From: OHRP-Edu@hhs.gov <OHRP-Edu@hhs.gov>
Sent: Friday, March 7, 2025 12:05 PM
Subject: Reminder from OHRP about Reporting Requirements for FWA-holding Institutions and IRBs Overseeing HHS-Supported or Conducted Research

You are receiving this information because your name is on your institution's Federalwide Assurance (FWA) or IRB registration filed with Office for Human Research Protections (OHRP). To unsubscribe, please have your institution remove your name from the FWA/IRB registration filed with OHRP. You may receive duplicate copies of this information if you hold multiple roles in your institution or organization's FWA or IRB registration record.

The Office for Human Research Protections (OHRP) is reaching out to all our Federalwide Assurance (FWA) holders and institutional review boards (IRBs) that are registered to conduct or oversee human research supported by the U.S. Department of Health and Human Services, or that are otherwise subject[1] to the regulations at 45 CFR part 46.

For Institutions: OHRP would like to remind you of your obligations to ensure proper oversight and reporting of incidents related to nonexempt human research conducted by your institution or overseen by an IRB that your institution operates.

- Please take a moment to evaluate your institution's written procedures to ensure that they include sufficient operational detail for investigators to understand which incidents need to be reported to the reviewing IRB, including when the reviewing IRB is not operated by the investigator's institution.
- Institutions that operate an IRB registered with our office should also ensure that the IRB's written procedures include sufficient detail for IRB staff and members to understand which incidents need to be reported to OHRP.
- The FWA-holding institution and the reviewing IRB should review reports of incidents to make sure that appropriate actions are taken to address the incident and report to OHRP as needed. Any agreement to document an institution's reliance on an external IRB should outline the reporting responsibilities per 45 CFR 46.103(e).

For external IRBs not operated by the research-conducting institution that review and oversee HHS-supported research on behalf of a relying institution(s): OHRP would like to remind you of your reporting requirements to the research-conducting institution(s) and to OHRP. The reviewing IRB should review the reports of the incidents identified below to make sure that appropriate actions are taken, by the IRB and the conducting institution, to address the incident and report to OHRP as needed. The documentation of IRB reliance should outline the reporting responsibilities per 45 CFR 46.103(e).

OHRP Reporting Requirements: Under pre-2018 Requirements at 45 CFR 46.103(a) and (b)(5) and 45 CFR 46.113 and the 2018 Requirements at 45 CFR 46.108(a)(4) and 45 CFR 46.113, these incidents include:

1. any unanticipated problems involving risks to subjects or others;
2. any serious or continuing noncompliance with 45 CFR part 46;
3. any serious or continuing noncompliance with determinations of the IRB; and
4. any suspension or termination of IRB approval.

For studies that are HHS-supported and are also regulated by the FDA, additional reporting to FDA may be required by FDA.

For more information on what must be reported and how to report to OHRP, please visit OHRP's webpage at: https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html.

If research has been suspended or terminated, it may be important to consider how to appropriately and safely transition research participants off the study. While not OHRP guidance, you may find the following recommendations of the Secretary's Advisory Committee on Human Research Protections to be helpful: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/interpretation-of-best-interests-standard-for-retention-of-human-subjects-research/index.html

NOTE: If an incident report to OHRP does not reflect the final outcome of the incident, the institution or IRB should send OHRP a follow-up report when all corrective actions related to an incident have been implemented to the satisfaction of the IRB and the conducting institution.

If you have questions related to this or other requirements of 45 CFR 46, please contact OHRP's general mailbox at OHRP@HHS.gov.

[1] Please note that OHRP is in the process of updating the FWA form to eliminate the option to extend the Common Rule or the Common Rule and subparts to all an institution's nonexempt human subjects research regardless of the source of support (frequently referred to as "checking the box"). This change has not yet been implemented. Once check-the-box is eliminated, research that is not supported or conducted by HHS will be subject to country, state, tribal, and institutional laws, regulations, and policies, as applicable, but OHRP will not have oversight of that research and there will be no reporting requirements to OHRP for such research.