Key points

- Review the NY Times Magazine article, “Taking the Least of You”
- Review key cases that highlight interplay of myriad issues
- Outline ethical issues of concern when dealing with tissue banking protocols
The New York Times Magazine

- April 16, 2006:
- “Taking the Least of You”
- By Rebecca Skloot
Fox Chase Cancer Center

- Ted Slavin
- Hepatitis B vaccine
- Decided he would maintain control over any tissue/blood removed
- Determined who could use them for research, how, and who made money
• John Moore
• Hairy Cell Leukemia
• David Golde: patent on the “Mo” cell line
• California Supreme Court ruled any ownership you might have in your tissue vanishes when they are removed from your body, with or without consent
Arizona State University

- Havasupai Indian Tribe gave blood samples for diabetes research
- Samples used without permission in unrelated studies of schizophrenia, inbreeding, and theories regarding migration of humans to North America
- Threats to the tribe’s ancestral beliefs
- “The bloodbath will start right now”
William Catalona, renowned prostate cancer surgeon
250,000 samples from >36,000 men
Wash U asserted they ‘owned’ the samples
Catalona left and went to Northwestern
Sought to transfer samples; Wash U sued
US District Court ruled in April 2006 that the university owns all biological materials that it stores
Ethical Issues

- Respect for Persons
  - Informed consent
  - Autonomy
  - Withdrawal
  - Privacy, confidentiality
- Minimizing risk
- Ownership issues
Infomedi consent

- Purpose of future research specified
- Access to information (what identifiers will be associated with sample?)
- Where human genetic research is anticipated, consent must describe consequences
- Conditions whereby subjects may withdraw their participation: destruction versus anonymization
Privacy/Confidentiality

- What identifiers are linked to samples?
- If genetic testing is planned, can identities really be protected?
- HIPAA research authorization is limited to a single purpose
- Government, law enforcement use of DNA biobanks (Patriot Act, Big Brother)
Risks

- Mainly involve breach of confidentiality
- Perceived fear of harm of discrimination
- Effect on access to or retention of benefits or entitlements (health or life insurance, employability, etc)
- Stigmatization, possibility of altered family relationships
- Psychological response to information
- Detection of biological relationships in families
Ownership issues

- Courts seem to say subject forfeits ownership upon donation (signing informed consent)
- Voluntary withdrawal from the research (repository) does not equate to directing use or transferring ownership
- Proprietary rights belong to the subject if cells are still within the subject
- Bioethicists may be more conservative on the issue than the general public
Ownership issues

- Unacceptable (Exculpatory) Language:
  - By agreeing to this use, you should understand that you will give up all claim to personal benefit from commercial or other use of these substances
  - I voluntarily and freely donate any and all blood, urine, and tissue samples to the US government and hereby relinquish all right, title and interest in said items
  - By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research
Ownership issues

- Acceptable language:
- Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.
- By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above.
Conclusions

- Evolving scenario
- Consent should be obtained for future research uses
- Put protections in place to minimize risks
- Deal with ownership honestly