



Delivering a Practical Framework for Ethical Decision-Making Involving Big Data in Health and Research

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The *Science, Health and Policy-relevant Ethics in Singapore (SHAPES) Initiative* is a programme at the Centre for Biomedical Ethics, National University of Singapore funded by Singapore's National Medical Research Council. SHAPES was funded to develop a Big Data Project in 2018–2019 and established an international Working Group to this end in 2018. This Special Issue presents the *Ethics Framework for Big Data in Health and Research* ('the Framework') (Xafis et al. 2019) developed by the SHAPES Working Group.

The topic of big data has been explored extensively in academic, technical, government, legal and private sector literature for a number of decades. The potential arising from the use of big data in health and research is widely recognised, as are the challenges posed in this fast-paced dynamic field. However, despite the wealth of literature, there is a lack of practical guidance for decision-making in the form of a framework that considers the ethical issues that arise from the use of big data in a variety of health and research contexts.

The Framework addresses this gap and is intended for a wide-range of professional audiences including biomedical researchers, clinician-researchers, data scientists, policymakers, those involved in the governance of big data activities in health and research (including ethics committees and data access committees) and data controllers. Beyond the professionals who may find this resource helpful, the Framework may also be useful to lay people with an interest in big data, patients and research participants.

The Framework itself comprises three main components: (1) a list of 16 values identified by the Working Group to be central to a number of big data contexts in which

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Framework users are most likely to find themselves when making decisions, (2) a six-step deliberative decision-making process to help guide users' thinking during the decision-making process and (3) articulation of three broader considerations that underlie decisions made using the Framework: the need to respect persons, to take account of community expectations and to consider issues of vulnerability, which can arise in uses of big data.

To illustrate how the Framework can be used in practice, it has been applied to six specific contexts. These are published as separate papers and referred to as 'Domains': *Openness in big data and data repositories* (Xafis and Labude 2019); *Precision medicine and big data* (Schaefer et al. 2019); *The use of real-world data to generate evidence about healthcare interventions* (Lipworth 2019); *AI-assisted decision making in healthcare* (Lysaght et al. 2019); *Big Data and Public-Private Partnerships in Healthcare and Research* (Ballantyne and Stewart 2019); and *Cross-sectoral big data* (Laurie 2019). These papers describe some of the context-specific ethical issues and values that are relevant to each Domain. Each Domain then provides examples and a case study to exemplify the workings of the Framework and to demonstrate how we can robustly arrive at and justify decisions where there is more than one 'right' approach.

The Framework, like all decision-making frameworks, does not therefore present solutions to ethical issues raised. Rather, it provides insight into how underlying values ought to occupy a central position in the decision-making process and how values can be balanced to reach justifiable decisions. The Framework differs from other decision-making tools as it articulates specific values and provides extensive analyses demonstrating how values and relevant issues are to be considered and thought through. This is the strength of this Framework, as it can function as a practical tool for those working in numerous fields employing big data. The variety and number of cases and examples considered in the Domains provide a model for users and offer ample opportunity to draw on the analyses provided when making decisions.

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