THE OHIO STATE UNIVERSITY

RESEARCH PERFORMANCE SITES AND COLLABORATIVE OFF-SITE RESEARCH

1. Overview

The ethical and regulatory requirements of The Ohio State University Human Research Protection Program (HRPP) apply to all research involving human subjects conducted on behalf of the university, regardless of funding or location. Research under the jurisdiction of the HRPP must be reviewed by an Ohio State IRB, unless the research is determined to be exempt or is covered by a cooperative (or other similar) agreement in which another appropriate IRB agrees to serve as the IRB of record. In certain situations, an Ohio State IRB may serve as the IRB of record for a collaborative research site and/or collaborating external investigator engaged in Ohio State research.

The purpose of this policy is to describe the requirements and procedures for establishing Ohio State University research performance sites, conducting collaborative off-site research, and for collaborating with external independent investigators. These requirements apply to non-exempt research that falls into any of the following categories:

- Research sponsored by The Ohio State University
- Research conducted or directed by any employee, staff member, or agent of the university
- Research involving the use of private information held by the university.

2. Definitions

Engaged: Involved in human subjects research in such a way (or to the extent) that the ethical and regulatory requirements for human subjects protection are applicable. An individual (or organization) becomes engaged in human subjects research when for the purposes of non-exempt research the individual (or organization's employee or agent) obtains any of the following:

- Data about research participants through intervention or interaction
- Identifiable private information about research participants
- Informed consent of research participants.

*Note: An organization is also **engaged** in human subjects research whenever it receives a direct federal award to support the research.*

Individual Investigator Agreement: A written agreement between an organization and a collaborating external investigator who will be engaged in the organization's non-exempt human subjects research that describes each party's responsibilities for research conduct and oversight.

IRB Authorization Agreement: A written agreement between organizations collaborating in non-exempt human subjects research that describes each organization's responsibilities for IRB review and oversight of the research.

Off-Site Research: Human subjects research sponsored or performed at a location/site that is not owned by or under the direct control of the organization responsible for the research.

Research Performance Site: Location/site at which human subjects research may be performed because of an understanding of the local research context and appropriate oversight mechanisms that ensure protection of research participants. *Note: A list of approved Ohio State University research performance sites is available at Research Performance Sites.*

3. General Information

A. Research can generally be conducted at locations/sites *not engaged* in research without additional requirements beyond IRB approval (or exemption) and the site's agreement that the research can proceed. This agreement should be documented in writing (e.g., as a "Letter of Support") and submitted for exempt determination or IRB review. Locations/sites that are *not engaged*, but where Ohio State research is performed (e.g., schools, nursing homes, or businesses that permit the use of their facilities for intervention/interaction with research participants by Ohio State investigators), are not usually added to the list of research performance sites.

B. External sites/individuals may perform certain *non-engaged* study-related activities in Ohio State research without additional requirements beyond IRB approval (or exemption). The following are examples of sites/individuals that are *not engaged* in research:

- Sites/individuals performing commercial services for investigators, provided that the services do not merit professional recognition or publication privileges and the study interventions being tested are not administered by the site or its individuals
- Sites/individuals providing study-related medical services to research participants that would typically be performed as part of routine clinical monitoring and/or follow-up (e.g., physical exams, blood tests, X-rays, assessment of adverse events), provided that the drugs, devices, or other study interventions being tested are not administered by the site or its individuals and investigators retain responsibility for overseeing protocol-related activities and reporting
- Sites/individuals providing information to potential participants about a study (including investigators' contact information) or obtaining potential participants' permission for investigators to contact them.

For more information and examples of engagement in research, see OHRP's Guidance on Engagement of Institutions in Human Subjects Research.

C. Collaborative off-site exempt research may be performed with knowledge of the local context (see "Knowledge of the Local Context" below) and documentation of the site's agreement that the research may take place. The additional requirements for IRB review and agreements between collaborating external entities/individuals do not apply to research determined to be exempt.

D. The responsibilities of the HRPP for understanding the local research context and for executing agreements between involved entities/individuals differ slightly when adding a

new research performance site, conducting collaborative off-site research, or collaborating with an external independent investigator. Each is described below, as well as the additional requirements that apply when conducting federally-sponsored collaborative research.

4. Knowledge of the Local Context

A. Knowledge of the local research context is essential for the IRB reviewing and overseeing non-exempt research conducted at an external location/site or for determining that the research is exempt. Sufficient information to assess the local context may be obtained in various ways, depending on the distance and differences between the IRB and the research site, previous experience with the location/site, presence of local collaborators, etc. The information that should be obtained also depends on the nature and scope of the research to be conducted at the site.

