NUFFIELD COUNCIL ON BIOETHICS

The linking and use of biological and health data

Open consultation

17 October, 2013

(Closing date: 10 January, 2014)

Contents

Part One
Background to the consultation

The Nuffield Council on Bioethics has convened a Working Party to examine ethical issues that arise in relation to the linking, analysis and use of biological and health data. Information about the project and the Working Party can be found on the Council's website. A glossary is provided at the end of the document; terms explained in the glossary appear in (hyperlinked) blue text when they are first used in each section.

Some relevant developments

We are undertaking this work now because technological advances are leading to new global opportunities and developments in biomedical data collection and linkage in the areas of health-related research, clinical practice and governmental activities.

Developments in which we are particularly interested include:

Developing resources:

- Large-scale biomedical research resources ('biobanks') collecting data from many participants that combine the comprehensive description of observable characteristics of people, their health records, analyses of their genomes (for example, whole genome sequencing) and/or other large data sets, such as proteomics, metabolomics and other 'omics', or imaging results (MRI, CT, etc.).

- The increasing intensity of biomedical data collection, analysis, use and retention in health care.

- The development of telemonitoring and assessment devices to provide biomedical data for research, clinical care or personal use.

- The availability of increasing volumes of open access data, both from research studies and from other sources that are potentially useful in combination (e.g. user generated/ self-published data/ social networking data).

Developing methods:

- Advances in data science and technology that support the management and analysis of the large data sets available to research, such as cloud computing, statistical imputation, machine learning, visualisation, and 'big data' approaches generally.

- The increased emphasis on the use of very large data sets and computationally intensive methods to attempt to understand underlying models and to generate hypotheses in areas such as the genetic epidemiology of common diseases.

- Developments in the use of data and predictive analytics to inform health interventions (e.g. identifying individual risk profiles for hospital readmission to devise personalised, preventative primary care plans) and use of algorithms that use diverse types of data in health care.

- Development of global interoperability standards that allow the combination of data from distinct sources to increase the statistical power of research studies, and the increasing globalisation of data linking and use (e.g. population biobanks and international genome research collaborations).

Developing contexts:

- An impetus from research funders and others for researchers to share their data, analyses and results with other researchers, and an accompanying movement towards open access publication of research results.
- The movement of biomedical data, medical records and other personal data internationally for research use under different regulatory frameworks.
- The movement of data use outside traditional, regulated research and health care contexts (e.g. Medicine 2.0, 'citizen science', apomediation).
- The potential for increased use of biomedical data and data linking for non-health purposes (e.g. government administration, insurance, marketing).
- Policy and legal developments that favour and facilitate the extraction of value through the reuse of data outside the scope of the purpose for which they were originally collected (e.g. using health records in biomedical research).

What ethical issues do these developments raise?

We are interested in the ethical challenges raised by these developments and their social and legal implications. Some of these ethical challenges will be familiar from other contexts but need to be reassessed in the light of the new opportunities, risks and uncertainties created by these new technological advances. At the same time, issues may arise that are specific to the new contexts created by these developments.

The main ethical questions in which we are interested relate to how, and how far, the different interests that are engaged by the use of biological and health data should be satisfied, and the ethically appropriate basis for doing so. In particular, they relate to determining ethically appropriate ways of avoiding or resolving conflicts between these different interests, where they occur.

We are interested in mapping the full range of ethical issues relating to the linking and use of data. However, it is striking that, in discussions on this topic, the issues are often articulated in relation to the concepts of privacy and the public interest. These include:

- How we understand and recognise people's relation to their biological and health data (e.g. in terms of ownership, personal rights, identity, interest, etc.)
- How the pervasive use of information technologies and their impact on wider culture affect behavioural norms (including moral norms of privacy) and expectations (e.g. about public and private spaces).
- The extent to which people should be able to exercise control over how data relating to them are used and accessed by third parties and the mechanisms through which this

may be achieved (such as consent procedures) or made unnecessary (e.g. through anonymisation).

- The extent to which people should be enabled to opt out of socially beneficial systems and relationships (e.g. a right to anonymity/to be forgotten) and the consequences of this (e.g. if joining in is linked to effective access to public services).

