



Portland Oregon Chapter

If They Don't Get It, You Don't Get It: Informed Consent

Jan 19th, 2011 from 9:00 am 11:30 am.

Program Description

Informed consent is the ethical cornerstone of clinical research. Despite regulatory, legal and ethical imperatives, significant deficiencies persist. Interventions which focus on form over process yield dismal results. Comparative analyses conclude that one-on-one interactive discussion is the most consistent intervention for improving understanding and thereby achieving valid, ethical, informed consent.

In a conversational style laced with humor, metaphor, and historical anecdotes, a foundation of trust and rapport is established with the research participant, a framework for understanding is built, awareness of protections is enhanced with illustrations from the Nazi Doctor's Trial and Tuskegee Syphilis Trial, and therapeutic misconception is diffused with resultant patient comprehension, compliance, recruitment and retention – a truly informed consent.

This interactive session is divided into two main sections: theory and practice.

Theory includes:

- Rationale (regulatory, legal, ethical, practical)
- Documented consent deficiencies (understanding the basic elements of informed consent, terminology, roles and responsibilities and therapeutic misconception)
- Literature review of the research on increasing understanding
- Lack of a "gold standard" for assessing participant understanding.

Practice includes the conversational model of:

- Establishing trust and rapport with motivational interviewing techniques increasing social value
- Building a framework for understanding with an overview of the roles and responsibilities of the sponsor, Food and Drug Administration, Institutional Review Board, Principal Investigator, study coordinator, and participant
- The informed consent document (preview, read, review with checks for understanding).

Learning Objectives

Upon completion of this webinar, attendees should be able to:

- Assess and address deficiencies in participant understanding
- Differentiate the higher legal and moral obligation in clinical research practice from standard therapeutic practice
- Construct a framework for understanding on a foundation of trust and rapport with a conversational overview of roles and responsibilities.

Presenter

Barbara Davis is currently an Associate Professor at George Washington University in Clinical Research/Leadership and a PhD student in Instructional Systems at Florida State University with a minor in Organizational Theory and focus in digital media e-learning.

Accreditation Information

Continuing Nursing Education

The California Board of Registered Nursing approves the Association of Clinical Research Professionals (ACRP) as a provider of continuing nursing education. ACRP's webinar program provides 1.5 contact hours of continuing nursing education credit (Program Number 11147-2010-402).

Association of Clinical Research Professionals

The Association of Clinical Research Professionals (ACRP) provides 1.5 continuing education credits for the completion of this educational activity with the completion of the online evaluation form. These credits can be used to meet the certification maintenance requirement (Program Number ACRP-2010-REP-402).

Space is limited and registration is required.

Please email seversol@ohsu.edu to register.