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| University of Washington Human Subjects DIvision | **SOP IRB Review**  |

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**1** **PURPOSE and APPLICABILITY** [**[top]**](#Top)

 This document describes the procedures used by the University of Washington Institutional Review Boards (IRB) and Human Subjects Division (HSD) for conducting IRB review. It also references the numerous tools (e.g., Worksheets) used by the IRB and HSD in support of the review process.

Separate documents describe additional processes for these specialized types of IRB review:

* **SOP Limited IRB Review**
* **WORKSHEET Options for IRB Actions**

**2** **POLICY** [**[top]**](#Top)

2.1 **IRB review requirement.** Prospective IRB review and approval is required for all non-exempt human

 subjects research activities in which the UW is engaged.

 Approval cannot be granted retrospectively, after a research activity has begun. Review is required:

* Before beginning a project (initial review).
* Before making any modifications to the project except when necessary to eliminate apparent immediate hazards to subjects (Section 4).
* At least once per calendar year for approved projects (continuing review), unless not required by the regulations governing the study or the IRB (Section 5).
* For any proposed corrective action and/or preventive action (other than those necessary to prevent immediate hazard to subjects) in association with a Report of New Information.

2.2 **Scope of IRB Review.** IRB review will cover and is limited to the activities in which the UW is [engaged](https://www.washington.edu/research/hsd/guidance/engagement/) and the activities in which any institutions or individuals relying on the UW IRB’s review are engaged.

2.3 **Actions of the IRB.** Federal regulations and Washington State law give the UW IRB the authority to take

specific actions. UW policy grants additional authority to the UW IRB, and to the HSD Director, for some

specific additional actions. See the **WORKSHEET IRB Review Outcomes**, **WORKSHEET Options for IRB Actions**, and **WORKSHEETs Primary Reviewer** for details.

**3** **PROCEDURES** [**[top]**](#Top)

3.1 **Materials reviewed.**

3.1.1 Researchers are expected to use the application forms and supplements, as well as guidance and instructions provided by the Human Subjects Division (HSD), to provide sufficient information to HSD and the IRB so that specific required determinations can be made and the applicable criteria for IRB approval can be assessed. IRB members, designated reviewers, and consultants may request additional information, materials, or clarification as needed.

3.1.2 All new and modified materials associated with an IRB review, as well as historical application materials, are available to IRB members through the *Zipline* electronic system, including the IRB Protocol and associated Supplements, all consent and recruitment materials, and any specialty items such as an Investigator Brochure. Continuing review applications also include a Status Report form which includes a summary of the following information: total enrollment; adverse events and outcomes; unanticipated problems; number of withdrawals and reasons; complaints; modifications not previously reported; relevant recent literature; interim findings; multi-center trial reports; researcher’s assessment about the risk/benefit ratio.

3.1.3 Requirements for providing review materials to IRB members for a convened IRB meeting are described in the **SOP Convened IRB Meeting Administration**.

3.2 **Researcher sign-offs.**

3.2.1 **Researchers or formally–designated proxies** are required to “sign off” on applications when they are submitted, as described in the **POLICY Signatures and Attestations** . This electronic process documents their acknowledgement of a few key responsibilities related to conducting human subjects research.

3.2.2 **Faculty advisor**. Faculty advisors are required to acknowledge and approve the initial IRB applications submitted by students, post docs, fellows, or residents (**POLICY Signatures and Attestations**). This is accomplished through the ancillary review process described in the **Faculty Advisor Guide**. The faculty advisor review may occur concurrently with the IRB review, but final IRB approval will not be issued until the faculty advisor sign-off has been provided.

3.2.3 **Participating non-UW sites**. When the UW IRB is acting as the Single IRB for non-UW sites, all site-specific materials for the non-UW sites are submitted with the site application. When there are site-specific materials, the PI or PI Proxy for the parent study must confirm that all site-specific materials have been received when they complete the **Submit Site Materials** activity.

