



POLICY: Prompt Reporting Requirements

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1. PURPOSE

- 1.1 This policy describes the information investigators must promptly report to WCG IRB .
- 1.2 For research overseen by an IRB other than WCG IRB, investigators should follow the requirements of that IRB.

2. POLICY

- 2.1 Report the following information items to the IRB within 5 calendar days:
 - 2.1.1 New or increased risk¹
 - 2.1.2 Protocol deviation that harmed a subject or placed subject at risk of harm
 - 2.1.3 Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject
 - 2.1.4 Audit, inspection, or inquiry by a federal agency
 - 2.1.5 Written report or action of a government agency, regarding the research, the PI, or the research staff, or if research staff are added, a past history of such report or action, including:
 - 2.1.5.1 Conviction of a crime
 - 2.1.5.2 FDA Warning Letter
 - 2.1.5.3 NIDPOE (Noticed of Initiation of Disqualification Proceedings and Opportunity to Explain)
 - 2.1.5.4 Suspension or termination by an IRB
 - 2.1.5.5 Suspension by a federal or governmental agency (such as FDA, HHS, or Health Canada)
 - 2.1.5.6 OHRP Determination Letter, Health Canada Inspection Letter with observations, or similar
 - 2.1.5.7 Form FDA 483 in the past 5 years
 - 2.1.6 Any site monitoring report that directly and materially affects subject safety or their willingness to continue participation.
 - 2.1.7 <Allegation of Noncompliance> or <Finding of Noncompliance>
 - 2.1.8 Unauthorized disclosure of confidential information
 - 2.1.9 Unresolved subject complaint
 - 2.1.10 Suspension or premature termination by the sponsor, investigator, or institution
 - 2.1.11 Incarceration of a subject in a research study not approved to involve prisoners
 - 2.1.12 Adverse event or IND safety report that requires a protocol or consent change
 - 2.1.13 State medical board or hospital medical staff actions, (denial, revocation, suspension, reduction, limitation, probation, non-renewal, relinquishment, sanction, fine, or discipline) regarding any of the following for the PI or research staff, or if research staff are added, a past history of such action:
 - 2.1.13.1 Clinical privileges at any site
 - 2.1.13.2 DEA licensure
 - 2.1.13.3 Fellowship/board certification
 - 2.1.13.4 Medical licensure in any state, nation, or province
 - 2.1.13.5 Membership on any hospital staff
 - 2.1.13.6 Prescribing privileges
 - 2.1.13.7 Professional sanctions including fines and public reprimands
 - 2.1.13.8 Professional society membership

¹ For example, publications indicating a new risk, new risk in an investigator brochure, FDA black box warning, new risk identified in a data safety monitoring report, information or change that adversely affects subject safety, or information or change that adversely affects the conduct of the research.



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3. PURPOSE

- 3.1 This policy describes the information investigators must promptly report to WCG IRB .
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4. POLICY

- 4.1 Report the following information items to the IRB within 5 calendar days:
 - 4.1.1 New or increased risk¹
 - 4.1.2 Protocol deviation that harmed a subject or placed subject at risk of harm
 - 4.1.3 Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject
 - 4.1.4 Audit, inspection, or inquiry by a federal agency
 - 4.1.5 Written report or action of a government agency, regarding the research, the PI, or the research staff, or if research staff are added, a past history of such report or action, including:
 - 4.1.5.1 Conviction of a crime
 - 4.1.5.2 FDA Warning Letter
 - 4.1.5.3 NIDPOE (Noticed of Initiation of Disqualification Proceedings and Opportunity to Explain)
 - 4.1.5.4 Suspension or termination by an IRB
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4.1.13.9 Research privileges at any site

4.1.14 Unanticipated adverse device effect²

4.1.15 Change in financial interest disclosure (submit as a modification)

4.1.16 Any findings from closed research when those findings materially affect the safety and medical care of past subjects. Findings will be reported for 2 years after the closure of the research.

4.2 Information not listed above does not require prompt reporting to the [Organization's] IRB.

5. REFERENCES

5.1 21 CFR §56.108(b)

6. REVISION HISTORY

4.1

Version	Name/Title	Effective Date	Section Changed	Revision Details (Reason for Change)
4.0	Heather Kim, QA Manager	02-Feb-2024	N/A	Reformat to WCG template and change document ID from HRP-071 to IRB.POL.HRP.071
5.0	Elizabeth Weisenfeld, Lead, Quality Control	24-Jul-2024	2	Add info about site monitoring reports, findings from closed research. Remove "Change in any other information previously submitted to the IRB (submit as a modification)"

² Unanticipated adverse device effect means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.