

PH1 IRB Submissions

The Human Investigation Committee (HIC) is pleased to announce the creation of a committee (effective January 2009) that specializes in the review of industry-sponsored Phase I Clinical Trials. This process enables Principal Investigators to submit new protocols to the **PH1 IRB** via **email**. The PH1 IRB accepts studies that involve both adults and minors.

In addition to emailing all the protocol documents (see the Protocol Summary Form for detailed list), Principal Investigators will also submit **one original** signed protocol summary form and protocol documents, as well as **two complete collated packets** to the HIC Office.

Below is a summary of the new instructions:

1. Check the HIC website for **submission deadline dates for PH1**.
2. **Download** new protocol forms from the HIC website (www.hic.wayne.edu)
3. **Email** the protocol summary form and the associated documents as attachments to PH1board@wayne.edu. The subject line of the email should read: **NEW PROTOCOL (PI Name and Protocol Number)**. It is preferred that forms be submitted as Word documents; information from pharmaceutical companies can be submitted as PDF. **In addition, all signature pages must be scanned and submitted as PDF files.**
4. All documents will be pre-reviewed by the Research Compliance Specialist and requested revisions will be emailed to the PI/designee within 24-48 hours in most cases.
5. The revised documents must be sent via email to PH1board@wayne.edu with highlighted revisions.
6. After all revisions are appropriately completed, the PI/designee will need to send final revised (clean) copies of documents, with updated revision dates, via email.
7. **Deliver** hardcopies to the HIC by the PH1 deadline. (On or before Friday at 12 Noon, 7 days prior to the scheduled meeting date) **NO EXCEPTIONS.**
 - a. ONE signed original protocol summary form (with associated documents)
 - b. TWO copies of the entire protocol packet

PLEASE USE THE PH1BOARD@WAYNE.EDU EMAIL ADDRESS FOR **ALL** PH1 SUBMISSIONS, INCLUDING UNEXPECTED PROBLEM REPORTING, EXPEDITED/EXEMPT APPLICATIONS, AMENDMENTS, CONTINUATIONS AND ANY OTHER PERTINENT PH1-RELATED COMMUNICATION.

*After the scheduled meeting date, the **memo will be generated within 5 business days.**

Specific Minor Revisions or Tabled memos:

Please email highlighted copies of all documents with revisions, along with clean copies. Electronic copies without highlighted changes will be returned.

- a. Please refer to the instruction guide at the bottom of the memo regarding the resubmission directions.
- b. The Chair is unable to review responses that do not include highlighted changes of all documents that include revisions. Please highlight the Protocol Summary Form via Adobe Acrobat Professional (Tools — Comment/Mark Up).
- c. If you do not have access to this program, you will need to highlight the changes manually, scan the individual pages and email all revisions to the PH1board. If yellow, pink or lavender highlighting is not visible after scanning, please underline revisions with a thin black marker prior to scanning.
- d. Please do not highlight entire sections of the Protocol Summary Form.
- e. It is required that only each individual word or phrase that is revised is highlighted.
- f. Please use the text highlighter for all changes made in the consent document(s).

Please Note: The IRB will be unable to provide a decision regarding any protocol that does not have changes on **all** documents clearly identified.

- g. After the HIC verifies that all required documents have been received, please send 1 hard copy of all documents (revised document with highlighting, clean copy of all documents and response memo from PI) to the HIC office.

Unexpected Problem Reporting:

- a. Submit IND report and Unexpected Problem Report via email.
- b. An email correspondence will be sent to the PI/designee to verify that the report has been received.
- c. An Unexpected Problem Memo will be sent via email to the PI/designee from the PH1 Unexpected Problem reviewer.

Amendment Submissions:

- a. Send an electronic copy of the amendment form, including scanned PDF versions of all pages that include PI/staff signatures.
- b. Send electronic copies of all new documents (protocol amendments, IB, consents, etc.)
- c. Send electronic copies of all revised documents with changes highlighted (as described earlier)
- d. An email correspondence will be sent to the PI/designee with instructions regarding when to send the revised hard copies and clean hard copies (1 of each document) to the HIC office.

Continuation Submissions:

- a. All required documents must be sent electronically 6 weeks prior to the expiration date.
- b. Send electronic copy of the continuation form, including scanned PDF versions of all pages which include PI/staff signatures.
- c. Send electronic copies of all documents currently in use (including all consents/assents, advertisements, information sheets).
- d. An email correspondence will be sent to the PI/designee regarding any necessary pre-review revisions that need to be addressed prior to assigning the protocol to a meeting date.
- e. An email correspondence will be sent to the PI/designee with instructions regarding when to send the hard copies (1 original plus 2 copies) to the HIC office.