3.3 **Level of review and reviewer system.**

3.3.1 Pre-reviewis conducted by HSD staff for all submissions to ensure that applicable regulatory requirements and determinations are identified and that the materials and information in the application are complete. The information gathered during the pre-review determines whether the application will be reviewed by the convened IRB or by [expedited review](https://www.washington.edu/research/glossary/expedited-review/) (**SOP Pre-Review**; **WORKSHEET Expedited Review**).

3.3.2 For submissions that require review by the convened IRB, an IRB member with appropriate expertise is assigned to be the **primary reviewer.** Another IRB member may be assigned to be a **secondary reviewer** if additional expertise is needed. Use of a secondary reviewer or consultant is required for the review of studies that involve harmonization of multiple documents (for example, in a clinical drug trial the risks may be described in a study protocol, investigator brochure, and drug package insert, in addition to the IRB Protocol and consent forms). The **SOP IRB Member Standards and Responsibilities** and **SOP Convened IRB Meetings** describe expectations and procedures for primary and secondary reviewers.

3.3.3 Applications that involve prisoner participation may also require assignment of a [prisoner advocate](https://www.washington.edu/research/glossary/prisoner-advocate/) reviewer or consultation from a prisoner advocate (**GUIDANCE Prisoners**; **SOP Prisoners**).

3.3.4 Applications that involve populations that may be vulnerable to coercion or undue influence may require additional safeguards and review by and/or consultation from individuals with appropriate expertise.

3.3.5 **Delegation of IRB authority, expedited review, and limited IRB review.** As allowed by federal regulations, a UW IRB Chair may delegate the authority to a **designated reviewer** to conduct expedited IRB review and limited IRB review of all types of IRB applications and to grant a waiver or alteration of HIPAA authorization (see **SOP IRB Members**). This includes the ability to exercise all of the authorities of the IRB except disapproval, suspension, or termination (**WORKSHEET Expedited Review**; **WORKSHEET IRB Review Outcomes**).

3.3.6 **Consultants** may be asked to provide information and expertise to the IRB to ensure an appropriate review. Consultation may be used for convened IRB review, either in person or through written comments provided to the IRB, and for expedited reviews through correspondence between the consultant and the designated reviewer (**SOP IRB Consultants**).

3.3.7 **Conflict of interest management**. There are restrictions on whether and how IRB members can participate in review of applications for which they have a conflict of interest. See **SOP Reviewer Conflict of Interest** for details on this topic.

3.4 **Convened meeting requirements.**

Details about requirements for, and conduct of, convened IRB meetings are described in **SOP Convened IRB Meetings**, **SOP IRB Members**, **SOP Reviewer Conflict of Interest**, **SOP IRB Member Standards and Responsibilities** and **SOP Convened IRB Meeting Administration**.

3.5 **Criteria for approval & IRB review outcomes.**

3.5.1 The UW IRBs apply the applicable criteria for granting IRB approval to all reviews. The Common Rule and FDA criteria for approval are described in the **WORKSHEET Criteria for IRB Approval**. Criteria and required determinations specific to particular regulatory agencies (e.g., Department of Defense, Food & Drug Administration) are described in regulation-specific WORKSHEETs, SOPs, and/or GUIDANCE documents, as are criteria and required determinations for federally-protected subject populations (prisoners, children, pregnant women and fetuses, nonviable neonates, and neonates of uncertain viability).

3.5.2 Possible IRB review outcomes are described in **WORKSHEET IRB Review Outcomes** and **WORKSHEET Options for IRB Actions**.

3.5.3 Researchers may appeal an IRB review outcome as described in the **SOP Appeal of IRB or HSD Determination**.

3.6 **Approval date, effective date, and duration of approval.**

3.6.1 The **approval date** for an application is the date when the IRB review outcome is “approval” or “conditional approval”. The **effective date** is the date when the approval is considered to be effective (i.e., the review has been fully completed and the researcher can begin the research).

* Studies that are “approved” by the IRB have the same approval and effective dates.
* When a study is “conditionally approved” by the IRB, the “effective date” is the date on which the conditions are verified.