- The circumstances in which individual privacy interests can be qualified by the interests of others (e.g. the privacy of family members, of groups or the interests of commercial firms) or the wider public interest.

- The role of public authorities and democratic processes in setting norms, defining options, and developing appropriate governance mechanisms for the use of biomedical data.

- The proper role and rewards for commercial firms in delivering public benefits through the use of biological and health data (e.g. developing commercial products, such as medicines, and delivering public goods).

- The cultivation of solidarity and the degree to which "free-riding" can be tolerated (i.e. when people benefit from goods without bearing their fair share of the cost of making them available).

- The ways in which public trust in biomedical research and health care data processing institutions may be created, maintained and lost, and the role of governance mechanisms in this.

- The implications of government or commercial control over what sets of options are available to individuals (e.g. making services available only on condition that an individual's personal data can be re-used for other purposes).

- Obligations (e.g. of public authorities and service providers) to those who are excluded or who exclude themselves from utilised data sets, for example groups that may be hard to reach, be wary of stigmatisation, etc.

Our aim is to develop an ethical analysis that will frame policy and governance approaches to linking and use of linked biomedical data. Where appropriate, we will make specific, practical recommendations for action. Our report will be published in 2014.

Below we set out a number of questions on which we would welcome responses to help to shape and inform our deliberations. In each case there is a general question, and some more specific questions that you may wish to tackle in your response. Please feel free to respond to as many or as few questions as you wish, and to suggest other questions that, in your view, we ought to tackle in our deliberations.

Part Two

Consultation questions

1   Do biomedical data have special significance?

We are interested in the linking and use of human biomedical data. This includes measurements and test results (e.g. blood test results, DNA results, X-ray and MRI scan images), reported information (e.g. descriptions of symptoms and responses to medicines), and experimental findings (e.g. clinical trial data) among many other things. Data of this kind might be collected as part of a diagnostic or treatment procedure, health assessment, research project, drug trial, etc.; they may be stored in databases, medical records or other types of record. We are also interested in the use of data about behaviour, lifestyle, social relationships, sexual history, occupational and environmental exposures, etc. where these are relevant to understanding human biology and health, the development of medical science or the delivery of health care. Our focus, however, is principally on the ways in which these data may be linked and analysed together in order to generate insights that can be applied in the treatment of individuals and populations.

> Consultation question 1:
> ### Do biomedical data have special significance?
>
> Possible aspects to consider:
>
> - Is it useful (or even possible) to define biomedical data as a distinct class of data? If it is, what are the practical and ethical implications of different ways of defining this class?
>
> - What factors contribute to the belief that personal biomedical data deserve special protection? Does the sensitivity of biomedical data depend entirely on context or do biomedical data have special attributes that make them intrinsically more sensitive than other kinds of data?
>
> - How are changes in the scope of the data in use providing meaningful insights into individual biological variation and health?
>
> - Do some sub-sets of biomedical data (such as genomic data sets) present particular ethical challenges or offer ethically important benefits?
>
> - To what extent should genomic data sets be regarded as belonging to one individual and to what extent should other interests (e.g. of family members sharing genomic sequences) be recognised? What implications might this have for consent to collection of such data, for feedback concerning the data and for its broader use?

2   What are the new privacy issues?

The protection of privacy is considered as a basic tenet of a civil society and is protected through established ethical and legal frameworks. Biomedical data relating to living individuals is usually given special protections because of the potentially sensitive nature of the data. However, the value and the protections attached to a given type of data may vary according to the circumstances and the social context. Furthermore, people's individual privacy preferences may be complex, and are sometimes contrary to the privacy interests of others or to the perceived public interest in using personal data for the benefit of the wider society.

Willingness to disclose personal data may depend on many things, including how sensitive people consider the data to be, the benefits they believe they or others may receive from disclosure, the perceived risks to their own interests or those of others, the level of confidence they have in how subsequent use will be governed, the level of control they may retain over the data, and norms of social behavior in similar situations, among many other things. Given the public and commercial interests in biomedical data, some decisions must be made collectively about what measures are most appropriate and desirable to ensure adequate protection of privacy, and to facilitate voluntary participation and legitimate activity. We are therefore interested in understanding the values that underlie the concepts of privacy and public interest in the use of biomedical data; we are interested, too, in understanding the nature and significance of actual harms and benefits involved.

