



The International Society for Biological and Environmental Repositories (ISBER) welcomes the opportunity to provide comments on the International Code of Conduct for Genomic and Health-Related Data Sharing.

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. While the Code of Conduct does not directly address specimen research, the document is highly relevant to the collection, storage, distribution and use of human specimens because genomic data is generated from the specimens. As such, ISBER has a keen interest in the Code and how it will be implemented. We offer the following comments regarding the Code:

The Code is very well written and the foundational principles, guidelines and core elements for responsible data sharing are generally reasonable and appropriate. The document may/should lead participating institutions/organizations to invest additional resources where needed to ensure compliance with the Code which could be a very important outcome. However, because the Code is a very high level document, it is difficult to determine how the guidelines in the Code would be implemented and what impact the code would have on the research enterprise without additional details. As the Code is further refined, consideration should be given to how it will comport with various national regulations on a global level given the wide variation globally.

Item 4 under Guidelines and Core Elements states that, "This Code applies to data that has been consented to for use and/or approved therefor by competent authorities." This statement appears to allow for situations where consent cannot be obtained for genomic data sharing as long as there is approval by a competent authority. This will be critical to allow important retrospective research to proceed, particularly research involving specimens collected during the course of routine care (e.g., pathology archives) which was not initially anticipated at the time the specimens were collected and for which consent would be difficult or impossible to obtain at the time the research would be conducted. There are valuable archived collections which could not be established prospectively today because of changes in standard of care (e.g. untreated node-negative breast cancer collections) and for which consent for research use was not obtained at the time the specimens were

collected. In these cases, it is difficult or impossible to re-contact individuals to obtain a new consent. Therefore, it will be important to allow for waivers of consent by an ethics review committee or other competent authority as this Code is implemented. We suggest changing the language in the cover note (third bullet) to reflect this and to be consistent with the statement referenced above in Item 4 in the main body of the document (e.g., changing the language in the cover note to something like, “Is based on the premise that such international data sharing has been consented to and/or approved for research”).

Additional fine-tuning comments are as follows:

- 1) It would be helpful if the document recognized the relationship between samples, the data derived from them and data that may be associated with the samples as these are inseparable. The relation between data and biological samples might be addressed in the Preamble.
- 2) Guideline 5.1 – This guideline is an important one. However, we note that disadvantaged people are not necessarily based in different parts of the world. They can be subpopulations within any community. We suggest revising the wording of this guideline accordingly.
- 3) We suggest that Section 8 “Accessibility and Dissemination” have Guideline 5.1 embedded within it. In other words, dissemination should be done in such a way to minimize harm and maximize benefits. Perhaps Guideline 8.3 could be modified along the following lines: Dissemination of research results should be conducted in a way that promotes broad access and minimizes obstacles to data sharing **while at the same time protecting the rights and welfare of those in the study population.**

Promoting collaborative partnerships should include partnerships with populations and subpopulations where appropriate. If dissemination is discussed with any subpopulation the work could unintentionally or otherwise marginalize, a better way of dissemination may be found. This would also embrace the founding principle “foster trust, integrity....”. That said, it is not the “right” of any population to veto the dissemination of any research just because they do not like what the results are, but more that there is often a better way of phrasing terms (e.g., non sensationalizing a perceived negative result), or improving release vehicles and timing, especially if that group requires some support with handling media attention.

- 4) We suggest the following editorial clarifications or corrections:
 - a) Guideline 4.1: To whom should assurances that confidentiality and privacy are protected be provided?
 - b) Guideline 4.2: Is this reference to aggregate or individual research results, or will that vary depending on the nature of the data?
 - c) Section 4, subsection 8.3 ends with data sharing .br. Is that an error?
 - d) Section 5.2: It would be helpful to clarify what is meant by “opportunity costs”.

- e) Split infinitives are used but should be avoided. For example, on p. 3 it states “to practically apply” rather than “to apply practically (page 3).
- f) On page 3, section 4, the word data is used as a singular noun, i.e., “data that has been” instead of “data that have been”. It might be useful to search on data and make verbs agree.
- g) Section 4.2, the phrase “to about” would be clearer as “about”.