Human Subject Research Noncompliance

1.0 Purpose

The purpose of this policy is to describe the requirements and process for identifying and managing any allegations and findings of noncompliance related to human subject research conducted at Wright State University.

2.0 Scope

This policy applies to all human subject research that is conducted by Wright State University (WSU) faculty, staff and students and human subject research for which the WSU 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 **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.

3.2 **Noncompliance** means conducting research in a manner that disregards or violates federal regulations or Wright State University (WSU) 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.

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

3.4 **Serious Noncompliance** means conducting research in a manner that disregards or violates federal regulations or WSU 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.

3.5 **Minor Noncompliance** means incidents or events which are not serious or continuing noncompliance.

3.6 **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 WSU 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.

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

3.7.1 Obtains information or biospecimens through intervention or interaction with the individual and uses, studies or analyzes the information or biospecimens; or

3.7.2 Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable specimens.

3.8 **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.

3.9 **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**:

3.9.1 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.

3.9.2 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).

3.9.3 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.

3.9.4 Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

4.0 Policy

The ethical conduct of research is a shared responsibility. It requires cooperation, collaboration and trust between the institution, investigators, human subjects who participate in research, the IRB and IRB staff. The primary responsibility of the IRB is to ensure the protection of the rights and welfare of human subjects. As part of its oversight responsibility, the IRB must establish the following procedures for evaluating noncompliance allegations and for prompt reporting of any findings of serious or continuing noncompliance.

5.0 Procedures

5.1 Submission and Screening of Allegations of Noncompliance

5.1.1 Submission

Anyone may submit allegations of noncompliance involving human subject research to the IRB or Office of the Vice Provost for Research and Innovation verbally or in writing. IRB members or IRB staff may also identify concerns during the study review process, via written internal/external audit reports or during routine operations.

The Principal Investigator (PI) is obligated to submit a Reportable Event form via the electronic submission system to the IRB within 10 calendar days of the occurrence if noncompliance occurs during the conduct of the research or upon notification of any potential noncompliance identified by the sponsor, external monitor, federal agency or study staff (see *Reportable Events* policy for more information).

The IRB Chair (or his/her designee) will be notified of any allegation received by IRB Office in a timely manner.

5.1.1.1 Dayton VA Research

In accordance with VA regulations, VA administration (RCO and/or Facility Director) and/or VA investigators are required to report the possible noncompliance to the IRB when the

WSU IRB acts as the IRB of record within 5 business days of becoming aware of possible serious or continuing noncompliance with VA or other Federal requirements related to human subject research or with IRB requirements or determinations.

5.1.2 Screening

The Director for Research Compliance (Director) or his/her designee will screen the allegation in collaboration with the IRB Staff to determine the following:

5.1.2.1 Whether the study affected is supported by federal funds and has specific reporting requirements

5.1.2.2 Whether the allegation is pertinent to other research review functions (i.e., Institutional Biosafety, Sponsored Projects, etc. …), and

5.1.2.3 Whether there are sufficient supporting documents or statements to allow the allegation to be reviewed.

If the Director or IRB Staff finds issues pertinent to other research review functions, he/she will coordinate with these functions, as applicable.

5.2 Assessment of Allegations

The Director will review the allegation to determine whether there is sufficient evidence for the WSU IRB to review it under this policy. If the Director deems an allegation unsubstantiated (i.e., not to have a basis in fact), he/she will consult with the IRB Chair or his/her designee and, if appropriate the Institutional Official (IO). The IRB Chair, Director and IRB Staff may decide no additional action is needed, further inquiry is necessary, or the issue should be presented to a convened IRB.

An allegation determined not to have a basis in fact will be forwarded to the Director for response to the source of the allegation, when applicable.

5.3 Review of Minor Noncompliance

The IRB Chair, in consultation with the Director and IRB Staff, may determine that the noncompliance does not meet the definition of serious or continuing

noncompliance and no additional action is needed, or determine further inquiry is needed, or determine the issue should be presented to the convened IRB.

