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| University of Washington Human Subjects DIvision | **SOP RNI Reporting by Researchers**  |

1. **PURPOSE and APPLICABILITY**

This document describes the policies and procedures that researchers follow for identifying and reporting Reportable New Information (RNI) to HSD and the UW IRB.

This applies to any researchers whose research is being reviewed by the UW IRB, including non-UW researchers whose sites or institutions are relying on the UW IRB for review (i.e., a Single IRB arrangement).

UW researchers whose research is reviewed by an External IRB (as documented in a formal agreement with HSD) should follow the problem reporting policies and procedures of the External IRB.

**2 CONTEXT**

This reporting is important for ensuring the safety, rights, and welfare of research subjects throughout a study. It is required by a combination of federal regulations and UW policies.

Some incidents and information may require notification or reporting to additional agencies, institutions, or UW offices. Examples: UW Medicine Patient Safety Net, study Sponsor, Food and Drug Administration.

**3 PROCEDURES**

3.1 **Who does the reporting**. Any member of the study team that was responsible for submitting the IRB application for the research, or anyone who has access to the Zipline e-IRB system.

* + 1. See section 3.5 for information about reporting RNI for non-UW sites or researchers that are participating in a multi-institutional study for which the UW IRB is the IRB for the sites.
	1. **What to report and timeframe for reporting**. The following events and incidents are Reportable New Information (RNI). The nature of the RNI determines how quickly it must be reported. The reporting “clock” begins when the researcher (i.e., any member of the research team) becomes aware of the RNI.

| **Information or Event** | **When to report \*** |
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| Breach (or risk of breach) or loss of subject confidentiality or privacy | **Report within 24 hours** |
| Inappropriate access or use of [protected health information (PHI)](https://www.washington.edu/research/glossary/protected-health-information-phi/) | **Report within 24 hours** |
| Qualifying medical problem in research covered by the **UW Human Subjects Assistance Program (HSAP)** | **Report within 24 hours** |
| Incidental incarceration of a research subject in a study that the IRB has not approved for the inclusion of prisoners **and** where study activities or data collection will continue while the subject is incarcerated | **Report within 3 business days** |
| For DOD funded EFICs studies only: **All** incidental incarceration of a research subject even if study activities and data collection will not occur during the incarceration | **Report within 3 business days** |
| [Unanticipated problem](https://www.washington.edu/research/glossary/unanticipated-problem/) | **Report within 10 business days** |
| [Unanticipated adverse device effect](https://www.washington.edu/research/glossary/unanticipated-adverse-device-effect/) | **Report within 10 business days** |
| [Serious noncompliance](https://www.washington.edu/research/glossary/serious-non-compliance/) | **Report within 10 business days** |
| [Continuing noncompliance](https://www.washington.edu/research/glossary/continuing-non-compliance/) | **Report within 10 business days** |
| Emergency deviation from IRB approved procedures made without IRB review to eliminate an apparent immediate hazard to a subject or others | **Report within 10 business days** |
| Continuation of research after IRB approval has lapsed, because the procedures are of direct benefit to the individual subjects or withholding the researcher intervention (if any) may increase risks to subjects | **Report within 10 business days** |
| Complaint from a subject or other person about the study, which cannot be resolved by the research team | **Report within 10 business days** |
| Audit, inspection, compliance, or safety-related inquiry from a federal agency including initial notification of an upcoming audit or inspection | **Report within 10 business days** |
| Information that indicates a new or increased risk or safety issue (or a decrease in study benefits) (e.g., A publication in the literature indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk; revised IB, package insert, or device manual; changes to FDA-approved labeling; FDA withdrawal, restriction, or modification of marketed approval of a drug, device, or biologic used in a research protocol) | **Report within 10 business days** |
| Humanitarian Use Devices (HUDs) - Medical Device Reports (MDRs) or incidents where a HUD may have caused or contributed to a death or serious injury or has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. | **Report within 10 business days** |
| Premature suspension or termination of some or all of the research by the sponsor, researcher, or institution | **Report within 10 business days** |
| All safety monitor or DSMB reports | **Report within 10 business days** |

