This response was submitted to the consultation held by the Nuffield Council on Bioethics on *The linking and use of biological and health data* between 17 October 2013 and 10 January 2014. The views expressed are solely those of the respondent(s) and not those of the Council.

Response to the Open Consultation of the Nuffield Council on Bioethics

'The linking and use of biological and health data'

Response from the Mason Institute for Medicine, Life Sciences and the Law
University of Edinburgh

The Mason Institute, based at the University of Edinburgh and located within the School of Law, serves as an interdisciplinary research network, developed within the University, aimed at investigating the interface between medicine, life sciences and the law in relation to medical and bioethical developments on a national and global scale.

The Mason Institute for Medicine, Life Sciences and the Law ('Mason Institute') welcomes the opportunity to respond to the open consultation on 'The linking and use of biological and health data'.

The Mason Institute recognises the importance of research using biological and health data, and the equal importance of adequately addressing the challenges around conducting such research through the application of sensitive and robust ethical and legal frameworks that continue to respect individual rights and interests with respect to personal data.

Consultation Question 1: Do biomedical data have special significance?

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?

1. From the governance perspective, where researchers may wish to link biological and non-biological data together, different regulatory regimes exist and as such, already complex governance landscapes are further complicated. Whilst the Mason Institute can appreciate the reasons behind distinguishing biomedical data from other forms of data, we would argue that a conceptual dichotomy such as this is not always helpful in practical terms. Research will rely on biological data (derived from tissue) and health data (derived from medical records and other medical investigations), in addition to social data. Whilst biomedical data may possess distinct features in comparison to other classes of data (e.g. census data, social care data etc.), it may be more practical, legally defensible and consistent to adhere to the current statutory basis for classification of data which is determined on the basis of sensitivity i.e. personal versus sensitive personal data. Any attempt to create – yet another – sub-category of data to be regulated will likely be counter-productive and obscure the principal objectives of current legal regimes, viz, to adequately protect personal privacy while facilitating appropriate processing of data for legitimate purposes.

2. From the point of view of personal privacy, what is important is not the categorisation of data as biomedical (or not), but rather the degree of risk that the use of data relating to individuals can represent to their personal interests and fundamental human rights. Risk-based assessments relative to the proposed *uses* of data, rather than their perceived defining characteristics – is a more balanced, pragmatic and ultimately workable means of achieving the twin objectives of promoting defensible uses of data without unduly diluting appropriate privacy protection.

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?

3. Some individuals may hold biomedical data as distinct from other data, and that this may be to do with the fact that this data has been physically taken from individuals, rather than merely documented (as in the case of electronic health records). However, the utility of raw biomedical data will be limited until such a point that it is translated into information, i.e. – once it is set in a context that allows meaningful interpretation. This will often require 'biomedical' data to be linked to non-biomedical or other 'social' data to reveal deeper understandings (and with likely increased implications for personal privacy).

4. There are numerous different ways in which concerns around sensitivity of uses of information might arise. For example:

> 1. Because individuals might be sensitive about the use of their information at all, or more specifically about certain kinds of uses (e.g. for intelligence research)
>
> 2. Or because certain uses of information might have implications for family members, who might not know that data relating to them is being processed at all (let alone be given the chance to object),
>
> 3. Or because future uses might not yet be known, and so governance mechanisms must be responsive to addressing future sensitivities that will depend both of what is proposed and what become possible.

Thus, for all of these reasons, this determination *is* necessarily context-based.

5. Indeed, multiple factors should be taken into account prior to processing biomedical data including the research participant's views (if known) on the use of that particular data, the level of anonymisation or pseudonymisation applied to that data and what information has been or will be provided to the individual research participant regarding the potential use of the data. An important question that arises in this regard is: what does it mean to take into account the participant's views? For example, consent may allow views to be taken into consideration but, in contrast, anonymisation is much more a risk-management tool than a

means to respond to individual wishes and this could be made more explicit. Issues therefore are not necessarily pertaining solely to use, but may also relate to access, as we go on to discuss.

