1. PURPOSE

1.1 This policy describes the IRB's expectations of investigators conducting <Human Research> overseen by 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 Do not commence research until receipt of IRB approval and all other required approvals, such as radiation safety approval, biosafety approval, and approvals of departments or divisions that require approval of the use of their resources.

2.1.1 If there are any questions about whether you are conducting research involving human subjects, contact the IRB before commencing the study.

2.2 Comply with all requirements and determinations of the IRB.

2.3 Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.

2.4 Ensure that research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.

2.5 Personally conduct or supervise the research.

2.6 Conduct the research in accordance with the relevant current protocol approved by the IRB.

2.7 Protect the rights, safety, and welfare of subjects involved in the research.

2.8 Submit proposed modifications to the IRB prior to their implementation.

2.8.1 Do not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.

2.9 Submit continuing reviews when requested by the IRB.

2.10 Submit a closure form to close research (end the IRB's oversight) when:

2.10.1 The protocol is permanently closed to enrollment

2.10.2 All subjects have completed all protocol related interventions and interactions

2.10.3 For research subject to federal oversight other than FDA:

2.10.3.1 No additional identifiable private information about the subjects is being obtained

2.10.3.2 Your analysis of private identifiable information is completed

2.11 If research approval expires, stop all research activities and immediately contact the IRB.

2.12 Promptly report to the IRB the information items listed in "POLICY: Prompt Reporting Requirements (IRB.POL.HRP.071)." The information is also listed on the Promptly Reportable Information form in Connexus when using the "Make a Submission" workflow.

2.13 Do not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees.")

2.14 Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments").

2.15 For studies regulated by a federal department or agency, follow the additional obligations labeled Investigator Guidance found on the WCG IRB "Resources" page, as applicable:

2.15.1 "INVESTIGATOR GUIDANCE: Additional DOD Obligations (HRP-810)"

2.15.2 "INVESTIGATOR GUIDANCE: Additional DOE Obligations (HRP-811)"

2.15.3 "INVESTIGATOR GUIDANCE: Additional DOJ Obligations (HRP-812)"

2.15.4 "INVESTIGATOR GUIDANCE: Additional EPA Obligations (HRP-813)"
2.15.5 "INVESTIGATOR GUIDANCE: Additional ED Obligations (HRP-814)"
2.15.6 "INVESTIGATOR GUIDANCE: Additional FDA Obligations (HRP-815)"

2.16 For studies where ICH-GCP compliance is required, follow additional the obligations in "INVESTIGATOR GUIDANCE: Additional ICH-GCP Obligations (HRP-816)."
2.17 When required by the IRB ensure that consent, permission, and assent are obtained and documented in accordance with the relevant current protocol as approved by the IRB.
2.18 Retain research records (including signed consent documents) for the greater of:

2.18.1 Three years after completion of the research
2.18.2 For drug studies conducted under an IND, two years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until two years after the investigation is discontinued and FDA is notified.
2.18.3 For device studies conducted under an IDE or abbreviated IDE, two years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.
2.18.4 The retention period required by the sponsor
2.18.5 The retention period required by local, state, or international law.

2.18.5.1 HIPAA requires signed authorizations to be retained for six years from the date signed or the date when it last was in effect, whichever is later.

2.18.6 The retention period required by a site that is not part of this [Organization].

3. REFERENCES

3.1 21 CFR §50, §56
3.2 45 CFR §46

4. REVISION HISTORY

4.1

Supersedes	Effective Date	Version
HRP-070 POLICY – Investigator Obligations	23-Jun-2023	4.3

4.2

Version	Name/Title	Effective Date	Section Changed	Revision Details (Reason for Change)
5.0	Heather Kim QA Manager	02-Feb-2024	N/A	Reformat to WCG template and change document ID from HRP-070 to IRB.POL.HRP.070
			2.14	Delete "without prior IRB approval"