SESSION III: Training on Conducting the Informed Consent Process

Jennifer Lentz, Eli Lilly & Co.

March 10, 2015
Session III Objectives

- Present examples of innovative informed consent training programs
- Solicit feedback and develop consensus on proposed recommendations related to informed consent process training programs
A Training Program for Improving the Informed Consent Discussion Between Clinical Researchers and Their Subjects

Mary Ellen Cadman (National Institute of Mental Health, NIH)
Julie Brintnall-Karabelas (National Institute of Mental Health, NIH)

March 10, 2015
Based on a True Story: Using Re-Enactments of Actual Clinical Visits to Improve Oncologist Communication about Clinical Trials

Susan Eggly (Karmanos Cancer Institute)

March 10, 2015
Proposed Recommendations for Informed Consent Training Programs

Michele Kennett, University of Missouri

March 10, 2015
Training for the Informed Consent Process

- Not a “one-size-fits-all” scenario
- Not all people learn in the same way, at the same pace and/or are at the same level of skill development
- Should include
  - How to tailor messages to the individual participant’s needs
  - How to address possible challenges that may occur
  - How to encourage participant questions
  - How to prioritize information shared with the participant
Visual—learning through charts, diagrams, and other forms of graphically presented information

Reading-writing preference—learning through reading and writing documents such as manuals, reports, essays, and presentations

Auditory—learning through lectures and group discussion

Kinesthetic—learning through case studies and live simulations

Learning Styles

Bloom’s Cognitive Development Process

- **Remember**
- **Understand**
- **Apply**
- **Analyze**
- **Evaluate**
- **Create**

Proposed Recommendations

- Strongly encourage study personnel participating in the ICP to take part in a formal training program
- May be required by individual research site, but should not be federally mandated
- Should be evaluated periodically and adjusted as needed to ensure they are meeting the needs of trainees
Proposed Recommendations

Because no empirical evidence exists validating an IC training methodology correlated to improved ICP

AND

Because training programs should be flexible to fit the needs and local norms of investigative sites

- Suggest a framework for training based on the 2 general educational principles described

- Local sites may develop other methods for fulfilling the general training principles.
Continuing Education
Remember understand, apply, analyze, evaluate, and create

Interactive
Apply, analyze, and evaluate

Didactic
Remember and understand
Didactic Training

Impart specific facts and information the learner should understand about the ICP

Provides a foundation and framework for additional training

May include lecture, video, and/or on-line training module
Didactic Training Content

- Elements of a good consent process
- Review of the federally mandated required elements of IC, including requirements for documenting the ICP
- Guidance on effective health-communication behaviors
- Writing a consent form, including health literacy issues and use of plain language
Interactive Training

Provides an opportunity to think critically about real-world application of IC information learned during didactic training

Allows the learner to practice or observe ICP best practices

May include case study exercises via video or on-line module, small group discussion, role-playing, and/or proctoring with a researcher experienced in conducting the ICP
Interactive Training Content

Examples of different situations research staff may encounter during the ICP

Tools for managing challenging situations

Opportunity to practice effective health communication techniques
Continuing Education

- Allows the learner to reflect or receive feedback on his or her experience managing the ICP
- Allows the learner to consider ways to improve the process in future situations
- May include review of the ICP by IRB or research office staff; ongoing opportunities for didactic and interactive learning for experienced research staff
Continuing Education Content

- Any content necessary to address deficiencies identified during ICP audits
- Constructive feedback for improving the ICP
- New information or new training resources available about effective management of the ICP
- Refresher sessions to remind research staff of the key principles of the ICP
Existing Resources and Programs

- Some training programs already exist and can be accessed as free resources for interested parties
- See the DRAFT Recommendations Document, Appendix E, for details
Additional Considerations

Policy Considerations
- Should there be policies requiring training?
- Should there be accreditation of training programs?

Future Research Needs
- Determine staff and participant satisfaction with the ICP
- Measure participant comprehension of the IC conducted by staff who had received formal training as compared with IC conducted by untrained staff
- Evaluate the effect of research staff training on enrollment and retention of research participants
- Compare different training models to evaluate effectiveness of training staff
Training Work Group

- Michele Kennett (University of Missouri)
- Kathy Kopnisky (NIH)
- Jennifer Lentz (Eli Lilly & Co.)
Discussion
Break 3:00 – 3:15pm