



“If They Don't Get It, You Don't Got It: Informed Consent” **An ACRP Webinar Replay**

Date: February 2, 2012

Speaker: Barbara Davis, MSHS, CCRC, CCRA
Adjunct Assistant Professor – Clinical Research/Leadership
George Washington University

Time: 6:30 pm Chapter Meeting
7:00-8:30 Webinar Education Program

Location: Missouri Baptist

Course 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).

Upon completion of this course, participants 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.

Target Audience: Study coordinators, nurses, CRAs, principal investigators, pharmacists, regulatory affairs/compliance officers, IRB members, bioethicists, and other members of the research community involved in the regulation, monitoring or conduct of human clinical research studies.

1.5 Contact Hours have been approved for this program by ACRP. Membership is not required for online registration/application of contact hours. These contact hours will be available to those that purchased them at the \$10 charge for members and \$25 charge for nonmembers. These credits can be used to meet the certification maintenance requirement. To receive contact hours: go to your “My Tests, Evaluations, and Certificates” (TEC) record on the ACRP website and complete the evaluation between 10-30 days following the event.

The Registration Fee for the event is \$10 for non-members, and is free for ACRP members.

***Come check us out!!! Non-members can attend one meeting **FREE!** (Registration fee waived if not requesting CEUs). Contact Kathryn Lindsay, MEd, RN, CCRN, CEN, CCRC at lindsayk@slu.edu or 314-393-1490 for more information.

REGISTER ONLINE @: <http://www.acrpn.org/GetInfoFor/USChapters/GreaterMissouri.aspx>

Cancellation policy: This program may be cancelled at any time without prior notice.

Sandwiches, chips, desserts and a mixed assortment of cold drinks will be served!

DIRECTIONS

LOCATION:

Missouri Baptist Medical Center (Map/directions attached)
3015 North Ballas Road
St. Louis MO 63131

MEETING ROOM:

Auditorium #3 – First floor of main hospital building

MoBap is located in mid-west St. Louis County (Town and Country, Missouri), at the southeast corner of I-270 and Highway 40 (I-64). Take the Ballas Road exit from Highway 40 (I-64), and travel south one block. Turn right at the traffic signal to enter the campus.

