Human Research Protection Program Purpose and Authority

1.0 Purpose

Wright State University (Wright State) is committed to advancing knowledge through research and protecting the rights and welfare of human subjects who participate in that research. All human subject research must be ethically sound and compliant with federal, state, and local regulations and requirements. The purpose of this policy is to describe Wright State's standards for human research protection and its authority and responsibility to ensure proper research conduct, oversight, and compliance.

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 IRB acts as the Reviewing IRB for an external entity via a reliance agreement.

This policy does not apply to Premier Health or Dayton VAMC human subject research when the Wright State IRB is not the Reviewing IRB, and the research does not involve Wright State information, facilities or funding. The only exception to this is human subject research conducted via the Clinical Trials Research Alliance (CTRA). Wright State is considered to be *engaged* (see Section 4.2) in research conducted via the CTRA and, therefore, the requirements of this policy apply to that research regardless of the location (e.g., Premier Health) of the conduct of that research.

3.0 Definitions

3.1 **Director** means a member of the HRPP Office who directs, manages, implements, and administers policies and procedures related to research involving human subjects. The Director provides for all compliance and regulatory functions of the IRB ensuring adherence to all federal, state, and local regulations and policies governing research involving human subjects, including the Belmont Report and the requirements set forth in Title 45, Part 46 of the

Code of Federal Regulations.

3.2 **Human Research Protection Program (HRPP)** means a multi-tiered program involving University administration, the IO, the Wright State IRB, HRPP Office, other research administrative and compliance offices, and investigators.

3.3 **Institutional Official (IO)** means a high-level official who is the signatory on the Federalwide Assurance (FWA) filed with OHRP and has the authority to represent the institution. The Vice Provost for Research and Innovation serves as the IO for Wright State University.

3.4 **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.

4.0 **Policy**

4.1 Ethical Principals and Regulatory Mandates

Wright State maintains an agreement, called a Federalwide Assurance (FWA), with the Department of Health and Human Services' (DHHS) Office of Human Research Protection (OHRP). The terms of this assurance require that Wright State have policies and procedures to properly communicate institutional and regulatory requirements to members of the Wright State research community.

This policy outlines the responsibilities and authority of involved individuals/committees to facilitate compliance with all applicable federal, state, and local regulations related to the protection of human subjects involved in research. The Wright State's FWA also requires that research must abide by the three following principles of the *Ethical Principles and Guidelines for the Protections of Human Subject Research*, generally known as the "Belmont Report:"

4.1.1 Respect for Persons

Respect for persons requires that studies (including the informed consent

process) be designed to promote personal capacity to consider alternatives, make choices, and act without undue influence or interference from others. The principle is reflected in federal regulations and IRB policy through requirements that legally effective informed consent be sought and obtained unless specific requirements for waiver of informed consent are met and appropriately documented, and that subjects with diminished capacity and others who are vulnerable to coercion or undue influence receive special protection or consideration.

4.1.2 Beneficence

Beneficence entails an obligation to protect individuals from harm. The principle can be expressed in two general rules: (1) do no harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm. It is reflected in federal regulations and IRB policy through a requirement that principal investigators (PIs) design, and IRBs approve studies only under circumstances where the benefits to the subjects and the importance of the knowledge to be gained justify the risks to the subjects sufficiently to warrant a decision to allow the subjects to accept those risks.

4.1.3 Justice

Justice requires fairness in distribution of burdens and benefits. The principle is often expressed in terms of treating persons of similar circumstances or characteristics similarly. It is reflected in federal regulations and IRB policy through requirements that selection of subjects is equitable and is representative of the group(s) that is intended to benefit from the research.

Additional ethical codes and guidelines, including ethical codes of professional societies, may also govern local research.

When Wright State is engaged in human subject research that is conducted, funded or otherwise subject to regulations by a federal department or agency, it will apply the regulations of that agency relevant to human subject protections.

