

**University of North Texas Health Science Center *at* Fort Worth
Office for the Protection of Human Subjects
Institutional Review Board**

IRB Submission of Research

In order for OPHS and the IRB to conduct an effective and thorough review of a protocol, the appropriate information and documentation needs to be submitted to OPHS in a timely manner. Note that this responsibility falls solely on the Principal Investigator. This document will provide information on *what to submit* to OPHS for review and *how to submit* these items for an effective review.

What items/ documents are necessary to submit for OPHS and IRB Review?

How to assemble and submit documents for OPHS and IRB review?

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When submitting a human subject research project for review, there are different types of categories which a protocol may fall into:

- **Exempt Category Review**
 - **Expedited Category Review**
 - **Full (convened) Board Review**
- } Type of Review for New Research Protocol
- **Continuing Review:**
 - **Expedited Review**
 - **Full (convened) Board Review**
 - **Protocol Modification:**
 - **Expedited Review**
 - **Full (convened) Board Review**
- } Review of an already IRB-approved Protocol

For guidance regarding what type of IRB review the protocol may receive, please call an OPHS Human Subject Protection Coordinator or visit the OPHS website.

The type of review will dictate which application, documentation and number of copies are necessary for IRB process and review.

Submission of a New Protocol:

The following are the documents required to submit to OPHS/ IRB for a new research protocol. For further information, please visit our website for a detailed explanation of each category/ type of review.

Exempt Category Review:

This is the simplest and often the quickest process if the following are submitted and the information given is complete and clear.

- The original SIGNED and dated **Exempt review application**

Although a protocol synopsis is not required for Exempt Category review, the application includes a section for a detailed project description. In this section, provide all pertinent information regarding the study including: purpose, procedures, possible risks involved in the study, and, if applicable, data storage and confidentiality. Recall that unclear and/or insufficient study information can delay the process of OPHS/ IRB review and approval.

Additionally, on the application, student investigators must have their advisor or a faculty member sign and date the Exempt application as the principal investigator. According to UNTHSC policy, a student cannot be the principal investigator on a research project involving human subjects.

- CITI certificates for ALL key personnel
- The cover letter (in lieu of informed consent) or informed consent

If applicable, also includes:

- Application for a Waiver of Written or Documentation of Informed Consent (must meet criteria)
- Any of the data collection tools (e.g. survey, educational tests, etc.)
- Include interview/phone script (if part of the study)
- Website address and a page print out for studies involving publicly available data (for example, National Center for Health Statistics www.cdc.gov/nchs/about/major/nhis/hisdesc.htm)
- Recruitment/advertisement material (flyers, ads, etc.)
- Letter of collaboration or permission and/or approvals from other IRBs
- A waiver of HIPAA authorization for studies involving protected health information (call OPHS staff for further guidance regarding HIPAA regulations)

Note that no e-version or e-signature of the above documents will be accepted. Only a hard copy documents will be accepted.

In most cases, review of Exempt category research may take from 1-5 business days. Turn-around time depends on the completeness of the packet and clarity of the information provided.

Expedited Category Review:

When submitting your Expedited research to the OPHS Office, please submit **2** complete compiled packets with the following information contained within **EACH** packet.

- IRB Expedited Review Application Form (with original PI signature on one copy)
- Protocol Synopsis
- Informed Consent Form (if applicable)
- Conflict of Interest Form for all key personnel listed on the project
- CITI Human Subject Research Training Certificates for all key personnel listed on the project

If applicable;

- Recruitment Materials (flyers, emails, advertisements, etc.)
- Surveys/Questionnaires
- Telephone scripts/oral scripts
- Assent Forms/Parental Permission Forms
- Research Agreements
- Letters of permission or cooperation, and/or approvals from other IRBs
- HIPAA Research Waiver

In order for the OPHS and the IRB Chair to make a timely and appropriate determination of the project, the documents and materials you submit must be thorough, clear and complete. If the application packet is missing some critical information or is otherwise incomplete, your entire set of IRB review documents and materials may be sent immediately back to you, resulting in a re-submission and delay.

Please ensure that the needed information (listed above) is submitted in each packet for a more streamlined "speedy" review of your research project.

In addition, please keep in mind that the review process takes time, and research may not be initiated until the application has been approved.

In most cases, Expedited Review can be completed within 5 - 7 working days, (sometimes sooner) unless needed information is missing or incomplete.

Full (convened) Board Review:

Investigators seeking Full Board review must complete and sign an IRB Application Form, and attach all appropriate documents relevant to that particular protocol for proper review at the IRB meeting. IRB meeting schedule and deadline dates are listed on the OPHS website. The deadline for new protocol submissions is usually the 3rd Monday of the month (again, see website).