3.6.2 **Duration of approval.** At the time of study approval (granted through initial review or continuing review), the IRB may be required to specify the duration of the approval period, if an approval period is required by the regulations that govern the study. The IRB may require more frequent continuing review than is required by the applicable regulations. The duration of the approval period determines the date of the next continuing review. See **WORKSHEETs Primary Reviewer** for details.

* Under the HSD Flexibility Policy (**GUIDANCE Authority and Responsibilities of HSD and UW IRB**) studies approved under the Original Common Rule may receive an approval period of up to three years so long as the following criteria are met: 1) there is no federal support; 2) the study is minimal risk; 3) FDA regulations do not apply to the study; 4) there are no restrictions imposed by HSD or the UW IRB on the researcher; 5) there is no institution relying on the UW IRB for review of its engagement in the research. If federal funding or support is obtained, a modification must be submitted to add the funding. If the last continuing review occurred more than one year prior, a continuing review application must be submitted in order to set the approval period to one year or less.

3.7 **Documentation and communication of IRB review outcomes.**

3.7.1 HSD staff document review outcomes through three processes: *Zipline* data entry (**INSTRUCTIONS Zipline for Staff**), completion of the **CHECKLIST Regulatory**, and the IRB Meeting Minutes (**SOP Convened IRB Meeting Administration**).

3.7.2 The IRB communicates its review outcomes, actions, and determinations, as required by federal regulations and as appropriate to the situation. These communications are generated through *Zipline*. Signatures are not provided on IRB approval letters. All approval letters generated through *Zipline* are considered official UW communications. They are generated and sent only by individuals who have been authorized to act on behalf of the UW IRB.

* **Researcher.** Outcomes are reported to researchers using standardized, written letter templates that are sent through *Zipline*. Designated reviewers prepare and send the letters for expedited reviews. HSD staff prepare and send the letters for convened IRB review outcomes, consulting with the primary or secondary reviewers and/or the IRB Chair when guidance is needed. When appropriate, a phone call may communicate the outcome in advance of written communication.
* **Institution.** Outcomes are reported to the UW by making the meeting minutes and reports of expedited reviews available to the Institutional Official listed on the UW Federal Wide Assurance.
* **IRB.** Outcomes of reviews conducted by the expedited process are made available to the IRB in an automatically-generated report that accompanies the agenda for convened IRB meetings.
* **Sponsor, other UW components, or external entities.** A copy of the IRB approval letter may be provided to these entities by the researcher or HSD.
* **Participating non-UW sites in research for which the UW IRB is acting as a Single IRB.** The lead researcher for the overall study is responsible for communicating review requests, requirements, conditions, and outcomes to participating researchers.

3.8  **Researcher response.**

 Researchers are expected to respond to IRB reviews by the deadline described in the written correspondence and in the **WORKSHEET IRB Review Outcomes**. See **SOP Administrative Actions** for information about reminder notifications and actions associated with researcher non-response.

**4** **MODIFICATION SPECIFIC PROCEDURES** [**[top]**](#Top)

4.1The requirements and considerations for IRB review of Modification applications are described in the **WORKSHEET Primary Reviewer, Continuing Review and Modification**.

4.2 Deviations from IRB approved procedures may be made to a study without obtaining prospective IRB approval if it is necessary to eliminate apparent immediate hazards to subjects. However, a report of the deviation (including rationale and outcome) must be provided to the IRB using the [RNI process](https://www.washington.edu/research/hsd/study-activities/report-events-and-new-information/guide-to-reporting-new-information/), within 10 days of the deviation. The IRB reviews the deviation(s) to determine whether they were consistent with ensuring subjects’ continued welfare.

**5** **CONTINUING REVIEW SPECIFIC PROCEDURES** [**[top]**](#Top)

5.1 The purpose of continuing review is to periodically reassess the totality of the research to assure that, among other things, risks to subjects are being minimized and are still reasonable in relation to anticipated benefits (if any) to the subjects and the knowledge that is expected to result. See the **WORKSHEET Primary Reviewer, Initial Application** and **WORKSHEET Primary Reviewer Continuing Review and Modification** for guidance about when continuing review is required, duration of approval period, and details about IRB procedures and requirements for conducting continuing review.