6. Thus, defining and delimiting a context will not always be straight-forward as increasingly data are being linked from smaller or stand-alone studies or health records to increasingly wider networks of knowledge. This implies new and only partially definable sets of users and uses. Moreover, as data sets are linked (or in some cases combined), and new scientific insights are fed into research this is likely to raise ethical issues, which may not be easy to predict at the outset. This will require a dynamic and responsive attitude to governance and a sensitivity to the perspectives of all those likely to be affected.

7. As such, we might take this opportunity to emphasise the need for ethical and legal regulatory frameworks to be reflexive and responsive to developments as these occur over time, and which can accommodate opportunities for mutual learning about what is appropriate or tolerable as new possibilities emerge. We have argued elsewhere for the need not only for on-going engagement with public and other stakeholders,[1] but also for mechanisms of reflexive governance that can deliver just such a mechanism[2] – and one that does not give the misleading view that up-front consent can address the plethora of ethical and social issues that arise in this setting.[3]

How are changes in the scope of the data in use providing meaningful insights into individual biological variation and health?

8. The importance of linking health data with administrative data should be acknowledged, as typified by two initiatives which we are involved in:

(1) The Farr Institute: http://www.farrinstitute.org

(2) The Administrative Data Liaison Service: http://www.adls.ac.uk

Do some sub-sets of biomedical data (such as genomic data sets) present particular ethical challenges or offer ethically important benefits?

9. Genomic data comes with many benefits and burdens. It enables a deeper understanding of the physiology of patients, which can be very 'rich' for research purposes; however such data and the information which it can reveal also have consequences which reach far beyond the individual patient. It is important to note that the law and regulatory regimes

[1] G Haddow, G Laurie, S Cunningham-Burley and KG Hunter, 'Tackling Community Concerns about Commercialisation and Genetic Research: A Modest Interdisciplinary Proposal' (2007) 64 Social Science and Medicine 272-282, and SHE Harmon, G Laurie and G Haddow, 'Governing risk, engaging publics, and engendering trust: new horizons for law and social science' (2013) 40(1) Science and Public Policy 25-33.

[2] G Laurie 'Reflexive Governance in Biobanking: On the Value of Policy Led Approaches and the Need to Recognise the Limits of Law' (2011) Human Genetics 130: 347-56.

[3] G Laurie and E Postan, 'Rhetoric or Reality: What is the Legal Status of the Consent Form in Health-related Research?' (2012) Medical Law Review 44pp, doi: 10.1093/medlaw/fws031.

are not set up to take account of multiple actors' claims over the same data, e.g. family members. For example, the Article 29 Working Party on family claims to data protection merely sets out two possible alternative approaches without offering guidance on either.[4] Moreover, it maintains a highly individualised stance, rather than seeking to give effect to the collective value that can be released by effective processing of such data in the public interest. This would require us to have a far more robust engagement with notions of public interest – and how they sit alongside individual or familial claims – than has happened to date. We would support the NCOB Working Party examining what these might be.

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?

10. Regarding 'belonging': biobanks are themselves of national and international interest and many purport to have a generic purpose, for example, to understand the relationship between genes, environment and disease. These may be considered a different type of databank from others that have a particular disease as a focus. Historically, the issue of ownership or property has found in favour of research scientists for example with respect to material taken from Henrietta Lacks or John Moore – yet more recently, patients have taken up a more active approach to controlling access to their resource – as illustrated by the example of PXE international which can be contrasted with the lack of success in property claims in both *Greenberg et al v Miami Children's Hospital Research Institute Inc* and *Washington University v Catalona et al*.[5]

11. Sociologically, the issue of 'belonging' has very different connotations to the legal concept of ownership or property and relates less to a sense of possession or exclusivity, and rather refers to a more generic feeling of origins, connectedness, acceptance, associations and place. [6]

12. While there have been legal moves in recent years to recognise property-like claims relating to personal tissue[7] – it does not follow that property in data is a meaningful legal concept (absent intellectual property which is a distinct category altogether and would not arise with respect to the individual(s) from whom data are derived since intellectual property requires some degree of 'creation' for it to be brought into existence. Indeed, given the mis-match between quasi-legalistic notions of 'belonging' and sociological understanding – not to mention the practical difficulties that rise from trying to apply legal property models to raw data – we strongly argue *against* talking about biomedical data in

