1.24 HRPP Training Requirements for IRB Members

1.0 Purpose

The purpose of this policy is to describe the Organization's requirements for training for IRB members and alternates.

2.0 Policy

It is the policy of the Organization that IRB members and alternates will be qualified through initial and continuing education in order to fulfill their responsibility to protect the rights and welfare of human subjects.

3.0 Definitions

- **3.1.** CITI (Collaborative Institutional Training Initiative) available through www.citiprogram.org or through the IRB website.

4.0 Initial Training and Orientation

- **4.1.** New IRB members, including alternate members, will meet with the IRB Executive Chair or designee, and appropriate IRB Administrators for orientation to cover the following items:
  - **4.1.1.** Overview of HHS and FDA regulations
  - **4.1.2.** HRPP overview
  - **4.1.3.** Structure of IRB meetings
  - **4.1.4.** Responsibilities of IRB members
  - **4.1.5.** Overview of the Research Support System (RSS).
- **4.2.** New IRB members and alternates who also act as investigators or research personnel will be required to complete CITI training (including GCP as appropriate) as per HRPP policy 1.23 (HRPP Training Requirements and Opportunities for Research Personnel). For new IRB members and alternates who do not act as investigators or research personnel, orientation (as described above) will be considered the equivalent of

initial CITI training.
- **4.3.** New IRB members are invited to attend an IRB meeting as a guest during the orientation period.
- **4.4.** Full orientation must be completed before the new IRB members may serve as a reviewer or count as a voting member. Prior to completion of orientation, agenda will record new IRB members as “non-voting”.
- **4.5.** New IRB members are assigned an experienced IRB member as a mentor, to provide assistance as necessary.

5.0 Continuing Education

- **5.1.** Continuing education for IRB members is required throughout service on the IRB in order to ensure ethical oversight of human subject research and compliance with current regulatory and policy requirements.
- **5.2.** IRB members are expected to participate in continuing education which may be obtained through any or all of the following mechanisms:
  - **5.2.1.** In-service training at IRB meetings.
  - **5.2.2.** Training workshops/webinars.
  - **5.2.3.** Regional IRB conferences.
  - **5.2.4.** Review of publications distributed by the ORA at IRB meetings or via email.
  - **5.2.5.** Review of new information affecting the HRPP such as new laws and regulations, new OHRP/FDA guidance documents, and new or revised HRPP policies distributed by the ORA via email or at IRB meetings.
- **5.3.** Completion of required continuing education will be assessed at the time of the annual evaluation of IRB members (see HRPP policy 1.22) in terms of general regulatory knowledge. Members who remain deficient after this review may have their appointment terminated.

DOCUMENT HISTORY:

? Written: 12/28/2015 (Approved: 12/28/2015) - original author not recorded

? Revised: 2/1/2018 - revision not documented

? Revised: 7/14/2022 - Deleted list of specific documents to be supplied to new IRB members; added requirement that full orientation of new members must be completed before the new member may serve as a reviewer or count as a voting member; clarified that completion of required continuing education will be assessed at the time of the annual evaluation of IRB members in terms of general regulatory knowledge; deleted requirement that ORA maintain initial and continuing education training records. {Approved: Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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