1. PURPOSE

1.1. This guidance describes the obligations of Principal Investigators conducting <Human Research> overseen by Carilion Clinic's local IRB.

1.2. For research overseen by an IRB other than Carilion Clinic's local IRB, investigators should follow the requirements of that IRB.

2. GUIDANCE

2.1. Do not begin research until you have the IRB approval letter and obtained all other required approvals, such as R&D authorization, 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, submit form Human Subjects Research Determination and wait for the IRB's determination before commencing the study.

2.2. Personally conduct or supervise the research.

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

2.4. Conduct the research in accordance with the relevant current protocol approved by the IRB, and comply with all requirements and determinations of the IRB, as well as Federal, state, and local laws and regulations, and be guided by the principles contained in the Belmont Report.

2.5. Ensure the research protocol is consistent with the proposal for funding for extramural or intramural support

2.6. Employ sound study design in accordance with the standards of your discipline and design studies in a manner that minimizes risks to subjects.

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

2.8. Education and training requirements are described in SOG 7.1 IRB Education and Training: INVESTIGATOR AND KEY STUDY PERSONNEL TRAINING.

2.9. Unless the IRB affirmatively approved a protocol to include the following populations, such subjects may not be enrolled:

2.9.1. Adults unable to consent
2.9.2. Children
2.9.3. Neonates of uncertain viability
2.9.4. Nonviable neonates
2.9.5. Pregnant women
2.9.6. Prisoners
2.9.7. Individuals unable to speak English

2.10. When consent, parental permission, or assent are required by the IRB, ensure that they are obtained utilizing the IRB stamped form and documented in accordance with the relevant current protocol as approved by the IRB prior to any study procedures bring performed.

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

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

2.12. Submit Continuing Review or Annual Check-in, as described in the approval letter, in the time frame requested by the IRB.

2.13. Submit a study closure to end the IRB's oversight;

2.13.1. When **all** the following apply:

2.13.1.1. The protocol is permanently closed to enrollment;

2.13.1.2. All subjects have completed all protocol related interventions and interactions;
2.13.1.3. No additional identifiable private information about the subjects is being obtained;
2.13.1.4. Analysis of private identifiable information is completed.

2.13.2. When a study has expired or been administratively closed due to a continuing review not being submitted before expiration

2.14. If research approval expires, immediately stop all research activities including analysis of identifiable data, and do not resume the research study until the Continuing Review has been approved by the IRB.
2.15. Promptly report to the IRB the information items listed in HRP-071 Prompt Reporting Requirements to the IRB and SOG 6.4 Non-Compliance.
2.16. Follow Carilion Clinic's requirements to disclose financial interests.

2.16.1. Disclose conflicts of interest for all study team members on submission of an initial review.
2.16.2. Disclose changes to your conflicts of interest.

2.16.2.1. On submission of continuing review
2.16.2.2. Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest that would have required disclosure on initial review

2.17. Retain research records for the greater of:

2.17.1. At least three years after completion of the research.
2.17.2. If the study involves Protected Health Information, research records must be maintained for a minimum of six years after the completion of the research.
2.17.3. 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.
2.17.4. 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.
2.17.5. The retention period required by the sponsor
2.17.6. The retention period required by local, state, or international law.
2.17.7. The retention period required by a site that is not part of Carilion Clinic.

2.18. Contact the Research & Development Department regarding the need for a contract and letter of indemnification if your study involves any funding or resources from an outside source, or if you will be sharing data outside of Carilion Clinic prior to publication. If it is determined that either a contract or letter of indemnification is needed, subjects cannot be enrolled until these documents are complete.
2.19. Maintain confidentiality of all information gained during the conduct of research at Carilion Clinic, including but not limited to information about patients, employees, physicians, and students.
2.20. Do not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees").
2.21. Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments") without prior IRB approval.

2.22. Notify the IRB immediately if involved in any regulatory or misconduct litigation or investigation by the FDA, or if you are debarred by the US FDA from involvement in clinical research studies.
2.23. If unable to perform the duties as outlined above for an extended period of time, you will close the study or transfer the duties of PI to the sub-investigator or to another qualified individual.

Artificial Intelligence

2.24. Investigators and research team members must use Artificial Intelligence (AI) tools responsibly and in accordance with Carilion Clinic policies. Specifically:
- 2.24.1. AI may be used to support efficiency (e.g., drafting documents, summarizing information, or assisting analysis), but cannot replace investigator's judgment, oversight, or compliance obligations.
- 2.24.2. Do not input identifiable private information, protected health information (PHI), or confidential data into AI tools unless expressed approved and securely configured by Carilion Clinic. Use of AI tools to process identifiable/confidential data for research is permitted only through approved workflows using Carilion Clinic managed devices and must be reviewed and approved by the IRB, Compliance, and Privacy in coordination with HART. Public or open-access AI tools must never be used for identifiable private information, protected health information, or business confidential data.
- 2.24.3. All outputs generated by AI must be critically reviewed and verified for accuracy, completeness, and appropriateness before use in research activities.
- 2.24.4. AI must not be used in ways that could introduce bias, compromise subject safety, or conflict with ethical principles and regulatory requirements.

3. APPROVAL AND REVISIONS

3.1. 14 SEP 17: HRPO Director, Carley Emerson, originally created and approved
3.2. 15 JUN 21: Revised by HRPO Director, Carley Emerson to refer to HRP-074 for education and training requirements.
3.3. 19 Dec 23: Revised by HRPO Director, Meredith Talmadge to remove reference to HRP-074 and HRP-801. Added reference to HRP- 071, SOG 6.4, and SOG 7.1.
3.4. 12 Nov 25: Revised by HRPO Director, Meredith Talmadge to add Artificial Intelligence section.

4. REFERENCES

4.1. 21 CFR §50, §56
4.2. 45 CFR §46