[4] Article 29 Data Protection Working Party, Working Document on Genetic Data (2004) available at http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2004/wp91_en.pdf see page 8.
[5] We discuss these and other property-based cases in JK Mason and GT Laurie, Law and Medical Ethics, Ninth Edition, Oxford University Press, 2013, chapter 14.
[6] Bond., R. (2006). "Belonging and Becoming: National Identity and Exclusion." Sociology 40(4): 609-626.
[7] See further note 5 above.

property-like terms. The analogy is unhelpful and likely to give rise to expectations that cannot be met in practice.

13. We prefer, instead, to consider the likely benefits and burdens that can arise from uses of (biomedical) data. Key among these is feedback, and it is particularly important on a number of levels. At one level, patient expectations must be managed with regards to how much feedback participants will receive, if any. It is paramount that when seeking consent for use, individuals are made aware of the potential implications that such feedback might have on themselves and their families. Some individuals may wish not to receive feedback, or may wish to only receive some types of feedback. A property-type paradigm is likely to give rise to expectations that feedback is part of the core set of entitlements arising from uses of (biomedical) data. We are not convinced that this is a normative position that is yet well justified, and the rejection of the language of property leads us further to explore and examine the basis upon which expectations of feedback might be justified.

Consultation Question 2: What are the new privacy issues?

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

14. Big data raises issues of scale for privacy, that is, issues of magnitude of risk. Big data science highlights the social and economic potential of the multiple layers of data collected about individuals. However, the increasingly varied and multi-faceted nature of data collected can lead to an unprecedented opportunity for profiling of individuals. The profiles that can be generated about individuals on the basis of big data must be accounted for in research governance frameworks and these possibilities must be adequately addressed in the new EU regulation on data protection. As we have argued above, we consider that a risk-based approach to data protection regulation is the most apt and most reflexive with respect to unknown future possibilities for use. Citizens should no longer be led to believe that absolute protection of their privacy is possible. At best, we must work to minimise unacceptable privacy risks, while identifying and engaging on the likely public and individual benefits that can arise from defensible data uses. Equally, consent is flawed in a number of respects, notably (i) that it cannot anticipate likely future uses, and (ii) that it cannot absolve unwarranted uses with respect to family members. As such, the limited role and value of consent to protect privacy must be acknowledged and reflected in law. More attention to well-justified uses of (biomedical) data – especially when claimed to be in the public interest – should be given.

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

15. It is well established within the literature that the more linkages which take place, the more the likelihood of (re)idenfiability of individuals increases. It is never easy to determine in the abstract the extent of the risk of linkage or indeed of the existence of growing numbers of data sources. New technologies and new research processes, combined with access to increasing amounts of data render it impossible (and irresponsible) to make promises of anonymity. Given this reality, the consequences of risk of (re)identifiability must be reflected within other regimes, particularly those which are of special concern to data subjects, for example, insurance companies.

16. Similarly however, it should be appreciated that whilst risks of (re)identification exist (and increase with increased linkages), risk should be considered in light of the 'data environment'[8] which attempts to develop some mechanisms of looking at the specific risks in the case of linking particular datasets given the number of reference data sets that may enable (re)identification. Further, the practicalities (and motivations) of (re)identification are dependent upon the skills, expertise and motivations of the individuals accessing data.[9]

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?

17. There is a public interest in advancing (health) knowledge, in effectively deploying research data to create interventions that benefit individual and public health and well-being, social conditions and addressing social determinants of health. Research that seeks to advance such objectives and is ethically sound is, by definition, 'in the public interest'. The overall or generalised outcome is a healthier and more productive society which bases decisions (and health interventions) on verifiable evidence.