Consultation question 2:

What are the new privacy issues?

Possible aspects to consider:

- Do new information technologies and 'big data' science raise privacy issues that are new in kind or in scale?

- What are the implications for individual anonymity of linking data across large numbers of databases?

- What is the 'public interest' in biomedical data? What benefits do we want to obtain? In what circumstances might the public interest take precedence over individual and minority group interests?

- What are the actual harms we should seek to avoid in using biomedical data (e.g. discrimination, stigmatisation)? What evidence is there of these harms having occurred?

- In what ways does it matter if people's data are used in ways of which they are unaware but that will never affect them?

- How are applications of computer-based technology (e.g. social networking, image sharing, etc.) affecting concepts of privacy, identity and social relatedness? How are related behavioural norms influenced (e.g. willingness to share and publish data)?

- Would it be helpful to treat biomedical data as 'property'?

3 What is the impact of developments in data science and information technology?

Holding biomedical data electronically, in digital form, allows their efficient storage, retrieval, transmission, replication, and manipulation. The main developments that make our inquiry timely are those associated with the unprecedented availability of digital data, and the increasing power of computing technologies and analytical techniques available to manipulate it. Combined with technologies that generate large data sets (such as genome sequencing), advances in fields such as database design and management, artificial intelligence, bioinformatics, statistical methods, machine learning, and visualisation all offer powerful and rapid ways to 'mine' large, varied and complex data sets for significant patterns. As a consequence of the growth of digital biomedical data, new opportunities are emerging to correlate data from diverse sources, including research collections, disease registries, and even social networking, internet browsing and geolocation data. So-called 'big data' technologies offer new approaches to enquiry that promise insights that could not be derived previously. Extracting value from rich data resources has become a priority for the knowledge economy. We are interested in the significance of developments in areas of knowledge through use of biomedical data, especially data that were initially collected for a limited purpose (e.g. a medical diagnosis) but that could now be reused for a further purpose (e.g. biomedical research), or many other purposes.

Consultation question 3:

What is the impact of developments in data science and information technology?

Possible aspects to consider:

- To what extent and in what ways has the availability of biomedical data and new techniques for analysing them affected the way in which biomedical research is designed and funded? Is there any evidence that these factors have affected (or are likely to affect) research priorities?

- What are the main interests and incentives driving advances in data science and technology that can be applied to biomedical data? What are the main barriers to development and innovation?

- Does 'big data' need a more precise definition or is it a useful concept in the life sciences even if loosely defined? Has enthusiasm for 'big data' led to over-inflated expectations on the part of governments, researchers and/or the general public?

- What are the significant developments in the linking or use of biomedical data, including any we have not mentioned, to which we should pay attention in our deliberations?

4   What are the opportunities for, and the impacts of, the use of linked biomedical data in research?

Life sciences research in general, and epidemiological and biomedical research in particular, are beneficiaries of the capacity to create and analyse large and complex digital data sets. Significant developments include the generation of data sets of unprecedented size in areas such as genomics and medical imaging. These large data sets are being created in many countries and used in different ways. Biobanks around the world hold, for example, DNA markers, information on lifestyle and environmental factors, and other health-related data (e.g., imaging data, laboratory test results and other quantitative data) from millions of individuals, and are a very valuable resource for medical research. The data collected when people are recruited to biobanks can be linked to pre-existing data, for example from health records, administrative databases or disease registries. These data sets are made available for research into the determinants of multifactorial diseases – such as cancer, diabetes and coronary artery disease. Researchers using these data may link them with other pre-existing data sets to answer new research questions (e.g. linking fertility treatment and childhood cancer registers to identify childhood cancer risk following assisted conception). Research groups and biobanks are also combining their data sets through national or international consortia to tackle research questions not answerable by one study alone. These collaborative efforts take place in both the private and public sector, with academic groups working alone, or with commercial or non-profit collaborators.

