IRB Review
A compilation of 'need to know' updates for UK Institutional Review Board (IRB) members, investigators and others involved in human subject research

UK UNIVERSITY OF KENTUCKY Office of Research Integrity

Informed Consent

How can you be sure you've obtained valid and effective informed consent? Are you confident that your subjects "understand" key concepts of informed consent and research participation? Is "understanding" enough?

Researchers work hard to describe research concepts in lay terms to enhance their participant's understanding. However, research on participant expectations indicates that having an intellectual understanding of a research concept such as randomization may not translate into making the connection to it's role in treatment assignment.[1] Moreover, understanding is only one component of decision making. Consent capacity experts describe understanding as an ability to grasp meaning of information, while appreciation involves applying the information to one's own situation.[2] Inflated perception or hope for a promising treatment may cloud one's ability to appreciate the probabilities and consequences of participation.

ORI, in conjunction with the Markey Cancer Center and the Center for Clinical and Translational Science, is pleased to announce the following opportunity to participate in the Dartmouth "teach-back" informed consent training program presented by Dartmouth Assistant Provost, Elizabeth Bankert. In addition to being an accomplished speaker, Elizabeth is actively involved in research ethics at the national level and is co-editor of the book, "IRB: Management and Function". Investigators, coordinators, researchers, and study personnel involved in obtaining informed consent are encouraged to attend one or both portions of this unique educational offering.

1. Scott, Y.H., et al. Research Participants' Irrational Expectations: Common or Commonly Mismeasured? IRB Ethics & Human Research 2013;(1):1-9.
2. Applebaum P.S., Grisso, T. Assessing patients' capacities to consent to treatment. NEJM 1998;(319):1635-1638.

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Co-sponsored by:
- Office of Research Integrity (ORI)
- Center for Clinical & Translational Science (CCTS)
- Markey Cancer Center (MCC)

Giving Research Participants Their VOICE

Elizabeth Bankert, MA
Assistant Provost, Dartmouth College

Thursday, March 21, 2012

Research Update

At the completion of this session, participants will be able to employ the skills and tools to improve the informed consent process by using the "teach-back" method.

Part One: Clinical Research Update (1 credit hour)
Methods, tools and enhancements to achieve effective and valid informed consent
12:00 p.m. to 1:00 p.m.
Hospital Pavilion A Auditorium

Part Two: Hands-On Work Shop (2 credit hours)
Role play and practice using the teach-back technique
1:30 p.m. to 3:30 p.m.
Wethington Commons Room

Register for one session or both!

To reserve your place, please register online
http://j.mp/X4VGym
by Monday, March 18, 2013.

REGISTRATION REQUIRED
If you require special physical arrangements to attend this program, please call 323-8545.
Target Audience: Faculty, Staff & Students involved in Clinical or Academic Human Subject Research

Up to 3 hours continuing education credit available. See full flyer for details.

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Federal Agency Specific Requirements

All research conducted at the University of Kentucky is subject to basic IRB review and informed consent regulations outlined by the Department of Health and Human Services (45 CFR 46). However research funded by or involving select federal agencies may involve additional, idiosyncratic requirements related to the nature of the research or population under study.
The new Federal Agency Specific Standard Operating Procedure (SOP) outlines ORI, Investigator, and IRB roles and responsibilities for the conduct and review of such research. Indicate if your study involves or is supported by a federal agency on the IRB application form. Detailed guidance and checklists are provided under the Federal Agency Specific Requirements section of the web-based IRB Survival Handbook.

The following is a list of some specific agency guidance documents:

- Summary of Department of Education (DoED) Requirements [PDF]
- Summary of Department of Energy (DoE) Requirements [PDF]
- Investigator Checklist for Verification of Compliance with the Department of Energy (DOE) Requirements for the Protection of Personally Identifiable Information (PII) or Protected Health Information (PHI) [PDF]
- Summary of Environmental Protection Agency (EPA) Requirements [PDF]
- Environmental Protection Agency (EPA) Research: IRB Reviewer Checklist [PDF]
- Summary of Department of Justice (DoJ), National Institute of Justice (NIJ), and Bureau of Prisons (BoP) Requirements [PDF]
- Department of Justice (DOJ), National Institute of Justice (NIJ), and Bureau of Prisons Supported Research: IRB Reviewer Checklist [PDF]
- Summary of Requirements for Department of Defense Supported Human Research [PDF]

***REMINDER*—Revised & Combined Informed Consent & HIPAA Templates**
As detailed in previous announcements, updated versions of the Medical and Nonmedical Informed Consent and HIPAA Forms are available on the ORI Forms Webpage . Use of the updated forms are mandatory as of March 1st for new IRB submissions only. A listing of the revisions and versions of the templates with highlighted edits were provided for reference on the 2012 ORI 'What's New' webpage

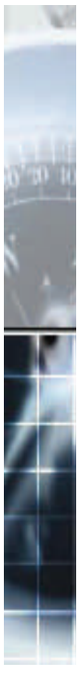
ORI Q &A

IND Exempt -still under FDA Jurisdiction

Question: Our drug study was determined to be "exempt" from the requirement to submit an Investigational New Drug (IND) application to FDA. **Do we still need to include reference to FDA in our informed consent/ HIPAA documents?**

Answer: Yes. The study is still conducted under the jurisdiction of the FDA, therefore subjects should know for instance that the study is evaluating the safety or effectiveness of a drug and FDA officials may view pertinent portions of their identifiable records.

As a matter of fact, one of the criteria that must be met to "exempt" a marketed drug study from IND requirements is compliance with the informed consent requirements. 21CFR312.2(b)



Human Subject Protection: Navigating the Institutional Review Board (IRB) Submission & Review Process

Are you new to the IRB Submission and Review Process?

ORI offers recurring sessions for students, faculty or staff new to human subject research or unfamiliar with the UK IRB submission process.

Speaker: Belinda Smith, MS, RD, CCRC

Next offering:
March 5, 2013
1:30 pm - 3:30 pm
Room 158 Taylor Ed Auditorium

RSVP to Selena Smith via email or at 859-257-0852.