18. The Mason Institute would particularly like to stress a point which is often overlooked in discussions around data use in research: that the use of data in biomedical research is in both the public and individual interest as opposed to the traditional portrayal of a public v private interest dichotomy which does not stand up to close scrutiny.[10] Public engagement around research is critical; it can highlight the beneficial uses to which biomedical data can be used that are both within the interests of society but also impactful on the everyday lives of individuals. Our own research has shown that on-going public engagement can help to 'unpack' nuances of understanding and tolerances around the conduct of medical research. For example, we found that publics did not necessarily object to commercial involvement in genetic research per se, but rather baulked at the prospect of 'excess profit' or obscene gains in the face of altruistic conduct on the part of research participants. This kind of insight

[8] E Mackey and M Elliot, 'Understanding the Data Environment', (2013) XRDS, doi: 10.1145/2508973

[9] N Homer et al., 'Resolving individuals contributing trace amounts of DNA to highly complex mixtures using high-density SNP genotyping microarrays.', (2008) PLoS Genet 4(8): e1000167. doi:10.1371/journal.pgen.1000167

[10] G Black and L Stevens, 'Enhancing Data Protection and Data Processing in the Public Sector: The Critical Role of Proportionality and the Public Interest' (2013) SCRIPTed 30pp, doi: 10.2966/scrip.100113.93.

can help design more responsive and effective governance mechanisms, for example, that include an element of benefit sharing in return for access to, and use of, (biomedical) data.[11]

19. Additionally, we would emphasise the importance of good communication in the regulation of research and the use of data, with effective means of monitoring compliance within regulatory frameworks. Communication is bi-directional.

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?

20. Learning lessons from the past, in order to inform the future, is not just an ideology that informs the mechanisms of genetic inheritance and screening but is also associated with the development and use of genetic information. For example, eugenics (ironically meaning 'the beautiful inheritance') whose eighteenth century proponents hoped to 'improve the race' through ethically dubious practices such as involuntary sterilisation and restrictions on reproduction. The question is not whether there is evidence of these harms having occurred but whether discrimination of particular groups may be repeated in relation to whether the information held by the government will be used alongside an individual's bioinformation by researchers to make wider claims about behavioural or psychological conditions.

21. There is a very real risk of reputational harm for researchers, institutes and regulators alike if robust, responsive and effective governance mechanisms are not in place, and seen to be so. Our own work on the Scottish Health Informatics Programme – involvement a series of engagement exercises with publics and other stakeholders – suggests strongly that this is the case.[12]

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?

22. If data are used in a way that is inconsistent with the purposes to which the data was originally obtained, good governance requires that this proposed use be communicated to the implicated individuals, whenever practicable. Even if a new and proposed use would not result in the type of substantial distress currently actionable under relevant legislation, good and proportionate governance requires a level of transparency and open communication with those individuals whose data are being used. Thus we would reiterate here that public engagement and communication are paramount. Further, whilst ongoing reflection of new uses of data is required given the changing landscape of data and research, we must also ensure that the burdens placed on researchers in conducting this ongoing consideration do not become onerous. Thus, it is important to develop mechanisms of *proportionate*

[11] See further, G Haddow, G Laurie, S Cunningham-Burley and KG Hunter, 'Tackling Community Concerns about Commercialisation and Genetic Research: A Modest Interdisciplinary Proposal' (2007) 64 Social Science and Medicine 272-282.

[12] See further, http://www.scot-ship.ac.uk/publications.

governance as we have advocated and implemented as part of the Scottish Health Informatics Programme.[13]

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)?

23. Developments in computer-based technologies (including social media) appear to have led to paradoxical effects on attitudes to privacy. On one hand, individuals appear more vocal on privacy issues, suggesting that perhaps there might be increased awareness around privacy issues, particularly in light of the Snowden revelations, phone-hacking scandals etc. On the other hand, individuals are volunteering a mass of information themselves, particularly on social networking sites such as Facebook. Within the research setting, people can be unaware of the fact that research involves data relating to them.

