

Investigator Responsibilities Poster

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Investigator Responsibilities: Protection of Human Research Subjects

YOU, as a UIC investigator, are responsible for conducting research in an ethical and professional manner. This responsibility entails a positive obligation to know and act in accordance with federal regulations (both the general regulations pertaining to human subjects protection in 45 CFR 46 and 21 CFR 50 & 56, and any specific regulations that may be imposed by the federal agency funding the research), state and federal laws (HIPAA, the Health Insurance Portability and Accountability Act is a federal law relevant to all research involving medical records), and UIC policies and procedures.

CHECKLIST: Investigator Responsibilities

This checklist has been designed to serve only as an aide to investigators and should not be considered comprehensive. You are strongly encouraged to regularly consult the UIC OPRS website (<http://tigger.uic.edu/depts/ovcr/research/>), federal OHRP and FDA websites (www.hhs.gov/ohrp/ and www.fda.gov), and the websites of your specific federal, state, foundation, and other agency funders for updated guidance regarding ethical research practices and the protection of human research subjects.

Section 1: Ready to go

- Research Protocol**
 - Is there a finalized research protocol in place that has been approved by the IRB and the funders/sponsors?
 - Is there a finalized clinical trial agreement, where appropriate, approved by UIC and the funders/sponsors?
 - If this is FDA-regulated research, are there adequate procedures in place for the control of the drugs, biological products, and/or devices under investigation?
 - If this is FDA-regulated research, are you knowledgeable of the investigator's responsibilities for conducting and supervising clinical trials under the FDA's Good Clinical Practice regulations?

- Research Recruitment and Consent Processes and Documents**
 - Have all recruitment materials (posters, flyers, brochures, information letters, introduction and recruitment scripts, web ads, emails and listserv notices, newspaper/tv/radio ads, etc.) been approved and stamped by the UIC IRB?
 - Have all consent documents been approved and stamped by the UIC IRB?
 - Have all HIPAA authorization documents, where appropriate, been approved and stamped by the UIC IRB?
 - Have waivers of consent, waivers of HIPAA authorization, and/or waivers of documentation (signed consent documents), where appropriate, been approved by the UIC IRB?
 - Is there an adequate plan in place to maintain secured files of signed consent and authorization documents for the required amount of time?
Note: The length of time that secured files must be maintained can vary by regulation, law, funder/sponsor, and/or professional organizational guidelines (for example, American Psychological Association guidelines) relevant to the specific research. UIC currently recommends retaining secured files for at least seven years, but please consult the guidelines relevant to your specific research funder/sponsor.

Research Personnel

- Do all research personnel have sufficient professional training and experience, including professional licensure where appropriate, to perform their roles?
- Do all research personnel understand your specific research protocol and their role(s) in it?
- Has a delegation log delineating the responsibilities of research personnel been completed and reviewed with the staff?
- Have all research personnel completed appropriate human subjects training?
 - **Note:** All research personnel accessing protected health information for research purposes, whether in medical records, data extraction forms, or a dataset, *must* complete HIPAA training.
 - UIC will accept most initial or basic non-UIC human subjects training for *non-UIC* research personnel (with the exception of NIH researcher training, which will *not* be accepted by UIC for any research personnel).
 - UIC investigators and research personnel are required to complete 2 hours of continuing education credit every 2 years.
- Do any research personnel have a financial or institutional conflict of interest? If research personnel have any conflict(s) of interest, an OVCR-approved conflict management plan must be in place.

Non-UIC Research Sites

- Are collaborative agreements or sub-contracts with non-UIC sites, where appropriate, approved by UIC and the non-UIC sites?
- Has appropriate human subjects protection documentation from all non-UIC site(s) been submitted to, and approved by, the UIC IRB?

Note: Appropriate human subjects protection documentation may include an IRB approval from the non-UIC site IRB, a finalized IRB Authorization Agreement between UIC and the non-UIC site, and/or a letter of support from an authorized executive at the non-UIC site. Please consult UIC OPRS regarding the documentation necessary for your research.
- For international research, has a local sponsor, host, or supervisor at the international site(s) been secured and, where appropriate, approved by the UIC IRB?

Section 2: Staying on Course

Continuing Review

- Have you noted the date on which the current approval of your protocol, and all of your recruitment and consent documents, expire?

Note: Unless you have received an exemption approval from the UIC IRB, your IRB approval will expire in no more than 1 year and must be re-approved, via a continuing review, before expiration. This is a federal regulation and there are no exceptions, “extensions,” or “grace periods.” It is your responsibility to submit the continuing review report in a timely fashion to ensure a lapse in IRB approval does not occur.
- Do your research personnel understand that all research activities - including subject recruitment, subject enrollment, data collection, and data analysis - must stop if your IRB approval expires? A lapse in IRB approval is non-compliance, and continuation of research activities after a lapse in IRB approval is serious non-compliance and reportable to unit heads, institutional officials, federal regulatory authorities and sponsors.
- Do your research personnel understand that only recruitment or consent documents stamped by the IRB with the current approval dates may be used to recruit and enroll subjects?

