

University of South Alabama

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Newsletters

Research Compliance and Assurance

2017

2017 Summer Newsletter

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IRB Submission: Getting Started

IRB review of new studies requires submission of a new project utilizing IRBNet. The IRB must approve all research and research-related documentation prior to use in a research study, and review/monitor the progress of research until the project is complete, followed by submission of a closure report. As part of the IRB approval process, investigators and key personnel listed on the IRB application are required to complete training. The IRB training requirements are categorized according to an individual's role and type of research activity. The training curricula for human subjects training is outlined as follows and located on the [human subjects training website](#).

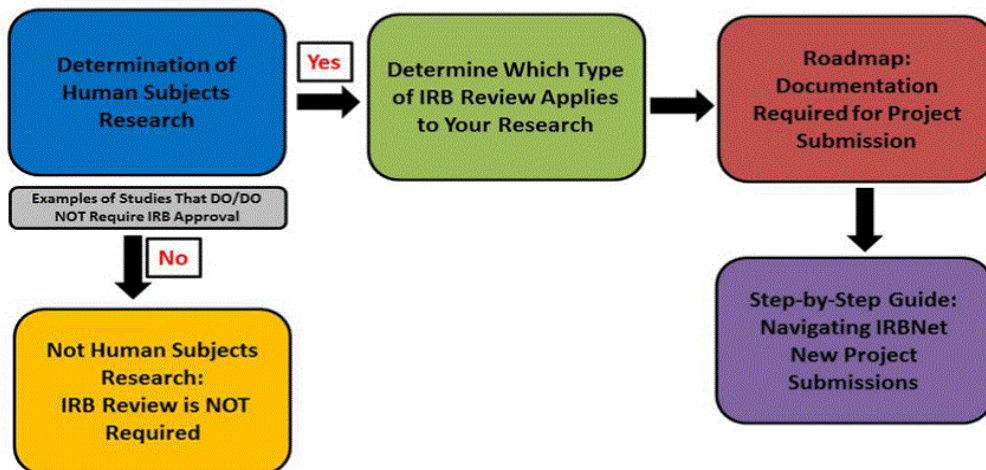
Human Subjects Education and Training

The University of South Alabama IRB requires Investigators, Co- investigators, coordinators, and key personnel involved (all persons who will be directly responsible for the study management, data collection, consent process, data analysis, transcription, participant recruitment, or follow up) in research to complete required human subjects training. The training curricula are as follows, according to your role:

- ▼ STUDENT RESEARCH
- ▼ INVESTIGATORS- NON-BIOMEDICAL RESEARCH
- ▼ INVESTIGATORS: CLINICAL RESEARCH
- ▼ CLINICAL RESEARCH KEY PERSONNEL
- ▼ ADDITIONAL TRAINING AND RESOURCES

If you are a new investigator or have not submitted an application recently, the [Getting Started](#) page is intended to provide information and resources to guide you through the IRB application process. The steps include, determining if you need to apply to the IRB, which type of IRB review applies to your research, documentation required for project submission, and step-by-step guide for navigating IRBNet new project submissions.

GETTING STARTED



SUMMER, 2017

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USA POLICY ON INVOLVEMENT IN CLINICAL RESEARCH FOR NON-HEALTH CARE PROVIDERS

PURPOSE: The University encourages and supports clinical research led by Principal Investigators who are not primary health care providers (e.g. basic scientists) and also the involvement of non-health care providers in clinical trials. This document clarifies the role and restrictions for basic scientists and other non-primary health care providers involved in clinical research.

NIH Definitions of Clinical Research and Clinical Trials

*“**Clinical research** is research that directly involves a particular person or group of people or that uses materials from humans, such as their behavior or samples of their tissue.*

*A **clinical trial** is one type of clinical research that follows a pre-defined plan or protocol. By taking part in clinical trials, participants can not only play a more active role in their own health care, but they can also access new treatments and help others by contributing to medical research.”*

This policy provides provisions for the following research activities involving clinical research and involvement of non-health care providers:

- Training and Standards
- Maintaining Separation between Clinical and Basic Research Components
- Handling of Biological Specimens
- Management of Intellectual Property

The policy may be accessed [here](#) and is located on the human subject’s website, policies & procedures page.

Western IRB (WIRB) Submission is Now Live

University of South Alabama has established a new agreement with WIRB Copernicus Group authorizing the Western Institutional Review Board (WIRB) to review and approve selective* industry sponsored multi-center clinical trials. Participation in the use of a centralized IRB review process will aid in the efficiency of IRB review, as well as offering business applications and resources to enhance and support the clinical research enterprise. WIRB Copernicus consists of 8 individual accredited panels and 60 plus years of combined experience in protocol and study-related review. The University will be provided the opportunity to connect to leading industry sponsored and CROs to expand our repertoire of industry sponsored clinical trials.

* Eligibility for WIRB submission is defined by selective criteria. NOTE: Studies which involve any of the following are **NOT** eligible for WIRB review: Phase I Studies (including I/II, studies), planned emergency research, single patient emergency use or compassionate use situations, embryonic stem cell or gene therapy research, federally funded protocols, investigator-initiated research, and research involving prisoners.

Visit the new [WIRB Submission web page](#) to learn about the process, located on the Office of Research Compliance & Assurance website.

CLINICAL RESEARCH FUNDAMENTALS TRAINING

A new training program was developed with efforts to engage in topics on fundamentals in clinical research and related institutional practices. The program is geared to clinical research coordinators, research nurses, regulatory specialists and other trial personnel. The 2017 program included 15 presentations spanning a two month period in May/June. The sessions were divided into four half day morning sessions and provided continuing education credits. The Office of Research Compliance and Assurance expresses many thanks to the individuals who participated in this program to help make it a success. This program will continue to evolve each year as we build upon training opportunities offered for clinical trial staff.

