Learning Objectives:
Overview of the Protocol and Study Management

Best Practice Statement:

The University of Chicago Hospitals and the University of Chicago Biological Sciences Division are committed to providing all employees with the appropriate training and tools to perform their job functions. Standardized training of Investigators and research staff in the process of protocol development and the specifics of FDA obligations will help to ensure data integrity and institutional compliance.

At the end of this module the participant will be able to:

1. Discuss protocol/clinical trial development.
2. Explain the purpose of the Investigators Brochure.
3. Identify the parties involved in the clinical research process.
4. Identify the four phases of clinical research.
5. Identify the key elements in a clinical research protocol.
6. Identify the regulatory process for protocol approval at a clinical site.
7. Discuss the FDA Form 1572 and associated commitments.
8. Identify the key processes in managing a clinical research protocol.
9. Identify the types of monitoring/auditing visits.

Version: 3MMay06
Learning Objectives:
Research Background

Best Practice Statement:

The University of Chicago Hospitals and the University of Chicago Biological Sciences Division are committed to providing all employees with the appropriate training and tools to perform their job functions. Standardized training in the history of clinical research and how it has influenced the development of local regulations, international standards of practice, and national policy laws governed by the Department of Health and Human Services will help to ensure data integrity and institutional compliance.

At the end of this module the participant will be able to:

1. Discuss the history of research and the importance of clinical research today.
2. Define what is considered clinical research and who meets the criteria of a human subject.
3. Discuss the role and responsibilities of the Institutional Review Board and the process by which it ensures ethical human testing.
4. Discuss how events in history influenced documents that guide the practice of clinical research. Explain the significance of the Nuremberg Code, the World Medical Association Declaration of Helsinki, The Belmont Report, Good Clinical Practice guidelines, and the International Conference on Harmonization guidelines.
5. Identify research governance, including identifying the Office of Health and Human Services, the Food & Drug Administration, and the Code of Federal Regulations.

Version 8/5/996
Learning Objectives:
Overview of the Institutional Review Board

Best Practice Statement:

The University of Chicago Hospitals and the University of Chicago Biological Sciences Division are committed to providing all employees with the appropriate training and tools to perform their job functions. Standardized training in the role of the IRB and its policies and procedures will help to ensure data integrity and institutional compliance.

At the end of this module the participant will be able to:

1. Discuss the history and ethical basis for the development of Institutional Review Boards.
2. Discuss the role of an IRB.
3. Identify the different types of research reviewed by an IRB.
4. Identify the documentation required to successfully initiate and maintain a study involving human subjects research.
5. Explain how proper documentation provides protection for research subjects.

Version 8/8/2010
Learning Objectives:
Informed Consent

Best Practice Statement:

The University of Chicago Hospitals and the University of Chicago Biological Sciences Division are committed to providing all employees with the appropriate training and tools to perform their job functions. Standardized training in the local and federal guidelines by which the informed consent process is regulated will help to ensure data integrity and institutional compliance.

At the end of this module the participant will be able to:

1. Explain the meaning of the three principals that govern the informed consent process as outlined in the Belmont Report.
2. Explain and demonstrate the informed consent process, including documentation.
3. Discuss types of consents and the requirements for those consents.
Learning Objectives:
Budgets & Contracts

Best Practice Statement:

The University of Chicago Hospitals and the University of Chicago Biological Sciences Division are committed to providing all employees with the appropriate training and tools to perform their job functions. Standardized training in the process of budgeting and contracting for clinical trials will help to ensure data integrity and institutional compliance.

At the end of this module the participant will be able to:

1. Identify the person responsible for initiating a protocol.
2. Identify the three types of support a sponsor may provide.
3. Explain when and why a contract is needed to conduct a research study.
4. Identify five essential items for the process of budget development.
5. Explain the elements of a schema and how it impacts budget development.
6. Identify the person responsible for reviewing the schema.
7. Define "double dipping."
8. Identify the four elements of a clinical trial budget.
9. Identify other points to consider when reviewing the monetary feasibility of a study.

Version 20Jun06
Learning Objectives:
Research Billing

Best Practice Statement:

The University of Chicago Hospitals and the University of Chicago Biological Sciences Division are committed to providing all employees with the appropriate training and tools to perform their job functions. Standardized training in the local and federal regulations that guide the research billing process will help to ensure data integrity and institutional compliance.

