Reviewer's report

Title: Biobanking research on oncological residual material: a framework between the right of individual and the interest of society

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Reviewer: Judy Allen

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This paper argues that the form of consent required for biobanking of residual oncological material should vary depending on the identifiability of the material. The authors propose that the opportunity to opt out is an adequate process if the material is permanently de-identified. If the material is re-identifiable, however, they conclude that 'opt in' consent is required and propose a model of broad consent.

There is extensive literature on the topic of biobank consent. This paper deals with the specific context of banking surgical waste donated by cancer patients, however, drawing on the broader literature would strengthen the article. See for example literature on patient perspectives such as:


Chan et al, 'Patients' experiences on donation of their residual biological samples and the impact of these experiences on the type of consent given for the future research use of the tissue: a systematic review. I'nt J Evid Based Healthc. 2012 Mar;10(1):9-26.

Allen & McNamara, 'Reconsidering the Value of Consent in Biobank research' Bioethics, 2011 25(3), 155–166


L. Johnsson et al. 'Patients' Refusal to Consent to Storage and Use of Samples in Swedish Biobanks: Cross Sectional Study.' BMJ 2008; 337: a345.

And generally on consent to biobanking:


H.T. Greely. The Uneasy Ethical and Legal Underpinings of Large-Scale


Major Compulsory Revisions

1. Background. The material in the Background section explaining the processes of preserving samples is interesting but the authors need to make clear its significance for the argument that follows. I was unclear whether the point was about the public benefit, the need for speed, efficiency or agreed processes, or the need for advance planning.

2. Discussion. The structure of the discussion is unclear to me. In the fifth paragraph of 'Informed consent in oncological residual materials biobanks' a number of ethical aspects are listed but these are not followed through systematically. A more explicit structure for the discussion is needed to assist the reader to follow the argument.

3. Irreversible anonymization of the sample. I have a number of reservations about this section.

   a. The authors appear to assume that the privacy interest is the only relevant concern that needs to be considered and that, since privacy will be protected by irreversible anonymization, presumed consent or opt out consent is justified. This assumption is also evident in paragraph 9 of the 'Reversible anonymization of the sample' section. There are other concerns that need to be considered, for example harms from group stigmatization (see eg Fullerton and Lee, 'Secondary uses and the governance of de-identified data' BMC Medical Ethics 2011, 12:16; Sandor & Baird, 'Anonymity and Privacy in Biobanking' chapt 14 in Lenk et al Biobanks and Tissue Research;The Public, the Patient and the Regulation, The International Library of Ethics, Law and Technology Volume 8, 2011), cultural or religious objections to particular forms of research or to the retention of tissue at all, and dignity interests related to the control of one’s own body.

   b. The authors conclude that irreversible anonymisation may be useful when the alternative is the loss of the sample ‘because the donor refuse to give his residual material with an opt- in form’. Surely if there is a refusal then one cannot ethically rely on the opt-out process advocated by the authors in these circumstances. There is fundamental contradiction here which illustrates the dangers of treating ‘opt out’ processes as ‘consent’ at all. This is not to deny that it may be justified but the ethical justification must be sought elsewhere since it is not provided by consent.

   c. The authors rely solely on the low risk to privacy to distinguish the two categories and to justify an opt-out process for irreversible anonymized samples. The argument would be strengthened if other justifications were considered more explicitly.

   d. The authors allude to the limited usefulness of irreversible anonymized samples but it would be helpful to elaborate these limits such as the inability to link additional health information.
e. Having recognised the limited usefulness of irreversible anonymized samples it is then necessary to provide a justification for adopting modified procedures to collect them. For example, is it justified because of an inability to obtain adequate supply of samples if consent is required

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Not suitable for publication unless extensively edited

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests