this may be provided by the Office of Research Support and Compliance upo request). An alteration may be requested if one or more elements/statements of HIPAA authorization are being removed/changed. Both of these requests can be found in the document "Request for Waiver/Alteration of HIPAA Authorization", found on IRBNet in Forms and Templates

e. Study Materials: Any tools, scripts, surveys, questionnaires, etc. that will be used in the study/administered to human subjects must be included/described as separate documents to be included in the IRB submission.
f. Advertisements/Recruitment materials: Any materials (flyers, social media posts, scripts, etc.) that will be used for the purposes of recruiting human subjects to participate in the study must be included in the IRB submission
g. CITI Training: All residents, faculty, and staff submitting to IRBNet must have completed the basic HSR CITI training course. A how-to for completing CITI training can be found on Resident Portal > Scholarly Activity > Bottom of the page

6. Once the documents are attached to your IRBNet project, click "Sign" and "Submit". This will lock the package, and a preliminary review of the materials will be conducted by the Office of Research Support and Compliance
7. If any changes are required to the materials in your submission, your team will be contacted via ema with the required changes. The IRBNet project/package will be unlocked to allow the revised document to be included (replacing older version of documents) in the IRBNet package. Check "Mark Revisio Complete" on the Designer tab of your IRBNet package to indicate the changes have been made. This will lock the package again.
8. If all appropriate changes have been made, and the materials are sufficient, the project will be forwarded to WCGMH IRB for either Expedited or Full-Board Review
    a. Expedited review: This is conducted by only the IRB Chair, and is reserved for minimal risk (no greater than the risks experienced in everyday life) studies that fit into one of the Expedited Review categories
    b. Full-Board Review: This is conducted by the convened WCGMH IRB committee at the monthly IRB meeting during which the agenda your study is on will be reviewed. This is for more complex research, greater than minimal risk, and/or studies that do not fit into an Exempt or Expedited category.
9. Your IRBNet submission must be revised and submitted to WCGMH IRB before the second Thursday of the month, in order to be reviewed during that month's agenda (the fourth Thursday of each month, except for the recess months of July and December, which have no meeting). A schedule of each month's material submission deadline and IRB meeting/agenda can be found on the research center.org
10. Once the committee has reviewed at the appropriate level, a determination letter will be sent. The determination may be:
    a. Approved: You are cleared to conduct your study per the approved protocol
    b. Approved with conditions: There are conditions listed in the letter that WCGMH IRB requires to be met before approval is granted. A second IRBNet package must be submitted within the existing IRBNet project, which must include the necessary changes, in order to secure approva A second letter, explaining the project has been approved, will then be issued.
    c. Deferred/Tabled, Modifications/Information Required: WCGMH IRB was unable to make a determination because there is important information missing and/or the study and its materials must be modified before approval can be secured. The required information/modifications will be described in the letter. A second IRBNet package, within the existing IRBNet project, must b submitted in order to secure approval.

d. Rejected/Disapproved – The protocol/proposal is not appropriate or safe to conduct, and so the concept of the project has been rejected.

11. When IRB Approval has been granted, you must conduct the study exactly as described in the protoco If changes are to be made, a "Request for Revisions to Approved Research" form must be complete (along with revised documents) and included in a new IRBNet package within the existing IRBNet proje This form can be found on IRBNet under Forms and Templates
12. An annual report or renewal (based on IRB determination) is required by the expiration date listed in the approval letter, until the study is closed/ended. A "Request for Continuing Review" form must be completed for the annual report/renewal, and a "Study Closure/Final Report" form must be completed to close the study with WCG IRB. At this time, results from the study are shared on the form.
13. The project must be uploaded to MyEvaluations along with the IRB Approval Letter.