24. With the spotlight on 'privacy' and its relation to computer-based technologies, the role of the data controller or processor in this relationship should be reconsidered.[14] Data controllers and processors of social networking websites are in the best position to affect individual's privacy, identity and social relatedness in a positive way. By building in stronger default controls on social sharing platforms, individuals will be better equipped to make informed decisions on whether or not to share certain information and with whom. To relate the discussion back to the health information context, many inferences can be made about people depending upon how they use social media, targeted advertising being the prime example. The question arises as to whether biomedical data are being inferred.

25. The movement towards Open Science is encouraging/mandating publishing of research results is also noteworthy, see for example the Joint Statement of Purpose which was issued in 2011 by a host of research funders; it articulated some key governance principles relating to data sharing, etc. However, Open Access initiatives must take into account the legal and ethical obligations of researchers as to the use of personal data. In this regard, we endorse the recommendations of the Royal Society in its 2012 report on *Science as an Open Enterprise*. The emphasis must be on both appropriate and realistic privacy safe-guards *as well as* robust and effective stewardship of large-scale data sets. To fail to implement both of these objectives, especially to allow the holding of useful data sets would be unethical.

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

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[13] See further: http://www.scot-ship.ac.uk/. Also, G Laurie and N Sethi, 'Towards Principles-Based Approaches to Governance of Health-Related Research Using Personal Data' (2013) 4(1) European Journal of Risk Regulation 43-57 and N Sethi and G Laurie, 'Delivering proportionate governance in the era of eHealth: Making linkage and privacy work together' (2013) Medical Law International, doi: 10.1177/0968533213508974.

[14] For instance, the Article 29 Working Party examined the evolving obligations of data controllers and data processors in light of social networking technologies: The Article 29 Working Party (2009) *Opinion 5/2009 on online social networking* pages 1-13 available at http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2009/wp163_en.pdf.

26. No. Please see our reply to an earlier question in this regard. We would only add further here that while there is a general societal familiarity and comfort with appeals to 'property' (i.e.: we all believe that we comprehend it and often make claims to it), it may not be the best metaphor for governing research data, not least because some stakeholders have very strong reactions against the model for its emphasis on markets, commerce and instrumentalisation. Even if such data were to be treated as property, quite how a property-based model would work in practical terms is very uncertain. For the reasons we articulate above, we do not support this approach.

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

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?

27. With the notable movement towards Open Access, many funders are requiring researchers to make publicly available any research results which they have funded (see the Joint Statement of Purpose which was issued in 2011 by a host of research funders; it articulated some key governance principles relating to data sharing, etc.) Initiatives such as the Wellcome Trust Case Control Consortium has radically changed the way in which data are accessed and research is funded. See 'Open science versus commercialization: a modern research conflict?' by Caulfield, Joly and Harmon in Genome Medicine (2012). Equally, such publications policies have had to respond to privacy concerns, such that the apparent dichotomised tension between public v. private interests endures. We have argued above that this is unhelpful and overlooks the public interest in robust privacy protection. Equally, policies must take the lead on communicating the message that absolute privacy is neither possible nor desirable in public interest terms. Some degree of risk is entailed in the benefits are to be delivered.

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?

28. 'Big Data' remains a somewhat vague and all-encompassing term which although increasingly referred, to, still lacks a coherent definition. Perhaps a clearer workable definition might be helpful, but it should be noted that it very much depends on who is defining the term. To date, it is largely used from the perspective of science and medical communities to mean large-scale opportunities to generate new knowledge. From the privacy perspective and on a risk-based analysis, it must therefore be accepted also that the

privacy threats might increase. This is not to say that this would be so to an unacceptable level, but the realities must be engaged with. There is a notable tendency in media reporting to equate 'Big Data' with 'Big Brother' and instil fears and insecurities around how data are being used. An easy answer relates to the velocity, variety and volume but even this does not tell us very much without considering who is affected, how and by what or whom. It is probably impossible to answer these questions in advance of the generation of, or linking of, Big Data. But a core objective must be to avoid the conflation of Big Data with, necessarily, Big (Unacceptable) Risk. Governance mechanisms must anticipate concerns and real risks and be seen to respond accordingly, proportionately, and timeously.

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?