5.1.1 Continuing review of the overall protocol is conducted for multi-institutional studies for which the UW IRB is acting as a Single IRB.

5.1.2 The IRB, as part of the continuing review process, may ask HSD staff to obtain verification from sources other than the investigators about specific aspects of the study.

5.2 Continuing review must occur as usual, even when there is an unresolved Report of New Information (RNI) or a suspension of some or all parts of the research. The IRB may or may not need to consider the suspension or pending RNI as part of the continuing review.

5.3 Tracking IRB approval periods and preventing alapsed approvalis ultimately the researcher’s responsibility. However, HSD does list the expiration date (if any) in approval letters and sends researchers automated courtesy reminders (**SOP Administrative Actions**) through *Zipline*.There is no regulatory basis for a “grace period” extending IRB approval beyond the expiration date. Activities that occur without current IRB approval are considered noncompliance (**SOP Research Procedures Conducted Without Prior IRB Approval**).

5.4 **Lapse in IRB Approval.**

5.4.1 **Expiration date**. IRB approval expires at 1:00 AM on the day following the last day of the IRB approval period. The Zipline system automatically changes the study status to “Lapsed Approval” and emails the researcher and appropriate study team members.

5.4.2 If IRB approval expires, no new subjects may be enrolled and all research activities involving human subjects must stop unless the activities meet one or more of the exceptions listed below. If an exception is applicable, information about the continued research activities, and the rationale for continuing them, must be communicated immediately to the IRB using the [RNI process](https://www.washington.edu/research/hsd/study-activities/report-events-and-new-information/guide-to-reporting-new-information/). Though the researcher makes the initial decision about the best interests of subjects, the IRB must concur and will determine on a case-by-case basis whether the activities may continue while re-approval is being obtained. The decision may be made by the IRB Chair, another IRB member(s) designated by the Chair, or the convened IRB. The determination may be made for all subjects or for specific individuals. If the IRB decides that already enrolled subjects should continue to receive any study intervention, data collection (especially safety information) should also continue.

Exceptions to the requirement that all research activities must stop once IRB approval has lapsed:

* Continuation of activities necessary to eliminate apparent, immediate hazards to subjects.
* The research intervention (if any) may be of direct benefit to individual subjects.
* Withholding the research intervention (if any) may increase risks to subjects.

5.4.3 Continuing review should be conducted as soon as possible after a lapse. Human subjects research activities may resume as soon as the study has been re-approved by the IRB. Any corrective actions associated with the lapse (e.g., a pattern of noncompliance with continuing review requirements) are handled using the RNI process (**SOP HSD Management of RNI**).

* **Lapsed studies that cannot be closed without the submission of a status report:** FDA regulated studies, studies that involve more than minimal risk, studies that were initially reviewed by the full board. Studies that are in data analysis, single patient expanded access applications, and Humanitarian Use Device (HUD) applications are excluded from this list and are eligible for administrative closure as described below. It is **HSD policy** that these studies can only be closed with the submission of a status report to confirm all human subjects research activities ceased at time of lapsed approval. At 60 days of lapsed approval, HSD may refuse to review new applications or modifications from the researcher until a status report is received. If no status report has been received and the study has been lapsed for 90 days, this will be considered continuing noncompliance and the study may be terminated by the IRB (as described in section 6).
* **Lapsed studies that will be administratively closed** **when IRB approval has been lapsed for 90 days and no continuing review application or closure has been submitted**: all studies excluding those that cannot be closed without the submission of a status report as explained above. It is **HSD policy** that these studies will be considered inactive and abandoned when IRB approval has been lapsed for 90 days and no continuing review application or closure has been submitted. These studies will be administratively closed by HSD staff.
* **Exceptions**: **(1)** The study must remain open if there is an unresolved RNI. **(2)** Multi-patient expanded access applications do not fall into either category above and require a separate follow-up process as described in **SOP Administrative Actions**. **(3)** Other exceptions may be made in extenuating circumstances (e.g., the PI has had a medical emergency) and only with the approval of a member of the Leadership Team.

