Commercialisation of Human Tissue

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Should We Care too Much?

• “I think people are morally obligated to allow their bits and pieces to be used to advance knowledge to help others. Since everyone benefits, everyone can accept the small risks of having their tissue scraps used in research” (David Korn, Association of American Medical Colleges, quoted in The New York Times, April 16, 2006)

• “It is one thing to argue that the prevention of the certain and uncontroversially serious harms of nonconsensual bodily invasion and disrespectful treatment justifies a serious restriction on research, quite another to argue that the mere possibility of various harms, some of which are not so serious and which are very unlikely to occur, provides an equally compelling reason to restrict research” (Allan Buchanan, “An ethical framework for biological samples policy (commissioned paper)’, Online Ethics Center for Engineering 6/16/2006 National Academy of Engineering. www.onlineethics.org/Topics/RespResearch/ResResources/)
Why We Do Care About Tissue Research

- Discrimination
- Stigmatization
- Interests in privacy per se
- Ascriptive (group based) harms
- Using samples for purposes the source considers immoral

- Sample’s financial interests
  - Could/should the source share in the profit?
- Dignatory harms (not being treated with respect)
  - Would the source be equally willing to donate to a commercial venture? (eg skin donation)
Case Studies

- John Moore
- Henrietta Lacks
- Catalona vs Washington University
- Alder Hay

- Empirical studies (U.S.) show people want to be asked
- Sense of harm seems worse when commercial considerations are at stake.
Can Informed Consent Provide the Solution?

• Types of Consent
  
  – Specific offers best protection, but often unrealistic;
  
  – Blanket is more practical, but offers little protection and barely counts as *informed* consent

• With respect to commercial considerations
  
  – All financial possibilities revealed;
  
  – Potential participants can decline participation
Limitations of Informed Consent

- Do models of consent based on a competent participant in the presence of the researcher have much relevance to tissue research?

- Consent provides only limited usefulness in key cases:
  - Stored tissue for which consent for research, or fully-informed consent, was not obtained
  - Waiver of consent often granted
The National Statement

• HREC may grant waiver of consent when:
  – No more than low risk;
  – Impracticable to obtain consent;
  – Protection of privacy, confidentiality

  – Benefits of research justify harms with not seeking consent
    (Dignatory harms? Financial harms?)
  – There is no known or likely reason for thinking that participants
    would not have consented (?);
  – Will not deprive the participants of any financial benefits to which
    they would have been entitled (?).

• Can any HREC ever be confident these conditions are fulfilled with
  commercial research?
Should Participants/Sources Share in the Profits?

- The participants receive some share of the commercial benefit; eg
  - Payment for participation
  - Profit-sharing arrangements
  - Free access to developed medicines for the community
  - Discounted medicines/products for the community
Problems: practical

• It can be virtually impossible to determine the exact extent of any given individual’s contribution
  – The John Moore and Henrietta Lacks cases relatively rare

• Determining legal and financial means of benefit-sharing for a very large number of individuals enormously complex
Problems: inducements

• “It is generally appropriate to reimburse the costs to participants of taking part in research, including costs such as travel, accommodation and parking. Sometimes participants may also be paid for time involved. However, payment that is disproportionate to the time involved, or any other inducement that is likely to encourage participants to take risks, is ethically unacceptable” (National Statement on Ethical Conduct in Human Research, 2007).
Problems: Intellectual Property Rights

• Research participants, unlike researchers etc, do not contribute skill, knowledge, nor do they transform material into an invention.

• Profits are made on the basis of intellectual property, not raw material
Problems: Dignity

• “Allowing people to exercise their rights to income and capital of human tissue might be regarded as allowing the human body to be commodified. This may alter community attitudes towards bodies and their parts, and as a result alter how communities perceive and treat living humans” (Australian Law Reform Commission, *Essentially Yours. The Protection of Human Genetic Information in Australia*, 2004).

• A free market in human tissue? Ova, womb, sperm and kidney selling
Problems: The Threat to Research

“The Inquiry recognises the need to avoid placing undue burdens on the conduct of research, given the considerable community benefit that is derived from the development of medical treatment and tests. Altruistic participation in research is regarded as beneficial to the community as it reinforces a sense of unity and sharing. At present, virtually all research participation in Australia, including the use of tissue samples, occurs without remuneration of sample donors. Recognising an individual’s right to sell tissue, as one incident of a property interest, would not only create an additional economic barrier to research, it would undermine the valuable system of community involvement in research” (Australian Law Reform Commission, Essentially Yours: The Protection of Human Genetic Information In Australia, 2004).
Questioning the Status Quo: Double-Standards

• “The links being established between academics and industry to profit from biological specimens are a subject of great concern. If this science has become science for profit then we fail to see any justification for excluding the patient from participation in those profits”.

• Doesn’t commercialised research also create practical problems, threats to human dignity, and threats to research?
  – Despite this, no one seriously questions profit-based research enterprise