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://www.citiprogram.org).

NOTE: Protocol title, COI title and IRB application title MUST be the same.


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

Step 13: Obtain sign-off by the Appropriate Institutional Official(s) (IO) at WMed, Bronson, Borgess or other sites.
   Provide the study protocol along with the Institutional Research Approval Form to the IO.
   Note: if the study is being done at multiple sites, you need to obtain institutional sign-off from all sites. This document is used to verify that the Institutional Official(s) 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.