

**Center for Clinical Research and Technology****Clinical Research Curriculum****Learning Objectives**

The Clinical Research Curriculum series is an education program designed to provide beginning clinical researchers with information necessary to successfully engage in human research projects conducted within University Hospitals. Following are the broad topics that will be covered and what you can expect to learn after completing each topic session. Upon completion attendees will have an understanding of IRB processes and institutional and Federal policies relating to the responsible conduct of research.

***Introduction to Human Subjects Research***

During this session, participants will gain an understanding of:

- The history of experimentation with humans which contributed to the development of current research regulation and guidance.
- Obtain an understanding of the Federal research regulatory organizations and their role in regulating human research participation.
- The importance of AAHRPP certification.
- The roles and responsibilities of the IRB.
- The role of the UH Center for Clinical Research and Technology in facilitating research at UH.

***IRB Review Process***

During this session, participants will gain an understanding of:

- How and when to apply for IRB review.
- UHCMC policies and procedures pertaining to human subject research.
- IRB submission and review process.
- Use of protected health information (PHI) in human subject research (HIPAA Privacy Rule).
- Red flags and potential problem areas in research submissions.

***Informed Consent***

During this session, participants will gain an understanding of:

- Informed consent as a process, not simply a document.
- The requirements of informed consent document including applicable Federal Regulations and UHCMC IRB Policies.
- The purpose and importance of obtaining informed consent from research participants.
- The importance and process for documenting the informed consent process
- The process of enrolling research participants who cannot provide consent for themselves (e.g. minors, decisionally impaired).

## Center for Clinical Research and Technology

### Clinical Research Curriculum Competency Checklist

#### ***Grants and Contracts***

During this session, participants will gain an understanding of:

- The services performed by the Pre-Award and Post-Award Offices in the Center for Clinical Research and Technology.
- Why all research grants and contracts are reviewed by the Office of Grants and Contracts.
- How to set up a grant account
- How to develop a research study budget.
- Research patient billing.

#### ***Event Reporting***

During this session, participants will gain an understanding of:

- The definition of an Adverse Event (AE) and a Serious Adverse Event (SAE).
- The definition of a protocol deviation and unanticipated problem.
- Reporting requirements for AEs, SAEs, protocol deviations and unanticipated problems.
- The difference between an internal and external event.

#### ***Study Activities and Compliance***

During this session, participants will gain an understanding of:

- The different roles and responsibilities of members on the research team.
- The tools and documents available for managing a clinical research study,.
- What happens during a 'monitor visit' and how to prepare.
- Drug and/or device accountability
- The critical documents required for the regulatory binder and maintenance to ensure compliance
- Scientific misconduct.
- The consequences of non-compliance with Human Subjects' Regulations
- The role of the UH Compliance and Ethics Committee.
- The role of the UHCMC Office of Research Compliance and availability of investigator support.

# Center for Clinical Research and Technology

## Clinical Research Curriculum Competency Checklist

Name:

Topic	
<b>Introduction to Human Research Protection Programs</b>	
UHCMC Center For Clinical Research and Technology overview	
Human Subjects Protections- <a href="http://www.citiprogram.org">www.citiprogram.org</a>	
<ul style="list-style-type: none"> <li>▪ Core Certification</li> <li>▪ Continuing Research Education Credits (CRECs)</li> <li>▪ Seminar Series Lectures (UHCMC and Case)</li> </ul>	
Association for the Accreditation of Human Research Protections Program (AAHRPP)	
Research Regulatory Organizations	
<ul style="list-style-type: none"> <li>▪ Department of Health and Human Services (DHHS)</li> <li>▪ Office for Human Research Protections (OHRP)</li> <li>▪ U.S. Food and Drug Administration (FDA)</li> <li>▪ Federalwide Assurance (FWA)</li> </ul>	
Standard Operating Procedures (SOPs)	
Key Regulations:	
<ul style="list-style-type: none"> <li>▪ 45 CFR 46</li> <li>▪ 21 CFR 56 (Institutional Review Boards)</li> <li>▪ 21 CFR 50 (Informed Consent)</li> </ul>	
<b>University Hospitals Case Medical Center Human Research Protection Program Policies and Procedures:</b> <a href="http://www.UHhospitals.org/research">www.UHhospitals.org/research</a>	
Trainer Name:	
Trainer Signature:	
Date:	
<i>I have completed this module and understand the above topics.</i>	
Name:	
Date:	

# Center for Clinical Research and Technology

## Clinical Research Curriculum Competency Checklist

Name:

Topic	
<b>IRB Review Process</b>	
UHCMC IRB Policies and Procedures	
UHCMC IRB Forms and Templates	
<b>Review of Protocol Submission Requirements</b>	
Elements of a site specific protocol	
Clinical events/endpoints	
Adverse events	
Amendments	
Protocol Submission Requirements	
IRB Reporting	
Protocol Continuing Review	
HIPAA/PHI	
Informed consent waiver or alteration criteria	
<b>Research HIPAA (Office of Civil Rights)</b>	
Research Privacy Board (RPB)	
UHCMC Authorization Template	
HIPAA waiver criteria	
HIPAA exemption criteria	
Trainer Name:	
Trainer Signature:	
Date:	
<i>I have completed this module and understand the above topics.</i>	
Name:	
Date:	