Activities that do not meet the definition of human subject research (e.g., quality

improvement activities and certain health surveillance activities) do not require review and approval by an IRB. However, an investigator must contact the HRPP Office for guidance and a formal determination if he/she is unclear whether his/her proposed activity falls under the definition of human subject research.

4.2 Engagement

"Engagement" is defined by the federal government (2008 OHRP Guidance) and is a factor in determining whether research requires IRB review. Wright State is engaged when its agents (faculty, staff or students) recruit and obtain informed consent, conduct research procedures, or receive or share private, identifiable information as part of non-exempt research.

Wright State is generally not considered to be engaged in human subject research if faculty, staff and students:

4.2.1 Only inform prospective subjects about the availability of research, or
4.2.2 Provide prospective subjects with written information about research (which may include IRB-approved consent documents) but do not obtain subjects' consent or act as representatives of the investigators.
4.2.3 Provide prospective subjects with information about contacting investigators for information or enrollment; or
4.2.4 Obtain and appropriately document prospective subjects' permission for investigators to contact them.

If a collaborating institution is not engaged in the research, the institution's investigators do not need to secure IRB approval. Questions about engagement should be directed to the HRPP Office.

4.3 Complaints, Concerns and Undue Influence

Questions, concerns, complaints, allegations of undue influence, allegations of non-compliance or input regarding the Wright State HRPP may be reported orally or in writing. Wright State employees/agents can report concerns to Research & Sponsored Programs, the IRB Chair, the Director, the Institutional Official, General Counsel's Office, or anonymously using the University Compliance Hotline or website.

Wright State employees/agents who report in good faith possible compliance issues will not be subjected to retaliation or harassment because of reporting. Concerns about possible retaliation should be immediately reported to the Institutional Official or Director.

4.4 Resources

Wright State must maintain adequate resources for support of the operations of the HRPP, including but not limited to resources such as space and personnel, to meet regulatory requirements. The need for study-specific resources is evaluated at the local level. Investigators and departments are responsible for ensuring that sufficient resources are allocated to all studies, whether sponsored or investigator initiated.

4.5 Institutional Review Boards (IRBs) of Record

The terms of the FWA (#00002427) require Wright State to designate at least one Institutional Review Board (IRB) to review and oversee non-exempt human subject research and to register that IRB with the OHRP. Wright State maintains the registration of the Wright State IRB (IRB#00000034) for this purpose.

However, federal regulations also allow institutions to designate external IRBs as the IRB of Record (or reviewing IRB) through a written IRB Authorization Agreement that is also known as a "reliance agreement."

Wright State investigators must follow the *Collaborative Research and External IRB Review Policy* when relying on an IRB other than the Wright State IRB and/or when the Wright State IRB acts as the reviewing IRB for an external collaborating organization.

4.6 Ancillary Reviews

Ancillary reviews are reviews of human research studies by officials or committees that are required in addition to the IRB review. These reviews vary, depending on the grant requirements and type of research performed and may be required by federal or state regulations, IRB policy or Wright Way policies. Approval for all required ancillary reviews must be obtained prior to the IRB issuing their initial review approval. Examples of ancillary reviews that may be

required include, but are not limited to, the following:

4.6.1 Institutional Biosafety Committee
4.6.2 Dayton Veterans Affairs Research Office
4.6.3 Premier Health Human Investigation Research Committee (HIRC)
4.6.4 Radiation Safety
4.6.5 Nursing
4.6.6 Pharmacy
4.6.7 Clinical Billing
4.6.8 Laser Safety
4.6.9 Registrar's Office (FERPA)

4.7 Audits, Quality Improvement Activities and Post-Approval Monitoring

Qualified internal/external individuals will conduct periodic reviews, including formal audits, quality improvement activities and post-approval monitoring, as part of the institution's oversight mechanism. Investigators must comply with all requests for information involving research under these types of review. In the case of potential non-compliance or other problems, for cause audits may be conducted and, if applicable, result in disciplinary actions.

