

## The Ethical & Social Aspects of Genetic Research on Stored Human Tissues

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## Background

- ☞ Tissue samples (e.g., blood, biopsies) have been collected & stored for decades for diagnostic and therapeutic procedures, secondary analysis, and for research.
- ☞ New genetic technologies over the last 30-40 years now make it possible to perform genetic testing of stored human tissues (e.g., frozen or histological specimens).
- ☞ Expanded use of human tissues in medical research opens up many positive possibilities for diagnosing and treating, if not curing, many diseases such as cancer and heart disease, as well as identifying links between genes and environmental factors.

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## Ethical & Social Issues

The use of human tissues obtained for one purpose that can now be used for another purpose (i.e., genetic testing) raises a number of ethical and social issues that clinicians will face in some fashion:

1. Informed Consent or Decisional Authority
2. Anonymity
3. Commercialization
4. Quality and Appropriateness of Research

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## Informed Consent to Storage and Future Use

1. Explicit Informed Consent: Research is only valid if the person is competent to consent.
2. Lack of Consent or Limited Consent: Persons are untraceable or dead in which case consent is impossible.
3. Implied Consent: There is precedent for this type of consent (e.g., the anonymous testing of stored blood samples for HIV).
4. Proxy Consent: A person close to the donor makes the decision on behalf of the donor who is incompetent or incapacitated, (e.g., uses best interest or substituted judgement standards).

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## Confidentiality & Anonymity

*Confidentiality* refers to the promise to the donor not to reveal information that the donor does not want disclosed.

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## Different Levels of Anonymity

1. Identified: Source is known and identity of the donor is tied to the sample.
2. Identifiable: Source is tied to the specimen by a link (e.g., a code number), but the identity of the source is not directly known.
3. Anonymized: Source's identity was known but is now irrevocably unlinked from the sample.
4. Anonymous: Source's identity is never known (i.e., sample is unidentified).

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## More on Confidentiality

- ⌘ Absolute confidentiality is nearly impossible to maintain in clinical practice.
- ⌘ Confidentiality is not always desirable, as it can hinder the potential research uses of samples.

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## Commercialization & Commodification

### Potential Benefits:

- ⌘ For-profit research spurs interests in investing in academic research.
- ⌘ The use of patents and other forms of intellectual property make it more likely that industry will support cutting edge and risky research.
- ⌘ Creates a more efficient transmission of knowledge between industry-based and academic-based genetic research on human tissues.

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## Commercialization & Commodification

### Potential Harms:

- ⌘ Desire for profit (e.g., stock options & royalties) could create conflicts of interests between industry and academe and undermine the quality of academic research.
- ⌘ On social, cultural, and psychological levels, many people think of the transfer of human tissues and organs as gifts, not things to be owned as sources or incentives for profit making. Commodification of human tissues in general diminishes our personhood.

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### Quality of Proposed Research

- ⌘ The demand for human tissues for genetic research is often greater than the supply.
- ⌘ Consequently, and related to the topic of commodification and conflicts of interests, tissues may be provided to commercial researchers because of the profit potential at the expense of higher quality research from non-commercial sites.

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### Implications for Clinical Genetics

- ⌘ Medical practitioners are the primary gate keepers of genetic testing and information, at least for clinical purposes.
- ⌘ Clinical genetics will playing an increasingly important role in the health care system.

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### Ideas for Safeguards & Best Practice Guidelines for Genetic Research on Human Tissues

1. Ethical oversight of genetic research and testing should comply with current IRB standards.
2. Clear protocols and consent forms should be used to provide guidance to researchers, clinicians, and participants.
3. The potential for the commercialization or profit from tissues samples should be made transparent to the donors when possible.

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Ideas for Safeguards & Best Practice Guidelines for Genetic Research on Human Tissues

- 4. Healthcare professionals should be able to disclose otherwise confidential genetic information to a genetic relative where failure to do so would pose a serious health risk to that relative.
- 5. Strict rules for maintaining the security of genetic databases and donor privacy should be enforced.
- 6. Clinicians should receive adequate education and training in clinical genetics, genetic counseling, and related ethical issues.

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Conclusion

Genetic research on human tissues raises significant ethical and social issues:

- 1. Informed Consent or Decisional Authority
- 2. Anonymity
- 3. Commercialization
- 4. Quality and Appropriateness of Research

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Conclusion

- ⌘ The development and enforcement of existing policies and regulations should help to minimize the risks of genetic research on human tissues.
- ⌘ Such a move would also provide clinicians with the needed training and appropriate knowledge base of new genetic technologies and their research and clinical implications for donors and their families.

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