# Center for Clinical Research and Technology

## Clinical Research Curriculum Competency Checklist

Name:

Topic	
<b>Informed Consent</b>	
Defining informed consent	
Purpose for obtaining informed consent	
Basic required elements of informed consent	
Additional elements of informed consent (FDA required)	
Additional elements of informed consent (IRB required)	
Informed consent (Language Template and Tutorial)	
UHCMC IRB Policies and Procedures: Informed Consent	
UHCMC IRB Forms and Templates: Informed Consent	
Documentation of informed consent	
Informed consent with vulnerable populations	
Obtaining assent when children/adolescents are participants in research	
Procedures for obtaining informed consent	
Trainer Name:	
Trainer Signature:	
Date:	
<i>I have completed this module and understand the above topics.</i>	
Name:	
Date:	

Name:

Informed Consent Observation	
Observer Name:	
Observer Signature:	
Date:	

# Center for Clinical Research and Technology

## Clinical Research Curriculum Competency Checklist

Name: \_\_\_\_\_

Topic
<b>Study Activities and Compliance</b>
Roles and responsibilities of staff
Study feasibility
<b>Study Management</b>
Source documentation
CRF completion
Screen/consent log
Enrollment log
Communication with physicians
Communication with other staff
Visit schedules & windows
Queries
Data collection
Data integrity review
<b>Sponsor Monitoring</b>
Scheduling: PI, space
Availability of charts
Availability of coordinator
Policies relating to monitors
<b>Drug Accountability</b>
Inventory
Dispensing logs
Documentation, labels, etc.
Restricted access
Patient compliance
Un-blinding
Drug destruction
<b>Study Completion</b>
Regulatory binder review
Records storage and retention
Study closure visit
IRB notification
<b>Research Compliance</b>

## Center for Clinical Research and Technology

### Clinical Research Curriculum Competency Checklist

Prospective monitoring (Office of Research Compliance and Education)	
Non-compliance with human subjects protections regulations	
Scientific misconduct	
UH Compliance & Ethics Committee	
UHC Policy 5.15- Clinical Research Investigation	
UHHS CP-7 Investigational Drugs	
Investigator Responsibilities	
Labs	
Other tests	
Trainer Name:	
Trainer Signature:	
Date:	
<i>I have completed this module and understand the above topics.</i>	
Name:	
Date:	

## Center for Clinical Research and Technology

### Clinical Research Curriculum Competency Checklist

Name:

Topic	
<b>Grants and Contracts</b>	
Overview of grants and contracts	
Contract negotiation	
Budget development	
Award set up	
Research billing policy	
Trainer Name:	
Trainer Signature:	
Date:	
<i>I have completed this module and understand the above topics.</i>	
Name:	
Date:	

Name:

Topic	
<b>Patient Reimbursement System</b>	
Anyone involved with providing compensation to research participants must complete training in the UH Patient Reimbursement System through the Center for Clinical Research and Technology.	
<i>To be completed by Center for Clinical Research and Technology</i>	
Patient Reimbursement System training required: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Reviewed by:	Date:
<i>If training required, complete following:</i>	
Trainer Name:	
Trainer Signature:	
Date:	
<i>I have completed this module and understand the above topic.</i>	
Name:	
Date:	

# Center for Clinical Research and Technology

## Clinical Research Curriculum Competency Checklist

Name: \_\_\_\_\_

Topic	
<b>Event Reporting</b>	
Definition	
Adverse Event log	
<b>Serious Adverse Events (SAEs)/Endpoints</b>	
Definition and the difference	
Reporting of SAEs/Endpoints	
To sponsor	
To IRB	
Protocol deviations and unanticipated problems	
Trainer Name:	
Trainer Signature:	
Date:	
<i>I have completed this module and understand the above topics.</i>	
Name:	
Date:	

## Center for Clinical Research and Technology

### Clinical Research Curriculum Competency Checklist

Required Reading/Classroom Assignments	Where to find
Belmont Report	<a href="http://ohsr.od.nih.gov/guidelines/belmont.html">http://ohsr.od.nih.gov/guidelines/belmont.html</a>
Declaration of Helsinki	<a href="http://www.wma.net/e/policy/b3.htm">http://www.wma.net/e/policy/b3.htm</a>
Research department SOPs & policies	
<b>Other Training</b>	
IATA/HAZMat training requirement /Shipping hazardous materials	
Trainer Name: _____	
Trainer Signature: _____	
Date: _____	
<i>I have completed this module and understand the above topics.</i>	
Name: _____	
Date: _____	

*I acknowledge I have been trained and understand the information outlined.*

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Printed Name of Employee	Signature of Employee	Date
Research Manager Signature	Date	