

AIRR-C Legal & Ethics Working Group Reporting - 5th Interval - 2021-2022

Date of this report: Wed, 2022-04-20

SC/WG Name: Legal & Ethics WG

SC/WG Co-leaders: Tania Bubela, Christian Busse

SC/WG Active Members (list): Alexander Bernier, Tania Bubela, Christian Busse, Dan Emerling, Susanna Marquez, Artur Rocha, Jamie Scott, Jacob Sherkow

Purpose: To address issues pertaining to legal (e.g., IP, GDPR) and/or ethical (e.g., human subjects) standards for the AIRR Community.

Goals:

(after re-scoping in spring 2021)

- Understand the restrictions on data sharing currently imposed by European database protection laws (i.e., Directive 96/9/EC), especially in the context of reference sequence sets (in cooperation with GLDB WG).

Long-term vision and how WG products integrate with the AIRR-C mission:

The Legal & Ethics WG aims to facilitate sharing and reuse of AIRR-seq and associated data types by providing insights into the relevant legal and ethical frameworks. The WG's products are considered individual steps towards this goal.

Products:

- Draft manuscript on Database Directive and its implications for biological data

Progress report on current purpose, goals, products and resources:

Following the rescoping in May/June 2021, the WG started to meet on a monthly basis, focusing around the topic of the impact of the EU Database Directive. These efforts were led by Alex, who is also the author of the (full-length) manuscript on this topic. Additional topics that were discussed are questions around medical devices. Finally, WG also provided input regarding Database Directive to GLDB WG and to the Comms SC regarding licensing of the AIRR-C logo.

Proposed plans for the coming interval:

Goals:

- Finalize and publish Database Directive manuscript and summary
- Plan, conduct and evaluate a survey regarding obstacles to data sharing
- Provide guidance on GDPR issues.
- Develop an ethical framework for patient engagement and studies involving indigenous people.
- Evaluate legal and ethical aspects of current Open Science practices and recommendations in collaboration with other stakeholders (e.g., RDA, IUIS).
- Support the Diagnostics WG and Meetings SC in organizing an event covering AIRR-seq, AI/machine learning and legal and regulatory aspects.

Products:

- Manuscript on Database Directive and its implications for biological data (audience: legal experts)
- Summary on Database Directive manuscript (audience: researchers, data curators, data stewards)

Proposed SC/WG Co-leaders: NN, NN