Guidelines for Submitting a Study for WMed IRB Review

If you have problems or questions while completing this process, please contact the IRB office.

Note: The last step in the submission process is obtaining the Appropriate Institutional Sign-off

Step 1: Develop a research plan and write a protocol. Use the finalized protocol to complete the IRB application.

Step 2: Complete the electronic COI (http://imedris.med.wmich.edu) and
CITI Human Subject Protection modules (http://wwwcitiprogram.org).
NOTE: Protocol title, COI title and IRB application title MUST be the same.

Step 3: Access WMed IRB information from the **WMed Research** website.

Step 4: Go to the **Compliance and Integrity** link then to the **Human Subjects** link.

Step 5: Locate on the Left side of the screen the link to **IRB Forms**.

Step 6: Select the appropriate application or form(s):

a) **IRB Study Application Forms**

Initial Submission Application
Request for Exempt Determination
Initial Application- HUD
Request to Rely on External IRB

b) **Additional Forms**

As applicable, Supplemental Forms A-M are for special conditions needing IRB review.

Form A- Research Involving Children as Subjects
Form B- Research Involving Prisoners as Subjects
Form C- Research Involving Pregnant Women
Form D- Research Involving Subjects with Impaired Decision Making
Form E- Request for Waiver, Alteration and/or Waiver of Documentation of Consent
Form F- Request for Waiver or Alteration of HIPAA Authorization
Form G- Research Involving Exercise Interventions, Testing or Training
Form H- Research Involving Drugs or Biologics
Form I- Research Involving Medical Devices
Form J- Storing Data or Specimens for Future Research
Form K- Research Involving the Internet
Form L- Collaborative Research
Form M- Transnational Research

c) **Researcher Forms and Documents**

Modification Form
Study Closure Form
Continuing Review Form
Continuing Review Form- HUD
Emergency Use Reporting Form
Event Reporting Form
Request to Rely on WMed IRB

Step 7: Save a copy of the fillable Word document to your desktop and provide the requested information on the application and any supplemental forms (if applicable).

Step 8: Create any informed consent document(s), assent document(s), script or information sheet (if applicable).

Step 9: Complete the HIPAA Authorization document (if applicable).

Step 10: Create the required documents (recruitment materials, surveys/questionnaires, investigator brochure, datasheets, etc.) that are needed to support the information provided in the application.

Step 11: Provide a copy of the WMed Affiliated CITI training certificates for all research team members. Provide a copy of the PI and any co-I CVs. People listed as research team members do not need to provide a CV.

Step 12: Choose the appropriate Institutional Research Assurance/Approval Form and obtain sign-off by the appropriate person.

Institutional Proposed Study Assurance and Approval- WMed Sites
Institutional Proposed Study Assurance and Approval- WMed Affiliated Institutions

Step 13: Investigators at Bronson, Borgess and other sites:

All investigators are **required** to submit a **Research Proposal** and **Institutional Proposed Study Assurance and Approval** form to:

Bronson Investigators submit to **Chris Sangalli**, VP Risk and Compliance; Chief, Compliance Officer
sangallc@bronsonhg.org

Borgess investigators submit to **Christine Campbell,** Corporate Executive Assistant, who will facilitate in obtain the needed signature. Christine.Campbell2@ascension.org

WMed investigators submit to **Dale Vandré**, Associate Dean of Research
Office.Research@med.wmich.edu

- **Note: if the study is being done at multiple sites, you need to obtain institutional sign-off from all sites.**
- The study protocol is to be included with the Institutional Assurance and Research Approval Form for sign-off. **A synopsis or brief description of the study will NO LONGER be acceptable.**
- This document is used to verify that the institution is aware and will allow the research to be conducted at their institution.

Step 14: Email the completed IRB application and all associated and required documents to irb@med.wmich.edu.

You will need to email a copy of the Word documents or print the documents, scan them then email them to the IRB.

Step 15: On the subject line of your email, indicate the specific application that is being submitted with the WMed IRB#, if known.

Step 16: In the body of your email, include the PI name and study title.

Step 17: The IRB will send a confirmation of receipt email.