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| University of Washington Human Subjects DIvision | **SOP Research Procedures Conducted without Prior IRB Approval**  |

**1 PURPOSE and APPLICABILITY**

This document defines the circumstances in which research is considered to have been conducted without first obtaining any required IRB approval. It also describes the consequences of such activities.

This applies to human subjects research activities in which the UW is engaged or for which the UW IRB is the IRB of record.

* If the research was reviewed by an External IRB (as documented in a formal agreement with HSD), the researcher should follow the policies and procedures of the External IRB.

**2 CONTEXT**

Federal regulations and UW policy require all non-exempt research involving human subjects to obtain IRB approval prior to doing the research.

**3 POLICY (UW IRB)**

3.1 Research procedures conducted without IRB approval is defined as any of the following:

3.1.1 **Not obtaining prior approval by the UW IRB**, or by an External (non-UW) IRB that has a formal reliance agreement with HSD to conduct the review on behalf of the UW IRB

* This may be for an entire study, or for specific procedures conducted without IRB approval as part of an otherwise IRB-approved study.

3.1.2 **Not obtaining informed consent** from the subjects or their legally authorized representatives, when the IRB had not approved a waiver of consent

3.1.3 **Using procedures that were not described in the IRB-approved** consent process or document, when the IRB had not approved a waiver for excluding the procedure from the consent process or documents

3.1.4 **Over-enrolling subjects** in a greater-than-minimal risk study or for a study in which the number of subjects was specified by the IRB

3.1.5 **Continuing research procedures after the expiration** of IRB approval

3.1.6 **Continuing research procedures after suspension or termination** of IRB approval

3.2 **Serious noncompliance**. Conducting a non-exempt research study or study activities without any prospective IRB approval (i.e., the entire study, or significant changes to the research, have received no IRB approval from any IRB) is always considered to be serious noncompliance.

**4 PROCEDURES**

4.1 **Identification**. These circumstances may be identified in a variety of ways, including researcher self-identification, identification by HSD, or through concerns brought to HSD.

4.2 **What to do**. The researcher should submit a Report of New Information (RNI) to the UW IRB. If the unapproved activities have been identified by HSD instead of the researcher, HSD will ask the researcher to do this.

4.2.1 **How to make the report.** Follow the instructions for reporting in the Zipline e-IRB system, as described in the **SOP RNI Reporting by Researchers**, using the **SUPPLEMENT RNI**, and also attaching any other relevant supporting documents. *Individuals who have not used the Zipline system before should first contact HSD at* *hsdreprt@uw.edu* *for guidance on what to do.*

4.2.2 **Content of the RNI report**. The report should describe the unapproved activities, circumstances, and any proposed corrective and preventative actions.

4.3 **Assessment and review.** The researcher may be asked for clarifications or additional information so that HSD can assess the report and make the following determinations:

4.3.1 **Immediate action**. Is there a need for immediate action (e.g., subject safety; involvement of sensitive subject information) or coordination with other institutions or UW offices?

4.3.2 **IRB approval requirement**. Was IRB approval required?

4.3.3 **Noncompliance**. Do the activities and circumstances meet the definition of [minor](https://www.washington.edu/research/glossary/minor-non-compliance/), [serious](https://www.washington.edu/research/glossary/serious-non-compliance/), or [continuing](https://www.washington.edu/research/glossary/continuing-non-compliance/) noncompliance?

4.3.4 **IRB review of the RNI**. Is IRB review of the RNI or the corrective plan required? If yes, IRB review is conducted.

4.4 **Consequences**

4.4.1 **No retroactive IRB approval**. Federal regulations and UW policy do not allow the IRB to grant retroactive approval for already-conducted activities.

4.4.2 **Use of the data/specimens obtained through unapproved activities**

4.4.2.1 **Federal regulations** are silent on the issue of how the data/specimens may or may not be used, or whether they should be destroyed.

4.4.2.2 **UW leaders** to whom the researcher reports up through the academic hierarchy have this authority (e.g., Provost, Vice Provost for Research, Deans, and sometimes Chairs). Although this authority has not been delegated to HSD or the UW IRB, HSD may formally recommend specific actions for consideration by the relevant UW office.

4.4.2.3 **Publications and presentations**. The data cannot be described as being part of a UW IRB-approved study. This may have implications for the publications or presentations, as many journals and conferences require IRB review as a condition of publication or presentation of research that involved human subjects.

4.4.2.3.3 A statement to this effect is communicated to the researcher for determinations of serious or continuing non-compliance.

4.4.3 **Reporting to federal funding agencies and federal regulators**. Federal regulations require HSD to report serious or continuing noncompliance to appropriate federal regulators and/or funding agencies. As described in the **SOP Federal Reporting**, copies may be distributed to other institutions or other UW offices, if they are involved in the identification and/or resolution of the matter or are impacted by it.

4.4.4 **Corrective and preventative action plan (CAPA)**. The IRB may require a CAPA plan to address or prevent the consequences of the already-completed research activities and the conduct of future research activities without IRB approval.

4.4.5 **Closure.** If the entire research study was conducted without IRB approval and an IRB application has been submitted in Zipline, HSD will administratively withdraw the study after all review activity related to the matter has been concluded.

**5 RELATED MATERIALS**

5.1 SOP Federal Reporting

5.2 [SOP RNI Reporting by Researchers](https://www.washington.edu/research/policies/sop-rni-reporting-by-researchers/)

5.3 [SUPPLEMENT RNI](https://www.washington.edu/research/forms-and-templates/supplement-rni/)

5.4 GUIDANCE Managing Minor Noncompliance

**6 REGULATORY REFERENCES**

6.1 45 CFR 46.108(a)(4) and 45 CFR 46.118 (2018 Regulations)

6.2 45 CFR 46.103(b)(5) and 45 CFR.118 (Pre-2018 Regulations)

6.3 21 CFR 56.113 and 21 CFR 56.108(b)

6.4 UW Executive Order 24, “Research with Human Participants”, 2015

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|  **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 2.3 | 06.26.2025 | 06.26.2025 | For SNC/CNC determination, PIs are notified of about publication implications |
| 2.2 | 05.27.2021 | 05.27.2021 | Remove references to paper process |
| 2.1 | 06.26.2020 | 06.26.2020 | Remove “POLICY &” from document title |
| 2.0 | 03.27.2020 | 03.27.2020 | Changed to a Guidance document for researchers; HSD and IRB procedures, and some other information moved to other documents to improve clarity or eliminate redundancy.  |
| 1.4 | 07.28.2019 | 07.28.2019 | Removed all references to Confidentiality Agreements and to WA State law RCW 42.48 |
| 1.3 | 06.23.2017 | 06.23.2017 | Updated links; added links to Zipline instructions |
| Previous versions |  |  | For older versions: HSD staff see the SharePoint Document Library; Others – contact hsdinfo@uw.edu.  |

**Key words:** Noncompliance; Reporting