29. The Wellcome Trust Case Control Consortium has been a significant development in linking and accessing existing data sources and subsequent sharing of data. This is a model which seeks to liberate data from more closed environments such as cohort studies for free and open sharing and linking of data.

30. We would also point to the Scottish Health Informatics Programme (SHIP), references to which have already been made above. For an accessible public-facing video on the benefits and approaches of SHIP see here:

http://www.scot-ship.ac.uk/public-interest

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

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?

31. An on-going discourse is that of personalised medicine and the potential to discriminate in a positive way to target those most likely to benefit from a particular treatment. The flip side is the fear that more information being available will ultimately allow biomedical data to be used in profiling or more directly to discriminate against individuals whose genetic information is associated with a risk of disease. There is a real paucity of evidence as to whether such concerns have any basis in reality. There is much work to be done in distinguishing what is possible from what is probable.

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?

32. More open mechanisms of access and sharing within the scientific community make more data available without the ability to determine in advance what the uses will be and what preferences and expectations the data subjects to possible uses. It also adds to the amount of data which could potentially be used as a reference dataset, which may be used in reversing anonymity or inferring the traits of individuals in a given population.

33. We found in our work on the Scottish Health Informatics Programme (SHIP) that there were varying degree of a 'culture of caution' within organisations and between organisations with respect to data linkage and sharing for research. Notably, in Scotland at least, the health sector was more comfortable and advanced in the development of governance mechanisms than non-health sectors. Our latest project involves the Farr Institute and seeks to learn lessons around the UK on data linkage for research. We have quickly come to the realisation that no single governance model will work for all, nor is this required. Rather, to facilitate multi-centre collaborations we require system of *mutual recognition of good governance*. Common objectives nonetheless include a commitment to principled and proportionate governance.

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

34. Subject to, and in line, with a researcher's outstanding legal and ethical obligations (as to the data) and public interest, then secondary uses of data should be encouraged when shared with accredited researchers working within a safe environment such as a safe haven. If such sharing of data is ever to really become effective, we need to re-think how we value the different aspects of research; currently we over-value the interpretation of data and under-value the collection of data (in terms of career development, reputation, etc.). If we are to encourage re-use, we must overtly value data collection and curation, and agree on ways to credit collectors when re-users are publishing (i.e.: **acknowledgement** is a key issue). See also discussions above on Open Access requirements which key funders are imposing upon researchers/projects which they fund. Many useful recommendations are to be found in the Royal Society report from 2012 on Science as an Open Enterprise.

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

35. Public opinion has typically demonstrated concerns with use of data by commercial firms for research, even if the research carried out is in the public interest. Particular concerns can arise around any decisions which might affect individuals (e.g. insurance companies) and where excess profit results from research. Transparency and public engagement initiatives could help alleviate concerns with how individuals' data are used by the commercial sector. Such uses should be encouraged when they are advancing the public interest, are subject to strict and transparent controls and especially when they are collaborative with the public sector and/or academic institutions. This having been said, we refer you to our answer above with respect to our own research on attitudes towards

commercial involved and our 2007 publication in Social Science and Medicine. Robust and on-going engagement is crucial to well-designed and effective policy and practice.

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

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?

36. Better access to more comprehensive and reliable data packages on patients by physicians could mean better treatment decisions and better health outcomes. However, it should also be appreciated that under pressure clinicians may now be expected to trawl through more data and have greater knowledge (i.e.: expectations placed on them may be too high given their time constraints). The complex regulatory landscape may provoke a level of uncertainty amongst the medical practice regarding the circumstances in which data should and should not be shared, with a reluctance to share data (even where this is legal and ethical) due to a fear of sanctions. The key will be how data are organised and presented, and this has implications for data stewards.

37. As part of our work on the Scottish Health Informatics Programme (SHIP), we developed an online training and accreditation module for researchers and other involved in data linkage to inform them about their responsibilities and also about the possibilities within existing legal frameworks. This development arose after our initial research showed considered unmet need (and much confusion) about law and regulation in this domain. See further:

http://www.scot-ship.ac.uk/toolkit

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?

