Human-tissue related inventions:

Managing intellectual property rights issues in collaborative research with developing countries

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Overview:

- Key questions in human tissue related inventions
- Ethico-legal frameworks for addressing the issues
- Deficiencies in the frameworks
- Possible remedies & the role of Research Ethics Committees
- The way forward: managing the issues
1. Key questions/issues:

- Is it acceptable to have a dichotomy between ownership of tissue samples and intellectual property rights in the products derived from the samples?

- Are the ethico-legal frameworks that govern the patenting and ownership of commercially viable inventions derived from human tissues adequate?

- If there are inadequacies in the ethico-legal frameworks, what are the possible remedies for such inadequacies and what strategies can RECs use in addressing them?
Ownership of samples vs ownership of human tissue-related inventions:

- The object of a patent is to exploit a technical disclosure; it does not transmit the proprietary rights of physical objects such as tissues, human organs or parts.
- Unsettled questions concerning the ownership of biological materials taken from humans by researchers.
- Consent for storage, reuse and exportation of samples is rarely sought in developing countries.
2. Ethico-legal frameworks

**International treaties:**
- Patent Law Treaty; deals with harmonisation of procedures for application, acquisition and maintenance of patents.
- Patent Cooperation Treaty; Clauses 5 and 6 (of Article 27) emphasise the key role of national laws in the evaluation of patentability of inventions.

**National guidelines:**
- The Indian Guidelines for Exchange of Human Biological Material for biomedical research purposes (November 1997) <http://icmr.nic.in/min.htm>
- The Kenyan HIV/AIDS research guidelines (March 2005)
a) Indian Guidelines:

- Clearly define human biological materials with potential use in biomedical research.
- Clear guidelines for the exchange and transfer of biological materials.
- Require the signing of memoranda of understanding or agreements on material transfer between the Indian and foreign collaborating partners.
- Prohibit filing of patent/intellectual property issues on any product or process so developed with the biological material without the written consent of the collaborating scientists.
b) Kenyan HIV/AIDS research guidelines:

- Require the signing of a Material Transfer Agreement (MTA) by the parties involved in research where biological materials are intended to leave the country.
- Important provision:
  “Any other use of materials and specimens or research results, including but not limited to commercial development, may proceed only after concluding a cooperative research and development agreement (RADA). Negotiations must be completed and the RADA executed before commercial sale of the products. This agreement must be binding on all parties with respect to intellectual property rights.”
3. Deficiencies in the frameworks

- Lack of harmonisation;
  see the Indian dispute (Mudur G. Indian scientists object to export of human biological material for research. Brit Med J. 23rd January 2006 <http://bmj.bmjournals.com/cgi/content/full/325/7371/990/b>)

- Lack of focus:
  - The inappropriate focus seems to be on the long term goal of access, which undermines the opportunities that ought to be utilised to invent the drugs.
  - See proposed solution in the Aids Vaccine Advocacy Coalition’s (AVAC) 2005 Report.
4. Possible remedies & the role of Research Ethics Committees

- The challenge
- Possible remedies
a) The challenge for RECs

The ethics review process should ensure that the two competing interests:

- 1) Satisfying legitimate public concern about the ethics of these inventions; and
- 2) Not inhibiting innovation and discouraging economic investment, are adequately catered for.
b) Possible remedies:

- Recasting the doctrine of informed consent:
  - such that the right to self determination must be interpreted as protecting not only an individual’s interest in bodily integrity, but in dignity.

See *the Washington University v William J Catalona & others* (14th April 2006) on the difficulties of recasting the doctrine

- Catering for tissue donor’s interests
5. The way forward: managing the issues

1. RECs should consider the following points when reviewing research protocols where human tissues are used:
   
   - Inclusion of benefit sharing arrangements in the memorandum of understanding between collaborating institutions or countries.
   
   - There should be clear guiding principles on cases where it is deemed expedient and just to compensate tissue donors, using the model of subsidies on drugs.
   
   - The scope of informed consent should be extended to take into consideration the tissue donor’s dignitary interests.
The way forward: managing the issues (cont).

2. Possible checklist to guide RECs:
   i. Are there aspects of the proposed study, which show that knowledge/expertise of local nationals is being exploited to access local biological materials?
   ii. Are there watertight procedures to ensure safe transfer of samples from one institution to another (particularly with regard to preservation of the tissue donors’ confidentiality)?
   iii. Have the tissue donors relinquished all benefits/rights that they may derive from their samples’ commercial applicability?
   iv. Was adequate time given to the tissue donor, when consent was procured, to consider the use of his/her tissues for research?
   v. Did the tissue donors give conditional consent?
   vi. What types of research are the tissues being donated for and are these specified in the Informed Consent form?