3.3 **How to report, and manage the report**

3.3.1 **Submit the RNI report**. Reporting is done through the Zipline e-IRB system. Follow the instructions about Reports of New Information, located in the Zipline Online Help Library on the HSD website. *Do not include any subject identifiers*. The report should include:

* **SUPPLEMENT Report of New Information** form, if the RNI involves: (a) safety monitoring or DSMB reports, or (b) research-related problems or events.
* DSMB or other safety monitoring report (if applicable)
* Audit or compliance report (if applicable)
* Any relevant supporting documentation

3.3.2 **Respond to requests for clarification**. HSD may send an email request for additional information or changes to the RNI report. Follow the instructions provided in the email or see the Reports of New Information section of the Zipline Online Help Library.

3.3.3 **Respond to requirements for additional action**. The IRB may require additional actions, described in an email. Follow the instructions provided in the email or see the Reports of New Information section of the Zipline Online Help Library.

3.3.4 **Withdraw or discard a RNI report prior to HSD review** (if necessary). Researchers may withdraw or discard a submitted RNI report if the RNI status (as indicated in the flow chart graphic in Zipline) is “Pre-Review” or “IRB Review”. See the instructions in the Other Actions section of the Zipline Online Help Library.

* **Withdraw** the RNI report **to make edits** to it
* **Discard** the RNI report if new information indicates that the incident or information does not meet the definition of a reportable RNI

3.4 **Non-UW sites or researchers** that are participating in a multi-institutional study and for which the UW IRB is the IRB for the sites

3.4.1 The non-UW researchers should promptly notify the UW lead researcher about the RNI. They provide all necessary information for the RNI report and for any clarifications requested by HSD or the IRB.

3.4.2 The UW lead researcher and study team:

* Prepare and submit the RNI report.
* Respond to HSD and IRB requests for additional information or actions.
* Inform the non-UW site at which the RNI occurred about actions required by the IRB and about the resolution of the RNI report.
* If the RNI and its resolution are relevant to any other non-UW sites that are also being reviewed by the UW IRB: the UW lead researcher is responsible for informing them and ensuring that any required actions are taken.

**4 RELATED MATERIALS**

4.1 [UW Human Subjects Assistance Program](https://www.washington.edu/research/policies/human-subjects-assistance-program-2/)

4.2 [Zipline Online Help Library](https://www.washington.edu/research/hsd/training/zipline-online-help-library/)

4.2 [SUPPLEMENT Report of New Information](https://www.washington.edu/research/forms-and-templates/supplement-rni/)

**5 REGULATORY REFERENCES**

5.1 45 CFR 46.103(a), 103(b)(5), and 111(a,b) (Pre-2018 regulations)

5.2 45 CFR 46.103(a), 108(a)(4), and 111(a,b) (2018 regulations)

5.3 21 CFR 56.108(b)

5.4 21 CFR 814.126(a)

5.5 OHRP guidance, “Reporting Incidents to OHRP”; June 20, 2011

5.6 OHRP guidance, “Unanticipated Problems Involving Risks and Adverse Events”; 2007

5.7 FDA guidance, “Adverse Event Reporting to IRBs – Improving Human Subject Protection”; January 2009

5.8 FDA guidance, “Humanitarian Device Exemption (HDE) Program”; September 6, 2019

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

5.10 UW Administrative Policy Statement APS 2.5, “Information Security and Privacy: Incident Reporting and Management”, February 2020.

5.11 UW Policy and Program Description, “Human Subjects Assistance Program”, February 2018.

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|  **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 3.2 | 08.25.2022 | 08.25.2022 | Add reporting requirements for HUDs |
| 3.1 | 06.26.2020 | 06.26.2020 | Revise document titles to remove “Zipline” |
| 3.0 | 03.27.2020 | 03.27.2020 | Significant re-organization; add information about non-UW sites reviewed by UW Single IRB |
| 2.0 | 03.30.2018 | 03.30.2018 | Clarifications to reporting process |
| 1.1 | 09.19.2017 | 09.19.2017 | Updated links |
| Previous versions |  |  | For older versions: HSD staff see the SharePoint Document Library; Others – contact hsdinfo@uw.edu. |

**Key words:** Noncompliance; Reporting; Unanticipated problem