Checklists and Guidance Documents for Human Subjects Research

Institutional Review Board and Human Subjects Office

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Introduction

The UI Human Subjects Office and Institutional Review Board provide checklists and guidance documents to help researchers successfully navigate various aspects human subjects research. This educational tool provides an overview of these resources and where to locate them on the Human Subjects Office website.

ClinicalTrials.gov Checklist

The ClinicalTrials.gov Checklist is a new consolidation of all previous checklists regarding compliance with the regulatory requirement for registration and reporting results for Applicable Clinical Trials. It provides guidance for creating a new record, results reporting and Good Cause Extension requests.

> Location: Human Subjects Office website > ClinicalTrials.gov page > under "Help and Resources," "Getting Started – ClinicalTrials.gov Checklist," and "Resources."

Course-Related Student Project Checklist

The UI IRB has a policy regarding Course-Related Student Projects (UI IRB Standard Operating Procedures and Researcher Guide, Section I, Part 12.D). This policy allows certain research projects conducted as a course requirement to be done without IRB approval. Projects must be minimal risk, conducted to learn how to

conduct research, and the data or results must not be used outside the classroom or beyond a company or agency for which the project was conducted.

Instructors should carefully review the policy and use the Course-Related Student Project Checklist to collect information about the project and evaluate whether it fits under the policy. The Checklist is a fillable pdf document. If there is any doubt about whether a course project can be conducted without IRB approval, the student researcher should submit a Human Subjects Research Determination (HSRD) form to ask prior to conducting the project. There will be a pop-up message and red STOP sign in the checklist when the researcher needs to submit an HSRD form.

> Location: Human Subjects Office website > below the aerial photo > under "Resources for Faculty & Staff" and "Resources for Students."

Exemption Tool

The Exemption Tool has the regulatory description and citations for the eight categories of research that qualify for Exempt Status. It also contains any conditions, allowance or limitations for each category. Human Subjects Office staff and researchers can use this tool to see if a project qualifies for Exempt Status. It is important to know this BEFORE submitting a HawkIRB New Project form, so you select the correct type of review in Section IV.1.

> Location: Human Subjects Office website > Education and Training page > Educational Tools

FDA Site Inspection Guide

When a PI receives notice from the FDA about an upcoming site inspection, the FDA Site Inspection Guide provides guidance for what to do at these timepoints: upon notification and then prior to, during and after the FDA inspection. The Guide also includes an example intake form and a list of questions that are often asked during a site inspection.

When you receive an FDA site inspection notice, notify the following:

- Research team
- Department Executive Officer (DEO)
- Clinic Director
- Human Subjects Office (irb-monitors@uiowa.edu)
- UI Health Care HIPAA Privacy Officer
- UI Health Care Pharmacy or Investigational Drug Service (IDS)
- Human Resources (to arrange access to the Electronic Medical Record)
- Study sponsor
- Contract Research Organization (CRO) or Coordinating Center

Location: Human Subjects Office website > on the left hand menu bar under the UI IRB Standard Operating Procedures and Researcher Guide

Informed Consent Document Checklists

There are separate Informed Consent Document Checklists for biomedical research and social/behavioral research. These checklists are intended to help researchers and Human Subjects Office staff verify that the Informed Consent Document is consistent with the HawkIRB application. These checklists can be used not only when submitting a New Project form, but also when modifying the application or Informed Consent Document.

Both checklists have two parts; one for the sections of the Informed Consent Document that are required by the federal regulations and the other for the sections that are required by state law, local law, or institutional policy and are only added as needed based on the study design.

Location: Human Subjects Office website > Education and Training page > Educational Tools

Investigational New Drug/Investigational Device Exemption Checklists

When a Principal Investigator holds the Investigational New Drug (IND) application or the Investigational Device Exemption (IDE) with the U.S. Food and Drug Administration (FDA) and conducts the research, they have dual responsibilities as the Sponsor and the Investigator for the project. The IND Checklist and the IDE Checklist each specify the additional responsibilities, record keeping and reporting requirements for someone in the role of Sponsor/Investigator. These checklists are useful if this is a new role for the PI, or even if they just need a refresher.

The IRB Compliance and Education Program uses the IND and IDE Checklists during visits with the PI and research team when the IRB approves a New Project form for a PI who is the Sponsor/Investigator.

In addition to Definitions, Responsibilities and Additional Resources, these checklists include guidance for submission and reporting requirements for the FDA and the Institutional Review Board. Use of these checklists can ensure consistency in reporting to the FDA and IRB and ensure compliance with regulatory requirements.

Location: Human Subjects Office website > Education and Training page > Educational Tools

PI Transfer/Departure Checklists

As soon as it is known that a PI is leaving the UI, the PI, student team or grant administrator should complete one of the PI Transfer/Departure Checklists. There are separate checklists for funded and unfunded projects. And there is a third Human Research Protection Program (HRPP) Checklist that provides contact information, PI/student team considerations and reminders for steps to take prior to departure. This HRPP Checklist does not need to be submitted to the Human Subjects Office or the Division of Sponsored Programs.

Submitting the funded or unfunded PI Departure Checklists provides broad notification to UI entities that need to know about the departure. Those committees provide assistance for the transition process go smoothly.

Location:

- Human Subjects Office website > under the aerial photo > Resources for Faculty & Staff.
- Division of Sponsored Programs website > PI Transfer / Departure / Change of Status.