

HUA HUMAN
RESEARCH
PROTECTION
PROGRAM



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ESTR WEBSITE (IRB.HARVARD.EDU)

ESSENTIAL READING

HUMAN RESEARCH PROTECTION PROGRAM PLAN

- HRP-101 (ESTR Library → General)
- The purpose of this plan is to describe this Institution's plan to comply with ethical and legal requirements for the conduct and oversight of Human Research.
- The Human Research Protection Program is based on all individuals in this Institution along with key individuals and committees fulfilling their roles and responsibilities described in this plan.

INVESTIGATOR MANUAL

- HRP-103 (ESTR Library → General)
- The Investigator Manual is designed to guide investigators and study staff through policies and procedures related to the conduct of Human Research that are specific to the Harvard University Area (HUA) IRB office.
- General information regarding Human Research protections, as well as relevant federal regulations and guidance, has been incorporated throughout the manual where applicable.

Within the ESTR Library, there are various tabs according to the type of document.

Name	Document
HRP-001-SOP-HLC-Definitions	HRP-001-SOP-HLC-Definitions.pdf(0.03)
HRP-001-SOP-HUA-Definitions	HRP-001 - SOP - HUA - Definitions.pdf(0.10)
HRP-012-SOP-HLC-Observation of the Consent Process	HRP-012-SOP-HLC-Observation of the Consent Process.pdf(0.03)
HRP-012-SOP-HUA-Observation of Consent Process	HRP-012 - SOP - HUA - Observation of Consent Process.pdf(0.03)
HRP-013-SOP-HLC-Legally Authorized Representatives Children and Guardians	HRP-013-SOP-HLC-Legally Authorized Representatives Children and Guardians.pdf(0.04)
HRP-013-SOP-HUA-Legally Authorized Representatives, Children, Guardians	HRP-013 - SOP - HUA - Legally Authorized Representatives, Children, Guardians.pdf(0.02)
HRP-020-SOP-HLC-Incoming Items Directed to the IRB	HRP-020-SOP-HLC-Incoming Items Directed to the IRB.pdf(0.03)
HRP-020-SOP-HUA-Incoming Items	HRP-020 - SOP - HUA - Incoming Items.pdf(0.03)
HRP-021-SOP-HLC-Pre-Review	HRP-021-SOP-HLC-Pre-Review.pdf(0.03)
HRP-021-SOP-HUA-Pre-Review	HRP-021 - SOP - HUA - Pre-Review.pdf(0.03)

MOST RELEVANT DOCUMENTS

WORKSHEETS TAB

- HRP-309: HUA Harvard Policies
 - See sections on:
 - *Harvard Principal Investigator (PI) Eligibility*
 - *PI Rights Requests*
 - *Faculty Sponsor Ancillary Review Process for non-PI eligible individuals (e.g., student, fellows, etc.)*
 - *Harvard Training Requirement*

CHECKLISTS TAB

- None

MOST RELEVANT DOCUMENTS

TEMPLATES AND FORMS TAB

- HRP-213: Not Human Subjects Research Request Determination
- HRP-502: HUA Adult Consent Form
- HRP-502a: HUA Child Assent Form
- HRP-502b: HUA Parental or Guardian Permission
- HRP-502c: HUA Exempt Human Research Consent Script
- HRP-503: HUA Protocol
- HRP-504: HUA Repository Protocol
- HRP-506: HUA IIR Request

ANCILLARY REVIEW AND OTHER REFERENCE TAB

- IRB Study Submission Guide
- Ancillary Review Reference—Faculty Sponsor Review
- Principal Investigator Assurance—Reference

MOST RELEVANT DOCUMENTS

STANDARD OPERATING PROCEDURES

- HRP-013: Legally Authorized Representatives, Children, Guardians
- HRP-090: Informed Consent for Research
- HRP-091: Written Documentation of Consent