Biospecimens: Challenges & Solutions in Clinical Research

CALGB Plenary Session
CARE (Committee on Advocacy, Research Communications, and Ethics)
November, 2005

CARE
Committee on Advocacy, Research Communications & Ethics
(Methods: Education & Research)

Patient Advocacy
Help trial participants by improving:
• Trial design
• Consent process
• Communication

Research Communications
Reduce clinical trial barriers in protocol development, activation & accrual

Ethics
Address ethical issues that pertain to CALGB research

Underserved Populations
Create effective solutions for unique issues

<table>
<thead>
<tr>
<th>Concept</th>
<th>Protocol Dev</th>
<th>Activation</th>
<th>Informed Consent</th>
<th>Accrual</th>
<th>Adherence</th>
<th>Results</th>
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CARE members include all roles throughout the clinical trial process
Goals of this Session

- Learn why biospecimens are important, but not easy
- Provide practical & balanced information on biospecimen-related issues:
  - Understand legal/regulatory issues and resolutions
  - Describe patient perspectives on tissue donation
  - Ethical implications of consent, collection, storage & use
- Learn how to deal with these issues on a daily basis

Today’s Agenda

- Introduction
  - Moderator: Deborah Collyar
- Speaker
  - Carolyn Compton, MD, Ph.D.
- Panel discussion
  - Covering the issues from many perspectives
    - Ethics, IRBs, patients, investigators and pathologists
    - CALGB collection and datasharing
- Q & A from you
  - Write down questions, pass them in, hear them asked
- Summary
Carolyn Compton, MD, Ph.D.

- Many roles today
  - Chair, CALGB Pathology Committee
  - Director of Biorepositories and Biospecimen Research, NCI
  - Filling in for Scott Jewell
    - Pathology Coordinating Office (PCO) perspective
  - Panel member as community pathologist
  - Carolyn's bio is in handout

- "Human Biospecimens:
The Key to Translational Research and
The Future of Cancer Medicine"

Time for the Panel

- Panel members (bios in your handout)
  - General concepts for clinical research
    - Ethics: Steven Joffe, MD (Dana-Farber)
    - IRBs: William Carson, MD (Ohio State University)
    - Patients: Laura Cleveland (Patient Advocate)
  - When developing a CALGB protocol
    - Investigator: Lyndsay Harris, MD (Dana-Farber)
    - CALGB PCO: Scott Jewell, MD (Ohio State)
    - Pathologist: Carolyn Compton, MD, Ph.D.
    - CALGB bioinformatics: Jennifer Shoemaker, Ph.D.
Panel Process

- Each panel member gets 5 minutes
  - Brief overview of each perspective
- Q & A from YOU! (audience)
  - Write down questions, hand to CARE member
  - Or come to mikes
- CARE members
  - In aisles, ready to collect your questions!
- Resources
  - Listed at summary, in handout

Now for the Brief Overviews

- Ethics: Steve Joffe
- IRBs: Bill Carson
- Patients: Laura Cleveland
- Investigators: Lyndsay Harris
- CALGB PCO: Scott Jewell
- Pathologists: Carolyn Compton
- CALGB bioinformatics: Jennifer Shoemaker
Q & A from YOU

- Remember why we do trials & biospecimens?
  - To get better answers more quickly for PEOPLE!
- Now, questions from the audience

What about specimens from deceased CALGB trial participants?

- Can we use the specimens for additional research?
  - Investigator cannot know whose tissue it is
- Not specifically addressed in regulations
  - OHRP: not a ‘human subject’ when dead
  - FDA: you’re always a subject, dead or alive
  - HIPAA: does consider subjects after death
Concern about how to predict what is needed in the future

- Comment: wouldn’t have known what was needed for the flu virus without old samples (> 100 years)
- Ethical dilemma
  - Most patients want to get as much out of samples as possible
  - Ethical limits – are they becoming unethical?
- How long are samples kept?
  - Used to think ~ 100 years, but now an economic issue
    - Can be much less time (7-20 years)
- Suggest using opt-out instead of opt-in language on consents
- Legislation and protections are actually necessary
  - Many people want the research done; may need more balance
  - Past atrocities (even in 2001) make protections necessary
    - See CALGB CARE “Ethics in Clinical Research – Getting It Right” for more information

Examples of how to use the 8/04 guidance?

- 8/04 guidance was more friendly to research, but very ambiguous
  - Those involved in collection should be separate from the researcher
  - But do they have to be aligned to the potential research participants?
Do we know for patients that have signed, that samples have not been collected?

- ~75% of accepted specimens have been collected
  - ~90% in breast
  - Lowest is 65%
- Not sure why haven’t received all
  - Many of the issues that Carolyn discussed in the community pathologist perspective

Q & A from YOU

- Remember why we do trials & biospecimens?
  - To get better answers more quickly for PEOPLE!
- Additional questions…
  - How do we minimize risks of storage/collection?
  - How to deal with unspecified ‘future research’?
  - Communicating with the patient
    - why, when and how?
  - CALGB community support
    - what are the barriers and how to improve?
  - Access to results and tissue for the patient?
In Summary…

- See handout for additional resources
- On CALGB web (member side)
  - CARE Ethics Sub-committee presentation
    - “Ethics in Clinical Research – Getting It Right”
      - Available to download for ‘grand rounds’, trainings, etc.
      - Has notes on how to use; Can include local information
  - This plenary session, bios, and handout available at:
- Coalition training modules
  - Module 5: Protecting Research Participants
  - Module 6: Tissue and Its Use
- NCI
  - New tissue brochure available soon; check back for url

Thanks to…

- CARE sub-committee members in
  - Patient Advocacy
  - Research Communications
  - Ethics
  - Underserved Populations
- Panel members
- Plenary helpers
  - Sandra Batte, Anne Battershell, Jennifer Zelazny
- CALGB & Rich Schilsky
- And YOU for your commitment & interest