NCI/NAPBC Model Informed Consent for Future Research Use of Tissue

Marianna Bledsoe

Resources Development Branch,
Cancer Diagnosis Program,

National Cancer Institute

Overview

- NCI/NAPBC Model Consent Project
  - History
  - Guiding Principles
  - Development/Testing of the Form
- Use of the Form
- Patient Attitudes About Specimen Use
- Summary: Key Points

History of the Model Consent Project

- National Action Plan for Breast Cancer (NAPBC) (1993)
  - Ensuring the availability of specimens for research identified as high priority
- NCI conference to assess specimen needs (1994)
  - Informed consent for use of specimens should be obtained at the time the tissue is collected

History of the Model Consent Project

- Ethical Issues subcommittee of the Biological Resources Working Group (NAPBC)
  - established to develop a model consent form for use in the routine care setting
  - Included patient advocates, ethicists, lawyers, pathologists, clinicians, and laboratory researchers

Guiding Principles

- Human specimens are critical to research
- Medical care of an individual must not be compromised
- Subject information must remain private
- Informed consent for research use of tissue must be explicit

Development of Model Consent

- Model consent developed
  - Met requirements of Common Rule
- Model consent tested in 27 focus groups
  - Different socio-economic levels, racial and ethnic groups, genders, and professional and patient groups
- Consent form simplified
  - Translated to low literacy level

Development of Model Consent

- Patient information sheet prepared
- Consent and information sheet presented to:
  - PRIM&R
  - Cooperative Groups
  - American College of Surgeons Commission on Cancer
- Field test planned

Testing of the Form: Main Questions

Is the form and the process acceptable to patients?

Is the form and the process acceptable to providers and/or those who administer the form?

Testing of the Form

Requirements:

- Separate consent for research use of tissue
- Independent document or separate section of surgical consent form
- Seven essential elements required

Testing of the Form: Required Elements

- Tissue used first and foremost for patient diagnosis and care
- Patient asked to allow left-over tissue to be stored for future research
- Decision regarding use of tissue will not affect patient care
- Research will not directly benefit patient and research results will not be provided

Testing of the Form: Required Elements

- Medical records may be reviewed for research purposes but all patient information will be kept confidential
- Tissue may be used for unspecified research which may include genetic research
- Patient has the right to change his/her mind at any time

Testing of the Form

- "Tiered" Approach asks consent for:
  - use of specimens for cancer research
  - use of specimens for other diseases
  - re-contact to participate in other research
- Study Design
  - 10 institutions; 100 patients/institution
  - Patient information sheet + consent form given at any time
  - Physicians and participant questionnaire

Testing of the Form: Observations

- High consent rate
- Institutions that incorporated the consent into the general surgical consent were more successful
- Information sheet was helpful to both providers and patients
- Consent form and information sheet clear and understandable to patients
- Patients demonstrated accurate recall of their consent

Experience with Use of the Form

- STAR Trial:
  - 14431 enrolled
  - Consent rate
    - Consent for use of specimens for cancer research 13,812 (95.7%)
    - Consent for use of specimens for other diseases

      13,763 (95.4%)
    - Consent for re-contact to participate in other research 13,816 (95.7%)

Experience with Use of the Form

- ECOG
  - 2154 patients (’98 – ’00)
  - Consent rate
    - Consent for use of specimens for cancer research 93.7%
    - Consent for use of specimens for other diseases 86.9%
    - Consent for re-contact to participate in other research 84.3%

Malone et. al, JNCI, 94(10), 2002

Subject Attitudes About Use of Tissue

- NBAC sponsored “mini-hearings”
  - Many felt a general, one-time consent (“blanket consent”) for research was enough
- Wendler and Emanuel, *Archives of Internal Medicine*, Vol. 162, No. 13, July 8, 2002
  - Once consent for research purposes has been given, most respondents viewed additional consent for other research as unnecessary

Subject Attitudes About Use of Tissue

- Stegmayr and Asplund:
  - Specimens collected in 1990, initial consent for “future research on cardiovascular disorders and diabetes”
  - Patients re-contacted in 2001 for consent to participate in hereditary genetic research on cardiovascular diseases
    - 93% Yes
    - 2% No
    - 5% No response/Incomplete response

      British Medical Journal, Vol 325, Sept. 21, 2002, p.634

Subject Attitudes About Use of Tissue

- Stegmayr and Asplund (Cont.)
  - Of those that consented:
    - 78% gave general consent for research on hereditary genetic research of cardiovascular diseases
    - 22% wanted consent for each new genetic project

British Medical Journal, Vol 325, Sept. 21, 2002, p.634

Use of the Model Consent: Key Points

- Model only
- Information sheet provided to patients before consent
- IRB reviews:
  - initial protocol for specimen collection and repository operation, **and**
  - each subsequent research project for which specimens will be used to determine when new consent is needed

Use of the Model Consent: Key Points

Advantages:

- Allows precious resources that would otherwise be discarded to be available for future research use
- Tiered consent minimizes the psychosocial risk of re-contact for new consent
- Simple, understandable
- Acceptability: Patients and advocacy groups, surgeons and physicians, National Bioethics Advisory Commission, NCI Clinical Cooperative Groups