B. For research conducted off-site, adequate knowledge of the local context may be obtained in various ways, including the following:

- Personal knowledge of one or more IRB members or an appropriate consultant, obtained through direct experience with the site, its populations, and the surrounding community
- Written materials submitted by the investigator or local site contact
- Site visit or conversation with the local site contact or other individual identified by the investigator or site contact as being knowledgeable about the research site.

C. Site visits are the preferred method for obtaining information to assess new performance sites. For distant locations, site information may be confirmed by telephone.

D. For collaborating external investigators engaged in non-exempt Ohio State research, the investigator's curriculum vitae, documentation of appropriate credentials to perform the proposed research, reported conflicts of interest, and completion of training in human subjects protection will be obtained.

E. For research conducted off-site, the following information should be obtained, depending on the degree of risk (i.e., minimal or greater than minimal) and nature of the research:

- Scope of the research activities to be performed at the external location/site
- Investigator and research staff experience, training, and qualifications appropriate for the research setting
- Populations likely to be involved
- Community in which the research will take place, including any customs or practices (e.g., cultural, political, or religious) unique to the location/population
- Language(s) understood by potential participants
- Facilities/equipment at the external site relevant to research performance and protection of participants
- Site policies and requirements relevant to the research
- Characteristics of the site that may affect selection and/or privacy of participants
- Appropriateness of proposed compensation (if any) at the external location

- Methods for maintaining confidentiality of data stored and transferred between sites
- Communication and oversight plans between Ohio State and the external site
- Applicable laws.

5. Research Performance Sites

A. A research performance site is established at an external location/site where a "program" of non-exempt research is performed by an Ohio State researcher at that location (i.e., rather than a single study) or at a site where an Ohio State researcher has an ongoing collaboration with individual(s) performing research at the site.

B. Most approved performance sites are open to any university investigator (as applicable to the research). Some sites are approved only for certain types of research (e.g., clinical research sites) or specific university departments or faculty practices (e.g., Division of Infectious Diseases). Limitations placed on performance sites, if any, are determined by considering the location, facilities, site personnel, potential participant population, etc. Site restrictions are specified in the list of Research Performance Sites.

C. An understanding of the local research context and appropriate oversight mechanisms to ensure protection of research participants are required for new performance sites. Minimally, the following are required:

- Policies and procedures for conducting research
- Identification of key personnel at the site who will be engaged in research
  - Completion of training in human subjects protection
  - Completion of conflict of interest disclosures
- Site visit (preferred) or other site evaluation
- Written agreement between Ohio State and the performance site
  - Documentation of IRB of record
  - Documentation of procedures for oversight and communication.

D. The Office of Responsible Research Practices (ORRP) will work with the Office of Legal Affairs, as necessary, to facilitate requests for addition of new performance sites. Individuals requesting site approval should provide the following information, as available:

- Documentation of the site's interest in becoming an Ohio State University research performance site (obtained from an individual with appropriate authority to commit the site)
- Documentation of approval/support from the applicable Dean, College Research Officer, or other signatory, as appropriate
- Description of location, facilities (including areas where research will be performed, records stored, etc.), site personnel, and population from which research participants will be drawn
- Documentation of completion of requirements for site policies and personnel training.

E. Whenever possible, site visits of proposed performance sites will be conducted by the ORRP Director or designated ORRP staff. For distant locations, site information may be

confirmed by telephone. Final evaluation of site characteristics and documentation will be made by the ORRP Director, in consultation with the applicable IRB Chair. Agreements between The Ohio State University and new performance sites will be signed by the Institutional Official, College Dean (or other signatory, as appropriate), and performance site official.

6. Collaborative Off-Site Research

A. IRB approval is required for collaborative sites/individuals engaged in off-site Ohio State research. Approval for the external site's or individual's research activities may be obtained from the local site's IRB, an Ohio State IRB, or another IRB designated to perform the review (e.g., central IRB). Whenever possible, arrangements will be made to avoid duplicative reviews.

B. Collaborative off-site research sponsored by the university or with an Ohio State investigator as the principal/lead investigator will be reviewed by an Ohio State IRB, except in unusual circumstances. Appropriate agreements will be executed (see "IRB and Investigator Agreements" below) and arrangements made to obtain knowledge of the local research context. If the local site also requires IRB, Ethics Committee, or other similar review, information obtained from this review may be used to assist in evaluation of the local research context.

C. Review of off-site Ohio State research can be performed by the IRB of an AAHRPP-accredited organization at the local site or, with sufficient knowledge of the local context, another accredited organization's IRB or other IRB that meets current accreditation standards. An authorization agreement naming the non-Ohio State IRB as the IRB of record and describing each organization's responsibilities for IRB review and oversight will be executed whenever possible. Decisions to rely on another IRB that meets current accreditation standards for review of collaborative off-site research may be made by the appropriate Ohio State IRB Chair or Vice-Chair, the QI Specialist-Research Agreements, or the IRB Operations Manager.

