

# Interpreting Consent for Research on Archived Tissue

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#### **Description**

A scenario that covers ethical issues that arise when a researcher wants to use human tissue originally collected for other research.

## **Body**

A researcher believes that breast cancer occurs only when a combination of inherited and acquired genetic mutations occur, and theorizes that biopsied breast tissue might be used to detect earlier pre-cancerous mutations that might help predict who is at increased risk of cancer. The scientist wants to use archived tissue samples and correlate them with later medical records indicating whether the person went on to develop breast cancer. The scientist wants to know whether certain early mutations are especially likely to predict later cancers, or alternatively whether the sheer number of mutations in key sites in the genome might be used as an index of risk.

Given the latency of breast cancer, the scientist prefers tissue at least ten to thirty years old, for which there is accurate and complete medical follow up. Unfortunately, at the time the tissues were obtained, informed consent for their use in research

was either not asked at all, or was obtained through a very brief and general consent form. Neither researchers nor patients anticipated this kind of research when the tissues were gathered.

- Were the consents given then adequate to use the tissue for research today?
- What if no record of consent exists for a particular sample?
- Should the persons be tracked down and asked to consent specifically for this study?
- What are the reasons for or against this course?

#### **Notes**

Caroline Whitbeck introduced methods and modules for discussing numerous issues in responsible conduct of research at a Sigma Xi Forum in 2000. Partial funding for the development of this material came from an NIH grant.

You can find the entire sequence on the OEC at <u>Scenarios for Ethics Modules in the Responsible Conduct of Research</u>. Some information in these historical modules may be out-of-date; for instance, there may be a new edition of the professional society's code that is referred to in an item. If you have suggestions for updates, please contact the OEC.

#### Contributor(s)

Caroline Whitbeck

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#### **Resource Type**

Case Study / Scenario

#### **Parent Collection**

Scenarios for Ethics Modules in the Responsible Conduct of Research

### **Topics**

Human Subjects Research Informed Consent

# Discipline(s)

Life and Environmental Sciences Genetics and Genomics

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