Access to data is dependent partly on the types of data held; anonymous data may be openly available on the internet while potentially identifiable data will require approval by an access committee and acceptance of rules guiding its use (including requirements for consent). Some data may not be available outside the original study. This may be true of commercial companies that have responsibilities to shareholders. It can also be true in academic studies where researchers do not wish to share data or consent has not been gained to allow use beyond those who gathered the data. There is increasing pressure from patients, participants and funders to ensure data is being made available. Commercial companies are responding to patient calls to release clinical trial data and many funding bodies now require researchers to specify plans for data sharing.

Different governance frameworks, consent arrangements, national jurisdictions, and political priorities condition what research is carried out, what data are collected, in what ways data can be linked and by what means, and for what further purposes data may be accessed. Our interest here is identifying how these systems align with underlying ethical and social values.

Consultation question 4:

What are the opportunities for, and the impacts of, use of linked biomedical data in research?

Possible aspects to consider:

● What are the hopes and expectations associated with data use for biomedical, public health and life sciences research? What are the main concerns or fears?

● To what extent do the kinds of collaborations required for data-driven research (e.g. international or multi-centre collaborations) generate new ethical and social issues and questions to those in other forms of research?

● Should researchers be required to allow others to access data they have collected for further research?

● What sorts of concerns are raised when research is carried out by a commercial firm?

5   What are the opportunities for, and the impacts of, data linking in medical practice?

As in research, the use of digital data is also expected to produce significant further transformations in health care. Increasing quantities of data are generated and recorded in the course of routine medical practice, including a variety of imaging and pathology test results (increasingly including the results of DNA tests), and metadata. These data support increasingly stratified or 'personalised' clinical decisions (adjusted to a greater number of the specific characteristics of the individual patient). Such data might be used to profile patients for particular interventions (for example, to tailor drug dosages to their individual metabolic response) or to predict future disease. The collection and retention of health data raises questions about how we should approach the possibilities for making use of it, not only to optimise individual medical treatment but also for wider public benefit. It is also important to consider how individuals should be able to control access to records about themselves to protect their privacy or to conceal sensitive information that they do not wish others to see.

Consultation question 5:

What are the opportunities for, and the impacts of, data linking in medical practice?

Possible aspects to consider:

● What are the main hopes and expectations for medical practice associated with increased use of linked electronic data? What are the main concerns or fears?

● What can be said about public expectations about the use of health care data, in terms of appropriate use, information and control? To what extent would members of the public expect health care data to be shared with other agencies or bodies?

● Is there potential for privacy controls to hide secrets, such as abuse, or to disadvantage people in unintended ways (by preventing best treatment, perhaps)?

● Are there particular issues raised by 'risk-profiling' where individuals at high-risk (e.g. of type 2 diabetes) are identified and approached for specific interventions? What might make the difference between this being intrusive and it being supportive?

● What are the implications of episodes of treatment across different care providers being used routinely as research data? How might this affect the ethical basis of the doctor-patient relationship?

● To what extent does the possibility that biomedical data can contribute to a research base to advance the effective treatment of others create a moral obligation to allow them to be used in this way? What might limit this obligation? How should we regard (and provide for) those who refuse to allow their data to be used?

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6 What are the opportunities for, and the impacts of, using biomedical data outside biomedical research and health care?

Most detailed human biomedical data are collected and stored for purposes of either health care provision or biomedical research. The circumstances in which they are collected often entail clear restrictions on their further disclosure, deriving from requirements of medical confidentiality, consent and data protection. Aside from medical practice and research there is also a range of other purposes for which biomedical data may be used, including uses as diverse as criminal investigations, genealogy, and marketing. In many cases, access to the data will be governed by specific measures (as in the case of forensic purposes). However, not all biomedical data are collected in a setting of medical confidentiality: the information may be offered voluntarily, for example, where it is required in order to receive a service such as insurance. Individuals may also provide biomedical data to commercial companies, for example, when purchasing direct-to-consumer health tests, in some cases (unwittingly or deliberately) in circumstances allowing it to be used for other purposes, such as marketing by the company or its affiliates. Data may be stored in private online health records, shared through patient support websites or mobile apps, or self-published on blogs, message boards, or social networking websites (such as quantifiedself.com or even Facebook). Finally, predictive analytic techniques can, in some cases, impute biomedical data (for example, pregnancy inferred from supermarket purchasing patterns), to inform targeted marketing of products and services. Here we are interested in the implications of the use of data not being definitively constrained by the purpose for which they were initially collected, and the possibility of unforeseeable subsequent uses of the data.

