

Maintenance of IRB Policies and Procedures

1.0 Purpose

The purpose of this policy is to describe the requirements for drafting, reviewing, distributing, and revising IRB policies and procedures.

2.0 Scope

This policy pertains to all Wright State IRB policies and procedures governing the conduct of human subject research conducted by Wright State University faculty, staff, and students that is exempt, reviewed by the Wright State IRB or reviewed by an external IRB of record (i.e., reviewing IRB).

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 **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.

3.3 **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

Written policies and procedures, compliant with federal regulations and guidance and Wright Way policies, must be in place to ensure the highest quality and integrity of the review and oversight of human subject research and for the appropriate documentation of such oversight. These policies and procedures also provide an ethical and scientific framework for investigators to promote consistency in the oversight and conduct of such research.

Situations that may warrant changes or additions to policies and procedures include, but are

not limited to, the following:

- Changes to federal regulations;
- New or revised federal guidelines;
- Changes to Wright State (or relying hospital) research practices;
- Changes to Wright Way policies; or
- Recommendations from external auditors, inspectors, or accreditors.

5.0 Procedures

5.1 Policy and Procedure Review

The Director is responsible for reviewing current IRB policies and procedures on a regular basis to ensure that they remain in compliance with applicable regulations, laws, and institutional policies. Each policy must be formally reviewed and updated at least once every five years.

5.2 Policy and Procedure Drafting

The Director or designee is responsible for drafting new and/or revised policies and procedures. The Director will ensure that policies and procedures follow applicable regulations, laws, and institutional policies.

If the draft policy involves coordination with other Wright State or affiliated hospital (e.g., Premier Health, Dayton VAMC) offices, the Director will submit the draft policy to the representative of the other office for review to ensure consistency. The Director will work with the representative of the other office to resolve any discrepancies.

Normally, drafts of new or significantly revised policies will be reviewed by an IRB sub-committee prior to presentation to the full IRB.

5.3 Policy and Procedure Approval

IRB policies and procedures are presented at convened IRB meetings for review and approval. The Director is responsible for making any changes required by the IRB. Training on new or revised policies and procedures will be provided to all IRB members and IRB staff, as appropriate. Evidence of training will be documented in meeting minutes.

External reliance policies and procedures are reviewed and approved by the Institutional Official and then presented to members at convened meetings to ensure overall understanding and awareness.

Minor and/or administrative revisions to all policies and procedures can be approved by the Director and do not need to follow the process for approving new or substantively revised policies.

Policies and procedures for IRB office workflow are not reviewed at the IRB meeting or by the IO. These policies and procedures are drafted by the Director or designee and then reviewed with the IRB staff. The Director gives the final approval for these policies and procedures.

5.4 Policy and Procedure Distribution

With the exception of internal workflow policies and procedures, all new and revised policies are posted on the IRB website. These documents are also saved on the IRB shared drive which is accessible by the IO, the Director and IRB staff.

If the IRB determines that the new or revised policy represents a major change, the IRB office may send out an electronic communication to alert investigators. Once a policy has been revised, the former version of the policy will be archived and saved on the IRB shared drive.

5.5 Investigator Guidance, IRB Forms, Checklists and Other Resources

Electronic forms, checklists and investigator guidance documents are utilized to facilitate investigator compliance with regulatory requirements and IRB policies and procedures. These tools are reviewed periodically and updated as necessary, but do not require formal IRB review and approval. However, the Director will normally collaborate with IRB members and leadership in drafting and revising these resources.

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**

- 45 CFR 46.108
- 45 CFR 46.115
- 21 CFR 56.108
- 21 CFR 56.115