

Data Governance in International Neuroscience Research



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Introduction

Medical research is governed by a number of universal principles like those laid out in the 1964 Declaration of Helsinki¹ which stipulates them as ‘ethical principles for medical research involving human subjects, including research on identifiable human material and data’². However, the details of its implementation vary from country to country. One reason for this is differences in legislation and agency policy which have an impact on the conduct of research and level of protection accorded research subjects. For example, since 2008 the U.S. Food and Drug Administration (FDA)³ only abides by the 1989 version of the Declaration rather than the more recent 2013 version and some have suggested this allows U.S companies to cut ethical corners when working abroad^{4,5}. In the arena of international collaboration in medical research, such differences raise issues for data governance because they affect how data is shared and used, what data is shared, and with whom data can be shared.

With an ever-growing appetite for collaborative research, one of the areas where issues relating to data governance can easily arise is in the field of neuroscience. Neuroscientists have come to realise that the complexity of the human brain and nervous system mean that, only by working collaboratively together, they can in good time hope to successfully unravel the mysteries of the brain for the benefit of humankind. However, it is not yet clear what rules will govern neuroscientific research collaborations particularly when it spans across national borders and what level of protection will be in place for research subjects when their data is shared across multiple geographic regions. In this era of big neuroscience data⁶ and large brain projects⁷⁻¹³, this type of collaboration raises serious concerns as the principles governing data collection, sharing, and use vary from country to country. This position paper therefore highlights how growing collaborations in neuroscience projects may raise important questions for data governance that needs to be addressed.

The evolving landscape of neuroscientific collaboration

In the last decade, the call for neuroscientific collaborations has become more urgent due to growing alarm at societies’ inability to deal with neurological and psychiatric disorders and the increasing costs of these conditions¹⁴⁻¹⁶. For example, Ivinson¹⁷ pointed out that more collaboration between basic, translational and clinical neuroscience will improve effectiveness, productivity, and efficiency. Similarly, Belin and Rolls¹⁸ maintained that multi-disciplinary and multi-systems collaborations offer unique opportunities for knowledge expansion and open up new ways of thinking. As researchers in this scientific environment come to the realisation that much benefit can be derived from collaboration between the different branches of neuroscience, while closely working with other relevant disciplines, an overwhelming volume of data¹⁹ is being generated and shared.

A marked increase in collaborations between institutions, both at the national and international levels, with a view to sharing data and resources is also being witnessed. Two examples that are particularly relevant are:

- The European Union-led Human Brain Project (HBP), which seeks to ‘create ICT based scientific research infrastructure for brain research, cognitive neuroscience, and brain-inspired computing’²⁰, is made up of over 100 partner institutions in 19 countries²¹. As well as being international, it is also interdisciplinary as it includes such disciplines as cognitive neuroscience, neuro-informatics, medical informatics, brain simulation and neurorobotics; and transdisciplinary covering computing, informatics, mathematics, as well as philosophy²².
- The International Brain Initiative (IBI), an international brain research collaborative project that is still at the proposal stage²³. It is a consortium of seven large brain²⁴ research initiatives that includes the already international (European) Human Brain Project. The six other brain projects that make up the IBI are the Australian Brain Initiative, the Canadian Brain Research Strategy, the China Brain Project, the Korean Brain Initiative, Japan’s Brain/ MINDS, and the U.S Brain Initiative.

The vision of the IBI to ‘catalyse and advance ethical neuroscience’²³ indicates that like the HBP²⁵, ethics is at the core of the project. Yet, differences in ethical principles and legislation (in terms of data protection, generation, sharing, use, and maintenance) that each of these large brain projects conform to, may have ramifications on their ability to collaborate effectively. These differences are not well known and the significance for ‘ethical neuroscience’ within the IBI remains a relatively unexplored arena. It is important therefore, to understand the consequences of such collaboration from an ethical perspective and to anticipate the potential for unintended consequences.

Methodology

For this paper, a narrative review^{26–28} has been done to provide a synthesis of collaboration in neuroscience research and how data governance issues might arise. The paper has provided a background understanding of the nature of collaborations in this area and how it raises interesting questions for data governance in the international arena. One important issue that has been pointed out here pertains to differences in legislation and policies governing scientific research and data protection in the various jurisdictions where the largest brain initiatives²⁴ are based and how this might have consequences for data governance in neuroscientific collaboration.

This outcome will form the basis for a more systematic review that will include doctrinal analysis of legal literature and scoping review of peer-reviewed literature. Hutchinson²⁹

describes doctrinal analysis as a 'critical conceptual analysis of all relevant legislation and case law to reveal a statement of the law relevant to the matter under investigation. It will be centred on legislation on scientific research and data governance policies relevant to the seven brain research projects that make up the International Brain Initiative. This will be done to highlight important pieces of legislation and policy that have an impact on international research collaboration. The scoping review on the other hand, will focus on two popular academic databases i.e. Scopus³⁰ and PubMed³¹. These are widely available databases that index a variety of subject areas and research themes. The objective will be to highlight current practices in terms of scientific research and data governance and the problems arising from such practices.

Conclusion

The complexities of neuroscientific research mean that, at different levels, international collaborations are bound to grow. Even so, the prospect for collaborations between big brain initiatives raise interesting questions and dilemmas for data governance (which need to be addressed because of differences in national legislations and agency regulations). This assessment will help to limit the potential for negative output of such large international projects as the International Brain Initiative and for their outputs to have unintended societal implications. It will also propose a set of policy recommendations for data governance to enable 'ethical' international neuroscience collaborations. At the heart of such data governance will be clear ethical principles that will enable the maximisation of the societal benefits of big brain projects. This output will help resolve potential ambiguities and address procedural concerns about international data transfers within the proposed International Brain Initiative.

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