Human Subject Research Mandatory Reporting

1.0 Purpose

The purpose of this policy is to describe the policies and procedures to ensure prompt reporting of HHS-supported prisoner research, unanticipated problems involving risks to subjects or others (including unanticipated adverse device effects), serious or continuing noncompliance, or suspension or termination of research to Wright State University official(s), affiliated hospital official(s) and the appropriate federal regulatory agencies as required by federal regulations.

2.0 Scope

This policy applies to all human subject research that is conducted by Wright State University (Wright State) faculty, staff and students and human subject research for which the Wright State Institutional Review Board (hereafter referred to as IRB) acts as the IRB of record for an external entity (e.g., Premier Hospitals, Dayton VAMC).

3.0 Definitions

3.1 **Unanticipated Problem Involving Risks to Participants or Others** means:

3.1.1 The problem/event is UNEXPECTED in terms of nature, severity, or frequency, given:

- The research procedures described in the protocol, Investigator Brochure, informed consent document and/or other study related documents; and
- The characteristics of the subject population being studied; and

3.1.2 The information indicates the research places subjects or others at SERIOUS risk (as defined below) **or** an increased risk of physical, psychological, economic, legal, or social harm than was previously known or recognized, and

3.1.3 The problem/event is RELATED or POSSIBLY RELATED to the procedures involved in the research.

3.2 **Serious** means a problem/event that:

- Results in death;
- Is life-threatening (places the subject at immediate risk of death from an event as it occurred);
- Results in inpatient hospitalization or prolongation of existing hospitalization;

- Results in persistent or significant disability/incapacity;
- Results in congenital anomaly/birth defect; or
- Based on appropriate medical judgement, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

3.3 **Suspension** means human subject research is temporarily stopped by the IRB.

3.4 **Termination** means human subject research is permanently stopped or prohibited by the IRB.

3.5 **Allegation** means an unproven assertion of noncompliance or suspected noncompliance. For the purpose of this policy it also means concerns identified during the IRB review process or via internal/external audit findings.

3.6 **Noncompliance** means conducting research in a manner that disregards or violates federal regulations or Wright State policies and procedures applicable to human subject research. Noncompliance with IRB policies and/or federal requirements may involve a range of issues from relatively minor, administrative, or technical violations to more serious violations which pose risk to subjects and/or violations of their rights and welfare.

3.7 **Continuing Noncompliance** means persistently conducting research in a manner that disregards or violates federal regulations or Wright State policies and procedures applicable to human subject research.

3.8 **Serious Noncompliance** means conducting research in a manner that disregards or violates federal regulations or Wright State policies and procedures applicable to human subject research that actually or potentially increases risks to human subjects, adversely affects the rights and welfare of human subjects or compromises the integrity/validity of the research. A single instance of non-compliance may be determined by the IRB to be serious noncompliance.

3.9 **Minor Noncompliance** means incidents or events which are not serious or continuing non-compliance.

3.10 **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.

3.11 **Institutional Official** means the Vice Provost for Research and Innovation or his/her designee. The Institutional Official (IO) is designated on Wright State's Federalwide Assurance as the person responsible for human subject research compliance and safety.

3.12 **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.

3.13 **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.

3.14 **Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, 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. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- 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 agency) in support of intelligence, homeland security, defense, or other national security missions.

4.0 Policy

Wright State University requires compliance with all applicable local, state, and federal reporting requirements in the conduct of research involving human subjects. The IRB or the external IRB of record is responsible for notifying the Wright State Institutional Official (IO) when research falls under the purview of a federal regulatory agency and one or more of the following events occurs:

- Approval of HHS-supported research involving prisoners;
- Unanticipated problems involving risks to participants or others;
- Serious or continuing noncompliance with the regulations or requirements of the IRB; and/or
- Suspension or termination of IRB approval for research.

The IO, or a delegate, is responsible for notifying external agencies and other internal parties in accordance with Section 5.3 of this policy.
Reporting to regulatory federal agencies is not required if the principal investigator (PI) voluntarily suspends new subject accrual or temporarily halts research procedures. The IRB, IRB Chair or other administrative officials may recommend voluntary closure/suspension to the PI, but the PI is responsible for deciding whether closure/suspension is appropriate. However, if the IRB/IRB Chair or external IRB of record requires suspension or termination, then the event will be reported under this policy.

Lapses of approval that occur in the continuing review process are not reportable under provisions of this policy unless such lapses have been determined by the IRB to constitute serious/continuing noncompliance (see *Human Subject Research Noncompliance Policy* for more information).