38. Public engagement work under SHIP suggest that the public do expect some of their health care data to be shared with other agencies, however opinion varies on *which* agencies/bodies.[15]

39. Public engagement is key to communicating with the public on the beneficial and impactful public interest uses to which health care data will be used by other agencies or bodies. If publics' expectations as to health care data are such that it will *not* be shared with

[15] Aitken, M; Cunningham-Burley, S; Pagliari, C (2011) Public Responses To The Scottish Health Informatics Programme: Preferences And Concerns Around The Use Of Personal Medical Records In Research Journal of Epidemiology and Community Health Volume: 65 Supplement: 1 Pages: A27-A27 DOI: 10.1136/jech.2011.142976a.71 Published: AUG 2011

other agencies or bodies, the health care system must clearly and transparently communicate the public interest case for sharing the data with these other bodies, but also give the individuals the opportunity to opt-out.

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

40. There is the potential for this and that more open access data arrangements would enable individuals who are willing to look to reveal negative outcomes or harmful practices. However, the detection of such issues would perhaps be best left to a dedicated body or bodies who have responsibility and are accountable for carrying out such a function. It would be difficult to justify a loss of privacy protection on the basis that some individuals may be doing something wrong so everybody ought to have access to everything. Note that in law – either under the common law duty of confidence or statutory data protection – there is no absolute guarantee of privacy protection. Notably, disclosure to the appropriate authorities in the public interest to protect the rights and freedoms of others is perfectly permissible and lawful. It is fully accommodated within Article 8(2) of the European Convention on Human Rights, as incorporated into domestic UK law by the Human Rights Act 1998.

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?

41. It would depend upon the type of research, whether the patient would need to be approached for further information, how much of their data would be accessed, and by whom. This possibility supports the importance of open and on-going conversations between health care professionals and patients in all kinds of interaction about the possibility of research uses. It also emphasises the importance of seeking and recording patients' *broad* consent to these possibilities (as opposed to informed consent in each and every instance which is impractical and ethical disproportionate).

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

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?

42. The public interest can be served by both biomedical *and* social sciences and humanities research. By linking biomedical data with other data obtained by social sciences and humanities research, a more holistic perspective can be gained in regards to pressing

societal issues. Subject to appropriate legal and ethical controls, the wider use of biomedical data should be encouraged. This further supports our rejection of a discrete category of biomedical data per se.

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?

43. We reiterate the broad principle-based view that scientifically sound, ethically robust research using (biomedical) data is in the public interest. We suggest that those seeking access to such data on such grounds be required to make a credible case that these criteria are met, for example in an application to an access committee. It is for the applicants to make the case for why the public interest will be advanced through access and use. Such a case can be made by potential users from any sector, albeit that the terms of any case will likely differ depending on whether or not profit is envisaged. Still, as a starting point, regulatory structures should be blind to the public/private distinction is soliciting applications for access. Only in this way can we hope to encourage the broadest possible pursuit of the public interest. Concerns about commerce, should they arise, should be addressed during the scrutiny phase.

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?

44. We do not support a dynamic consent approach on both principled and pragmatic grounds. First, as a matter of principle this re-enforces a highly individualistic (property-like) approach to data and its control which is likely to compromise solidarity interests in data uses for a range of purposes that can benefit both individual and public interests. Pragmatically, we question whether this is the best use of finite research resources to have to design such mechanisms when this will necessarily be at the expense of other research-focused expenditure.

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

45. To allow this re-enforces a property approach that we have argued against above.

Consultation Question 7: What legal and governance mechanisms might support the ethical linking and use of biomedical data?

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?

46. As part of our work on the Scottish Health Informatics Programme (SHIP), we developed a set of Guiding Principles and Best Practices that sits at the heart of the SHIP governance framework. These can be found here:

http://www.scotship.ac.uk/sites/default/files/Reports/Guiding_Principles_and_Best_Practices_221010.pdf

Furthermore, these have been picked up by Scottish Government as part of its sector-wide data linkage initiative, serving as the basis of a public consultation. See further here:

Scottish Government Consultation based heavily on SHIP Principles: http://www.scotland.gov.uk/Publications/2012/03/3260/4 or http://tinyurl.com/nepbmfq

Scottish Government Strategy and Guiding Principles for Data Linkage acknowledging impact of SHIP's research (ISBN: 9781782562047):

http://www.scotland.gov.uk/Publications/2012/11/9015/1 or http://tinyurl.com/nw52myj.