*Note that investigators must submit the appropriate amount of hard-copies for proper IRB review. **No E-versions** of research-related documents will be accepted at this time.*

(1) Signed Original of the IRB New Protocol Application.

(2) Twenty (20) Copies of the following documents:

- IRB New Protocol Application
- Protocol Synopsis
- Informed Consent Document(s)
- Recruitment ads, flyers, questionnaires, etc.

(3) Four (4) Copies of the following documents:

- Federal grant application (if applicable)
- Clinical Protocol (for Clinical Trials)
- Investigator's Brochure (if applicable) and for Clinical Trials
- All Correspondence related to this protocol for the Sponsor

(4) One (1) Copy of the following documents:

- Curriculum Vitae of Principal Investigator
- Conflict of Interest (COI) for EACH listed key personnel on project
- Certificate of Training for Human Subject Research (CITI) for EACH listed key personnel on project

*The twenty copies of the IRB-submitted research-related documents (see above...bullet point "#2") must be collated (compiled) into packets. Compiling these packets for submission minimizes any potential delay in OPHS distribution of the packets to Board members and facilitates IRB review. For a detailed description on how these IRB packets should be compiled, please refer the following section titled "**how to assemble and submit documents for OPHS and IRB review**".*

Review of an IRB-approved Protocol

Continuing Review of an Expedited Category Protocol:

As per federal regulations, all research protocols must be reviewed by the IRB at least once per year, or more frequent, depending on the level of risk associated with the study. Studies receiving Expedited Category approval are reviewed on an annual basis. A courtesy reminder for Continuing Review is sent by OPHS staff to the PI well before the study's expiration date in order to process the review and approval in a timely manner. However, *it is the responsibility*

of the PI to promptly submit the appropriate documents as well as the correct number of copies to carry out such review. The following is a breakdown of what is required for continuing review of an Expedited Category protocol.

(1) Two (2) **hard-copies** of the following documents:

- Progress Report Form (with original SIGNED copy on top)
- Protocol Synopsis (current IRB-stamped version)
- EACH version of the CONSENT FORM [current IRB-stamped version(s)]
- Other IRB approved research-related documents (i.e. flyers, questionnaires, etc.)

(2) One (1) hard-copy of the following documents:

- An **Updated** Conflict of Interest forms for **EACH** listed key personnel
- Copy of a "clean" copy of the Consent Form

*Note that no e-version or e-signatures of the above documents will be accepted. For a detailed description on how these IRB packets should be compiled, please refer the following section titled "**how to assemble and submit documents for OPHS and IRB review**".*

Continuing Review of a Full Board Category Review Project:

Note that investigators must submit the appropriate amount of hard-copies for proper IRB review. **No E-versions** of research-related documents will be accepted.

(1) Original SIGNED Progress Report

(2) a CLEAN (hard) copy of EACH version of the Consent Form

(3) Twenty (20) hard-copies of the following documents:

- Protocol Synopsis (current IRB-approved stamped version)
- Informed Consent (current IRB-approved stamped version)
- Recruitment ads, flyers, questionnaires, etc.

(4) One (1) hard-copy of the following documents:

- CITI for EACH listed key personnel on project
- Conflict of Interest forms for EACH key personnel

Expedited Review of Protocol modification(s):

Protocol modifications, just as in a protocol review, are initially reviewed by OPHS Director and staff to determine risk to subject. They are then referred to the IRB Chair for review. If the IRB Chairperson concurs with OPHS staff that the modifications are "**minimal risk**" to subject, it is then processed in an "expedited" manner. Under an expedited review process, the review may be carried out by the IRB Chairperson, or by one or more experienced IRB members designated by the Chairperson. This often is a faster level of review and can be

processed within 1-7 business days depending on the clarity as well as completeness of information provided.

Recall that even modifications deemed as "**minimal risk**" can be sent for Full Board Review if the protocol requires additional consideration and review as indicated by federal regulations, or if the IRB Chair deems it appropriate for review by a convened IRB.

The following needs to be submitted for an **expedited review** of a protocol modification:

- (1) SIGNED original memo from the PI requesting protocol amendment. *The memo should include the elements or modifications found within the proposed amendment and provide a brief justification for each change. Additionally, please incorporate the study title and IRB number in the memo.*
- (2) One (1) copy of the following:
 - Track changes version of the modified research documents (i.e. informed consent, protocol synopsis, etc.) reflecting the proposed modifications/amendment
- (3) One CLEAN Copy of the modified research document(s) reflecting proposed modifications/ amendment. (This copy will later be stamped- "IRB Approved").

No e-version or e-memo will be accepted for a protocol modification request.