5.4.4 Review **SOP Administrative Actions** for additional HSD procedures associated with lapsed approval.

**6** **SUSPENSION AND TERMINATION SPECIFIC PROCEDURES** [**[top]**](#Top)

6.1 Information about the purpose and rationale for suspension and termination can be found in the **WORKSHEET IRB Review Outcomes**.

6.2 Suspension or termination is immediately reported in writing (and usually, by phone) to the researcher and to HSD Leadership.

6.3 A suspension may imposed by the IRB Chair (rather than the convened IRB) if it is documented with a detailed Note to File. Alternatively, the IRB Chair may request that HSD Leadership impose a suspension (**SOP HSD Management of RNI**).

6.4 Requirements for the formal IRB suspension or termination letter include:

* A statement describing the reasons for the suspension or termination
* Identification of which activities are suspended or terminated, otherwise it is assumed the suspension or termination applies to all research activities.
* Identification of appropriate action to protect the safety and welfare of past or currently enrolled subjects, and a timeline for fulfilling those requirements. The IRB may consult with the researcher about these issues and the IRB should always consider: a) what activities (if any) should be allowed to continue (e.g., monitoring visits); and b) what information or additional procedures (if any) should be provided to past or currently enrolled subjects or other parties, as well as how and by whom.

**Examples of actions that may be required to protect subjects.**

* + Inform subjects about termination or suspension
	+ Make appropriate plans for discontinuing subject participation such as requiring gradual withdrawal from study medication
	+ Allow already enrolled subjects to complete certain procedures such as a study intervention or monitoring procedures and/or require additional follow-up or monitoring of subjects.
	+ Require the responsibility for subjects to be transferred to another researcher
	+ Require reporting to other parties
* A timeline for fulfilling the requirements

6.5 For terminations, a formal IRB termination letter must be sent to the Institutional Official on the UW’s FWA, Associate Vice Provost for Research Compliance, HSD Leadership, School of Medicine Director of Compliance (for SoM studies only), and the researcher’s academic department chair.

6.6 Reporting of the suspension or termination to a federal oversight agency, funding body, other institution(s) relying on the UW IRB, or other components of the UW may be required and appropriate, as described in any applicable reliance agreements, the **SOP Federal Reporting**,and **INSTRUCTIONS Reporting to Others**.

6.7 Continuing review must occur as usual, even when the study, or a part of the study, has been suspended. The date by which the continuing review must occur does not change due to either a suspension or the lifting of a suspension, unless the IRB specifically makes a change.

6.8 Terminated research is permanently closed and no longer requires continuing review. However, the IRB may require a Closure Report from the researcher before it closes the IRB application.

**7. T****RANSFERS OF IRB OVERSIGHT** [**[top]**](#Top)

7.1 **Between UW IRBs.** In general, the same IRB retains oversight of a study throughout the life of the project. However, it is sometimes necessary to transfer the review responsibility from one UW IRB to another UW IRB, on a temporary or permanent basis. Transfer from one UW IRB to another may be necessary in situations including but not limited to:

* Proposed modifications or Reports of New Information that make the capacity or expertise of another UW IRB more appropriate.
* Changes to the distribution of workload across the UW’s IRBs.
* A change to the lead researcher’s departmental affiliation.

7.1.1 **Identifying the need.** The need to transfer a study may be identified by any HSD staff member but must be approved by a Team Lead or a member of the HSD leadership team. The decision to transfer between UW IRBs is made exclusively by HSD staff and leadership. There is no role for study teams in this decision or in accomplishing this transfer.

* + 1. **Temporary transfers.** These are transfers for which another IRB will review only one or a few submissions. The need for this transfer is communicated directly between staff and is documented by naming the IRB that reviewed the submission in the outcome letter for the submission. Study teams are not typically informed in advance of this transfer but may be informed at the discretion of staff.
		2. **Permanent transfers.** These are transfers for which another IRB will assume full oversight of a study, either permanently or for an extended period. The need for this transfer is communicated directly between staff. Study teams are notified, and the transfer is documented by a staff member by:
* Adding a public comment to the application in Zipline documenting the reason for the transfer, and
* Changing the letter designation of the study in Zipline to the letter designation of the new IRB.

