



International Society for Biological and Environmental Repositories

A Division of the American Society for Investigative Pathology

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Project Officer – National Statement Chapter 3.4 & 3.6
Health and Research Ethics Section
Research Translation Group
NHMRC GPO Box 1421
CANBERRA ACT 2601

Delivery via email to: ethics@nhmrc.gov.au

Dear Sir:

This letter is a comment in response to the Proposed Revisions to *Chapter 3.4: Human tissue samples* and *Chapter 3.6: Human stem cells* of the *National Statement on Ethical Conduct in Human Research (2007)* (National Statement), as published by the Australian Government National Health and Medical Research Council (NHMRC) at http://consultations.nhmrc.gov.au/open_public_consultations/national-statement, from and on behalf of the International Society for Biological & Environmental Repositories (ISBER), a division of the American Society for Investigative Pathology (ASIP).

In short, ISBER is an international organization addressing the technical, legal, ethical, and managerial issues relevant to repositories of biological and environmental specimens (see www.isber.org for additional information). Although not restricted to human specimens intended for research, the great majority of ISBER members focus on human tissues procured for research purposes, either directly or indirectly (e.g. from clinical specimens procured for non-research purposes). ISBER membership and expertise in the area of human tissues used for research is extensive, longstanding, ongoing, and representative of the best practices. ISBER's thought leaders in this area are worldwide, including many in the United States. As such, we have a keen interest in the Australian National Statement and are pleased to submit for your consideration our comments and views as follows:

We fully endorse the proposed changes to the National Statement as being sensible and practical approaches to ensuring that due ethical consideration is given when collecting and using human biospecimens. Additionally, ISBER invites the NHMRC to engage with us as appropriate in the future when drafting such guidelines.

Respectfully submitted,

Marianne K. Henderson, MS
President

Mark E. Sobel, MD, PhD
Executive Officer

Attachment: National Statement on Ethical Conduct Submission Form