At the end of this module the participant will be able to:

1. Discuss the differences between research related and standard of care costs in the research process.
2. Identify five parties involved in the research billing process and their roles.
3. Discuss steps that can be taken to reconcile billing errors after they have occurred.
4. Discuss the impact that the National Coverage Decision had on the research billing process.
Learning Objectives:  
Documentation & Research Sample Processing

Best Practice Statement:

The University of Chicago Hospitals and the University of Chicago Biological Sciences Division are committed to providing all employees with the appropriate training and tools to perform their job functions. Standardized training in local and federal regulations that guide documentation practices will help to ensure data integrity and institutional compliance.

At the end of this module the participant will be able to:

1. Define source documentation and list examples.
2. Discuss strategies for organizing a research shadow file.
3. Explain the general rules regarding completion of CRFs.
4. Define major protocol deviation and minor protocol deviation (according to the UC BSD IRB).
5. Explain the importance of screening logs.
6. Explain strategies for developing and maintaining a master subject list.
7. Explain the purpose and process of drug accountability.
8. Identify requirements for data storage as specified in ICH-GCP Guidelines and institutional policy.
9. Explain the basic steps involved in processing central and local labs.

Version 7/Jul06
Learning Objectives:
Adverse Events

Best Practice Statement:

The University of Chicago Hospitals and the University of Chicago Biological Sciences Division are committed to providing all employees with the appropriate training and tools to perform their job functions. Standardized training in the local and federal regulations that guide the process of adverse event reporting will help to ensure data integrity and institutional compliance.

At the end of this module the participant will be able to:

1. Define Adverse Event (AE) and Serious Adverse Event (SAE).
2. Identify the deadlines for reporting events to the IRB, FDA, and sponsor (as applicable).
3. Identify required documents for reporting events to the IRB, FDA, and sponsor (as applicable).
4. Identify the basic responsibilities of the involved parties regarding collecting and reporting events.

Version 10/4/06
Learning Objectives:
Medical Devices

Best Practice Statement:

The University of Chicago Hospitals and the University of Chicago Biological Sciences Division are committed to providing all employees with the appropriate training and tools to perform their job functions. Standardized training in the local and federal regulations that guide the use of investigational devices will help to ensure data integrity and institutional compliance.

At the end of this module the participant will be able to:

1. Explain the function of an Investigational Device Exemption (IDE).
2. Explain the difference between Class I, II and III medical devices.
3. Explain the differences between category A and category B medical devices, including differences in billing categories.
4. Understand that processes are in place for approval of early and expanded use of devices.

Version 16Jul08
Learning Objectives:
Audits & Monitoring

Best Practice Statement:

The University of Chicago Hospitals and the University of Chicago Biological Sciences Division are committed to providing all employees with the appropriate training and tools to perform their job functions. Standardized training in the purpose of auditing and monitoring and the policies and procedures by which these practices are regulated will help to ensure institutional compliance and data integrity.

At the end of this module the participant will be able to:

1. Define the three levels of standards that guide the conduct of clinical research studies
2. Identify the role of the Investigator
3. Explain the purpose of clinical monitoring
4. Define the three types of FDA audits
5. Define the role of OHRP & OIG
6. Discuss the difference between Pre-Qualification Visit, Site Initiation Visit, Monitoring Visit and Close-Out Visit
7. Cite the UC policy regarding scheduling and access for study monitoring visits

Version 25A05
Learning Objectives:
Blood Pressure Measurement

Best Practice Statement:

The University of Chicago Hospitals and the University of Chicago Biological Sciences Division are committed to providing all employees with the appropriate training and tools to perform their job functions. Standardized training of investigators and research staff in measuring blood pressure will help to ensure data integrity and institutional compliance.

At the end of this module the participant will be able to:

1. Identify three arteries that can be used to measure blood pressure.
2. Identify the systolic and diastolic components of a measurement.
3. Differentiate between normal and abnormal measurements.
4. Explain what to do if an abnormal measurement is observed.
5. Obtain an accurate blood pressure measurement using the brachial artery.

Version 7d1010