

HUA HUMAN RESEARCH PROTECTION PROGRAM



This is where you can find documents (e.g., SOPs, Worksheets, and Checklists) that are part of our HRPP Toolkit.

HARVARD UNIVERSITY

ESTR - IRB

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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.
- **Please read about additional considerations when there is a fCOI in the Investigator Manual.**

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

General	Worksheets	Checklists	Templates and Forms	Ancillary Review and Other Reference	Standard Operating Procedures
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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 section on *Harvard Conflict of Interest Policy*

CHECKLISTS TAB

- HRP-450: fCOI Determination

MOST RELEVANT DOCUMENTS

TEMPLATES AND FORMS TAB

- HRP-220: Non-Harvard Personnel
- HRP-221: Financial Interest Disclosure

ANCILLARY REVIEW AND OTHER REFERENCE TAB

- HRP-Ancillary Review Reference-
Financial Interest Review

MOST RELEVANT DOCUMENTS

STANDARD OPERATING PROCEDURES

- HRP-054: Institutional Conflicts of Interest
- HRP-055: Financial Conflicts of Interest