

Bioethical Issues In Clinical Biospecimen Research

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Recommended Readings:

Add full references:

Robert Weir – Tissue Issue

Norbert Ehrenfreund – The Nuremberg Legacy

Presentation Abstract:

Reports indicate that over 300 million biospecimens exist in banks and repositories in the US alone. This material, including biopsies, blood samples, saliva, and surgical tissue, provides an enormous resource for clinical research. The collection, storage, and use of such human material, however, raises significant ethical, legal, and social challenges. These include not only issues of consent, but also issues of genetic privacy and confidentiality, control over materials, appropriate testing, and donor access to scientific results. (Maschke, KJ, 2008).

Discussion Summary:

Biospecimens were defined as stored materials from the human body (blood, tissue biopsies, urine, skin etc.). Stored human samples are important for research as well as for clinical purposes. These samples are stored in organized banks or in private freezers that are unregulated. As such we have no central database that contains information regarding all the biospecimens stored today. Group discussion thus began by considering possible regulation of biobanks.

Discussion turned next to the use of so-called medical waste and the process by which hospitals give tissue samples classified as “wastes” to clinical researchers. Some participants raised concerns about patient anonymity as technology for genetic identification advances. Others asked about how biobanks and researchers using them should handle incidental findings, e.g., information of potential clinical significance to donors. On a related note, most participants agreed that tissue samples used in research should have clear documentation of donor consent and appropriate IRB review. Participants expressed the need for clearer and perhaps different consent forms for the collection of biospecimens.

Questions discussed

Should the NIH be more involved with regulation of biospecimen banking? Do we need an organization outside the NIH to perform this task?

What should be the criteria when establishing a bank for human biospecimens?

Under what conditions may researchers remove samples from a bank?

Who has access to biospecimens?

What are the limits to the use of biospecimens?

Does the age of the specimen matter when it comes to banking and use?

With the genetic technology that exists today, is true anonymity with regards to human material really even possible?

Philosophically, do we own our bodies/parts of our bodies?

How can we regulate commercialization of these specimens?

Conclusion

Discussion closed with a consensus that we need more education in this area for members of the general public who may have their tissues stored and/or used for research. Members of the scientific community involved in working with human specimens also need greater awareness of the ethical, legal, and social issues related to collecting, banking, and using human biospecimens.

Summary: NR