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IRB 250 Modules and Descriptions

For a full-day training, institutions can select up to four modules. Please note the Criteria for the Approval of Research is a standard module in all ***IRB 250*** programs and is not considered one of the four modules.

Criteria for the Approval of Research [a standard in all *IRB 250* programs]
This module reviews regulation 45 CFR 46/21 CFR 56 §111(a) and how it relates to the Belmont principles. More specifically, this module covers risk/benefit, subject selection and recruitment, informed consent, data safety monitoring, privacy and confidentiality, and vulnerable populations.

Case Studies in Biomedical Research and/or Social, Behavioral, and Educational Research
In advance of the program, PRIM&R will schedule a conference call between the site and the faculty to discuss the case studies. The case studies can reflect the other modules selected, or be on different topics.

Children & Adolescents: Pediatric Research Subpart D
The curriculum for this module aims to familiarize attendees with the ethical principles as they pertain to subpart D and the regulations. In addition, the module reviews what is sufficient pediatric expertise, pediatric risk/benefit assessment and definitions, parental permission and assent, wards of state, and subpart D documentation requirements.

Conflicts of Interest
Using several well-known examples, this module begins with a brief introduction on the definition of conflicts of interest. The module then goes into detail on the following topics: the federal agencies and regulations governing conflicts of interest and disclosures by researchers, the laws and regulations governing IRB members, and the governmental and non-governmental guidance documents, and best practices relating to conflicts of interest in research.

Applying the Exemption Categories
The curriculum for this module will review what types of research are exempt, the OHRP guidance on research that evaluates public benefit service programs, vulnerable populations, and FDA exemptions. In addition, the module will discuss OHRP Guidance on exemptions, as well as using exempt review.

Applying the Expedited Categories
Similar to applying the exemption categories, this module will review the federal regulations governing expedited categories, including what types of research are expedited. In addition, the modules will review OHRP Guidance on expedited categories, as well as using expedited review.

HIPAA as it Pertains to IRBs and Research
The curriculum for this module will begin with an overview of the HIPAA privacy regulations, and will continue with a discussion on HIPAA and research and research authorizations. In addition, the module will present information on the use of PHI without authorization, including purposes of preparatory research, decedents' information, waiver of authorization, limited data sets, de-identified data, and transition provision. Finally, the module will cover databases and tissue banks, recruitment of research subjects, and institutional considerations.

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Informed Consent
The module on informed consent will review the historical and ethical underpinnings of informed consent, the process and regulatory requirements, documentation of informed consent, waivers and alterations, and informed consent in special circumstances.

*Please note this module was designed to support a presentation of 60-90 minutes in length.

International Research
This module will begin by reviewing international research trends, and will then discuss assessing host country performance sites, including their unique culture and ethics. In addition, the module will identify applicable international policies, regulations, and law, and will discuss how communication flows within international sites. Finally, the curriculum will review education and training for research investigators, staff, and IRB/REC members.

Internet Research
The curriculum for this module will review recruiting subjects over the Internet, observation of Internet activity, and collecting data over the Internet. In addition, the module will consider IRB review issues, including risk/benefit, consent, participation by minors, and privacy and confidentiality. Finally, this module will discuss electronic data security and IRB review requirements.

Unanticipated Problems and Adverse Events
This module begins with a brief introduction on the confusion surrounding unanticipated problems and adverse events. The curriculum then defines an unanticipated problem and clarifies its relationship to an adverse event, states the HHS and FDA requirements for reporting unanticipated problems to the IRB and Institutional Officials, discusses IRB review of unanticipated problems, states the HHS and FDA requirements for reporting unanticipated problems to the federal government, and determines whether or not specific scenarios describe an unanticipated problem.

Research on Biological Specimens
The curriculum for this module begins with a background on the topic. The module then reviews the use of a specimen in a single protocol and specimen banking, including discussion on the Bank itself, depositing into the Bank, and accessing specimens from the Bank. Finally, the module presents information on gnarly issues, including the scope of consent, tiered consent, secondary uses, ownership of specimens (withdrawal of consent), and return of results.

*Please note this module was designed to support a presentation of 60-90 minutes in length.

IND and IDE: Requirements and the IRB
This module begins with a review of the basics on IND and IDE by providing the audience with important definitions. The curriculum then aims to make participants familiar with the federal regulations pertinent to the IRB review of IND and IDE studies, as well as the factors the IRB needs to consider when reviewing these studies. Finally, the curriculum reviews common instances of IRB non-compliance as cited in FDA warning letters.