Consultation question 6:

What are the opportunities for, and the impacts of, using biomedical data outside biomedical research and health care?

Possible aspects to consider:

- What are the main hopes and expectations associated with the wider use of biomedical data (outside biomedical research and clinical practice)? What are the main concerns or fears?

- What factors are relevant to determining the legitimate scope of further uses of biomedical data? For example, should it be restricted to a 'compatible purpose' (and, if so, how might this be defined)? To uses that are in the 'public interest'? To use only by public authorities (and those providing public services under contract)? To non-commercial or non-profit uses/users?

- What are the ethical implications of using predictive analytic tools with biomedical data outside health care and research (e.g. in recruitment or workforce management)?

- Would the ability of individuals to maintain direct control over the use of data about them be likely to affect the range of further uses to which they would allow the data to be put?

- Should individuals be able to profit from the use of their biomedical data (e.g. by selling access to the data to commercial companies)?

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7 What legal and governance mechanisms might support the ethical linking of biomedical data?

Knowledge of the identity of individuals is not always necessary for data to be used beneficially: many kinds of research can be undertaken using anonymised data and public health measures can be applied to populations or subgroups generally, rather than to individuals. The same is true of other public and commercial services. However, we are interested in cases in which strict anonymisation is either impossible (because of the possibility of identifying individuals within data sets) or the use of anonymised data is not feasible (for example, where clinical characteristics and biological data are being linked, as in the case of linking different disease registers). We are interested in how the risks of identifying individuals can be avoided or mitigated, in the context of incentives to collect ever more data, extract secondary value out of existing data collections, and to increase the efficiency and power of research.

In health systems, confidentiality usually creates a barrier to the broader disclosure of data while allowing it to be used to support the provision of treatment within the system. The stipulation that data use must be subject to consent, which is a legal requirement in most jurisdictions, allows individuals to exercise control over the use of data about them. However, consent operates at different levels of specificity and requires different levels of commitment. When research data is collected it is increasingly common to ask participants for 'broad' consent to a wide range of types of health-related research; this model is usually used because the full scope of future research studies is not known at the time of recruitment. Instead participants can give consent knowing that governance mechanisms (e.g. oversight committees, data access rules) will be in place to ensure their data is accessed by only approved researchers who agree to use it for scientifically valid, ethical and appropriate research activities. In fact, consent may be neither necessary nor sufficient to protect individual privacy.

Some linking is possible using 'pseudonymised' or key-coded data, where a code may be assigned to data in a recognised safe haven (or by a trusted third party) before data are more widely released. Alternatively, the data can be interrogated using algorithms supplied to trusted third parties and applied by them, with the commissioning party (a biomedical researcher, for example) receiving only the results and without them seeing the raw data at any stage. These safeguards are not perfect; as more data become available through a variety of sources, protected and open, it has been shown that identification of individuals from 'anonymous' data is possible. This has led some to suggest that a guarantee of confidentiality is increasingly implausible and that genetic data, for example, should be openly shared, with regulations and sanctions put in place for misuse; others are exploring additional means by which data can be protected, such as ever more secure encryption. It is unlikely that a single approach will be appropriate to all contexts, although there is value in approaches being consistent (in terms of underlying values) and interoperable (given advantages of linking data between contexts).

Consultation question 7:

What legal and governance mechanisms might support the ethical linking and use of biomedical data?

Possible aspects to consider:

- What ethical principles should inform the governance of biomedical data? For example, should the principle of 'respect for persons' be given primacy here? How might this relate to principles such as solidarity and tolerance?

- Does the use of linked biomedical data require distinctive governance arrangements compared to the use of other personal data?

- Are the current principles of consent – including the principle that consent can be withdrawn – still 'fit for purpose' in relation to the linking of biomedical data?