7.1.4 **Notifying key parties.** It is the responsibility of the research team to notify any other offices or organizations (such as the funding agency, the FDA, the sponsor, etc.) who require information about these changes in IRB oversight.

* 1. **Between the UW IRB and a non-UW IRB.** In general, the IRB(s) of one institution retain oversight of a study throughout the life of the project. However, it is sometimes necessary to transfer the review responsibility between a UW IRB and a non-UW IRB, on a temporary or permanent basis. Transfer from one UW IRB to another may be necessary in situations including but not limited to:
	+ The ongoing activities become subject to a single IRB requirement and a different IRB will assume the role of the single IRB.
	+ The institutional affiliation of the PI changes and the IRB of their new institution will assume oversight.
	+ The organization that runs the IRB is acquired by another organization whose IRB will assume oversight of the research.
		1. **Identifying the need.** The need to transfer a study may be identified by the study team, the funding agency or sponsor, another institution, or any HSD staff member, but must be approved by a Reliance Administrator or a member of the HSD leadership team.

7.2.2 **Documenting the transfer.** Reliance Administrators follow the instructions in the **SOP Internal Reliance Agreements** and the **SOP External Reliance Agreements** to assess the potential transfer, document transfer related information, and identify who will notify key parties of the change of IRB oversight.

7.2.3 **Review upon transfer from a non-UW IRB.** When the transfer is from a non-UW IRB to the UW IRB, the UW IRB typically performs a complete review of the research as it is currently being conducted which includes establishing a new approval period and frequency of continuing review. In some circumstances, with the approval of a member of HSD’s leadership team, this review may be limited to performing a continuing review.

**8** **CLOSING THE IRB APPLICATION** [**[top]**](#Top)

8.1 When the human subjects research activities that are being reviewed by the UW IRB are complete, the

UW IRB application may be closed. See **WORKSHEET Human Subjects Research Determination** for regulatory definitions and guidance about what constitutes human subjects research. In short, when all research interactions and interventions with subjects are complete and the collection and approved analysis of private, identifiable subject data is complete, human subjects research activities are complete and the application can be closed.

 8.1.1 Some funding entities require IRB approval to be maintained for the duration of the funding,

 even if human subjects research activities are complete; it is the researcher’s responsibility to

 be aware of these requirements and work with HSD staff so that a study is not closed.

8.2 **Multi-institutional studies**.

 8.2.1 **UW researcher participating in a multi-institutional study** and the UW involvement is reviewed by the UW IRB. The IRB application may be closed when the UW’s participation in the study has been completed, even if the parent study has not yet been completed. However, if the UW is the direct recipient of federal funding for the overall study, IRB oversight must continue until all human subjects activities supported by the funding have been completed at all participating sites.

8.2.2 **UW IRB is the single IRB** for one or more non-UW sites in addition to the UW involvement. The IRB involvement of each participating site can be closed when the site has completed its participation. However, human subjects research for the study as a whole cannot be considered completed until the approved human subjects research activities have been completed at all sites, including any coordinating or data center.

8.3 Researchers are expected to formally inform HSD when a study no longer includes human subjects research activities. The closure procedure for researchers is described on [this webpage](https://www.washington.edu/research/hsd/study-activities/close/) with additional details for HSD staff in the **SOP Administrative Actions**.

8.4 **Administrative status inquiry**. Studies approved under the Revised Common Rule that have no regulatory requirement for continuing review and no expiration date and are led a student PI may be contacted by HSD to verify whether the submission is still active. If there is no response within 30 days, HSD will administratively close the submission for inactivity. Administrative closure procedures are described in the **INSTRUCTIONS Zipline for Staff**.