4.8 Disciplinary Actions

The Wright State IRB and/or the IO may terminate or suspend human subject research. In addition, the IRB and/or the IO and/or the Director may place limitations or conditions on an investigator's privilege to conduct human subject research whenever such actions are required to maintain research integrity. Any disciplinary action will be in accordance with all related Wright State policies and procedures.

5.0 **Procedures**

Implementation of the HRPP will be in accordance with all applicable Wright State policies and procedures and in accordance with the authority and responsibilities described under these procedures.

5.1 Institutional Official

Wright State's Vice Provost for Research and Innovation acts as the Institutional Official (IO) for the HRPP. In addition to oversight, the IO is responsible for ensuring that conflicts of interest in research are properly managed and that sufficient education and training in the responsible conduct of research is provided to all investigators.

The IO has the responsibility and authority to take the following actions or delegate the following to a designee:

5.1.1 Allocate sufficient local resources to ensure proper operations.
5.1.2 Appoint and remove Wright State IRB members and chairpersons.
5.1.3 Approve and rescind IRB Authorization Agreements (also known as Reliance Agreements).
5.1.4 Suspend or terminate research approved by the Wright State IRB or other IRB of Record.
5.1.5 Disapprove research approved by the Wright State IRB or other Reviewing IRB but may not approve research disapproved by the Wright State IRB or other Reviewing IRB.

5.2 Director

The Director has the authority to take the following actions or delegate these authorities to a designee:

5.2.1 Develop related budget(s).
5.2.2 Make related personnel decisions.
5.2.3 Determine whether Wright State will enter agreements to rely on external IRBs for review and approval of Wright State research.
5.2.4 Determine whether Wright State will enter agreements to allow external institutions to rely on the Wright State IRB's review and approval.
5.2.5 Limit an investigator's privileges to conduct human subject research.
5.2.6 Develop related policies and procedures.

The Director also has the responsibility for the following:

5.2.7 Oversee the review and conduct of human research under the jurisdiction of Wright State.

5.2.8 Institute regular, effective educational and training programs for all individuals involved in human subject research and ensure that federally mandated education requirements are met.

5.2.9 Ensure that the research review process is independent and free of undue influence and ensure that Wright State officials cannot approve research that has not been approved by one of the IRBs designated by Wright State.

5.2.10 Implement a process to receive and act on complaints and allegations regarding human subject research.

5.2.11 Implement an auditing program to monitor and improve compliance.

5.2.12 Investigate and remediate identified systemic problem areas and, where necessary, remove individuals from involvement in human subject research.

5.2.13 Ensure that the institution has sufficient resources, including IRBs appropriate for the volume and types of human research to be reviewed, so that reviews are accomplished in a thorough and timely manner.

5.3 Institutional Review Board

The Wright State IRB, as well as any other reviewing IRB, has the authority to:

5.3.1 Approve, require modifications to secure approval, and disapprove human subject research.

5.3.2 Suspend or terminate approval of human subject research not being conducted in accordance with institutional/regulatory requirements or that has been associated with unexpected serious harm to subjects.

5.3.3 Observe, or have a third party observe, the consent process.

5.3.4 Determine whether an activity is human subject research.

5.3.5 Determine whether additional protections are warranted for studies involving vulnerable subject populations.

5.3.6 Evaluate investigator financial interests and have the final authority to decide whether the financial interest and management plan, if any, allow the human subject research to be approved.

IRB members and staff have the responsibility to follow all related policies and procedures, including disclosure of significant financial interest and recusal for review of research with which the member or staff may have a conflict of interest.

