Sensitive data: legal, ethical and secure storage issues

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20mins

DESCRIPTION

Sensitive data are data that can be used to identify an individual, species, object or location that introduces a risk of discrimination, harm or unwanted attention. Human medical, health and personal data are a major category of sensitive data. These data need particular care, both during the management of a research project and when planning to publish them. The Australian National Data Service (ANDS) has developed guides [1] around the management and sharing of sensitive data. ANDS is convening this panel to explore issues around legal, ethical and secure storage of sensitive data.

The legal framework around privacy in Australia is complex and differs between states. Many Acts regulate the collection, use, disclosure and handling of private data. Contravention of these acts may lead to heavy financial penalties. Principles to follow around sensitive data include the management of personal information in an open and transparent way, only collecting necessary information, and adequate de-identification of data when possible.

There are also many ethical considerations around the management and sharing of sensitive data. Informed consent by research participants is essential for the collection, use and sharing of sensitive data. Storage, access, de-identification and plans for sharing are very important considerations. The National Health and Medical Research Council (NHMRC) has developed the Human Research Ethics Application (HREA) as a replacement for the National Ethics Application Form (NEAF). The aim of the HREA is to be a concise streamlined application to facilitate efficient and effective ethics review for research involving humans. The application will assist researchers to consider the ethical principles of the *National Statement of Ethical Conduct in Human Research (2007)*[2] in relation to their research. The HREA is designed to be compatible with existing IT systems used to manage ethics applications and to streamline other processes, such as reporting.

National security standard guidelines and health and medical research policy drivers underpin the need for a national fit-for-purpose health and medical research data storage facility to store, access and use health and medical research data. med.data.edu.au is and NCRIS-funded facility that underpins the Australian health and medical research sector by providing secure data storage and compute services that adhere to the privacy and confidentiality requirements of data custodians who are responsible for human-derived research datasets.

This panel will consider legal, ethical and secure storage issues around sensitive data, in the stages of the research life cycle [3]: research conception and planning, commencement of research, data collection and processing, data analysis storage and management, and dissemination of results and data access.

REFERENCES

1. Australian National Data Service. Medical and Health Data, available from http://www.ands.org.au/working-with-data/enabling-data-reuse/medical-and-health; accessed 1/6/16
2. National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015). The National Health and Medical Research Council, the Australian Research Council and the Australian Vice-Chancellors' Committee. Commonwealth of Australia, Canberra
3. National Health and Medical Research Council. NHMRC Statement on Data Sharing, available from https://www.nhmrc.gov.au/grants-funding/policy/nhmrc-statement-data-sharing; accessed 1/6/16

ABOUT THE SPEAKERS

Kate LeMay has worked as a Pharmacist in both community and hospital pharmacy. She has also worked for several years as a Project Manager at Sydney University and the Woolcock Institute of Medical Research, in community pharmacy based programs to assist patients with chronic disease management. Kate now works at the Australian National Data Service as a Senior Research Data Specialist, focusing on health and medical data.

Gabrielle Hirsch is the General Counsel for the Walter and Eliza Hall Institute of Medical Research in Parkville, Victoria. In her role as in-house counsel, Gabrielle is involved in a wide range of legal matters, ranging from the management of institute generated intellectual property and general commercial matters to advising on corporate governance, privacy and regulatory compliance. She is also the institute's designated privacy officer. Prior to joining the Walter and Eliza Hall Institute in 2011, Gabrielle worked in private practice for a large global law firm, specialising in the areas of intellectual property, biotechnology, health and commercial law. In addition to holding a Masters of Law from the University of Melbourne, Gabrielle has formal qualifications in biochemistry, genetics and governance and was engaged as primary researcher in a collaborative research project between the Walter and Eliza Hall Institute and the University of Melbourne (IPRIA), published in early 2016.

Dr Gordon McGurk is Director of NHMRC's Clinical Trials Section. His main role is to ensure that funding provided by the Australian Government budget measures, is used to improve the clinical trials environment in Australia. This role encompasses the development of strategies and policies and significant liaison with state, territory and industry representatives to implement proposed policies. This work has recently included the development of the Human Research Ethics Application, a contemporary and intuitive replacement for the national ethics application form. He is currently Chair of Australian Standards Committee CH-026, which has just revised AS/NZS 2243.3 *Safety in Laboratories (2010)* and is a Director of the Association of Biosafety for Australia and New Zealand (ABSANZ). He is also a member of the Australian Institute of Company Directors.

Dr Jeff Christiansen is based at Intersect Australia and is the Project Manager of the RDS Health and Medical Sciences project (http://med.data.edu.au). He has a PhD in Biochemistry from the University of Queensland, and started his career conducting research in the fields of cancer, molecular genetics and embryo development in both Australia and the UK, prior to moving into the management of large biological data assets (gene sequence, images, etc.) through the establishment of a UK-based international database of gene expression and anatomy. Prior to joining Intersect, Jeff was employed at the Australian National Data Service (ANDS), primarily involved in biology/medicine-focused projects.