Making Changes

- Have you submitted an Amendment form and received UIC IRB approval for any changes made to the research before implementing those changes?
Note: Changes include, but are not limited to:
 - Research design, methodologies, and instruments
 - Research funding, sponsors, contracts, sub-contracts, collaborative agreements, and clinical trial agreements
 - Recruitment and consent processes and documents
 - Research personnel
 - Number or type of research subjects, particularly when vulnerable populations may be involved (for example, minors, prisoners, and/or the developmentally/decisionally impaired)
 - Research sites
 - Handling and control of drugs, biological products, and devices
 - Data and research document security and storage, particularly regarding JBVAMC-based research
- You may not initiate any amendments or changes to the research without first obtaining written IRB review and approval. The only exception is when it is necessary to avoid direct risks to subjects and the IRB should be immediately informed of this emergency change.
- Have you had to make an emergency change in order to prevent immediate danger or harm to a subject?
 - **Note:** An emergency change to the research may be made without prior approval by the IRB only when necessary to prevent immediate danger or harm to a subject. An emergency change must be reported to the UIC IRB within 5 days.

Adverse Events and Unanticipated Problems

- Have you reviewed with your staff what events require prompt reporting to the IRB?
 - Adverse events occurring locally that are unanticipated and related to the research;
 - Adverse events occurring at external sites that are unanticipated, related, and increase risk of harm;
 - Publication, interim analysis, safety monitoring report, or updated investigator's brochure that indicates an unexpected change to the risks or benefits of research;
 - Change in FDA labeling or withdrawal from marketing of a drug, biologic or device used in the research;
 - Subject complaints that indicate an unanticipated problem which cannot be resolved by the research staff;
 - Changes to the protocol made without IRB approval to eliminate apparent immediate harm to subjects;
 - Protocol violations that cause harm to subjects or others, place them at increased risk of harm, impact the scientific integrity, have the potential to recur or represent possible serious or continuing noncompliance;
 - Unanticipated adverse device effects;
 - Breach in confidentiality;
 - Incarceration of a subject in a protocol not approved to enroll prisoners;
 - Administrative hold by investigator or sponsor;
 - Events requiring prompt reporting by the protocol or sponsor;
 - Observed or apparent noncompliance
- Have events requiring prompt reporting been submitted to the IRB via the *Prompt Reporting* form

within the specified timeline?

- Unanticipated events and problems may be identified by research personnel, subjects (including subject complaints), research collaborators, or sponsors, and may be reported via the investigator to the IRB or directly to the IRB
- Local adverse events and unanticipated problems that are unanticipated, related and considered serious (e.g., death, life threatening injury, hospitalization or prolongation of hospitalization, persistent or significant disability, or a congenital anomaly) and changes made to eliminate immediate harm to subjects must be submitted to the IRB within 5 days of becoming aware of them.
- Other incidents requiring prompt reporting must be submitted to the IRB within 10 days of becoming aware of them.

Reporting and Record Keeping Requirements

- Has a signed consent document, unless a waiver of consent or a waiver of signed consent has been granted by the IRB, been obtained for each subject enrolled in the research?
Note: For subjects who are not legally able to consent for themselves (such as minors and the developmentally/decisionally impaired), has assent from the subject plus permission from their legally authorized representative been obtained, where applicable?
- Have you taken care not to enroll more than the total number of subjects approved by the UIC IRB?
- If the FDA or other funder/sponsor requires regular research reports, have you submitted a copy to the UIC IRB (usually in the annual continuing review packet submitted to the IRB)?
- If the FDA or other funder/sponsor has initiated a review, inspection, or audit of your research, did you immediately notify the UIC IRB?
- Have you maintained receipts and records of the use and disposition of all drugs, biological products, and/or devices?

Section 3: Crossing the Finish Line

Completing Your Research

- Has all data been stripped of both direct and indirect identifiers or destroyed?
 - **Note:** Fully de-identified data may be maintained after the closure or completion of the research. Please consult OHRP guidance regarding standards for the stripping of both direct and indirect identifiers from datasets.
 - Data should be de-identified or destroyed in strict accordance with the terms agreed to by subjects in the informed consent documents.
- Have you permanently closed or completed work on your research and submitted a final report to the UIC IRB?
 - **Note:** Research remains open until all analysis of directly or indirectly identifiable data, and all publications, reports, and presentations, are completed.
- Have all drugs, biological products, and/or devices been returned or destroyed in accordance with FDA standards and/or funder/sponsor agreements?
- Have adequate and appropriate provisions been made for the secure storage of all data and identifiable research-related documentation (such as consent documents)?

Questions? Call OPRS at 312-996-1711 or email uicirb@uic.edu