A finding of minor noncompliance may include a determination of what appropriate corrective action, if any, should be implemented by the PI and study team. The IRB may require a range of actions to correct minor noncompliance, including, but not limited to:

5.3.1 Additional training of the PI or study team
5.3.2 Additional supervision of the PI
5.3.3 A limit on the number of research activities conducted by the PI
5.3.4 A limit on the number of participants who may be enrolled by the PI

In cases where the IRB decides that the noncompliance is not serious or continuing, the Institutional Official (IO) is still authorized to take additional action, which may include suspending or terminating the research. The PI will be notified in writing of the WSU IRB's finding of minor noncompliance and any required corrective actions via the electronic submission system.

5.4 Suspension of Research

If, in the opinion of the IRB Chair (or his/her designee), the allegation may expose study subjects to immediate risk, the IRB Chair may suspend research activities immediately until such time that a convened IRB can appropriately review the matter.

Any suspension or termination of IRB approval of research will be reported to the appropriate regulatory agencies and institutional officials in accordance with the *Mandatory Reporting* policy.

5.5 IRB Review of Potential Serious or Continuing Noncompliance

If the allegation involves more serious issues than administrative or minor concerns, the convened IRB, the IRB Chair or the Vice Chair will decide whether to initiate an inquiry based on the circumstances of the case. The decision will be based on the seriousness and/or the frequency of the violations and/or disregard for the federal regulations or WSU policies and procedures applicable to human subject research.

Information will be collected using a variety of methods, such as, but not limited to, communicating directly with the PI and study team, or requiring the PI and

study team to provide a written report and/or meet with the IRB. The IRB may also request a for-cause audit by the Director, IRB staff or an external consultant.

The convened IRB is responsible for reviewing any and all information related to the case and determining whether serious and/or continuing noncompliance has occurred. The review and any subsequent findings must be documented in the meeting minutes.

5.6 Corrective Actions, Institutional Review and Reporting

When the convened IRB determines that there has been serious or continuing noncompliance, the IRB will determine what steps must be taken, if any, to protect enrolled subjects. The IRB will also determine the elements of a corrective action plan to address the noncompliance and prevent recurrence. The IRB may take any of the following actions in the case of serious or continuing noncompliance, including, but not limited to:

5.6.1 Modify the study protocol
5.6.2 Modify the information that must be disclosed in a consent document
5.6.3 Provide information about the noncompliance to current study participants, when such information may affect willingness to continue participation
5.6.4 Require re-consent of all subjects
5.6.5 Modify the continuing review schedule
5.6.6 Monitor the research activities
5.6.7 Monitor the consent process
5.6.8 Suspend the conduct of research until all corrective actions are implemented
5.6.9 Terminate the research

The IRB determination of serious or continuing noncompliance must be reported to the IO within 15 calendar days of the IRB's determination. The IO is not authorized to change the IRB's determination of serious or continuing noncompliance or require a less stringent corrective action plan. However, the IO is authorized to determine whether a corrective action plan recommended by the IRB should include additional measures.

If the case involves Dayton VA research, then the IRB must notify the Facility Director and the Associate Chief of Staff for Research (ACOSR) of that finding within 5 business days of the IRB's determination.

If the apparent serious or continuing noncompliance was identified by an RCO audit, the IRB must notify the RCO within 5 business days after its determinations under paragraphs 6.f.(2) and 6.f.(3)(a), regardless of outcome.

Any suspension, termination, or findings of serious or continuing non-compliance will be reported to regulatory agencies and other applicable parties in accordance with WSU IRB's *Mandatory Reporting* policy.

6.0 Responsibilities and Authorities:

The IRB, IRB Chair (or his/her designee), IRB Staff and/or Director are responsible for implementing this policy. The IO is responsible for ensuring that there are sufficient resources to implement the policy and to enforce corrective actions.

7.0 Records:

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

8.0 References:

8.1 21 CFR 50
8.2 21 CFR 56
8.3 45 CFR 46
8.4 VHA Handbook 1200.05
8.5 VHA Handbook 1058.01
8.6 36 CFR 16