# PURPOSE

## This document describes the policies and procedures for developing, implementing, and revising policies and procedures for the UW Institutional Review Board (IRB) and the Human Subjects Division (HSD).

# POLICIES

## HSD has and maintains written policies and procedures for the major functions of the UW IRBs and HSD. As required by federal regulations, this includes procedures which the IRB will follow for:

### Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and institution;

### Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and

### Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to subjects.

## HSD and IRB policies and procedures must be consistent with:

### Applicable federal and state regulations;

### The terms of the UW’s Federalwide Assurance (FWA);

### UW Executive Order No. 24.

## The HSD Director has delegated authority from the Vice Provost of Research to develop, implement, and revise policies and procedures for the IRB and HSD (Reference 7.3).

### The HSD Director is expected to consult with other UW offices, groups, and individuals in developing policies and procedures, and in interpreting regulations and regulatory guidance.

## As established by the Vice Provost for Research (Reference 7.3), policies must have the written concurrence of the Institutional Official listed on the UW’s FWA.

## Procedures should provide sufficient step-by-step description with key operational details so that an independent observer can understand how HSD and the IRB operate and conduct their major functions.

# DEFINITIONS

## Federalwide Assurance (FWA): A written assurance of compliance with federal human subjects regulations that is provided by an institution conducting federally-supported, non-exempt, human subjects research. Through the FWA, an institution commits to federal agencies that it will comply with the regulations and requirements.

### Institutions conducting human subjects research that is supported by any component of the federal Department of Defense (DOD) are required to have a DOD Addendum to the FWA.

## Guidance: Written discussion of issues. Guidance may be free-standing documents or may be embedded within a Standard Operating Procedure (SOP). When embedded within a SOP, guidance is clearly labelled as “guidance”.

### Guidance enhances policies and procedures by providing additional information about specific ethical or regulatory issues.

## Institutional Official (IO): A high-level institutional official who has the authority to represent the institution named on a Federalwide Assurance (FWA), as well as the institutional components listed in the FWA. The individual should be at a level of responsibility that would allow authorization of necessary administrative or legal action should that be required.

### The IO is the Signatory Official on the Federalwide Assurance.

### The IO must assure that human subjects research to which the FWA applies is conducted in accordance with the terms of the FWA.

### At the UW, the IO is an Associate Vice Provost for Research.

## Material: In a SOP, this section refers to any equipment or materials needed to perform the activities described in the SOP. Examples: forms, checklists, templates, other SOPs.

## Policy: A guiding principle of operation, broad decision-making, or service.

## References: In a SOP, this section lists reference documents that are referred to, that provide the basis for the procedure, or that describe related or additional information.

## Standard Operating Procedure (SOP): The term used by HSD to refer to documents containing HSD and IRB policies and procedures.

# RESPONSIBILITIES

## Institutional Official. The Institutional Official is responsible for reviewing all IRB and IRB-relevant HSD policies, prior to implementation.

## HSD Director. The Director is responsible for the following areas, though any of these responsibilities may be delegated to others in HSD on a routine or *ad hoc* basis:

### Overall management of HSD and IRB policies and procedures. This includes: drafting new and revised documents; obtaining consultation and feedback; obtaining Institutional Official approval; and communication.

### Promoting and ensuring consistency in interpretation and implementation of the policies and procedures.

## HSD Staff. All HSD positions include the requirement to follow implemented HSD and IRB policies and procedures.

## IRB members. All IRB members are responsible for following implemented IRB policies and procedures.

# PROCEDURES

## New policies and procedures (SOPs)

### Format. New SOPs are written using the **TEMPLATE: SOP**. Variations in structure and content are permissible when appropriate for the content or for ensuring clarity.

### Content. Initial content is drafted by the HSD Director or designee.

#### The **TEMPLATE: SOP** specifies the required content sections.

#### The SOP may (optionally) include guidance in addition to the TEMPLATE-specified sections.

### Consultation and feedback. Consultation and feedback are obtained as appropriate to the content.

#### From whom. This may include (but is not limited to):

##### The Human Subjects Advisory Board

##### IRB members

##### HSD management and staff

##### The UW Attorney General’s Office

##### Faculty groups, such as the Faculty Council on Research or the School of Medicine Council on Graduate Education and Research

##### Other UW research compliance offices

#### Method. Consultation and feedback may be obtained through any methods and mechanisms that seem appropriate. For example, this may include: emailed draft documents, “brown bag” discussions, presentations at HSD staff meetings and IRB meetings, or presentations to other campus groups.

### Approval process. The HSD Director obtains approval from the IO by providing the IO with a copy of the final SOP document. This may be preceded or accompanied by a briefing – e.g., about the content, the feedback and consultation obtained, implications, regulatory basis, etc.

#### Approval is documented by the IO’s dated signature on the first page of the printed SOP.

### Implementation. SOPs are considered to be implemented when they are posted on the HSD website.

#### In rare circumstances, a SOP may instead be implemented by posting it to the secure internal HSD shared server. This implementation route is used only for a few SOPs that describe internal HSD processes not tied to regulatory requirements. Example: the SOP on shredding.

### Distribution and communication. SOPs are formally distributed to their audiences (e.g. HSD staff, IRB members, researchers, etc.) by being posted on HSD’s website. Implementation and distribution is formally communicated to all audiences through the regularly-published HSD e-Newsletter.

#### Exception: the rare SOPs that are implemented by being posted on the HSD internal server. These are communicated to HSD staff through internal email and/or all-staff meetings.

## Revision of SOPs

### Revisions of existing SOPs follow the same process as described above for new SOPs.

### SOPs are revised as needed, which is generally at least once every two years.

## Management of SOPs

### HSD and IRB SOPs are maintained by the HSD Information Manager.

### The implemented documents are stored as electronic documents in HSD’s Sharepoint Document Library.

#### When a new SOP is uploaded to the Document Library, it is automatically assigned a unique, identifying, Document Number. This number is included in the document. It is used for identification and tracking purposes.

### SOP management information is created, maintained and revised for each document.

#### It includes, for example: document ID #, date of implementation, version number, type of document, change notes, etc.

#### The management information is maintained in the document itself (e.g., footer) and in the HSD Document Library.

## Retirement of SOPs

### SOPs are retired for many possible reasons, such as regulatory changes that eliminate the need for the SOP.

### The HSD Director is responsible for making the decision to retire a SOP.

### The retirement process consists of:

#### Removing the SOP from the HSD website (or server);

#### Moving the SOP into the “Archived” section of the Document Library;

#### Updating the document management information.

## HSD and IRB Practices

### HSD staff and IRB members may occasionally develop practices for doing certain operations or handling certain issues.

### Such practices are not considered official HSD or IRB SOPs, even when they exist in writing and have been widely adopted.

### Practices must be consistent with implemented HSD or IRB SOPs.

### Practices that arise out of interpretation of regulations or policies should be evaluated by HSD management:

#### For consistency with existing SOPs, and

#### As a possible indication of the need for a new or revised SOP.

### Practices should not be construed as limitations on the flexibility or range of possibilities inherent in regulations and in official SOPs.

# MATERIALS

## **TEMPLATE: SOP** (available in the HSD Sharepoint Document Library)

# REFERENCES

## 45 CFR 46.103(b)(4) and (5); 21 CFR 56.108(a) and (b)

## OHRP, “Guidance on Written IRB Procedures”; July 1, 2011.

## Memo from Interim Vice Provost for Research; December 30, 2010; “Roles, responsibility, and delegated authority of the Human Subjects Division and the UW Institutional Review Boards”

## Executive Order No. 24, “Research with Human Participants”