E.8.2 International Data Sharing

It has been suggested that over the next 5 years more than 60 million patient genomes are to be generated through research and healthcare efforts across the globe. In addition, governments of at least 14 countries have invested over US$4 billion in establishing genomic medicine initiatives with the goal of improving health outcomes for their communities [1]. There is therefore a pressing need to harmonize the processes related to genomic data generation, in particular data sharing, to maximize the potential benefits on a global scale. Data sharing is a core requirement of public funding agencies as it is well established as fundamental to promoting better outcomes from scientific research and is embedded within many federal policies [5,6,7] and more recently in the OECD Recommendation on health data governance in 2017, among others [2,3,4]. From an ethical viewpoint it not only advances science but

importantly respects the fundamental contribution of participants by ensuring their contributions deliver the maximum benefit.

The ICGC has pioneered international data sharing through its policies and practices [8] and therefore follows the Global Alliance for Genomics and Health (GA4GH) belief that members should be encouraged to share data as widely as is possible and will work with groups to maximize data sharing to the greatest extent possible within accepted legal and ethical boundaries[9]. ICGC ARGO is also committed to raising awareness of the duty to share data for societal benefit and value.

Much of the data contributed to ICGC ARGO will be retrospective in nature. As well, because membership will span many different countries with differing regulatory requirements and cultural norms, there will be limitations in how and with whom some data can be shared. The global regulatory landscape surrounding data privacy, protection and security is complex and there are a multitude of laws, regulations and guidelines in place requiring jurisdictional and local compliance, even within individual countries. Ultimately, member programs are responsible for ensuring their privacy, data protection and confidentiality policies and processes comply with applicable federal, institutional, and jurisdictional data protection and privacy regulations as required (see Appendix I).

ICGC ARGO experts will keep abreast of any changing laws and regulations that might impact the cross-border sharing of data and will act to ensure ICGC ARGO respects any changing circumstances. As a driver project for the GA4GH, ICGC ARGO will have access to new technologies and expert communities to assist its work, as well as through which it can disseminate its gained knowledge.

POLICY: ICGC ARGO members will be encouraged to work towards ensuring that data sets can be shared to the greatest extent possible while recognizing differing legal and ethical requirements.

E.8.2.1 Core Data Sharing Principles

ICGC ARGO Data sharing principles are aligned with foundational principles of data management and stewardship of Findability, Accessibility, interoperability and reusability[10]. Furthermore, ICGC ARGO observes purposeful. proportionate and responsible use and sharing of data as additional key principles. Examples of implementation of these principles are described below:

1. Responsibility and commitment; data sharing through ICGC ARGO can deliver the intended outcomes set by the strategic aims of the project and that the benefits are tangible, recognized and valued by the communities we aim to benefit.
2. Making data and research results widely available, through publication and digital dissemination, to impact multiple beneficiaries (not limited to the scientific community but patient and public communities and services) for maximum benefit.
3. Encouraging a culture of data sharing within the consortium through members, collaborators, and supporters.
4. Instituting a data sharing framework that provides robust governance and security and promotes public trust. Resourcing and promoting best practices in data management and dissemination through the Data Access Compliance Office and Data Management Policies.
5. Ensuring the sustainability of ICGC ARGO data for future use through archiving, use of appropriate identification systems and curating data types in interoperable formats to facilitate ease of data pooling and analysis.
6. Contributing learnings and knowledge with the broader community to inform public debate and policy development on international data sharing. Specifically, engaging with the patient and public communities on data sharing principles of trust, risks and benefits and value to deliver positive social outcomes.
7. Support programs to uphold acceptable Informed Consent and ethical standards for international data sharing. This may include transparency through the informed consent processes about the purpose, process and procedures of data sharing through international mechanisms such as ICGC ARGO.
8. Respecting jurisdictional regulatory requirements and restrictions in data sharing, such as where local data residency and processing is required under specific legislation or regulations (see Appendix I).

Appendix I_ Resource of Applicable ICGC ARGO Member Program Laws and Regulatory Frameworks Guiding Privacy, Data Protection and Sharing.pdf

Appendix II_ Further Reading (1).pdf

References

[1] Zornita Stark et al: Integrating Genomics into healthcare: A Global Responsibility. American Journal of *Human Genetics*, 104, 13-20, January 3 2019.

[2] 1948 Declaration of Human Rights (art. 27)

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[4] UNESCO Science and Scientific Researchers Guidelines 2017 (ref UNESCO 2017).

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[7] Jane Kaye, Data sharing in genomics — re-shaping scientific practice. *Nature Genetics,* May 2009.

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