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 risk[1]
- 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.

2.1.13.9 Research privileges at any site

2.1.14 Unanticipated adverse device effect[2]
2.1.15 Change in financial interest disclosure (submit as a modification)
2.1.16 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.

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

3. REFERENCES

3.1 21 CFR §56.108(b)

4. 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.