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NHMRC Consultation -Draft Principles for accessing and using publicly funded data for health research

ACTA SUBMISSION- FEBRUARY 2015

Responses

1. Would you describe you or your organisation as a:

c. other (both a and b)

Thank you for the opportunity to comment on the *Draft Principles for Accessing and Using Publicly-Funded Data for Health Research (*'the Principles'*)* on behalf of the Australian Clinical Trials Alliance (ACTA) – a community of 60 different clinical trials networks, trial coordinating centres and clinical registries that representing more than 10,000 clinicians, researchers and data custodians who collaborate to conduct vital 'public good' clinical research within the Australian healthcare system.

2. How could the principles in the draft Guide add value when making a request to access existing health and health related datasets for the purposes of health research and for your use of the data?

ACTA strongly supports the NHMRC's stated rationale for developing the Principles – chiefly, the need to foster better communication and understanding of the roles and responsibilities of researchers and data custodians in order to optimise the appropriate use of publicly-funded data for health-related research. However, as highlighted in the document, these principles necessarily sit alongside a number of existing pieces of legislature, policies, statements and codes that guide and govern the collection, management and use of health and health-related data in Australia. In order to maximise the potential for an additional framework to "add value" for researchers and data custodians, and to support the various national and state-based efforts (particularly those focused on developing of data linkage capabilities), we believe the following key points warrant consideration for inclusion in the document ahead of publication.

1. **Access to data for population-level safety and quality activities.**
The current draft of the Principles and accompanying glossary don't provide guidance on a) what constitutes "research" for the purposes of applying the framework, or b) how the principles relate to activities such as long-term follow-up of registry participants or safety monitoring of drugs and devices. These activities most often fall under the 'safety and quality' rubric and are therefore distinguished from 'research' but they represent a critical means by which access to publicly funded data is used (and has the potential to be used to a much greater extent) to promote, protect and maintain the health of the public.

   Whilst we recognise that it is appropriate for legal and ethical reasons to differentiate between 'quality assurance and evaluation' and 'research' activity, we believe the

publication of these Principles provides a unique opportunity to provide guidance to researchers and data custodians (most of whom at one time or another undertake or support both research and quality-related activities) around access to publicly funded data for both research and quality-related activities, and where the two integrate (such as registry-nested trials and data linkage for long-term follow up of clinical trial participants).

2. Eligibility requirements

2.1 Eligible research and researchers

The draft Principles don't make any reference to ensuring that research that utilises publicly funded data is meritorious (ie. it has the potential to improve health outcomes or the delivery of health services and is methodologically sound), and that the researchers accessing publicly funded data have the appropriate experience, qualifications, and capacity to conduct the proposed research.

We believe the Principles should include high level guidance about what constitutes eligible research and who are eligible researchers – particularly in relation to requests for access to low risk re-identifiable data or high risk identifiable data – and how this should be evaluated.

2.2 Evaluating Public Benefit and Risk

We believe that Principle 1b "*Use of existing datasets for research should be promoted, encouraged and maximised when the public benefit is expected to outweigh any risk to privacy or confidentiality*" is an extremely important one that rightly deserves its prominence in the document. However, for this Principle to impact positively on the level of optimal and appropriate use of publicly funded data, we believe it needs to be broadened to provide researchers and data custodians with guidance about the *process* for evaluating and determining whether expected public benefit outweighs any privacy imposition and risks to confidentiality.

Principle Four: Public Benefit of the *High Level Principles for Data Integration Involving Commonwealth Data for Statistical and Research Purposes* provides an example of how such guidance could be presented in a clear and concise way.

3. Streamlining access policies

These principles could assist by ensuring that data custodian's policies are updated and reflective of modern policy advancements. Processes for accessing data can occasionally appear discretionary where the access policies are not detailed or easily accessible. For example, it is known that some publicly funded data holdings acknowledge the opt-out consent process, yet others may not. Opt-out consent is recognised by the *National Statement on Ethical Conduct in Human Research* as an appropriate form of consent in specified circumstances, and therefore where this consent mode has been approved by an authorised Human Research Ethics Committee, this should be reflected in data access polices.

4. Determining priorities

We strongly agree with the premise of principle 1e that "*To maximise public benefit, key priority areas for research using publicly-funded data should be identified by researchers in collaboration with data custodians, policymakers, practitioners and the community.*" However, while we agree that priorities determined by the NHMRC may be a useful reference point, we suggest that it is critical that Australia develops formal mechanisms for bringing researchers, data custodians, policymakers, practitioners and the community together to identify key priorities for public investment in the development of, and access to, large health and health-related data holdings. In particular, we suggest that priority should to be given to developing a national approach to raising the general level of understanding among the Australian community about what can be achieved (and what is not currently being achieved) to optimise our health and our healthcare system through the collection and

use of health and health-related data, and what the risks to our privacy and confidentiality are relatively.

3. **How could the principles in the draft Guide add value (to you or your organisation) when considering an application to access existing health and health related datasets for the purposes of health research?**

   Addressed above

4. **What barriers exist in adhering to or achieving the principles in the draft Guide? How could these be overcome?**

   Addressed above

5. **Is there other relevant legislation, regulations and/or policies that could be added to Appendix A in the draft Guide? Please specify, including their relevance.**

   Relevant to these Principles is the *Framework for Australian Clinical Quality Registries* published by the Australian commission for Safety and Quality in Health Care and endorsed by the Australian Health Ministers' Advisory Council (AHMAC) in March 2014.

6. **If the Guide was co-badged by other Australian Government Departments would you or your organisation be more likely to implement it? Why? Why not?**

   Once finalised, a process to seek formal endorsement/reciprocal recognition of the Principles by all of the major agencies that guide and govern the collection and use of publicly funded data in Australia, as well as the relevant peak bodies representing various arms of the research community and leading consumer advocates, could be considered. Incorporation of the Principles into the accreditation frameworks for organisations that collect, house or facilitate access and linkage to health and health-related data could also be considered.

7. **Do you have any other comments or concerns on particular sections of the document?**

   Once again, we thank the NHMRC for this opportunity to review and provide feedback on the draft Principles.