- What level of continuing involvement is it reasonable to expect individuals to have in how their data are used after they have been collected?

- Should there be an opt-in or an opt-out system for people to decide whether to allow their personal medical data to be used for public benefit?

- Under what conditions ought individuals to be content to delegate authorisation of the use of health and biological data about them?

- What role should public engagement and democratic processes play in the determination of governance measures? In what circumstances, if any, might the outcome of democratic procedures mandate overriding individual interests?

- What inconsistencies exist in current ethical guidance and governance structures relating to biomedical data?

- What examples are there of innovative initiatives that promote privacy while encouraging participation?

Glossary

Algorithm: a method for calculation or problem-solving in a finite set of steps, which may be automated.

Anonymisation: the removal of personally identifying information from a record in order to prevent the identification of an individual subject of the record.

Apomediation: the involvement of agents (individuals, groups, tools, or processes) to guide consumers in the acquisition of products or services that fulfill specific criteria (e.g. quality) without acting as a gatekeeper (i.e. the use or agreement of such agents is not a pre-requisite to access).

Big data: a relatively informal term used to describe data sets large or complex enough to pose problems for traditional methods of storage, management and analysis, thus necessitating the development of new techniques to replace and supplement those methods. The term is increasingly used to characterise approaches employing these new techniques and methods to extract value out of 'big data' resources.

Biobank: a repository of biological material samples and associated data for research use. The content of biobanks varies, but may include tissue, blood, and urine samples, and also information associated with the sample donors (such as phenotypic or lifestyle information).

Bioinformatics: the scientific field of processing, storing, distributing, analysing, and interpreting biological data. Encompasses many disciplines, including biology, computer science, and engineering.

Biomedical data: Data relating to the state or functioning of human beings as biological systems, e.g. those derived from biological research or clinical investigations.

Citizen science: the inclusion of non-scientists in the scientific research process.

Cloud computing: provision of computational capacity as a virtual 'resource pool', available over a network connection.

Confidentiality: the restriction of access to certain data. This may derive from an agreement or implicit understanding between two or more parties, or from the nature of the relationship between them. For example: a contractual agreement to restrict access to commercially sensitive data, or the doctor-patient relationship (the confidential nature of which is assumed and obliges the doctor to keep secret some information imparted while providing care.)

Data set: a collection of data in a structured format, such as a database.

Epidemiology: the study (or the science of the study) of the patterns, causes and effects of health and disease conditions in a defined population.

Ethics: the study of values and moral reasoning, and their application to human conduct; formally a branch of philosophy.

Genome: the full complement of genetic material (or hereditary information) in the cells of an individual organism or species; the totality of the DNA sequences of an organism or organelle.

Genome sequencing: the biochemical procedure by which the complete DNA sequence of an organism's genome is determined.

Health record: a transcript of information regarding a patient's medical data, often from multiple sources and over time (as distinct from a 'medical record' which normally concerns only a single episode of care at one institution).

Machine learning: a branch of computer science concerned with developing techniques to enable a computer program to improve its own performance.

Medicine 2.0: a term used to describe the relationships between medicine and 'Web 2.0' (second generation internet services, characterised by greater web-based participation, interactivity and collaboration, and the move towards these behaviours and away from the use of 'static' webpages; exemplified by wikis and social networking). Medicine 2.0 therefore refers to the possibilities those methods and behaviours have for the delivery of health care.

Metabolomics: the systematic study of metabolic responses to external stimuli.

Metadata: data about data. For example, data attached to a digital picture describing the time of its creation, or data describing the structure of a database.

Omics: an informal term used to describe biological fields of investigation ending in '-omics'. It refers particularly to fields concerned with complex, integrated biological systems, the study of which is intended to lead to an understanding of the organism as a whole. Examples include: genomics, metabolomics, microbiomics, proteomics, and transcriptomics.

Predictive analytics: the use of data science techniques to predict future events in a variety of fields (business, health care, insurance, sports etc.). Draws on many disciplines, including statistics, machine learning, and data mining.

Privacy: the right (or ability) to acquire and maintain freedom from intrusion or public attention. It can relate to a number of different conditions, such as physical seclusion/concealment, freedom from external interference, or positive control over access to one's personal information.

