



American Society for Investigative Pathology
Investigating the Pathogenesis of Disease

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**Comments on WMA Draft Declaration on
Ethical Considerations regarding Health Databases and Biobanks**

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The American Society for Investigative Pathology (ASIP) welcomes the opportunity to comment on the WMA Draft Declaration of Ethical Considerations regarding Health Databases and Biobanks. ASIP is a nonprofit educational organization of physicians and scientists whose mission is to promote the discovery, advancement, and dissemination of basic and translational knowledge in experimental pathology and related disciplines. This is achieved by fostering investigation into the pathogenesis, classification, diagnosis, and manifestations of disease through meetings, publications, and educational activities.

Preamble: ASIP heartily endorses Preamble Statements 1 and 2. However, we are concerned that the broad definition of a Health Database provided in Preamble Statement 3 will lead to confusion and misunderstandings. Based on Preamble Statement 2, a medical record or electronic health record is a Health Database. Therefore, we believe that Preamble Statement 4 and Ethical Principles 15, 16, and 17 are consequently imprecise. Furthermore, informed consent for clinical procedures should not be confused with informed consent for the collection of research data. It is critical that a distinction be made between (1) the health information gathered by the medical team to record health care events and to aid physicians in the ongoing care of patients (usually referred to as the “medical record”) and (2) data from research studies. Perhaps this is what you mean by “this declaration is intended to cover any use of health information beyond the individual care of patients,” but the terminology you have chosen will be misunderstood unless the entire Declaration is read in context. We recommend that Preamble Statement 3 be re-written and should also include the exemption of “fully anonymized and non-identifiable data and biological material” included in Preamble Statement 8. While ASIP supports and encourages the use of anonymized and non-identifiable data and biological materials, we caution that the power of new technologies such as next-generation DNA sequencing is causing regulatory bodies to question the definition of “anonymized” and “non-identifiable.”

Recommended edit (combine Preamble 3, 4, and 8): A Biobank is a collection of biological material and associated data from different individuals. A Health Database is a system for collecting, organizing, and storing information about individuals. Health Databases and Biobanks are both collections of information on individuals, and both give rise to the same concerns about autonomy, privacy, and confidentiality. For the purposes of this Declaration, the term “Health Databases and Biobanks” does not include the official medical record of individuals that is used to guide physicians in the ongoing care of patients; nor does it include collections that exclusively contain fully anonymized and non-identifiable data and biological material.

Ethical Principles: A clarification such as the one we suggest for the definition of ‘Health Databases and Biobanks’ then makes it possible to endorse Ethical Principle 15.

Ethical Principle 16 states that “individuals have the right to solicit and be provided with information about their data and its use as well as to request necessary corrections or mistakes or omissions.” We believe that the problem with #16 is that it again conflates the “medical record” with a “Health Database” collection of research data. 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 is a controversial topic that is fraught with concerns about the use of research data in making health care decisions. Recent reports of concerns by the United States National Institutes of Health¹ and National Science Foundation² 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 laboratories³.

Ethical Principle 17 states that “individuals have the right to, at any time and without reprisal, withdraw their consent for their identifiable information to remain included in a Health Database and their biological material to remain in a Biobank.” 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 Health 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.

Ethical Principle 18: ASIP endorses the use of “broad consent.” We disagree that “blanket or open consent for future use of health data or biological material not envisaged at the time of collection is not ethically acceptable.” It is our position that it is disrespectful of individuals’ autonomy to deny them the right to agree to an open broad consent as long as they are informed that such broad consent involves dangers and risks that cannot be predicted at the time of consent. Opt-in informed consents are consistent with ethical principles.

Thank you for the opportunity to comment on the draft Declaration. We are available to have more substantive discussions with the WMA at your convenience. Please contact Dr. Mark Sobel at mesobel@asip.org.

Sincerely,



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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 certified under the Clinical Laboratory Improvement Act (CLIA).