**American Society for Investigative Pathology**
*Investigating the Pathogenesis of Disease*

**MARK E. SOBEL, MD, PHD**
**EXECUTIVE OFFICER**
9650 Rockville Pike, Bethesda, MD 20814-3993 (USA)
Tel: 301-634-7130 • Fax: 301-634-7990 • Email: mesobel@asip.org • www.asip.org

July 19, 2016

World Medical Association 203rd Council & WMA Work Group on Health Databases and Biobanks

Comments filed at: hdbb@wma.net

**Re: Proposed WMA Declaration on Ethical Considerations regarding Health Databases & Biobanks Request for Comments**

Dear Dr. Jón Snædal:

The American Society for Investigative Pathology (ASIP) welcomes the opportunity to comment on the revised version of the World Medical Association (WMA) Draft Declaration of Ethical Considerations regarding Health Databases and Biobanks. ASIP is a society of biomedical scientists who investigate disease, linking the presentation of disease in the whole organism to its fundamental cellular and molecular mechanisms. Our members use a variety of structural, functional, and genetic techniques, seeking to ultimately apply research findings to the diagnosis and treatment of patients. Membership includes primarily professionals from academic medicine, as well as from the government, clinical testing laboratories, and industry.

ASIP commends the significant improvements in the revised document. In particular, we note the clarification that the policy applies to only "the use of identifiable data and biological material…" (Preamble 3). Such a clarification allows ASIP to support many of the principles outlined in the revised Declaration, including the requirement of a positive consent for the collection, storage, use and reuse of identifiable data and biological materials (Ethical Principles 11 and 12).

We suggest further clarification is needed in the following areas.

Ethical Principle 13: This Principle states that individuals have the right to "request corrections of mistakes or omissions." ASIP endorses the rights of individuals to solicit and be provided with information in their medical record so that they can use that information, and request corrections or omissions. However, the return of research results continues to be a controversial topic that is fraught with concerns about the use of research data in making health care decisions. ASIP does not support a blanket statement requiring the return of research results. For example, where research is being conducted on the validity of a proposed clinical test, it would be entirely inappropriate to return the results of that proposed clinical test to a research participant. The test has not undergone a thorough and complete review such that an individual could reliably use the test result in making healthcare decisions.

Furthermore, recent reports of concerns by the United States National Institutes of Health[1] and National Science Foundation[2] and publications on the lack of reproducibility of some research studies should engender extreme caution in endorsing the return of research results to individuals that are generated in non-certified laboratories.[3]

Ethical Principle 14: This Principle states that individuals have the right to alter their consent or ask that their identifiable data be withdrawn from use. ASIP agrees that individuals have the right to withdraw their consent for future research on their biological materials, but the right to remove information already gathered in a Database will endanger the statistical power of research data already collected. It is also important to note that where Database information has already been released to a researcher, and possibly de-identified in the process, it may not be possible to withdraw data. ASIP suggests a further clarification allowing consents, such as described in Ethical Principle 12, to limit the ability of a successful withdrawal or modification of consent. Where a donor has consented to limits on their ability to withdraw or modify their consent, then the broad goals set forth in Ethical Principle 14 may be reduced.

Ethical Principle 18: This Principle uses the term 'independent ethics committee.' This term has not been defined earlier in the document. ASIP is particularly troubled by the word 'independent' as it may be interpreted in such a way as to preclude an institution or organization from having its own ethics committee. We suggest that a better phrasing may be to request that ethics committees be free from significant conflicts of interest and include at least one individual who is not employed by that institution.

Governance 19.1: This Principle indicates that governance should be designed so the "rights of individuals and population prevail over the interests of other stakeholders and science." ASIP suggests that the words 'prevail over' be replaced with the phrase 'be balanced with.' Specifically, we note that in many cases the interests of populations are in the advancement of science and thus not something to be weighed 'against' scientific advancement.

Thank you for the opportunity to submit these comments. If ASIP may be of further assistance, please contact Dr. Mark Sobel at mesobel@asip.org.

Sincerely,

Mark E. Sobel, MD, PhD
Executive Officer

---

1 Collins F, Tabak LA: NIH plans to enhance reproducibility. Nature 2014, 505:612-613

2 Reproducibility_NSFPlanforOMB_Dec31_2014.pdf

3 In the United States, such a certified laboratory would be a laboratory certified under the Clinical Laboratory Improvement Act (CLIA).