D. When an external site engaged in Ohio State research does not have an accredited IRB or another IRB that meets current accreditation standards, an Ohio State IRB can serve as the IRB of record, with sufficient knowledge of the local research context and execution of appropriate agreements describing each entity's responsibilities for research conduct and oversight (see "IRB and Investigator Agreements" below). Decisions that an Ohio State IRB will serve as the IRB of record for minimal risk off-site research may be made by the appropriate Ohio State IRB Chair or Vice-Chair, the QI Specialist-Research Agreements, or the IRB Operations Manager. For greater than minimal risk off-site research, such decisions will be made by the appropriate Ohio State IRB Chair or Vice-Chair, the QI Specialist-Research Agreements, or the IRB Operations Manager and confirmed by the appropriate convened IRB.

E. Additional requirements may apply for federally-funded off-site research (see "Additional Requirements for Federally-Funded Research" below).

7. Collaborating with External Independent Investigators

A. When a collaborating external investigator does not have an IRB responsible for review of his/her research activities, an Ohio State IRB can serve as the IRB of record, with sufficient knowledge of the local research context and execution of appropriate agreements describing each entity's responsibilities for research conduct and oversight (see "IRB and Investigator Agreements" below).

B. Decisions that an Ohio State IRB will serve as the IRB of record for a collaborating external investigator involved in minimal risk non-exempt Ohio State research may be made by the appropriate Ohio State IRB Chair or Vice-Chair, QI Specialist-Research Agreements, or the IRB Operations Manager. For a collaborating external investigator involved in greater than minimal risk Ohio State research, such decisions will be made by the appropriate Ohio State IRB Chair or Vice-Chair, the QI Specialist-Research Agreements, or the and IRB Operations Manager and confirmed by the appropriate convened IRB.

8. IRB and Investigator Agreements

A. External organizations engaged in non-exempt Ohio State research (including non-US locations) will obtain/maintain a separate Federalwide Assurance (FWA) with the Office for Human Research Protections (OHRP) whenever possible. An alternate agreement with collaborating organizations assuring human subjects protection may also be executed by The Ohio State University Institutional Official on behalf of the HRPP for collaborative research that is not federally funded.

B. An IRB Authorization Agreement describing each organization's responsibilities for IRB review and oversight of the research will be executed between the university and an external organization relying on an Ohio State IRB for review of its engaged non-exempt research activities. In some cases, the IRB Authorization Agreement may be combined with the overall research agreement between the university and the external site.

C. An IRB Authorization Agreement will be executed between the university and an external organization performing review of collaborative off-site Ohio State research whenever possible. An alternate agreement with the organization/IRB providing review that describes each organization's responsibilities for IRB review and oversight of the research may also be executed. In some cases, the IRB Authorization Agreement may be combined with the overall research agreement between the university and the external site.

D. IRB Authorization Agreements will not generally be executed between the university and an external organization when both sites review a collaborative research project. The responsibilities of each organization for review and oversight of the research will be described in the overall research agreement between the university and the external site.

E. An Individual Investigator Agreement will be executed for external collaborating investigators engaged in non-exempt Ohio State research who are not employees or agents of The Ohio State University or another entity responsible for oversight of their

research-related activities. Minimally, the agreement should describe investigator responsibilities and IRB oversight of the research.

9. Additional Requirements for Federally-Funded Research

A. Performance sites or other external entities engaged in federally-funded Ohio State research (including non-US locations) must obtain/maintain a separate FWA with OHRP. For more information on FWAs, including FAQs, terms, and steps to file an assurance, see the OHRP website at OHRP Assurances.

B. An IRB Authorization Agreement describing each organization's responsibilities for IRB review and oversight of the research will be executed between the university and a collaborating organization or other external entity engaged in federally-funded, non-exempt Ohio State research (including non-US locations). Minimally, the agreement should describe the IRB that will serve as the IRB of record, IRB and organizational responsibilities for research oversight, and communication and reporting requirements.

C. An Individual Investigator Agreement must be executed for external independent investigators engaged in federally-funded, non-exempt Ohio State research who are not employees or agents of The Ohio State University or another entity responsible for oversight of their research-related activities. Minimally, the agreement should describe investigator responsibilities and IRB oversight of the research.

10. Applicable Regulations/Guidance

21 CFR 56.114, 45 CFR 46.114, FDA Information Sheets: "Non-Local IRB Review" (01/25/16), OHRP "Assurance Process Frequently Asked Questions," OHRP "Guidance on Engagement of Institutions in Human Subjects Research" (07/18/14), OHRP Guidance "Knowledge of Local Research Context" (07/21/00)

11. History

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