CITI CRC Course: NOTE Items Below That Are Not Consistent with NIH Process/Policy

MODULES

Planning Research

- NIH does not have sponsor-investigators except for single patient expanded access protocols.
- Resources and Financial Feasibility and Budgeting Basics would likely vary at NIH.
- NIH is not a HIPAA covered entity and, as such, is not required to follow HIPAA. Instead, NIH is subject to the Privacy Act of 1974.
- The training says IRB may grant a waiver of consent for screening, recruiting, or determining eligibility of prospective subjects when investigators access identifiable private information/biospecimens. The 2018 Common Rule includes provisions for collecting private medical information for the participant recruitment without informed consent or IRB waiver of consent when specific conditions are met. The plan must be described in the protocol. See OHSRP Information Sheet titled *Guideline for Recruitment and Screening of Participants* under Policy 302 on the OHSRP webpage for HRPP Policy and Guidelines.

Working with the Institutional Review Board (IRB)

- At NIH, some of the responsibilities related to interaction with the IRB may be undertaken by individuals with other titles (e.g., protocol navigator, study coordinator).
- This module notes "the CRC must report any reportable event that is not consistent with the protocol to the IRB as soon as it is known." Investigators conducting research under oversight of the NIH IRB should refer to NIH Policy 801, *Reporting Research Events* to determine which events require expedited reporting in the electronic IRB (eIRB) system and which may be reported at the time of CR.

Protocol Review and Approvals

- Module refers to Conflict of Interest (COI) Review Committees. As a federal department, NIH has specific COI requirements. Refer to NIH Policy 102, *Investigator Conflict of Interest and Government Royalties*

CRC Responsibilities

- Although this section mentions records retention, the NIH IRP follows the NIH Policy 1743, *Managing Federal Records.*

Sponsor Responsibilities

- Not all studies at NIH undergo pre-study feasibility assessments or pre-study qualification visits.
- NIH does not have sponsor-investigators such as those mentioned in this module except for single patient expanded access protocols .
- Investigators need to be familiar with record retention requirements of the sponsor and FDA. The NIH IRP also follows the NIH Policy 1743, *Managing Federal Records.*

Informed Consent

- NIH sponsored studies overseen by the NIH IRB with an NIH PI will not usually include a Health Insurance Portability and Accountability Act (HIPAA) authorization since NIH is not a HIPAA covered entity but is, instead, subject to the Privacy Act of 1974. (However, non-NIH sites that are part of a multi-site study overseen by the NIH IRB may be HIPAA covered and their consent language may reference HIPAA.)
- When a potential NIH subject is illiterate or blind, the English long form should be used to obtain consent from the subject and requires signature by a witness. The short form consent document should not be used. See the Consent FAQs on the OHSRP website for more information on this topic.

Site Management, Quality Assurance, and Public Information

- References to HIPPA in this module may not be applicable as NIH is not subject to HIPAA but is, instead, subject to the Privacy Act of 1974.