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RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS, CO-INVESTIGATORS, AND KEY PERSONNEL

1. Overview

Principal investigators (PIs) at The Ohio State University are ultimately responsible for the ethical conduct of human subjects research and for compliance with federal regulations, applicable state and local law, and university policies. These responsibilities are shared with investigators' research staffs and the university's Human Research Protection Program (HRPP), including the Institutional Review Boards (IRBs) and Office of Responsible Research Practices (ORRP). This policy describes the scope of responsibilities for principal investigators, co-investigators, and key personnel (collectively, "researchers") who conduct human subjects research at The Ohio State University.

2. Definitions

Principal Investigator: An individual with the appropriate scientific and/or scholarly training and expertise to assume direct responsibility for the ethical conduct of a study involving human subjects, providing technical and administrative oversight of the research and making important study-related decisions.

3. General Information

A. All investigators and key personnel will adhere to the principles outlined in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research report entitled, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* ("Belmont Report") when conducting research involving human subjects.

B. All investigators and key personnel will conduct research according to all applicable university policies and Human Research Protection Program Policies, as well as federal, state, and local laws and guidance for the protection of human subjects in research. Researchers will also consider the applicable professional practice standards of their disciplines and other generally accepted good research practice guidelines in the development and performance of human research studies.

4. Principal Investigator Qualifications, Oversight, and Resources

A. Principal investigators will have appropriate education, training, and experience to assume overall responsibility for the ethical conduct of their human subjects research. This includes training in human subjects protection requirements, as described by Training Requirements on the ORRP website. Additional training requirements may also apply for investigators receiving funding from specific sponsors (e.g., NIH or NSF requirements for instruction in the responsible conduct of research for certain training grants or requirements for good clinical practice training for NIH awardees involved in NIH-funded clinical trials).

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B. For purposes of HRPP policy, only one individual is designated as the principal investigator of a human research study. For the university's guidelines on requirements for PI status, see Principal Investigator Status Appointments.

C. Principal investigators are responsible for knowing when proposed activities are defined as "research involving human subjects" by HRPP policy [Research Involving Human Subjects] or for seeking guidance, as appropriate. PIs will provide the IRB (or designees) with sufficient information and materials to make the determinations required by HRPP policies [Review of Research by the Convened IRB] and [Exempt Research]. PIs will ensure that research does not begin until IRB approval or exemption has been obtained.

D. Principal investigators are responsible for the selection and training of individuals who may assist with their research and will obtain IRB approval for the involvement of (and any changes in) co-investigators and key personnel. Training of study personnel should provide staff a general familiarity with the research methods and objectives (as applicable), as well as study-specific information relevant to the tasks to be performed.

E. Principal investigators may delegate study-related tasks to appropriately qualified and trained study personnel. PIs will maintain oversight of and retain ultimate responsibility for the conduct of those who perform delegated functions.

F. Principal investigators will ensure that all researchers assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies. PIs will keep co-investigators and key personnel informed of any changes made to the research while the study is ongoing.

G. Principal investigators will ensure that they have sufficient time to properly conduct and/or supervise proposed research and study personnel and that adequate resources (e.g., qualified staff, facilities, medical/psychosocial services) are available to safely carry out the approved project.

H. If a principal investigator leaves the university or is unavailable to personally conduct or supervise ongoing research (e.g., on sabbatical or extended leave), he/she must make arrangements to amend (including a change in PI) or terminate the research, as appropriate. Primary research data and research-related records will be retained at the university (see "Reporting and Recordkeeping Requirements" below).

I. Principal investigators and their co-investigators and key personnel will disclose all personal financial interests relevant to their institutional commitments, as required by regulations and university policy, and will work to eliminate or manage potential conflicts of interest when applicable. For more information, see university policy, Policy on Faculty Financial Conflict of Interest.

5. Conduct of Human Subjects Research

A. Investigators are responsible for designing and conducting research in a manner that minimizes risks, using sound research design and generally accepted scientific and/or

scholarly standards. Investigators performing research involving investigational drugs, biologics, or devices will comply with applicable FDA regulations and HRPP policies [Research Involving Investigational Drugs] and [Research Involving Medical Devices].

B. Investigators and key personnel will perform the research as approved (or as determined exempt) and will follow the terms of an associated grant, contract, and/or signed funding agreement, if any. Researchers will not make changes to the research or informed consent process until approved by the IRB, except where necessary to eliminate apparent immediate hazards to participants, and will inform the IRB (and sponsor as applicable) of any such changes.

C. Investigators will obtain continuing review and approval of ongoing non-exempt research (i.e., until research-related interactions/interventions with human subjects or analysis of individually identifiable private information have been completed) at the interval determined by the IRB (at least annually) to avoid expiration of IRB approval and cessation of all research activities.

6. Protecting the Rights, Safety, and Welfare of Research Participants

A. Investigators and research staff will recruit participants in a fair and equitable manner that avoids the potential for coercion and undue influence. For more information on equitable selection and recruitment, see HRPP policy [Recruiting Methods, Recruitment Materials, and Participant Compensation].

