Outreach Activities for the Research Community

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Introduction

The purpose of the activities described is to develop and foster a collaborative culture for the Vanderbilt research community. Included are brief summaries of available resources for Investigators, key study personnel, faculty and students.
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Outreach Activities

Human Subjects Research Brochure

In an effort to educate the research community on activities requiring IRB review, a brochure was developed entitled “Are You Conducting Human Subjects Research?” which is made available at each presentation and educational activity. This brochure includes an introduction to the role of the IRB, definitions of “research” and “human subjects” according to the Federal regulations, types of IRB review, informed consent, and where to go for additional information.

Link to IRB FACTS

Attendance and Presentations at New Student Orientations

IRB staff and, when available, Committee members attend orientation sessions for new graduate students, providing materials designed to inform students about which activities are required to be reviewed and approved by the IRB prior to initiation. These are held annually, in the fall, as students are arriving and becoming familiar with requirements for completion of their program.

A similar mechanism will be in place for incoming medical students, as additional requirements are implemented.

Meeting with Departments and Faculty

As part of providing education to the Vanderbilt community, the IRB staff has contacted faculty and department chairs to request time to meet with faculty and students to discuss involvement of human subjects in research and what requires IRB review. It is a goal of the IRB to place an emphasis on this outreach in order to educate those who may be unaware that their activities require IRB review.

Investigator Handbooks

The IRB has developed handbooks for researchers involved in both biomedical and social and behavioral research. The handbooks include relevant information for a “quick” reference guide to all IRB processes and submissions. Links to the manuals are below.

Investigator’s Handbook for the Protection of Human Participants in Biomedical Research

Investigator’s Handbook for the Protection of Human Participants in Social and Behavioral Research
IRB Application

In response to feedback from Investigators in social and behavioral research, the IRB has implemented a new application (Social and Behavioral Application) specifically addressing the issues related to these areas of research. The information requested on the application is specific to the unique situations often involved in social and behavioral research and is designed to assist in the review process. It was created with input from both the IRB Committee members and Investigators.

The IRB continues to have available for biomedical Investigators the Health Science Application which contains pertinent information relative to the issues related to these areas of research.

Educational Programs

Research Matters

This educational activity involves a three hour presentation and discussion of introductory issues regarding human subjects protections and applicable Federal regulations. Following this presentation, Investigators and key study personnel may complete a test to meet the requirement for training as outlined in the VU IRB policies and procedures. Each session is offered quarterly and may be provided more frequently by the request of a department, instructor or group of investigators wanting to have the presentation tailored to their group. Below are links to the past PowerPoint presentations.

Past Power Point Presentations of IRB Workshops

IRB 201

The IRB is in the process of developing a supplemental presentation for more advanced issues pertaining to human subjects protections. These topics may include further discussion on vulnerable populations, deception in research, ethnographic research, qualitative research issues, determining engagement in research, etc.

CITI (Collaborative IRB Training Initiative)

The IRB requires that all Investigators and key study personnel successfully complete a human subjects protections training program. This requirement may be met through completion of specific modules through a web-based program.

The training is divided into two tracks - Biomedical Research and Social/Behavioral Research. Investigators and key study personnel are to take the track applicable to their field of study.
**Biomedical** Research Modules:
Module 1 - History and Ethics
Module 2 - Defining Research and Regulatory Overview
Module 3 - Informed Consent

**Social and Behavioral** Research Modules:
Module 1 - History and Ethics
Module 2 - Defining Research with Human Subjects
Module 3 – The Regulations and the Social and Behavioral Sciences
Module 5 - Informed Consent

Each CITI module takes approximately 10 to 30 minutes.

CITI also offers additional biomedical and social/behavioral modules which provide a wealth of information in human research protections including, but not limited to, training on international research, assessing risks, research with vulnerable populations, use of the internet in research, etc.

**IRB Essentials**

IRB Essentials sessions are scheduled regularly to address current issues impacting Investigators and key study personnel. These topics include: reporting of adverse events, conflicts of interest, informed consent, completing IRB forms, continuing review submissions, etc. These sessions are posted on the IRB website under **IRB Workshop Schedule**.

**IRB News You Can Use**

This large group presentation format allows for Investigators, key study personnel, faculty and students to be informed of current issues impacting research at Vanderbilt. Often topics are driven by amendments to regulations, changes in IRB policy and procedures, new and/or revised Federal regulations, and other applicable topics. Typically these sessions are one hour in length and are open to attendance to the University, Medical Center and the local community. In addition to being posted on the IRB website under **IRB Workshop Schedule**, a mass email is sent to all Investigators and key study personnel at least 2 weeks prior to the event.

**Request for In-service**

Investigators, key study personnel, faculty and administrators can make a request via the IRB website or through phone contact for education on specific topics relevant to their research. IRB staff will provide educational materials and instructions responding to the specific need. For example, the IRB staff may attend and present at a department faculty meeting or to a small group of Investigators and key study personnel.

**Consultation with Unaffiliated Professionals for Expertise Regarding Related Research Topics**
Often the IRB staff calls upon the expertise of unaffiliated professionals to provide information regarding local, regional and international issues pertaining to specific research proposals. They may be asked to attend IRB Committee meetings or present to the VU research community information involving specific populations in research.

Web-based Resources

The IRB website contains access to multiple sites for obtaining further information relevant to human subjects protections. These sites include but are not limited to: OHRP, FDA, IRB Policies and Procedures, Ongoing Educational Opportunities and University Resources.

http://www.mc.vanderbilt.edu/irb/

Suggestion Box

A new addition to the IRB website provides a vehicle for the VU research community to request or respond to specific issues of concern to the individual Investigator or key study personnel. If no response from the IRB is necessary, these comments may be submitted anonymously. However, the inquirer may request a response from the IRB by including his or her email address in the submission.

These suggestions are reviewed each business day by IRB staff and feedback is provided when appropriate.

IMPACTT

The IRB has developed, through a grant award, a quality improvement program designed to assist Investigators in increasing the level of protection for research participants through improvement of the research process. IMPACTT (IRB Measured Performance and Collaborative Training Techniques) is a program that offers support, consultation, and collaboration with the goal of strengthening Vanderbilt University's Human Subjects Research program.

To accomplish this goal, the IRB invites Investigators to schedule a consultation by the IMPACTT team. In addition, some research programs will be selected at random for this initiative. The consultation will include an on-site visit, preliminary interview and an on-site assessment. The purpose of the short preliminary interview with the Investigator and coordinator is to communicate the goals of the IMPACTT program. These goals are three-fold: to assist the research team in identifying strengths and weaknesses, to provide education, and to make recommendations for improvement. Following the preliminary interview, an on-site assessment will be performed on a single protocol utilizing a
comprehensive assessment tool developed to examine the necessary elements involved in managing a research study.

At the conclusion of the on-site assessment, an exit interview will be conducted. A final report which includes the findings and recommendations will be issued by the IMPACTT team.

Investigators interested in voluntarily initiating this process may submit a request by contacting Research Support Services at (615) 322-7343.

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**Toll Free Number**

Investigators and research participants are provided with a toll free number for access to an IRB representative. The toll free number should appear on every informed consent document following a statement about whom the participant may contact regarding questions or for additional information concerning their rights as a research participant. Investigators may also access the IRB through this number for assistance with questions regarding the protection of research participants.

(866) 224-8273