UPDATE TO THE NATIONAL STATEMENT: IMPLICATIONS FOR RESEARCHERS WORKING WITH HUMAN BIOLOGICAL SPECIMENS

Date: July 2014

The National Statement on Ethical Conduct in Human Research (2007) was updated in March 2014. This update contains significant information for researchers working with biospecimens in laboratory based research.

A summary of the changes:
- Existing Chapter 3.4 “Human tissue samples” and Chapter 3.6 “Human stem cells” were revoked in full
- New Chapter 3.4 “Human biospecimens in laboratory based research” was inserted.

DEFINITION
The National Statement defines human biospecimens as:

“…any biological material obtained from a person including tissue, blood, urine, sputum and any derivative from these including cell lines. It does not include non-human biological material such as micro-organisms that live on or in a person.”
(National Statement (2007), pg 36)

KEY POINTS REGARDING THE NEW CHAPTER 3.4
- Recognises human stem cells and human tissue as “human biological specimens” (biospecimens).
- Clarifies that the chapter is applicable to laboratory use of human biospecimens, i.e. the chapter is not applicable to therapeutic uses.
- Makes a clear distinction between:
  a. the harvesting of embryonic stem cells and the derivation of embryonic stem cells (governed by the Research Involving Human Embryos Act 2002 (RIHE Act) and the Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research 2007 (ART Guidelines), and
  b. the research use of established embryonic stem cells and stem cell lines.
- Provides clear guidance on the requirements of informed consent from donors of biospecimens, or where a waiver of consent may be ethically permissible.
- Stipulates the requirements for HREC review of an ethically defensible plan in research where there is anticipated or incidental findings of important health information for the donor, relatives or community.
- Provides clear ethical guidance on when an HREC must review proposed research using biospecimens.
- Provides for a low-risk pathway of ethical review.
- Provides clear ethical guidance on the requirements for the exportation and importation of biospecimens to and from international sources.

MORE INFORMATION
Over the coming months the Ethics Administration Office will be rolling out resources and training to assist researchers with formulating ethically defensible plans.

Please contact the Ethics Office at ro.humanethics@sydney.edu.au should you have any further questions or require guidance regarding this matter.