Scholarly Activity Submission Guide

All *Case Reports, Research/Quality Improvement (QI) Projects, Community Oriented Primary Care Projects (COPC), and Poster Presentations* must be submitted to the **Office of Research Support and Compliance***.* The process reviews for 1) quality assurance, 2) compliance with institutional review board (IRB) WCGME and federal regulations (the 'Common Rule'), 3) compliance with the HIPAA Privacy Rule, and 4) Scholarly Work tracking for reports to ACGME. Below are the steps to follow when submitting each Scholarly Work type:

Case Reports:

1. Researchers identify a unique case they have treated/encountered, and obtain approval from their faculty mentor (if applicable)
2. Researchers will identify a venue/publication they would like to submit to, if any
3. Submit the case report to **IRBNet.org**
    a. How-to's for creating an IRBNet account and submitting a project (IRBNet Training Energizer-Researcher) can be found on the Resident Portal→ Scholarly Activity→Bottom of the page
4. The IRBNet package/project submission must include the following:
    a. **Case report** per venue guidelines and/or TWCCH guidelines (TWCCH guidelines are identical to ACP guidelines, and can be found on acponline.org). If venue guidelines conflict with TWCCH guidelines, the venue/publication guidelines receive priority.
    b. **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
    c. **Case Report Submission Form**: This can be found on IRBNet.org→Forms and Templates
    d. **Consent form for Case Reports**: This must be used if the case is of a patient you currently see and you are obtained written consent. "Case Report Patient Consent Form" can be found on IRBNet.org→Forms and Templates
    OR
    Waiver of Consent/Documentation of Consent: If verbal consent was obtained and documented in patient notes, complete Waiver of Documentation of Consent. If the patient was unable to be contacted, complete Waiver of Consent→Full Waiver. These are both within the same form titled "Request for Waiver of Informed Consent/Document of Consent (for Case Reports)" on IRBNet→Forms and Templates
5. Once the documents are attached to your IRBNet project, click "Sign" and "Submit". This will lock the package, and an administrative review will be conducted.
6. The case report will be reviewed by the Office of Research Support and Compliance (not the Wright Center for Graduate Medical Education Institutional Review Board [WCGME-IRB]) for appropriate formatting, grammar, and compliances with the HIPAA Privacy Rule (must be de-identified data only)
7. You will be contacted directly via email if any revisions to your IRBNet submission are required. The IRBNet package will then be unlocked to allow for revised documents (replacing older version of documents) to be attached. Check "Mark Revisions 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, you will be issued an IRB Letter of Exemption, and the project will be tracked. Exemption means the WCGME-IRB does not need to review the project.
9. Submit the final project and IRB Exemption Letter to ***MyEvaluations***

