



Consent Form and IRB Challenges that Arise with Specimen Banking in a Multicenter Trial Setting

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NSABP Overview

- One of 9 adult cancer cooperative groups funded by the National Cancer Institute
- Conduct Phase III clinical trials in the areas of breast and colorectal cancer

NSABP Overview (cont.)

- Involves a large network of over 6000 researchers at over 1000 institutions in North America
- Membership includes nearly 1000 IRBs
- NSABP trials create large repositories of specimens linked to patient-specific, long-term clinical trial data

IRB and Consent Form Problems Can Affect:

Patients

- Inaccurate information can lead to distrust
- Delays result in denying access to care

Local Institutions

- Problems result in suspension of accrual privileges
- Funding may be adversely affected

IRB and Consent Form Problems Can Affect: (cont.)

Coordinating Center for the Trial

- Accrual delays lead to delays in answering trial-specific scientific questions
- Significant staff time and resources are required to resolve issues

Example of Effect on Stakeholders

Resolution process involved:

- One consent form at one institution
- 7 NSABP staff; at least 4 site staff
- About 16 NSABP staff-hours; unknown number of hours at the site
- 41 days to resolve, during which 5 patients were denied access to the trial or had delays in the start of treatment

Four Major Problems Identified with Banking Issues

- Linkage and identifiable data
- Future, unspecified research
- Restrictive local laws
- Inappropriate changes in local consent form text

PROBLEM #1: Linkage and Identifiable Data

Problem:

- IRBs insert local template wording that is inconsistent with NSABP banking policy and procedures

Solution:

- Explain to IRB —
 - » Why do we keep a link?
 - » What is actually linked?
 - » Who has access?

Reasons We Keep A Link

- Patient history associated with a specimen can be updated with long-term survival
- We need to accurately identify the correct specimen if a patient withdraws consent for storage and use

Which Information Is Linked?

- Repository: Specimen stored only with Patient Study Number and a separate repository code number
- Statistical center: Patient data is stored with Patient Study Number
- Patient data and specimen are linked by a unique Patient Study Number

Which Information Is Linked? (cont.)

- Repository and statistical center are separate physical facilities
- Outside researcher only receives a specimen with a repository number, i.e., “de-identified”

Who Has Access to Specimens/Patient Data?

Statistical Center

- Statisticians and researchers at the statistical center do not have access to patient-identifying information
- Only designated staff (e.g., QA) at the statistical center have access to patient identifying information; they do not have access to the repository code number

Who Has Access to Specimens/Patient Data?
(cont.)

Repository

- Repository staff and outside researchers have access to specimens with only numbers
- No outside researchers have access to patient-identifying information

Bottom Line for Specimens from NSABP

- Research will be performed using the consent by which it was collected
- It will involve “de-identified” specimens
- It will not require further consent for use

In the rare case that research requires identification of patient in order to be conducted, the NSABP will only consider patients who agreed to be contacted in the future about more research.

PROBLEM #2: Future, Unspecified Use

Problem:

- IRBs refuse to include language in consent form that allows specimens to be used in future, unspecified research

Solution:

- Clarify difference between Authorization and Informed Consent

PROBLEM #2:
Future Unspecified Use (cont.)

- HIPAA Authorization allows for collection of specimens to create a repository, even though future use may be unknown
- Consent Form informs patient that specimens will be collected, stored, and used

PROBLEM #2:
Future Unspecified Use (cont.)

- As long as future use involves specimens not identifiable to researcher, or HIPAA identifiers, a study-specific authorization or consent form is not required
- Easier to understand when authorization and consent form are separate documents; harder to discuss when combined

PROBLEM #3: Restrictive Local Laws

Problem:

- Local law requires a banking policy or procedure change that NSABP cannot accommodate

Example: Time limit on specimen storage/use

Solution:

- NSABP maintains current system and places burden on local institution to address restriction at local level and notify NSABP

PROBLEM #4: Inappropriate Changes in Local Consent Form Text

Problem:

- Consent form language used by the local IRBs is inconsistent with NSABP banking procedures

Solution:

- Problems fall into 7 categories, each addressed differently

7 Common Problems Encountered with Consent Forms

1. Deletion of the banking text and/or questions
2. Combining NSABP standard questions — does not permit differentiation in permission for cancer research from research in other diseases

7 Common Problems Encountered with Consent Forms (cont.)

3. Addition of the option to be given results of the research done with the samples
4. Addition of questions that put more specific restrictions on the use of the samples
5. Addition of the option to choose to be recontacted before doing future research or before conducting specific types of research

7 Common Problems Encountered with Consent Forms (cont.)

6. Adding inaccurate text to the questions, e.g., a statement that the samples will not be linked to the patient
7. Addition of language stating that the local IRB will review any future research studies before samples are used

The NSABP's Commitment

- **PROVIDE** patients with accurate information that is consistent with NSABP banking policies and procedures and with government regulations
- **UTILIZE** the samples according to the permissions granted by the patient, within government guidelines



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