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

47. There are suggestions that biomedical data or rather, data related to health is perceived as to be of a particularly sensitive nature. This is also reflected in the common law duty of confidentiality. This does not necessarily suggest that distinctive arrangements are necessary but rather, that any mechanisms in place should reflect appropriately the sensitive nature of health related data and any particular concerns should be taken into account as part of a risk-based assessment. Any governance arrangements must ensure clarity around data steward responsibilities, transparency of governance frameworks, and accountability (i.e.: monitoring of use and sanctions for mis-use of data). We have argued for these features to be part of a principled proportionate governance mechanisms for data linkage in the heath research context here:

G Laurie and N Sethi, 'Towards Principles-Based Approaches to Governance of Health-Related Research Using Personal Data' (2013) 4(1) European Journal of Risk Regulation 43-57, and

N Sethi and G Laurie, 'Delivering proportionate governance in the era of eHealth: Making linkage and privacy work together' (2013) Medical Law International, doi: 10.1177/0968533213508974.

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?

48. There are potential problems to consent-based approaches which have been discussed in the literature and in practice.[16] The practicalities of obtaining consent, and the level of (and potentially on-going nature of) consent required are particular hurdles for researchers. Beyond this, whether or not withdrawal of consent can be operationalised (i.e. that biomedical data relating to an individual will be removed once consent is withdrawn) is not always something that can be guaranteed. It should also be considered whether withdrawal of consent has implications for the viability and effectiveness of longitudinal repositories in particular; this must be considered carefully. While withdrawal is considered a key factor for trust, it could be argued that if someone is wishing to withdraw from a bank, trust has already been lost and the withdrawal will not restore it; it is a post-facto band aid.

49. We have argued elsewhere for the recognition of the limits of consent as a one-off event and also as a governance mechanism that can address the bulk of concerns associated with data access and use.[17]

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

50. In light of public engagement findings as part of our work on the SHIP initiative, we advocated a governance mechanism that first requires the consent approach to linkage and use to be considered. If researchers consider this route is not appropriate, they must explain and justify why it is in the public interest to depart from it. In this way, the role and value of consent in the governance hierarchy is preserved, while also allowing acknowledgement of its limits in certain cases. We discuss this further in our recent publication here:

N Sethi and G Laurie, 'Delivering proportionate governance in the era of eHealth: Making linkage and privacy work together' (2013) Medical Law International, doi: 10.1177/0968533213508974.

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?

51. Opt-out but with a dedicated public education campaign to raise awareness about how information is being used. This must be subject to obvious practical limitations once data have been used or transferred.

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

52. In SHIP, we have implemented a three-prong approach to principled proportionate governance which is based on mechanisms that support:

[16] See Working Papers No.1 and 2 here: http://www.scot-ship.ac.uk/publications

[17] G Laurie and E Postan, 'Rhetoric or Reality: What is the Legal Status of the Consent Form in Health-related Research?' (2012) Medical Law Review 44pp, doi: 10.1093/medlaw/fws031.

1. **Safe people** (through mechanisms of information governance training and accreditation)
2. **Safe environment** (operating according to established Guiding Principles and Best Practices)
3. **Safe data** (using state-of-the-art linkage mechanisms)

These are described in the SHIP Blueprint, available here:

http://www.scot-ship.ac.uk/sites/default/files/Reports/SHIP_BLUEPRINT_DOCUMENT_final_100712.pdf

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?

Please see answers above.

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

53. Overall a complex and confusing landscape, over-burdensome approvals processes and duplication of approvals processes. The perpetuation of a dichotomy between public and private interests, and an over-reliance on beliefs about what can truly be delivered with respect to effective privacy protection.

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

Please see the Scottish Health Informatics Programme: http://www.scot-ship.ac.uk/

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