

Non-Human Subject Research Determinations

1.0 Purpose

The purpose of this policy is to define the Wright State University (Wright State) process and related requirements for determining whether or not an activity meets the definition of human subject research or a Food and Drug Administration clinical investigation (hereafter referred to as “human subject research”).

2.0 Scope

This policy applies to all activities that are conducted by Wright State faculty, staff and students, except activities conducted solely at Premier Health or Dayton Veterans Affairs Medical Center (Dayton VAMC) facilities. In such cases, institutional officials at Premier Health or the Dayton VAMC may also determine that activities conducted at their facilities do not meet the definition of human subject research and, therefore, do not require IRB review.

3.0 Definitions

3.1 **Clinical investigation** means any experiment that involves a test article and one or more human subjects, and that is either subject to the requirements for prior submission to the FDA under section 505(i) or 520(g) of the Act, or need not subject to the requirements for prior submission to the Food and Drug Administration under these sections of the Act, but the results of which are intended to be later submitted to, or held for inspection by the FDA as part of an application for a research or marketing permit. An example that meets this definition is a clinical trial that involves an investigational drug or device.

3.2 **Generalizable knowledge** means that the intent or purpose of the systematic investigation is to produce knowledge from which conclusions will be drawn that can be applied to populations outside of the specific study population.

This usually includes one or more of the following concepts:

- knowledge that contributes to a theoretical framework of an established body of knowledge
- the primary beneficiaries of the research are other researchers, scholars, and practitioners in the field of study
- dissemination of the results is intended to inform the field of study (this alone does not make an activity constitute research “designed to contribute to generalizable knowledge”)
- the results are expected to be generalized to a larger population beyond the

site of data collection

- the results are intended to be replicated in other settings

3.3 **Human Research Protection Program (HRPP)** means a multi-tiered program involving Wright State University administration, its Institutional Official (IO), its Institutional Review Board, its other research administrative and compliance offices, and its investigators.

3.4 **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable specimens.

FDA further defines a human subject as an individual who becomes a participant in research, either as a recipient of a test article or as a control.

Why “about whom” is key:

Consider if the project focuses on the person or if the focus is on policies, practices, or procedures about which the person is knowledgeable. Projects which collect information about policies, practices, or procedures – even if the person who provided that information is identified – do not constitute human subject research. Asking a person about someone else does not make that person a human subject.

3.5 **Identifiable private information** means private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

3.6 **Identifiable biospecimen** means a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

3.7 **Institutional Review Board (IRB)** means a committee established to review and approve research involving human subjects. The purpose of the IRB is to ensure that all human subject research be conducted in accordance with all federal, institutional, and ethical guidelines.

3.8 **Investigator** means the Project Director/Principal Investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposing of research, including persons who are

subcontractors, collaborators, or consultants. At Wright State this definition includes, but is not limited to, the following roles: Principal investigator, co-investigators, research coordinators, research associates, collaborators, and consultants, and may include research assistants and students as identified by the PD/PI depending on their specific roles and responsibilities. **For the purposes of this policy, it also refers to individual leading non-human subject research activities.**

- 3.9 **Intervention** means both the physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- 3.10 **Interaction** means communication or interpersonal contact between investigator and subject.
- 3.11 **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- 3.12 **Private information** means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
- 3.13 **Office of Human Research Protections (OHRP)** means the administrative agency that oversees the United States' system for protecting volunteers in research conducted or supported by the U.S. Department of Health and Human Services (DHHS).
- 3.14 **Quality improvement (QI)** means an activity where the primary purpose is to monitor or improve a process, program or system delivered by an institution. It involves systematic data collection to compare a program/process/system to an established set of standards to improve performance of the institution. Types of QI activities can include, but are not limited to, practice reviews, satisfaction/knowledge surveys, service improvements, and program evaluations.
- 3.15 **Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. In accordance with DHHS regulations the following activities are **deemed not to be research**:
- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship),

including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each “federal” agency) in support of intelligence, homeland security, defense, or other national security missions.

- 3.16 **Systematic investigation** means an activity that involves a prospective plan that a detailed or careful examination that has or involves a prospectively identified approach to studying a specific topic, answering a specific question(s), testing a specific hypothesis(es), or developing theory based on a system, method, or plan.

Systematic investigations include observational studies, interview or survey studies, group comparison studies, test development, interventional research, analysis of identifiable data or biospecimens.

