



IRB Submission Instructions and Checklist for New Research

Use this guidance to avoid incomplete submissions and other errors that can delay the IRB Review process.

A. IRB Committee and Review Type

To determine how to submit new research for IRB review, use this chart and follow the steps indicated in the chart. The steps for new submissions varies, and is based on the type of review requested (exempt, expedited or full board) and the IRB committee (M1, MP2, B3, MP4, or PH1) that will review.

IRB Review Type/Committee	Complete Steps:
Exempt or Expedited Medical Review (M1, MP2, MP4)	B only
Exempt or Expedited Behavioral Review (B3)	B and E
Full Board Review (M1 and B3)	B, C and E
Full Board Review Medical (MP2 and MP4)	B, C, and D
Full Board Phase 1 Review (PH1)	B and E

B. Complete One “Packet” for Review Using the Following Checklist

- The appropriate IRB form has been filled out and is the most recent version on the IRB website
- The form is complete with typed text and all questions have an appropriate response
- All signatures are original and inked by pen (faxed, digital and Xeroxed copies are not allowed)
- A bio-sketch for the Principal Investigator is included (not required for exempt review)
- The Scientific Review on the form has been completed and signed by Department Chair or Dean (not required for exempt review)
- CITI training has been completed and is up to date for everyone who has signed the form
- A Financial Conflict of Interest (FCOI) question has been answered by hand and in ink by everyone who has signed the form
- Any communication from the FCOI committee regarding FCOI disclosures is included
- The Narrative Summary is no more than 4 pages total and written in non-technical language
- All questions on the form have been answered and enough detail provided where appropriate
- Any appendices for the form that are required have been completed and are included
- Letters of approval from all required review committees are included; if applicable
- Letters of support for research activity at outside institutions are included; if applicable
- Required FDA correspondence for research on drugs or devices is included, if applicable
- A HIPAA Summary Form for the use of Protected Health Information is included; if applicable
- The PI has signed the HIPAA Summary Form in Section A; if applicable, and Section D; if applicable
- Two copies of all documents needing IRB approval stamp, are attached as follows:

- Advertisements (flyers, emails, study brochures); if applicable
- Data collection tools (survey questions, questionnaires): if applicable
- Consent/assent/parental permission documents; if applicable (templates are available on IRB website)
- A descriptive protocol (proposal) with scientific references, or grant application is included
- All Investigational Drug Brochures (IBs) or Drug Package Inserts are included; if applicable
- Each document is stapled individually and then a copy of each is collated (assembled) into one packet (using binder clip)

C. Assemble 2 Additional Packets

These 2 additional collated (assembled) packets should contain **all** documents listed in part A, but only **one copy** of each. Any signatures must be included but can be copies of the original.

D. Assemble 15 Additional Packets

These 15 additional packets should contain **one copy of:**

- IRB Form + any appendices
- Any consent documents
- Non-standardized instruments (data collection tools developed by the PI)
- Data collection tools that deal with sensitive subjects (drug use or sexual practices)
- Any advertisements or flyers.

Other documentation may be included if appropriate.
Any signatures must be included but can be copies of the original.

E. Additional Electronic Copy Required

There are no deadlines for submitting for expedited or exempt review. Electronic copies for full board reviews **must** be submitted by the deadline*. Any pages with signatures must be scanned and submitted as PDF files. All other documents should be Word files, but PDFs are acceptable if provided to the PI in that format.

The subject line of the email should read: NEW PROTOCOL (PI Name).

Email the electronic copies of the documents to:

- M1board@wayne.edu for the M1 committee
- B3board@wayne.edu for the B3 committee
- PH1board@wayne.edu for the PH1 committee

Submitting the Hard Copies

Assemble the packets in order, A – C as applicable. Submit to the IRB Administration Office in person (preferred) or by mail. Submissions are accepted in person, Monday - Friday, 8:30 am – Noon and 1:00 pm - 4:30 pm. The office is closed Noon – 1:00pm for lunch.

*The PH1 deadline is on or before Wednesday at noon, (for a meeting on the following Friday).

*[WSU IRB Full Board Meeting Deadlines](#)