8.5 Researchers may maintain identifiable, private data or specimens after the IRB application is closed so

 long as the data or specimens are not being studied or analyzed for research purposes. Future,

 secondary research analysis of existing data or specimens may require prospective IRB approval or

 determination of exempt status.

8.6 **Not an IRB action**. Closure is not an IRB process. It marks the end of IRB oversight (except in cases of subsequent RNIs). Researchers are automatically notified via email when the study’s IRB oversight is concluded.

8.7 After an IRB application is closed, researchers remain responsible for complying with [records retention](https://finance.uw.edu/recmgt/)

 [requirements](https://finance.uw.edu/recmgt/) and maintaining subject privacy and confidentiality and honoring any other commitments

 made to subjects as described in the IRB application and consent form. The IRB is responsible for

 retaining the study record in compliance with records retention requirements.

**9** **IRB Records** [**[top]**](#Top)

9.1 IRB records consist of all items reviewed by the IRB, including staff pre-reviews. At a minimum, this includes:

* Protocols (in the form of the IRB Protocol application form)
* Scientific evaluations (e.g., funded grant applications)
* Records of continuing review activities, if required by regulations or the IRB, including the frequency for next continuing review
* Reports of injuries to participants if the injuries meet the definition of an unanticipated problem
* Correspondence between the IRB and researcher
* Statements of significant new findings provided to participants
* For reviews conducted by the expedited procedure: the specific permissible category; description of the action taken by the reviewer (e.g., approval); any findings required by the applicable regulations
* Regulatory Checklist, which includes determinations required by the regulations

9.2 All IRB records are retained for the period described in the UW Records Retention Schedule for HSD, which is at least three years after completion or cancellation of research.

9.3 IRB records are organized so as to allow a reconstruction of a complete history of IRB actions related to review and approval of the study.

9.4 IRB records are accessible for inspection and copying by authorized representatives of federal agencies or departments at reasonable times and in a reasonable manner.

9.5 IRB records are stored in a manner that maintains confidentiality, on a secure server or (for paper records) in a locked, limited-access location.

**10** **RELATED MATERIALS** [**[top]**](#Top)

 10.1 CHECKLIST Regulatory

10.2 [Faculty Advisor Guide](https://www.washington.edu/research/hsd/training/zipline-online-help-library/faculty-advisor-guide/)

10.3 [GUIDANCE Prisoners](https://www.washington.edu/research/hsd/guidance/prisoners/)

 10.4 INSTRUCTIONS Reporting to Others

 10.5 [INSTRUCTIONS Zipline for Staff](https://www.washington.edu/research/hsd/training/zipline-online-help-library/hsd-staff-guide/)

 10.6 POLICY Signatures and Attestations

10.7 SOP Administrative Actions

10.8 [SOP Appeal of IRB or HSD Determination](https://www.washington.edu/research/policies/sop-appeal-of-irb-or-hsd-determination/)

10.9 [SOP Convened IRB Meetings](https://www.washington.edu/research/policies/sop-convened-irb-meetings/)

 10.10 SOP Convened IRB Meeting Administration

 10.11 SOP External Reliance Agreement

 10.12 SOP Federal Reporting

 10.13 SOP HSD Management of RNI

 10.14 SOP Internal Reliance Agreement

 10.15 [SOP IRB Consultants](https://www.washington.edu/research/policies/sop-irb-consultants-2/)

10.16 [SOP Reviewer Conflict of Interest](https://www.washington.edu/research/policies/sop-reviewer-conflict-of-interest/)

10.17 [SOP IRB Members](https://www.washington.edu/research/policies/sop-irb-members/)

10.18 [SOP IRB Member Standards and Responsibilities](https://www.washington.edu/research/policies/sop-irb-member-standards-and-responsibilities/)

10.19 [SOP Limited IRB Review](https://www.washington.edu/research/policies/sop-limited-irb-review-2/)

10.20 [SOP Pre-Review](https://www.washington.edu/research/policies/sop-pre-review-2/)

10.21 [SOP Research Procedures Conducted Without Prior IRB Approval](https://www.washington.edu/research/policies/sop-research-procedures-without-irb-approval/)

