

Joint response to EAGDA statement on identifiability

MRC, ESRC, CRUK and the Wellcome Trust are grateful to EAGDA for highlighting the issue of participant identifiability through potential re-identification of anonymised individual research subjects from genomic and other data in the UK and for providing guidance on actions funders could take in light of this. This is a highly topical issue, highlighted by the markedly different approaches to participant confidentiality taken by two recently launched large-scale genomic studies: the 100,000 Genomes Project being developed by Genomics England,¹ and the UK branch of the Personal Genome Project.² We would like to take this opportunity to provide a joint response to EAGDA on this statement.

We are committed to maximising the value and the benefits of data collected and produced by the researchers we fund, whilst safeguarding the confidentiality of research participants. The risks raised by EAGDA are highly pertinent. It is timely to respond to them now and we are keen to ensure that a proportionate approach to risk can be taken that provides appropriate reassurance and privacy for participants without unduly constraining or impeding valuable research to improve health and wellbeing by advancement of social and medical science .

We accept EAGDA's recommendations. These include the need to:

- Assess the risk of re-identification when studies are planned and review this risk regularly during the lifetime of the study;
- Proportionately control access to data that could potentially identify individual subjects, which will include reviewing what data will require controlled access in light of emerging technologies;
- Include sanctions that are proportionate to the nature of the offence, such as a withdrawal of funding, if researchers deliberately attempt to re-identify individuals from anonymised data.
- Explain the small risk of re-identification to research participants when obtaining consent for studies where this is a risk;

It is clear that when deciding on access controls for data, risk assessments need to consider the possibility of different data sources being linked to yield identities. For prospective studies, these recommendations on risk assessment and access control can be built into requirements for study lead investigators. For established studies, we will disseminate these recommendations to our research communities as representing good practice that we strongly endorse.

The funders agree with EAGDA that sanctions can be an appropriate deterrent for researchers from attempting to re-identify individuals from their anonymised data. This behaviour would be in breach of data transfer/ access agreements and would be handled under existing funder policies for research misconduct. Researchers should also be aware of the legal framework in which they operate and that deliberate unauthorised identification is likely to breach Data Protection and /or confidentiality laws.

¹ <http://www.genomicsengland.co.uk/>

² <http://www.personalgenomes.org.uk/>

For UK based funders there are limits on the extent to which sanctions could be imposed if data are transferred abroad and international parties are found to have attempted re-identification. However, there can be a clear expectation that international partners need to comply with our standards and policies. If they fail to do so, funding for collaborations should be withdrawn and sanctions applicable in their respective countries be pursued. This can be clarified in our respective policies for research integrity and misconduct.

Investigation of an alleged attempt by researchers to re-identify individuals from research data will fall to the researcher's employer in the first instance, as is the case for any misconduct allegations. There may also be an investigation by the Information Commissioner's Office and other regulatory bodies. As with other issues relating to misconduct, employers should inform funding organisations of proven misconduct relating to funded projects or programmes. Funders have a range of sanctions that can then be applied, such as withdrawal of funding, or exclusion from further funding for a period of time. Any sanctions imposed would need to be proportionate for the specific nature of the offence committed.

The four funders will commit to the following actions:

- Publish EAGDA's statement and the funders' response on the EAGDA website, alert our funded communities to this and publish or link to it on our own respective websites;
- Reference and incorporate as appropriate the statement in relevant guidance for studies, and ensure it is easily discoverable and accessible for our research communities;
- Ensure that the principles and sanctions are included in our respective existing policies on research misconduct;
- Commit to working together to address these risks and develop opportunities for engagement with the research community and the wider public;
- Report back to EAGDA on the implementation of these actions at its March meeting (and thereafter).

We will continue to work with one another and cross-border initiatives (such as Data without Boundaries³) to understand the international regulatory and legal environments for data access and sharing, and to ensure that the risks of identifiability when data are shared across countries are mitigated by robust governance arrangements.

³ <http://www.dwbproject.org>