B. Using the IRB-approved consent process(es), investigators and research staff will obtain and document informed consent (unless waived) and HIPAA research authorization (when applicable) from participants or their legally authorized representatives prior to the participants' involvement in the research. Researchers will provide participants or representatives sufficient opportunity to consider whether to participate and will ensure that participants' (or representatives') choices are voluntary and based upon informed decisions. For more information, see HRPP policies [Informed Consent Process and the Elements of Informed Consent] and [Documentation of the Informed Consent Process].

C. To minimize risks to participants, investigators and key personnel will follow procedures to protect the privacy of participants and maintain the confidentiality of research data as described by HRPP policy [Privacy and Confidentiality].

D. When populations vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity , or economically or educationally disadvantaged persons are included in research, investigators will provide additional required protections.

E. For greater than minimal risk research, investigators will appropriately monitor research data to ensure participant safety as described by HRPP policy [Data and Safety Monitoring].

F. Investigators and research staff will be available to participants to address concerns or complaints and to answer participants' questions during the research. Researchers will involve the IRB (or designees) in their responses when appropriate.

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G. During and following the conduct of the research, investigators will provide subjects with significant new findings that may relate to the subjects' well-being and/or willingness to continue to participate.

7. Reporting and Recordkeeping Requirements

A. Investigators and key personnel will follow HRPP policy [Event Reporting-Unanticipated Problems Involving Risks to Subjects or Others, Adverse Events, and Other Problems] for reporting problems to the IRB.

B. Investigators and key personnel will follow HRPP policy [Noncompliance] for reporting to the IRB any potential noncompliance with applicable regulations, state or local laws, university policies, HRPP policies, or the requirements or determinations of the IRB.

C. Investigators will provide a final study report to the IRB and any other required reports to sponsors or funding/regulatory agencies, as applicable, when all research activities have ended (including data analysis with individually identifiable private information).

D. Investigators will report to the IRB (or designees) requests for audits, inspections, or other research-related inquiries from a federal agency. For information on preparing for FDA inspections, see Investigator/Staff Guidance for FDA Inspections on the ORRP website.

E. Investigators will maintain research-related records (including original or "source" documents) in a manner that documents the validity of the research and integrity of the data collected, while protecting the data's confidentiality and the privacy of research participants. Investigators are responsible for the accuracy, completeness, legibility, and timeliness of the data recorded and reported in research and in research publications.

F. Investigators will retain research-related records (e.g., the study protocol, consent forms, IRB correspondence, etc.) at the university for audit or inspection for a period of at least three years after the research has ended (or longer, according to sponsor or publication requirements). Such records may be preserved in hardcopy, electronic, or other media form that comply with sponsor, Federal, and university requirements. Combined informed consent and HIPAA research authorization forms or stand-alone HIPAA research authorization forms must be retained for a period of at least six years after the study is closed. Primary research data will be retained for a minimum of five years after final project closeout. Arrangements will be made for appropriate transfer of data/record retention responsibilities for investigators who leave the university. For more information on data retention or transfer in the event an investigator leaves the university, see university policy [Research Data Policy]. Note: Electronic FDA-regulated research records must comply with 21 CFR Part 11.

G. Methods for handling and storing data (including the use of personal computers and portable storage devices) must comply with university policies [Policy on Institutional Data] and [Research Data Policy].

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8. Additional Requirements for Investigators Following ICH-GCP Guidance

A. Good Clinical Practice (GCP) guidance developed by the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) defines the roles and responsibilities of IRBs, investigators, monitors, and sponsors in clinical trials involving human subjects. The responsibilities described by ICH-GCP guidance include requirements for investigators conducting clinical trials in addition to those of DHHS and FDA regulations and HRPP policies. For a list of the added investigator responsibilities required by ICH-GCP guidance, see HRPP policy [Additional Requirements for Clinical Research ICH-GCP].

B. All investigators conducting human subjects research at Ohio State who follow ICH-GCP guidance must also comply with other applicable HRPP policies.

C. For more detailed information on ICH-GCP guidance, including a glossary of terms and the complete list of institutional, investigator, and sponsor responsibilities, see ICH E6: Good Clinical Practice: Consolidated Guidance.

9. Applicable Regulations/Guidance

21 CFR 56.111, 21 CFR 312, 21 CFR 812, 45 CFR 46.111, FDA Draft Guidance "Protecting the Rights, Safety, and Welfare of Study Subjects – Supervisory Responsibilities of Investigators" (05/10/2007), FDA Guidance "Part 11, Electronic Records; Electronic Signatures – Scope and Application" (09/2003), ICH "Guidance for Industry: E6 Good Clinical Practice: Consolidated Guidance" (03/2018), OHRP Frequently Asked Questions About Human Research "Investigator Responsibilities FAQs"

10. History

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