Full Board Protocol Amendment:

Protocol modifications, just as in a protocol review, are initially reviewed by OPHS Director and staff to determine risk to subject and then sent to the IRB Chair for review. If the IRB Chairperson concurs with OPHS staff that the modifications are "**more than minimal risk**" to subject, it is then processed as a "**full board amendment**" and taken to the convened (board) meeting for review and approval. Note that *substantial amount* of "**minimal risk**" modifications to a protocol, particularly when the review/ category of the protocol involves more oversight or attention as per regulations (for example, a prisoner study), can be processed and reviewed by a convened board. Again, this determination is made by the IRB Chair.

The following are the items necessary for IRB review of a full board amendment:

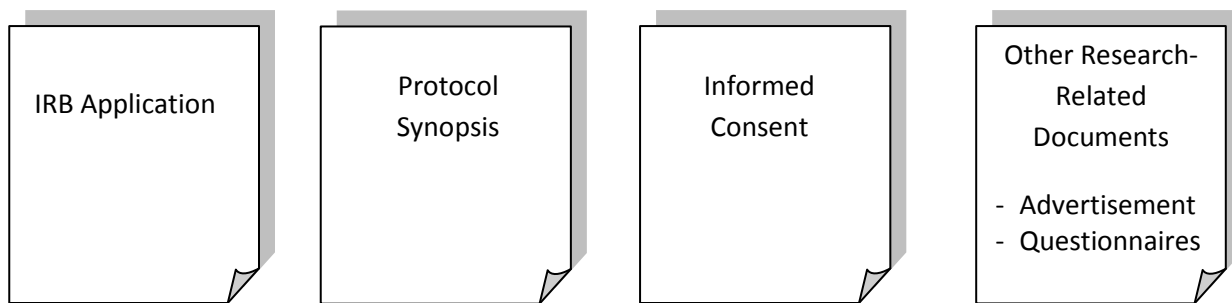
- (1) SIGNED original memo from the PI requesting protocol amendment. *The memo should include the elements or modifications found within the proposed amendment and provide a brief justification for each change. Additionally, the memo must include the protocol title and IRB number.*
- (2) Twenty (20) Copies of the following:
 - Copy of Signed Memo
 - Track changes version of the modified research documents (i.e. informed consent, protocol synopsis, etc.) reflecting the proposed amendment/ modifications

(3) One CLEAN Copy of the modified research document(s) reflecting proposed amendment/ modifications. (This copy will later be stamped- "IRB Approved").

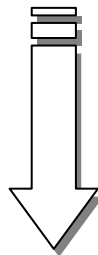
How to assemble and submit the appropriate documents to the IRB

When submitting to the OPHS-IRB, the relevant documents (e.g., IRB application, protocol synopsis, informed consent, etc.) must be compiled into organized packets. This helps OPHS manage and distribute the IRB-submitted packets as well as facilitate final IRB review. This is particularly necessary for all protocols being reviewed at a convened (IRB) meeting.

Please see below for an example of how the IRB documents **must be submitted** to OPHS-IRB. *Please have the original signed IRB application (e.g., IRB application for New Research Protocol, Continuing Review, signed cover memo, etc.) on top for faster OPHS review.*



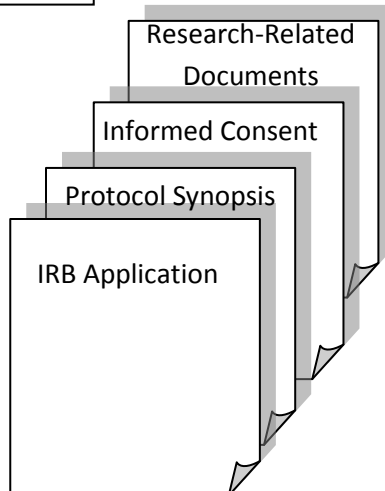
CORRECT FORMAT TO COMPILE IRB PACKETS FOR SUBMISSION TO THE IRB



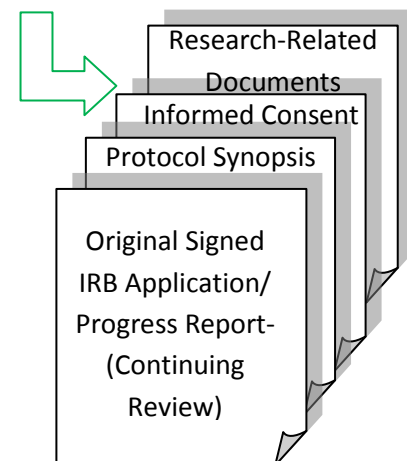
Full (convened) Board Review:
20 Collated Copies

Expedited Review:
2 Collated Copies

These Go Out for IRB Review:

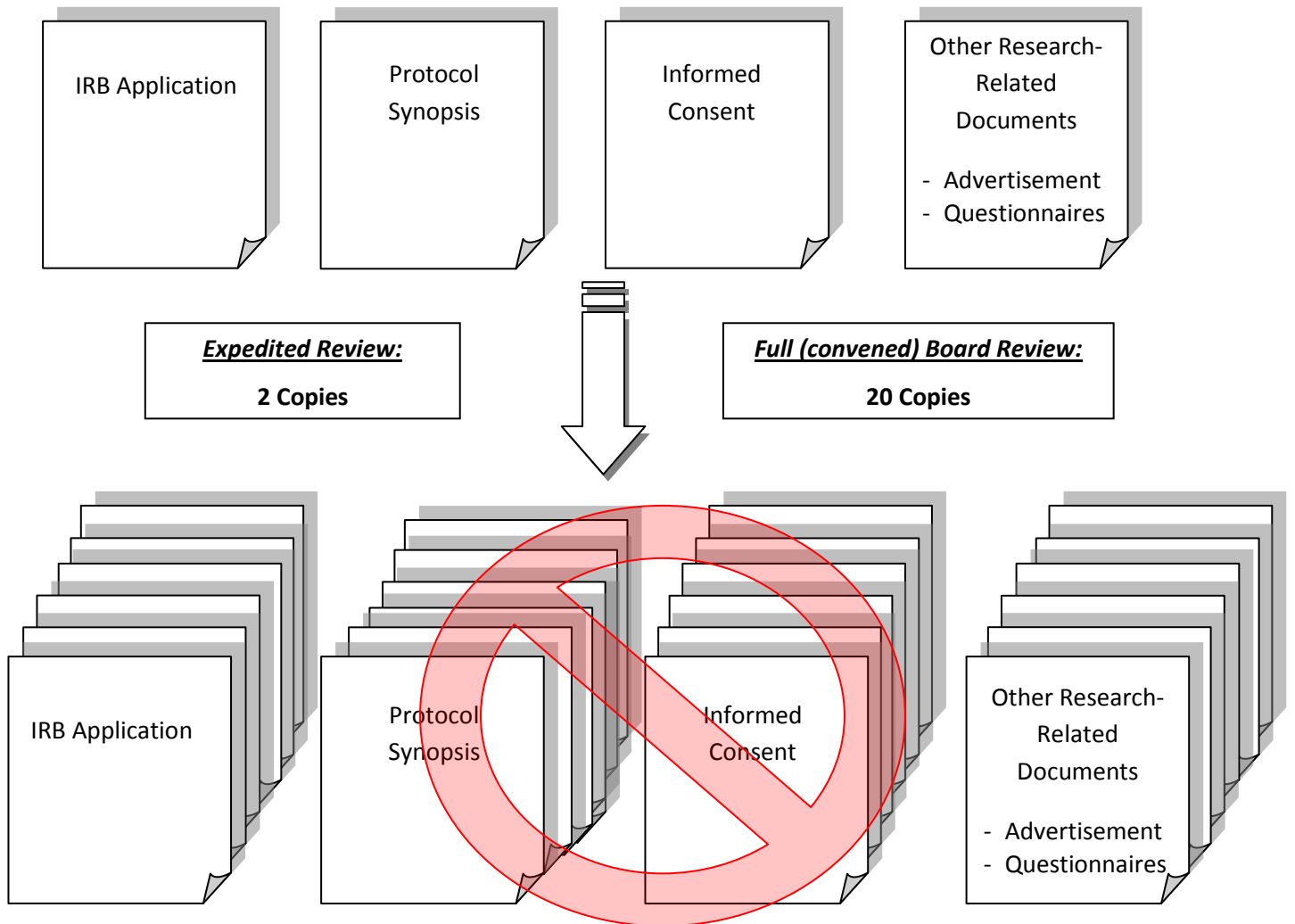


These are for internal (OPHS staff) use... Please include one original packet in addition to the corresponding copies



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PLEASE DO NOT SUBMIT LIKE THIS... This will NOT be accepted.



Simply submitting "stacks" of identical copies will cause delays in processing your application. The best (fastest) approach is to make individual complete "sets" of documents...then send them in to OPHS.

Submit the IRB packets to the Office for the Protection of Human Subjects (OPHS) during business hours, 8 a.m. - 5 p.m. Note that any submissions turned in after 5 p.m. will be recorded and documented as being submitted on the following (next) business day.

OPHS is located in the Center of BioHealth (CBH) building, Suite 160. Please send all inter-office mail correspondence to "OPHS". For more information about submitting an IRB protocol, please contact OPHS at 817-735-0409 or visit our website.

Also note, at this time, that no e-version or e-signature of an IRB-related document/ application will be accepted. An e-signature or e-version of a Conflict of Interest form may be accepted

when attached to an email sent by the signee (however, no "on behalf of" emails will be accepted).