Program Presenters:

- Cathy Blache, RN, MSN, CCRC, RNFA, Precision Clinical Research, LLC
- Karen Fagan, M.D., Professor, Medicine & Pharmacology, and Chief, Division of Pulmonary and Critical Care Medicine
- Allie Howell, Association Clinical Research Professionals (ACRP)
- Linda Hudson, Chief HIPAA Compliance Officer
- Hamayun Imran, M.D., IRB Chair, and Medical Director, Pediatric Hematology/Oncology
- Dusty Layton, MPA, BS, Executive Director, Office of Research Compliance and Assurance
- Spencer Liles, M.D., Assistant Professor, Division of Oncologic Surgery, MCI, Director, Mitchell Cancer Institute Biobank
- Edward Panacek, M.D., MPH, Professor and Chair, Emergency Medicine
- Thad Phillips, Asst. Chief HIPAA Compliance Officer-HIPAA Security
- Priscilla Smith, Director, Revenue Integrity & Revenue Cycle Integrity – USAMC
- Paul Taylor, Director, College of Medicine Marketing & Communications
- Ashley Turberville, Director, Health Systems Grants Administration and Development
- Theresa Wright, RN, DNP, CCRC, Vice-Chair and Associate Professor, Adult Health Nursing
- Western IRB (WIRB) Copernicus Group

Training events for clinical research staff will continue to evolve and offering of new educational opportunities.

Additionally, the Office of Research Compliance is developing an in-house educational training program for clinical research physicians. We look forward to working with our clinical research sites in the development of new programs.

ANNOUNCING NEW CLINICAL TRIALS MODULE

The Office of Research Compliance and Assurance would like to thank Paul Taylor, Director, Marketing/Communications, College of Medicine for the acquisition of a clinical trials module for reporting active USA IRB clinical trials. The module is accessible from the USA Health Systems website. The IRB Office has added integrated posting active clinical trials as part of the IRB workflow process.

REMINDER: Research Application Forms

Please make sure you access IRBNet Forms/Templates to obtain the most up-to-date protocol application related materials. We do not encourage saving template forms on your computer's desktop, rather the document(s) should be obtained via IRBNet, when needed.

QUALITY ASSURANCE & IMPROVEMENT PROGRAM

WELCOME STEFANIE WHITE NEW MEMBER TO OUR STAFF

The Office of Research Compliance and Assurance welcomes Stefanie White to our research compliance team. Stefanie will serve in the position as Associate Director, Research Quality Assurance and Improvement to strengthen research compliance oversight. Emphasis will be placed on development and implementation of continuous quality improvement, as well as performance enhancement initiatives.

The purpose of a quality assurance and improvement program is to heighten awareness of regulatory requirements and improve the ethical conduct of research. The QA/QI program will aid the Office of Research Compliance & Assurance in evaluation of our programs effectiveness, post approval monitoring, identify issues to be addressed for educational training, and evaluation of informed consent process to assess if standards have been met and can be improved upon.

Specifically, to facilitate compliance of human subject's research, the QA/QI program will also provide services to assist researchers at the time of study start-up regarding appropriate study management documents, assist with PI-initiated studies, organize orientation for new study coordinators, and external audit preparation, for example.

Quality Assurance and Improvement Activities: Observation of the Consent Process

The Quality Assurance and Improvement program aims to promote a culture of compliance and ethical standards in the conduct of research.

The IRB has the authority to observe the consent process for ongoing studies as part of its quality assurance and quality improvement activities. The following are examples of information that will be assessed when observing the consent process:

- Whether the subject appeared to understand the information and voluntarily consented to participation
- Whether the information conveyed was accurate and in understandable language
- Whether the participant was allowed sufficient time to consider participation
- Whether the process of consent was appropriately completed and documented

This process will support the study teams by offering a holistic viewpoint to study procedures. Feedback from this process can potentially aid in study recruitment.

More information regarding this process, including a FAQ, can be obtained by contacting Stefanie White at 460-7573 or swhite@southalabama.edu.

UPCOMING TRAINING EVENTS

2017-2018 Responsible Conduct of Research (RCR) Training Series

A new institutional training program will be offered to promote the responsible conduct of research. RCR not only applies to specific types of research activities, but also on topics related to the proper conduct of research and general awareness.

The training program will launch in October as a series of eight monthly sessions. Program details will be forthcoming.

Conducting Research Responsibly: Data Management Practices

Managing research data is a fundamental component of conducting research responsibly. It is the process of controlling information generated throughout the life cycle of a research project. This includes the acquisition, management, access, storage, and preservation of the data. The University's data management policy defines "data" to mean recorded factual material commonly accepted as necessary to validate research findings. Research Data covers a broad range of types of information. Digital Data can be structured in a variety of formats. Data differs amongst disciplines and can include but is not limited to: documents, notebooks, Laboratory Notebooks, audiotapes, transcripts, photographs, test responses, slides, and algorithms. In practice, Research Data include intangible (statistics, findings, conclusions, etc.), as well as tangible Data. Research laboratories should carefully consider best practices and procedures for the proper recording and storing of research data.

The University has several best practice documents and policy on data management and lab notebook ownership. These documents include:



Data Management and Laboratory Ownership Policy



Laboratory Notebooks: Best Principles and Standards



Data Management Best Practices Written Agreement on Disposition of Research Data/Lab Notebook



Written Agreement on Disposition of Research Data and/or Lab Notebooks

The above documents are accessible via the Office of Research Compliance website under [Responsible Conduct of Research: Standards & Resources](#)



Have a Question or a Comment?

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