5.4 Investigators

Investigators are responsible for the following:

5.4.1 Understanding the definition of human subject research and consulting the HRPP Office when there is uncertainty about whether an activity meets that definition.
5.4.2 Following all institutional policies and procedures and complying with all related institutional, federal, state, and local requirements.
5.4.3 Obtaining a written exemption determination or IRB approval before starting any human subject research activities.
5.4.4 Ensuring that research staff or students do not start any human research activities prior to obtaining a written exemption determination or IRB approval for those activities.
5.4.5 Complying with all determinations and additional requirements of the reviewing IRB, the IRB Chair, and the IO.
5.4.6 Reporting allegations of undue influence regarding the oversight of Wright State human subject research or concerns about human research protections to the Director or IO.
5.4.7 Reporting non-compliance with the human research protection standards to the Director or Institutional Official.

5.5 Deans, Department Chairs and Relying Hospital Research Officials

Deans, Department Chairs and Hospital Research Officials are responsible for conducting appropriate scientific review and oversight of the conduct of the human subject research under their jurisdiction. This includes affirming, via the IRB electronic submission system, that each study proposed under their jurisdiction can be executed responsibly with appropriate resources and personnel.

Deans, Department Chairs and Relying Hospital Research Officials are also responsible for forwarding any related complaints or allegations to the Director.

5.6 Research and Sponsored Programs

The Research and Sponsored Programs Office is responsible for ensuring that contracts and funding agreements are thoroughly reviewed for compliance with all Wright State HRPP policies and procedures.

6.0 Records

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

7.0 References

Laws, regulations, and other rules relevant to human research conducted by Wright State include rules pertaining explicitly to research and human subject protections and rules that are not specific to research, but that may affect its conduct or oversight. Key references include the following:

7.1 20 U.S.C. 1232h (Consent in School-Based Surveys/Evaluations)
7.2 42 U.S.C. 241(d) (Certificates of Confidentiality)
7.3 42 U.S.C. 290dd-2 (Confidentiality of Substance Abuse Records)
7.4 Pub. L. No. 104-191, 110 Stat. 1936 (HIPAA)
7.5 Pub. L. No. 111-5, 123 Stat. 226 (HITECH)
7.6 Pub. L. No. 113-240, 128 Stat. 2851, § 12 (Informed Consent for Newborn Screening Research)
7.7 21 CFR Part 11 (Electronic Records; Electronic Signatures)
7.8 21 CFR Part 50 (Protection of Human Subjects)
7.9 21 CFR Part 54 (Financial Disclosure by Clinical Investigators)
7.10 21 CFR Part 56 (Institutional Review Boards)
7.11 21 CFR Part 210 (Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs: General)
7.12 21 CFR Part 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals)
7.13 21 CFR Part 312 (Investigational New Drug Application)
7.14 21 CFR Part 314 (Applications for FDA Approval to Market a New Drug)
7.15 21 CFR Part 320 (Bioavailability and Bioequivalence Requirements)
7.16 21 CFR Part 330 (Over-The-Counter (OTC) Human Drugs which are Generally Recognized as Safety and Effective and Not Misbranded)
7.17 21 CFR Part 361 (Radioactive Drugs)
7.18 21 CFR Part 601 (Biologics Licensing)
7.19 21 CFR Part 610 (Biological Products)
7.20 21 CFR Part 803 (Medical Device Reporting)
7.21 21 CFR Part 812 (Investigational Device Exemptions)
7.22 21 CFR Part 814 (Premarket Approval of Medical Devices)

7.23 21 CFR Part 820 (Quality System Regulation)
7.24 21 CFR Part 860 (Medical Device Classification Procedures)
7.25 34 CFR Part 98 (Consent in School-Based Examination/Treatment)
7.26 42 CFR Part 2 (Confidentiality of Alcohol/Drug Abuse Records)
7.27 42 CFR Part 50 (Research Integrity: Objectivity in Research – Financial Conflicts of Interest
7.28 45 CFR Part 46 (Protection of Human Subjects)
7.29 45 CFR Parts 160 and 164 (Security and Privacy; Breach Reporting)
7.30 VHA Directive 1200.5
7.31 38 CFR 16