Navigating the Research Institutional Approval Process

A Western Michigan University Homer Stryker M.D. School of Medicine (WMed) Human Research Protection Program (HRPP) Guidance Document

Purpose

This document provides a quick reference guide on the purpose of and process for institutional approval of research proposals.

Regulations

45 CFR 46.111(a) Risk to participants are minimized (1) by using procedures consistent with sound research design and which do not unnecessarily expose participants to risk and (2) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

21 CFR 56.11(a) Risk to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

Discussion

Institutional review and approval assures researchers that the necessary resources are available to conduct the study at WMed and/or with our community partners. The institutional approvals are coordinated with the ethics review process. The institutional approval process takes place after the electronic submission to the WMed Institutional Review Board (IRB) and before the IRB reviews the project.

Although the institutional approval process is independent of the IRB review, it is designed to enhance the quality and validity of the research. Institutional support involves multiple individuals including faculty leadership and ancillary departments. Researchers should consult with their department chair or program chief/director on the research to ensure the scholarly activity is aligned with the goals of the department or program. When reviewing for institutional approval, the chair or program chief/director will serve in a peer reviewer capacity. They will consider the rationale for the study and if the aims are clearly defined.

Ancillary departments involved to support the research such as epidemiology and biostatistics are available to contribute to research design and statistical analysis. Whenever ancillary services are needed, all feedback from the area of expertise and commitment of resources should be discussed with the relevant department and included in the protocol prior to IRB submission.
Procedure

The WMed IRB staff facilitate the Institutional Approval process through our IRB electronic submission system as follows:

**Step 1.** Researcher submits application to the IRB for review utilizing the electronic system [https://imedris.med.wmich.edu](https://imedris.med.wmich.edu). A notification of receipt from the IRB will be received. This starts the process of institutional approval.

**Step 2.** Your protocol will be forwarded to the appropriate individuals based on where and what types of services you will be utilizing. The WMed IRB staff will route the approvals based on how you’ve answered the questions in Section 5 “Site Information” of the application. The following steps outline the routing structure for institutional approval:

**As applicable:**

- PI is Hospital Employee — No Affiliation with WMed
  - Yes
  - *Hospital (Borgess Bronson) Approval

- PI is WMed Faculty
  - Yes
  - PI’s Department Chair or Program Chief/Director Approval
  - Assoc. Dean for GME (if using data from Residents/Fellows)
  - Assoc. Dean for Ed Affairs (if using data from Medical Students)
  - Assoc. Dean for Faculty Affairs (if using data from Faculty)
  - Other as applicable (i.e. Family Health Center)

- *Hospital (Borgess Bronson) Approval

- Ancillary Dept. Approval (Epi/Bio; IT)

- Assoc. Dean for Ed Affairs (if using data from Medical Students)

- Associate Dean for Research

- Assoc. Dean for Faculty Affairs (if using data from Faculty)

- Other as applicable (i.e. Family Health Center)
*When requesting either a data pull or interaction with Bronson patients for research purposes, the institutional approval will be submitted to the research compliance office at Bronson. The research compliance office will direct approvals as needed. The final approval for Bronson is currently the Chief Medical Officer.

*When requesting either a data pull or interaction with Ascension Borgess patients for research purposes, the request for institutional approval will be submitted to the Chief Physician Officer.

**Step 3.** If the Institutional Approval reviewers request changes to your protocol, they will appear as “Stipulations” in iMedris. The PI and study contacts will be notified by email when stipulations are posted. Keep in mind these requests are related to the institution review vs. the IRB review and the stipulations must be addressed before your project will be reviewed by the IRB.

**Step 4.** IRB Reviews.

If you have questions about the status of your study during either the Institutional Approval or IRB review process, call 269-337-4345 or email irb@med.wmich.edu and request an update on the status of your review.

**Summary**

- Research Institutional Approval is **not** an IRB process. However, it is facilitated by the IRB administrators and it is required before an application will be reviewed by the WMed IRB.
- The length of time it takes to complete the Institutional Approval Process is dependent on the time required by the Department Chair, Associate Deans, and approving officials at WMed affiliates to review the protocol. PI’s should consult with approving officials before an application is submitted in order to facilitate the review process.
- Contact the Office of the IRB if you have questions about the Institutional Approval Process at irb@med.wmich.edu or by phone 269-337-4345.
Supplemental Information

Process for Data Pull Requests from the EMR at Bronson

IT Analytics receives information via the IRB application as illustrated below:

Bronson IT Analytics will review this request during the institutional approval process. Based on the information provided here and potentially further discussion with the PI, parameters of the report are established.

Bronson IT Analytics generates a ticket and places it in a 'hold bucket'. Once the WMed IRB communicates a review determination and a Waiver of HIPAA Authorization, if applicable, data will be released and transferred to WMed via a secure method. The timing on the report generation varies with the complexity of the request.

If you have any questions about this process or need assistance, please contact the WMed Research Navigator at 269-337-6471.
Supplemental Information

Process for Data Pull Requests from the EMR at Ascension Borgess

Data pull requests from Ascension Borgess are independent of the institutional approval process. Should you have questions regarding feasibility in the protocol development phase, you may contact the local clinical informatics group:

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<tr>
<th>Holly DeKilder</th>
<th>Ronda Clawson</th>
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<tbody>
<tr>
<td>Email is <a href="mailto:holly.dekilder@ascension.org">holly.dekilder@ascension.org</a></td>
<td>Email is <a href="mailto:ronda.clawson@ascension.org">ronda.clawson@ascension.org</a></td>
</tr>
<tr>
<td>Phone is 269-552-0224</td>
<td>Phone is 586-753-1175</td>
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No data will be released from Ascension Borgess for research purposes until after the WMed IRB has issued the Review Determination and a Waiver of HIPAA Authorization.

To make the data pull request go to Ascension’s national request portal. The Principal Investigator (PI) is responsible for making this request. In the request, the question: “Is this request related to data for a research study?” Indicate “Yes” on this question.

The follow-up to this question will prompt you as follows:

Attach the IRB letter documenting the Review Determination and Waiver of HIPAA Authorization. This request will not be processed until this documentation has been provided and placed on file for HIPAA accounting purposes.

The timing on the report generation varies with the complexity of the request.

If you have any questions about this process or need assistance, please contact the WMed Research Navigator at 269-337-6471.
Supplemental Information

Listing of Institutional WMed ‘Approvers’

**Department Chairs and Program Chiefs**

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<th>Departments</th>
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<tr>
<td>Anesthesiology</td>
<td>Biomedical Informatics</td>
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<td>Biomedical Sciences</td>
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<td>Emergency Medicine</td>
<td>Medical Ethics, Humanities, and Law</td>
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- Research involving Medical Students as subjects - [Medical Education](#) – Associate Dean for Educational Affairs must approve

- Research involving Residents and/or Fellows as subjects – Associate Dean for Graduate Medical Education must approve

- Research involving Faculty members as subjects – Associate Dean for Faculty Affairs must approve

**Ancillary Support Services**

[Epidemiology, Data Support & Biostatistics, Director](#)

Information Technology, Director