Proteomics: the systematic study of all the proteins encoded by the genome of an organism.

Pseudonymisation: the process of removing identifying associations between data and the subject of that data, possibly including the replacement of those associations with artificial identifiers.

Statistical imputation: the process of identifying missing data and replacing them with substituted values.

Telemonitoring: the monitoring of patients at a distance (i.e. not in the same location as the health care provider). Data from the monitoring devices are transmitted for storage, analysis and recording elsewhere. For example, values such as blood pressure, heart rate, and blood glucose levels can be monitored regularly or continuously using home-based, wearable or even implantable devices.

Visualisation: visual representations of data, primarily for the purpose of rapidly conveying possible meanings of complex data (i.e. the animated representation of a sifting algorithm.)

How to respond

We would prefer it if you could send your response to us electronically. Responses can be sent via email to Tom Finnegan (tfinnegan@nuffieldbioethics.org), with 'Biological and health data consultation' as the subject line. It will greatly assist the Working Party if responses are in the form of a single Word document, with numbered paragraphs throughout.

Please ensure that you also include a completed response form with your submission, which can be found on page 16 of this document or downloaded from www.nuffieldbioethics.org/biological-and-health-data/how-to-respond.

If you would prefer to respond by post, please send your submission to:

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Telephone: +44 (0)20 7681 9619
Fax: +44 (0)20 7323 6203

Closing date for responses: 10 January 2014, 17:00.

For more information about the Working Party, or the Nuffield Council, please follow the links listed below:

- Terms of reference of the Working Party
- List of Working Party members
- Terms of reference of the Council
- List of Council members

Before submitting your response, please make sure you have filled in the respondent's form telling us how we can use the information you have given us. We will not publish your name without your express permission.

Respondent's form

Please complete and return with your response by **10 January 2014**. We will **not** publish your name without your express permission.

Your details:

Name: _____

Organisation (if applicable): _____

Email: _____

About your response:

Are you responding personally (on your own behalf) or on behalf of your organisation?

☐ Personal   ☐ Organisation

May we include your name/your organisation's name in the list of respondents that will be published in the final report?

☐ Yes   ☐ No, I/we would prefer to be anonymous

If you have answered 'yes', please give your name or your organisation's name as it should appear in print (this is the name that we will use in the list of respondents in the report):
_____

May we quote your response in the report and make it available on the Council's website when the report is published?

☐ Yes, attributed to myself or my organisation   ☐ No
☐ Yes, anonymously*

*If you select this option, please note that your response will be published in full (but excluding this form), and if you wish to be anonymous you should ensure that your name, and any other identifying information, does not appear in the main text of your response. The Nuffield Council on Bioethics cannot take responsibility for anonymising responses in which the individual or organisation is identifiable from the content of their response. Obtaining consent to publish a response does not commit the Council to publishing it. We will also not publish any response where it appears to us that to do so might result in detriment to the Council's reputation or render it liable to legal proceedings.

Why are you interested in this consultation? (Tick as many as apply)

☐   Personal interest (please state): _____
☐   Professional interest – biomedical researcher
☐   Professional interest – Caldicott guardian
☐   Professional interest – clinician
☐   Professional interest – data owner
☐   Professional interest – data protection officer
☐   Professional interest – information technology professional
☐   Professional interest – knowledge and information management professional
☐   Other professional interest (please state): _____
☐   NGO
☐   Government
☐   Academic interest
☐   Legal/regulatory interest
☐   General interest
☐   Other (please state): _____

Please let us know where you heard about the consultation:

☐   Received notification by email
☐   Newspaper, radio or television
☐   Nuffield Council on Bioethics website
☐   Twitter
☐   Facebook
☐   Other website (please state): _____
☐   Other (please state):_____

Using your information

We ask for your email address in order that we can send you a link to the report when it is published and notify you about activities related to this project. (Please note that we do not make your email address available to anyone else, and we do not include it with the list of respondents in the report.)

May we keep your email address for these purposes?

☐   Yes
☐   No

Would you like to receive our regular newsletter by email which provides you with information about all of the Council's activities?

☐   Yes
☐   No