

# Clinical Research Ethics KFC: Key Milestone and Projects Summary

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CTSA Consortium Steering Committee (CCSC)

Face to Face Meeting

Place

October 9, 2009

# Functions & Organization

## ■ Functions:

- Support collaborative clinical research ethics
- Expand the use of best practices
- Facilitate use of educational materials & templates
- Address ethical issues germane to C&T research



## ■ Organization - KFC, Operations Group, and...

■ Consultation Group

SGs #1 & #3

■ Education Materials Group

SGs #2 & #5

■ Community Based Research Group

SG #4

■ CRE-CHOC collaboration

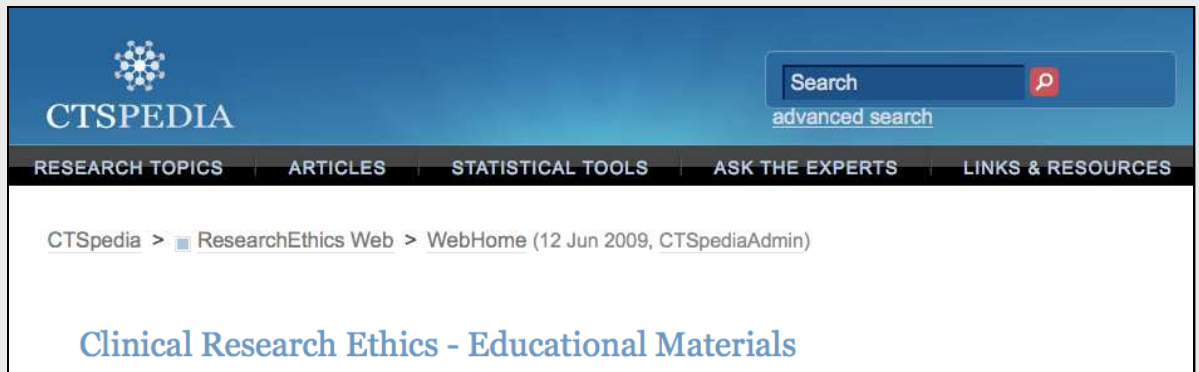
SGs #1, #2, #3

# Research Ethics Consultation (REC)

- Step 1. Relationship of IRBs and REC?
  - Addressed by working group, will publish report:
    - Laura M. Beskow, Christine Grady, Ana S. Iltis, John Z. Sadler, and Benjamin S. Wilfond, "Points to Consider: The Research Ethics Consultation Service and the IRB," *IRB: Ethics & Human Research* 30, no. 6 (2009): 1-
  - Report describes:
    - Clients
    - Examples of relevant questions and actual cases
    - Model consulting services
  - Concludes with a discussion of added value
- Step 2. Develop & implement national program

# Training materials

- Step 1: Information on program and materials
  - National survey of existing programs & materials
  - Available on CTSPEDIA
  - Report ready to submit for publication
    - DuBois, Kon, Heitman, and Steneck, “Instruction in the Responsible Conduct of Research: An Inventory of Programs and Materials within CTSAAs,”
- Step 2: Model curriculum for RCR instruction
  - Ensure Core Competencies reflect model curriculum



# Community Engagement Research

- Step 1. Detailed study of ethical issues
  - “360 Degrees of Human Subjects Protections in Collaborative Community Engagement Research”
  - Framework for analysis
    - 3 perspectives (individual, group member, and group)
    - 3 categories of risk
  - Three publications ready to submit
    - Research Ethics Framework
    - Life Cycle of a Research Project
    - Nine Key Functions of HSP
- Step 2. New CRE/CE group to apply analysis



Lainie Friedman Ross, MD,  
PhD Allan Loup  
Robert M. Nelson, MD,  
PhD  
Jeffrey R. Botkin, MD,  
MPH Rhonda Kost, MD  
George R Smith, Jr, MBA  
Sarah Gehlert, PhD

# Future challenges

- CRE- CHOC on-going collaboration
  - Develop federated IRB model, multi-site trials
- Two new groups:
  - Research on Research Ethics
    - Identify issues & provide guidance on design issues
    - Help identify sources of funding
  - IRB project for Strategic Goal #1 Committee
    - Propose and validate quality measures for IRB HSP
- Additional goals
  - Institutionalize annual meeting (R13 application)
  - Raise awareness of ethical issues across programs

# For more information...

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