Projects that are not systematic investigations include, for example, oral histories, journalism, and phenomenological activities. Program evaluation is seen as a gray area and requires further assessment of design and intent.

- 3.17 **Test article** means any drug (including botanicals, biologicals, and gene therapy, and genetically derived products that meet the definition of a drug) or medical device for human use.

4.0 Policy

The Department of Health and Human Services (DHHS) and FDA regulations define human subject research and clinical investigations that require IRB review, but there are some types of activities that involve human beings or information about human beings that do not meet these definitions. This policy is to define the evaluation process for those activities, including how an activity can be determined to be non-human subject research.

Investigator activities that clearly do not involve exempt and non-exempt human subjects research or clinical investigations (as defined in Section 3.0 above) are not required to be submitted for IRB review under this policy. However, incorrect determinations resulting in the conduct of human subject research without prior IRB review will be considered non-compliance. Wright State may prohibit an investigator from publishing or otherwise making

use of the data from the activity, as well as, imposing other appropriate sanctions upon the investigator based on this non-compliance.

Therefore, if an investigator is unsure if an activity is human subject research, he/she should consult with the IRB Office prior to engaging in the activity.

5.0 Procedures

5.1 Non-Human Subject Research Determinations by Investigators

Investigators should use this policy and the definitions contained herein, relevant local guidance on the IRB website, applicable federal regulations and guidance, and the Human Subjects Research Decision Chart located at the OHRP website at <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html> to determine whether or not a proposed activity meets the definition of human subjects research or a clinical research investigation.

In addition, if changes are made to the conduct of the non-human subject research activity, the investigator must re-evaluate the activity (using the same list of resources) to ensure it still does not require IRB review and if it does immediately seek IRB review by submitting application via the IRB's electronic submission system.

The IRB cannot give after-the-fact approval to an investigator who requests IRB approval to continue a clinical investigation or human subjects research that was initiated without IRB review/approval, nor can it give after-the-fact approval to use data for a clinical investigation or research that was collected with the intent of being used for a clinical investigation or research without prior IRB approval.

In addition, the IRB may not approve activities in which it appears that the investigator attempted to circumvent IRB review by collecting data as non-research/non-clinical investigation data and then applying to the IRB for use of the data in research and/or a clinical investigation. Investigators should err on the side of caution and seek IRB review and approval for any project/study concerning or involving humans, particularly if publication of the project/study is anticipated.

5.2 IRB Office Formal Non-Human Research Determinations

Even though investigators may make the determinations themselves, there are many situations for which an official determination may be needed (e.g. publication or collaborator requirements). To receive a formal Wright State determination, an investigator must submit an Initial Review Request via the electronic submission system providing as much information as possible regarding the proposed activity.

However, if the activity is determined to constitute exempt or non-exempt human subject research, submissions will be returned to the investigator to revise the initial review request based on this determination.

The IRB Office will be responsible for reviewing all submissions, obtaining additional information from investigators when necessary, making non-human subject research determinations and documenting them in the electronic submission system, as well as, sending a formal non-human subject's research determination letter via e-mail.

The IRB Office can only make these determinations on behalf of Wright State and cannot make these determinations for non-Wright State investigators/collaborators or non-Wright State institutions, except if requested by either Premier Health, Wright State Physicians, and/or Dayton VAMC for investigators who act on behalf of both institutions (e.g., Premier Health physician who is adjunct Wright State faculty member).

5.3 Proposals Lacking Definite Plans for Involvement in Human Subjects Research

The regulation at 45 CFR 46.118 provides a mechanism by which IRB review is not required if a project is either a type of grant (institutional or training grants), cooperative agreement, or contract, and when the specific activities of the research have not yet been determined because there is significant activity that is needed prior to involving human subjects.

To receive a formal Wright State determination, an investigator must submit an Initial Review Request via the electronic submission system providing as much information as possible regarding the proposed activity. The investigator should select the "Delayed Onset" application type. The IRB Office will be responsible for reviewing all submissions, obtaining additional information from investigators when necessary, making the non-human subject research determinations and documenting them in the electronic submission system, as well as, sending a formal delayed onset/118 determination letter via e-mail.

6.0 Records

All records related to this process will be stored and maintained in accordance with any Wright State policy, federal regulations and sponsor requirements associated with activity under review.

7.0 References

- 45 CFR 46.101-102
- 21 CFR 50
- 21 CFR 56.101-105

- <https://www.hhs.gov/ohrp/sites/default/files/human-subject-regulations-decision-charts-2018-requirements.pdf>