UNIVERSITY OF SOUTH ALABAMA

IRB SOP 806
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.

Scope

This policy and procedure apply to all researchers and the USA IRB members where research is engaged at the University of South Alabama.

Definitions

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."

Policy

1.0 Training and Standards

All those involved in clinical research must comply with all Federal as well as University policies and standards for the conduct of research in human subjects. Training is provided to all involved in clinical research, this training must be completed in a timely fashion. For new IRB project submissions, all Principal Investigator's and key personnel must complete the required training prior to receiving IRB approval. Additionally, supplemental training required for clinical trial investigators accessible through Association of Clinical Research Professionals (ACRP) must be completed annually.

2.0 Maintaining Separation between Clinical and Basic Research Components

It is critical that the clinical/patient/participant care component of the research is independent of the basic science research and analysis, especially in clinical trials.

The entire clinical portion of all research protocols will be the responsibility of the clinician. These include but are not limited to:

- recruiting of participants
- consenting of patients/participants
- prescribing of any pharmaceuticals
- laboratory testing
- collection of specimens and any other portions of protocols that involve patients/participants or Personal Health Information (PHI)

NOTE: The IRB will not approve a protocol for any of the above to be administered by non-health care providers except under exceptional circumstances.

All clinical and PHI data will reside in files maintained and controlled by healthcare providers (HCP) or placed in approved Biobanks, except under exceptional circumstances as approved by the IRB . All policies and procedures regarding the protection of PHI must be adhered to when PHI is maintained by non-health care providers (i.e. basic scientists) Any clinical data shared with researchers must be de-identified, except under exceptional circumstances as approved by the IRB. All policies and procedures regarding privacy and security of PHI must be adhered to when PHI is maintained by non-health care providers

There will be no transfer of specific data or results of clinical trials or other clinical research to participants unless specifically approved by the IRB in exceptional

circumstances.

Under NO circumstances are individual clinical research patient/participant results to be discussed with individual participants or individual donors.

Absolutely no interactions/interventions with individual patients/participants by any basic scientists, unless specifically approved by the IRB in exceptional circumstances.

No administration or interpretation of ANY clinical tests (such as pregnancy tests or other clinical tests) by basic scientists or their students, employees or other members of a basic science lab is acceptable. All such clinical tests must be administered, reviewed and interpreted by a licensed HCP and must be performed by a clinical lab, except otherwise when specifically approved by the IRB.

3.0 Handling of Biological Specimens

When biological specimens are needed for analysis for basic research, they are to be requisitioned from the Health Care Provider or, for Mitchell Cancer Institute (MCI) to the core facility bio bank.

MCI Specific: When fresh clinical specimens are needed for basic or translational research, the collection of such specimens must be in conjunction with the MCI biobank and other approved USA biobanks via an IRB approved protocol.

4.0 Management of Intellectual Property

All Investigators will generate data, presentations or publications that may constitute an invention as defined in the USA Patent and Invention Policy. Prior to disclosure to the public, Investigators shall submit any such data, presentations or publication to the USA Office of Commercialization and Industry Collaboration for the purposes of reviewing and assessing whether any real or potential intellectual property will be disclosed. *For MCI*, review should first be carried out by the MCI Associate Director of Basic/Translational Research.

In addition, Investigators and basic scientists may generate inventions or discoveries in the course of conduction Clinical Research or Clinical Trials. These inventions and discoveries shall be promptly disclosed in writing to the University Office of Commercialization and Industry Collaboration in accordance with the USA Patent and Invention Policy. Investigators and basic scientists agree to assist and cooperate with USA in executing and delivering all assignments and other documents necessary to obtain and enforce patents within the United States or any other country.

HISTORY

Effective Date: February 22, 2016
Revisions:

Responsible Parties:

Director, Mitchell Cancer Institute
Vice President for Research and Economic Development
Office of Research Compliance and Assurance