The mandated reporting described in this policy may be delegated to an external IRB of record per the conditions of an IRB Authorization/Reliance Agreement. However, in all cases Wright State retains the right to provide additional reports to federal agencies.

5.0 Procedures

5.1 Institutional Official Notification

When research is under the purview of an external IRB, mandated reporting to the IO will be in accordance with the executed Reliance Agreement and the IRB of Record's policies and procedures for noncompliance, unanticipated problems, reportable events and mandated reporting.

When research is under the purview of the Wright State IRB, the IRB Chair (in cooperation with the IRB Staff) will provide the IO with an incident letter/report within 5 business days of a finding by the convened IRB or IRB Chair (or sooner depending on severity of event). Additional documentation may be submitted with the report (e.g., meeting minutes or PI reports) to facilitate the IO's review.

If the research involves the Dayton VA, the IRB will notify the VA Facility Director and the Associate Chief of Staff for Research (ACOSR) no later than 5 business days after the IRB's determination.

5.2 Content of Incident Reports

The following information will be included in the incident report developed by the IRB Chair and IRB Staff:

For unanticipated problems involving risks to subjects or others:

- Title of the research project and/or grant proposal in which the problem occurred;
- Name of the principal investigator on the protocol;
- Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the problem;
- Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.); and
- Plans, if any, to send a follow-up or final report.

For serious or continuing noncompliance:

- Title of the research project and/or grant proposal in which the non-compliance occurred, or, for IRB or institutional non-compliance, the IRB or institution involved;
- Name of the principal investigator on the protocol, if applicable;
- Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the noncompliance;
- Actions the institution is taking or plans to take to address the noncompliance (e.g., educate the investigator, educate all research staff, educate the IRB or institutional official, develop or revise IRB

written procedures, suspend the protocol, suspend the investigator, conduct random audits of the investigator or all investigators, etc.); and
- Plans, if any, to send a follow-up or final report.

For suspension or termination:
- Title of the research project and/or grant proposal that was suspended or terminated;
- Name of the principal investigator on the protocol;
- Number of the research project assigned by the IRB that was suspended or terminated and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the reason for the suspension or termination;
- The actions the institution is taking or plans to take to address the suspension or termination (e.g., investigate alleged noncompliance, educate the investigator, educate all research staff, require monitoring of the investigator or the research project, etc.); and
- Plans, if any, to send a follow-up or final report.

For Approval of HHS-supported research involving prisoners:
- Institution Name and address
- Title of the research project and/or grant proposal;
- Name of the principal investigator;
- Certification of seven required findings (see Vulnerable Populations Policy)
- Copy of IRB-approved protocol;
- Copy of grant application or proposal;
- Copy of all IRB application forms; and
- Any other materials considered by the IRB.

5.3 Notification of External Agencies and Other Appropriate Parties

The IO and IRB Chair will finalize the incident report and send it (or a summary letter when appropriate) to the IRB and all applicable parties listed below within 7 calendar days of the IO notification:
- Office for Human Research Protections (OHRP) for all research that falls under Wright State's active Federalwide Assurance (FWA) via online incident reporting system as of January 2, 2022
- Food and Drug Administration (FDA) - when research is FDA regulated
- Any agency that is subject to "Common Rule" but not DHHS, including:
    - Department of Agriculture
    - Department of Energy

  - National Aeronautics and Space Administration
  - Department of Commerce - National Institute of Standards and Technology
  - Consumer Product Safety Commission
  - Agency for International Development (USAID)
  - Department of Housing and Urban Development
  - Department of Justice - National Institute of Justice
  - Department of Defense
  - Department of Education
  - Department of Veterans Affairs - Office of Research Oversight - Office of Research and Development
  - Environmental Protection Agency - Research and Development
  - National Science Foundation
  - Department of Transportation
  - The Central Intelligence Agency
  - The Department of Homeland Security
  - The Social Security Administration
- PI and other members of the research team
- PI's Department Chair or Supervisor
- Other Wright State University Administrative Officials
- Premier Health Administrative Officials
- Other organizations, such as sponsors or contract research organizations
- Other sites involved in the research.

6.0 Records:

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

7.0 References:

- 45 CFR 46.113
- 21 CFR 56.108(b)(1)
- *Guidance on Reporting Incidents to OHRP* – June 20, 2011
- *Instructions for Completing OHRP Online Reporting Form* – January 2, 2022
- VHA Handbook 1200.05
- VHA 1058.01
- 36 CFR 16