

## IRBMED Education: Course Descriptions & Objectives

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### eResearch

**Initial Project Applications (Level 1):** This course is intended for those unfamiliar with eResearch, the university's electronic research administration site. This course will provide a basic knowledge of working in and using eResearch while examining the process for creating and submitting an initial project application.

**Amendments and Scheduled Continuing Reviews (Level II):** This course is a follow-up to Initial Project Applications and will examine the process for submitting amendments and scheduled continuing reviews to IRBMED using eResearch once a project's initial application has been approved.

### Informed Consent

**The Elements of Informed Consent (Level 1):** This course offers an overview of informed consent in human subject research. The course will examine IRBMED's standard consent template and focus on how it reflects federal requirements.

**Writing Informed Consent Documents (Level I):** This course offers guidance on writing informed consent documents. Discussion will explore strategies for creating documents that are easy to read, easy to understand, and compliant with federal and IRBMED requirements.

**Waivers, Alterations, and Alternative Forms of Informed Consent (Level II):** This course offers an overview of some special situations relating to informed consent. Specifically, waivers and alterations of informed consent, waivers of documentation of informed consent, and obtaining consent from non-English speakers.

**Informed Assent (Level II):** This course provides an overview of obtaining assent from minors and decisionally impaired adults.

**Verbal and Non-English Informed Consent (Level III):** This course examines the special procedures required to obtain consent from non-English speaking individuals and illiterate individuals.

**Exceptions from Informed Consent (Level IV):** This course will review the exceptions from the usual informed consent requirements for studies in emergency medicine.

**Waiver of Informed Consent for Third-Parties (Level IV):** There are situations when a human subject provides information to researchers about individuals who are not involved in the study; these individuals are called third parties. This course will examine who qualifies as a third party in the above scenario and when the obligation to obtain informed consent from third party individuals can be waived.

## **Privacy and Confidentiality**

**HIPAA (Level I):** This course will review the basic principles of the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH) as they apply to human subjects' research.

**Storage and Retention (Level 1):** This course will review the fundamentals of maintaining confidentiality of subject data, including data encryption and protection, using secure environments and external websites, and distinguishing among anonymized, coded, and de-identified datasets.

**Waivers of HIPAA Authorization (Level II):** This course will review when and how to apply for a Waiver of HIPAA Authorization. This will include the requirements necessary to secure a Waiver of HIPAA authorization from the IRB and comparison of Waivers of HIPAA Authorization and Waivers of Informed Consent.

**Exceptions from HIPAA Authorization (Level III):** This course will review when HIPAA authorization or a waiver of HIPAA authorization is not required to obtain, create, use, and/or disclose PHI for the purpose of research. Specifically this course will review activities that are preparatory to research, research on the protected health information of decedents, and limited data sets with a data use agreement.

## **Regulations**

**Federal and Institutional Requirements for Human Subject Research (Level I):** This course will introduce the basics of conducting human subject research in compliance with federal regulations and institutional practices.

**Research with Prisoners (Level II):** This course will examine the additional regulatory requirements for conducting research involving prisoners, including the required procedures for enrolling prisoners in a research project. Additionally, the course will review the required procedures when an already enrolled subject becomes incarcerated.

**Research with Children (Level II):** This course will examine the additional regulatory requirements for conducting research involving children, including the requirements for enrolling children in a research project, obtaining assent, and obtaining parental permission.

**Research with Pregnant Women, Fetuses, and Neonates (Level II):** This course will examine the additional regulatory requirements for conducting research involving pregnant women, fetuses, and neonates, including the requirements for involving pregnant women, fetuses, or neonates in a research project and obtaining informed consent.

**Research with Special Populations (Level II):** This course will examine the additional requirements for conducting research involving special populations. Special populations include: Lactating Women, Women of Child Bearing Potential, Cognitively Impaired Adults, College Students, Economically or Educationally Disadvantaged Persons, Patients of the Study Team, Employees, Students, or Trainees of the Study Team, and Family Members of the Study Team.

**Drugs and Devices (Level III):** This course will review the FDA requirements for conducting research with a drug or medical device, including conducting research under an IND (Investigational New Drug Application) and an IDE (Investigational Device Exemption). This course will also include discussion on Compassionate Use.

**Department of Defense (Level IV):** This course will review the additional regulatory requirements for conducting research sponsored or funded by the Department of Defense, including the additional requirements Principle Investigators must meet.

**Department of Education (Level IV):** This course will review the additional regulatory requirements for conducting research activities that are supported by the Department of Education, including the requirement for Assurance and IRB approval prior to an award.

**Department of Justice (Level IV):** This course will review the additional regulatory requirements for conducting research activities that are supported by the National Institute of Justice, including the requirement for IRB approval and assurance prior to the initiation of any research.

## **Reporting**

**Adverse Events, ORIOs, and Unanticipated Problems (Level I):** This course will identify what constitutes an Adverse Event, ORIO, and Unanticipated Problem and how such events impact risk to subjects. Additionally, the course will review the requirements of reporting such events to the IRB and other entities.

**Data Safety Monitoring Boards (DSMB) and Data Safety Monitor Plans (DSMP) (Level II):** A DSMB is an independent group that advises the study team regarding subject safety, study conduct, and efficacy. The DSMB will also make recommendations concerning the continuation, modification, or termination of the trial. A DSMP outlines how subject safety and data integrity will be maintained to ensure the validity of collected data. This course will review when studies are required to have a DSMP or DSMB and how to develop an appropriate DSMP.

**Study Specific Adverse Event Reporting Plans (Level III):** This course will examine when it is appropriate to use a study specific AE reporting plan as opposed to the standard UM time table for reporting adverse events to the IRB.

**Audits (Level IV):** This course will review how to prepare for an audit and what to expect during the audit process.

### **Agreements**

**Material Transfer Agreements and Data Use Agreements and IORs (Level I):** This course will examine both material transfer and data use agreements as well as IRB of Record Agreements. Material transfer and data use agreements will include discussion of limited data sets and de-identified data sets. IRB of Record agreements will include discussion of Individual Investigator Agreements, Collaborating Institution Agreements, and IRB Authorization Agreements.

### **Non-Standard Applications**

**Exempt/Not Regulated (Level I):** This course will review the Exempt and Not Regulated application types in eResearch and when these application types are applicable.

**Secondary Use/Umbrella (Level I):** This course will review the Secondary Use and Umbrella application types in eResearch and when these application types are applicable.

**Emergency Use (Level II):** This course will review the Emergency Use application type in eResearch. The course will also discuss when an emergency use for an unapproved medical device or investigational drug or biologic is appropriate and the required reporting procedures of an emergency use to the IRB and the FDA.

**Humanitarian Use Devices (Level II):** This course will review the Humanitarian Use Device application type in eResearch and when this application type is applicable.

**Requesting Review by a Non-UM IRB (Ceding Application) (Level III):** This course will review the Requesting Review by a Non-UM IRB application type in eResearch, including instruction on how to appropriately complete this application type and what study materials will need to be submitted to IRBMED for review.

**Repositories:** This course is pending development and implementation of an eResearch application.

### **Specialty Courses:**

**Study Team Responsibilities (Level I):** This course will explore the ethical and regulatory requirements that the study teams must adhere to throughout the conduct of a research project in order to protect the rights and welfare of human subjects.

**Data Coordinating Center (Level II):** This course will examine the requirements of serving as and working with a data coordinating center for a large, multi-site or network based clinical trial. Data coordinating centers provide project management, regulatory management, data management, and other types of research support.