10.22 [WORKSHEET Criteria for IRB Approval](https://www.washington.edu/research/forms-and-templates/worksheet-criteria-for-irb-approval/)

10.23 [WORKSHEET Expedited Review](https://www.washington.edu/research/forms-and-templates/worksheet-expedited-review/)

10.24 [WORKSHEET Human Subjects Research Determination](https://www.washington.edu/research/forms-and-templates/worksheet-human-subjects-research/)

10.25 [WORKSHEET IRB Review Outcomes](https://www.washington.edu/research/forms-and-templates/worksheet-irb-review-outcomes/)

10.26 [WORKSHEET Options for IRB Actions](https://www.washington.edu/research/forms-and-templates/worksheet-options-for-irb-actions/)

10.27 WORKSHEET Primary Reviewer, Continuing Review and Modification

10.28 WORKSHEET Primary Reviewer, Initial Applications

**11** **REGULATORY REFERENCES** [**[top]**](#Top)

 11.1 45 CFR 46 and 21 CFR 56

 11.2 45 CFR 46.103b4 [pre-2018 requirements] and 45 CFR 46.108a3 [2018 requirements]

 11.3 45 CFR 107 [pre-2018 and 2018 requirements]

 11.4 45 CFR 108b [pre-2018 requirements and 2018 requirements]

 11.5 45 CFR 109e [pre-2018 requirements] and 45 CFR 46. 109e-g [2018 requirements]

 11.6 45 CFR 46.110 [pre-2018 requirements and 2018 requirements]

11.7 45 CFR 164.512

 11.8 21 CFR 56.107

11.9 21 CFR 56.108(a)

11.10 21 CFR 56.108(c)

11.11 21 CFR 56.109(f)

11.12 21 CFR 56.110

11.13 SACHRP Recommendation regarding definition of a minor change in research under 45 CFR 46 and 21

CFR 56, Attachment B, October 13, 2011. <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2011-october-13-letter-attachment-b/index.html>

 11.14 OHRP, “Guidance on Continuing Review of Research”, November 10, 2010

11.15 OHRP, “Memorandum to the Cancer Therapy Evaluation Program (CTEP) of the National Cancer

 Institute Regarding IRB Review of Protocol and Informed Consent Changes”, 9/29/08.

11.16 OHRP, “2018 Requirements FAQs: How should IRBs approach the continuing review of research that

 remains active beyond long-term follow-up or data analysis, but that is eligible for expedited review

 under categories 8(b) or 9 of the 1998 OHRP Expedited Review List in light of the new provision at

 46.109(f)(1)(i) of the 2018 Requirements, which eliminates the requirement for such continuing

 review unless an IRB determines otherwise?”

11.17 FDA, “Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Continuing Review after Clinical

 Investigation Approval”, February 2012

11.18 FDA, “Guidance for IRBs, Clinical Investigators, and Sponsors: Considerations When Transferring Clinical Investigation Oversight to Another IRB”, May 2014

11.19 OHRP, “Considerations in Transferring a Previously-Approved Research Project to a New IRB or Research Institution”, May 23, 2012 (DRAFT)

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|  **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 3.4 | 09.25.2025 | 09.25.2025 | Add administrative status inquiry section |
| 3.3 | 11.26.2024 | 11.26.2024 | Add information about scope of IRB review |
| 3.2 | 06.25.2024 | 06.25.2024 | Revise reference to CHECKLIST Regulatory |
| 3.1 | 11.02.2023 | 11.02.2023 | Move information about transfers of IRB oversight to this SOP from other SOPs |
| 3.0 | 07.27.2023 | 07.23.2023 | Revise Zipline lapsed approval section to include HUDs with expanded access applications |
| 2.9 | 01.26.2023 | 01.26.2023 | Add lapsed approval policy for expanded access applications |
| Previous versions |  |  | For older versions: HSD staff see the SharePoint Document Library; Others – contact hsdinfo@uw.edu. |

**Keywords:** Closure; Continuing review; Flexibility policy; IRB review; Lapsed approval; Modification; Transfers