Guidelines for Submitting a Study for WMed IRB Review

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

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

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**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](http://imedris.med.wmich.edu)) and CITI Human Subject Protection modules ([http://wwwcitiprogram.org](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

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WMed IRB Submission Guidelines

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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.

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

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.