Required Training and Credentialing Policy for Investigators

1.0 Purpose

The purpose of this policy is to describe the training and credentialing requirements that individuals who act as investigators must complete prior to conducting exempt or non-exempt research which involves human subjects.

2.0 Scope

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

3.0 Definitions

1.1 **Federally funded or supported** means any of the following:

- Funded by a direct federal grant
- Funded through a sub-award or pilot grant associated with federal dollars
- Includes personnel on a federally funded training grant
- Research conducted under a no-cost extension
- Data will be used to support an application for FDA approval or a grant application (e.g., data collection in response to a scored grant submission with plans to re-submit)
- Involves an FDA-regulated product or dietary supplement
- Involves data collection about FDA-regulated products
- Conducted under a contract that requires the investigator to adhere to federal human subjects' regulations (e.g., 45 CFR 46, 34 CFR 97 or other references to the HHS Common Rule)
- Involves any services that could be billed to a federal program

3.1 **Financial interests** means anything of monetary value (e.g., salary, stocks, ownership rights, etc.)

3.2 **Institutional Responsibilities** means responsibilities performed on behalf of the Institution (e.g., teaching, clinical or professional practice, research, service activities, etc.).

3.3 **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.

4.0 Policy

Wright State requires that investigators who participate in the conduct of human subject research be trained in human subject protections, disclose information to allow for screening for potential conflicts of interest, and provide evidence of their qualifications**.** The process of verifying completion of requirements is called credentialing.

Federal and sponsor requirements together with assurances Wright State makes to conduct research drive the scope and timing of the submissions and training described in this policy. Specifically, the NIH requires education on the protection of human research subjects for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects. Investigators must provide a description of education completed in the protection of human subjects for each individual identified as "key personnel" in the proposed research.

In addition, effective January 1, 2017, the NIH requires investigators and clinical trial staff to be trained in Good Clinical Practice when involved in the design, conduct, oversight, or management of NIH-funded clinical trials. The FDA also expects IRBs to evaluate the qualifications of investigators, which may include verification of GCP training, as appropriate.

The training requirements described here reflects Wright State's commitment to the protection of research subjects and the conduct of scientifically valid and reproducible research. Training investigators in regulations, guidelines, ethics, and policies applicable to human subject research is critical to Wright State's ability to protect the rights and welfare of research subjects consistently throughout the institution.

All required training is available online through the Collaborative Institutional Training Initiative.

5.0 Procedures

The following describes the specific training, disclosure and submissions that are required to obtain and maintain credentials to conduct human subject research:

5.1 Collaborative Institutional Training Initiative (CITI) Training Requirements

Investigators must successfully complete and pass examination for all applicable required courses. *Note that investigators who conduct both biomedical and social/behavioral research only need to complete the biomedical modules.*

5.1.1 For all **Biomedical Investigators**, the following CITI courses are required:

- Basic - Biomedical Research Investigators -Initial training and Refresher every 4 years
- Good Clinical Practice (Clinical Trials only)- Initial training and Refresher every 3 years
- IPS for Researchers – Initial training only
- Conflict of Interest – Initial training and Refresher every 4 years (Only investigators required to complete an annual conflict of interest (COI) disclosure)

5.1.2 For all **Social/Behavioral (SBE) Investigators**, the following CITI modules are required:

- Basic - Social Behavioral Research Investigators – Initial training and Refresher every 4 years
- Good Clinical Practice for SBE Researchers (Clinical Trials only)- Initial training and Refresher every 3 years
- IPS for Researchers – Initial training only
- Conflict of Interest – Initial training and Refresher every 4 years (Only investigators required to complete an annual COI disclosure)

5.1.3 For all **HUD clinicians**, the following CITI module is required:

- HUD Clinicians -Initial training only

Wright State will accept the completion of Dayton VAMC or Dayton Children's Hospital human subject and conflict of interest required training in lieu of the above requirements for applicable investigators from those two institutions.

5.2 Research Involving Protected Health Information (PHI)

Investigators who are not affiliated with Premier Health, Dayton Children's Hospital, or the Dayton VAMC, but who want to utilized PHI that is subject to the Health Insurance Portability and Accountability Act (HIPAA) for research must also complete the CITI Health Privacy course as part of their credentialing requirements.

5.3 Significant Financial Interest Disclosure Requirements

All principal investigators involved in any **human subject research**, are required to complete a project-specific conflict of interest disclosure on behalf of the project investigators for each human subjects' research project. This disclosure is embedded in the initial application in the electronic submission system.

In addition, all investigators of human subject research projects must complete the Wright State Annual Conflict of Interest (COI) form in the electronic submission system if any of the following apply to the project:

- Funding sponsor requires disclosure of financial conflicts of interest (e.g., federally funded or sponsored projects);
- Includes materials or activities regulated by the Food and Drug Administration (FDA);
- Involves collaboration with an institution outside the U.S; or
- WSU IRB determines an annual disclosure is ethically appropriate.

This form is used to disclose all significant financial interests (SFIs) investigators have that are or appear to be related to their institutional responsibilities. This form must be completed annually every January and updated within 30 days if there is a change in an investigators' SFIs. Please reference the *Research Conflict of Interest and Financial Disclosure (University Policy 6110)* for more information.

Investigators conducting research solely on site and/or on behalf of Dayton VAMC or Dayton Children's Hospital will not be required to submit an Annual Conflict of Interest disclosure through Wright State as each respective institution is responsible for meeting this requirement.

5.4 Curriculum Vita (CV) Requirements

Principal investigators (PIs) and Faculty Mentors listed on non-FDA regulated studies and all investigators listed on FDA regulated studies must upload their CV into the IRB electronic submission system via their individual user profile. Once uploaded, the CV will be accessible for all studies in which the individual is listed and must be updated every four years.

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 the human subject research protocol under review.

7.0 References

- NIH Guide Notice, June 5, 2000. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html
- NIH Guide Notice, September 5, 2001. http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-01- 061.html
- NIH Frequently Asked Questions for the Requirement for Education on the Protection of Human Subjects. http://grants2.nih.gov/grants/policy/hs_educ_faq.htm
- NIH Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-Funded Clinical Trials. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html