Research/QI/COPC Projects

1. Residents will form a group of no more than 4 (unless otherwise approved by program director/faculty mentor) and work with their faculty mentor on developing a concept for their research/COPC project (not applicable if a faculty/staff-only project)
    a. Assess community needs (COPC), perform preliminary literature search, identify needs to be addressed, develop a hypothesis, develop specific aims, propose intervention strategies (COPC, may be research as well), research questions, and implementation plan (COPC, may be research aswell)
    b. A document titled "How to write up a QI/COPC" can be found on the Resident Portal→Scholarly Activity→Bottom of the page
2. Residents will identify a venue/publication they would like to submit to, if any
3. Residents will create a draft Research protocol or COPC proposal and get approval from their faculty mentor (and COPC director, if COPC)
    a. Templates for a Research Protocol can be found on the Resident Portal→Scholarly Activity→Bottom of the page
        i. Prospective template: Used for studies on data that does not exist at the time of IRBNet submission (i.e. studies involving direct interaction/intervention with human subjects)
        ii. Retrospective template: Used for studies on data that exists at the time of IRBNet submission (i.e. studies that involve protected health information [PHI] and data/chart review only)
    b. A template for COPC projects, "QI_COPC Template", can be found on the Resident/Faculty Portal→Scholarly Activity→Bottom of the page
4. Once faculty approval is obtained, the project must be submitted to IRBNet.org. IRB review and approval will be required for these projects.
    a. How-to's for creating an IRBNet account and submitting a project (IRBNet Training Energizer-Researcher) can be found on the Resident/Faculty Portal→ Scholarly Activity→Bottom of the page
5. The IRBNet package/project submission must include the following:
    a. **Protocol/COPC Proposal**
    b. **New Protocol Submission Form:** Can be found on IRBNet→Forms and Templates
    c. **Consent Form:** Consent must be obtained in compliance with federal regulations. An Informed Consent template can be found on IRBNet→Forms and Templates
    OR
    Waiver of Consent/Documentation of Consent/Alteration: If the project is minimal risk, and does not require direct interaction/intervention with human subjects, a Full Waiver of Consent may be requested. If your team plans to obtain verbal consent, a waiver of documentation of consent may be requested. If your team would like to remove/change one or more required elements/statements of informed consent, a request for Alteration of consent may be requested. All three requests can be found in the document "Request for Waiver, Alteration, and/or Documentation of Informed Consent" on IRBNet→Forms and Templates
    d. **HIPAA Authorization**: If the project involves access, use, or disclosure of PHI, required elements and statements must be included either in the informed consent form or in a separate HIPAA Authorization form. A checklist of these required elements/statements ("HIPAA Authorization Checklist") can be found on IRBNet→Forms and Templates
    OR
    Waiver/Alteration of HIPAA Authorization: Your team may request a waiver of HIPAA authorization if the study is minimal risk and there are appropriate confidentiality/data security measures in place. These will be described in the protocol/proposal and the waiver request

(assistance with this may be provided by the Office of Research Support and Compliance upon 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→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 email with the required changes. The IRBNet project/package will be unlocked to allow the revised documents to be included (replacing older version of documents) in the IRBNet package. Check "Mark Revisions 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 WCGME-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 WCGME-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 WCGME-IRB before the second Thursday of the month, in order to be reviewed during that month's agenda (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 thewrightcenter.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 IRB-approved protocol
    b. **Approved with conditions:** There are conditions listed in the letter that WCGME-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 approval. A second letter, explaining the project has been approved, will then be issued.
    c. **Deferred/Tabled, Modifications/Information Required**: WCGME-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 be 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 protocol. If changes are to be made, a "Request for Revisions to Approved Research" form must be completed (along with revised documents) and included in a new IRBNet package within the existing IRBNet project. This form can be found on IRBNet→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 WCGME-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.

Poster Presentations

1. If a poster presentation is being submitted to a venue, it will be based on a project previously submitted to IRBNet, and will undergo the Poster Approval Process
2. The "Poster Presentation Approval Form" must be completed, and the completed form must be submitted to research@thewrightcenter.org. This form can be found on the Resident/Faculty Portal→Scholarly Activity→Bottom of the page
    a. If the venue is virtual, note this on the form. Certain items may not apply.
3. Once the form is complete, a draft of the poster presentation must be submitted to research@thewrightcenter.org for quality assurance. The TWCCH-approved templates for poster presentations can be found on the Resident/Faculty Portal→Scholarly Activity→Bottom of the page.
4. The Office of Research Support and Compliance may make edits, and work with you to develop the final draft
5. You will receive notifications of approval to present once the final draft has been developed
6. If the venue is virtual, the submission is complete. You will then submit the project to MyEvaluations, along with the IRB letter from the original IRBNet submission (poster presentations on Case Report, COPC, Research/QI).
7. If the venue is in person and requires a physical poster, the poster will be printed for you and travel expenses will be reimbursed per the Poster Presentation Approval Form. You will be notified when the physical poster is ready to be retrieved from the Scranton Administrative Hub (501 South Washington, Scranton, PA).
8. Once the presentation has been given, report any awards granted to your poster. Return the physical poster to the Scranton Administrative Hub, and it will be displayed at one of the TWCCH clinics. **This poster is TWCCH property**.
9. Submit the project to ***MyEvaluations***, along with the IRB letter from the original IRBNet submission (poster presentations on Case Report, COPC, Research/QI)

Congratulations!

You've got an understanding of how to submit your Scholarly Activity projects. For more information, or if you have any questions, contact research@thewrightcenter.org.

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