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.

amrc
ASSOCIATION OF MEDICAL RESEARCH CHARITIES
Charles Darwin House
12 Roger Street
London WC1N 2JU
Tel: 0207 685 2620
Fax: 0207 685 2621
Email: info@amrc.org.uk
www.amrc.org.uk

Joanna White
Nuffield Council on Bioethics
28 Bedford Square
London
WC1B 3JS

By email: jwhite@nuffieldbioethics.org

15 January 2014

RE: The linking and use of biological and health data

Key points:

- **Data are vital for health research to improve care and save lives.**
- **It is important that people can have confidence that their data are being handled safely and securely.**
- **With their close links to patients, charities are a trusted source of information about sharing data. Many have established or supported recruitment to patient data registries valuable for health care delivery and medical research.**
- **Charities have worked alongside the NHS and public research funders to enable the better use of data in medical research. They have funded improvements in information technology essential to maximising the value of data, built infrastructure to support research and created strategic partnerships to coordinate research and optimise patient benefit.**
- **Medical research needs data from healthy volunteers as well as those affected by conditions. The motives for sharing data may be different between these two groups; ethical considerations may therefore be different and consent models may need a degree of stratification in response.**
- **Consent should have primacy in any regulatory system; a person's decision not to share their personal information, even in anonymised form, should be respected.**
- **Whilst welcoming the current Secretary of State for Health's discretion to allow the public to opt out of allowing their data to be shared, making this a statutory right would both engender public trust and ensure that the principle of consent is more enduring.**
- **There is a need for greater awareness among the public and healthcare professionals of not only the value of their data for research but also the safeguards that are in place for its use. Charities, government, regulators and industry all have a role to play in communicating this.**
- **It is important to communicate when gaining consent that industry are key partners in bringing new medicines to market and like other researchers, they need controlled and secure access to biomedical data.**
- **Regulation and governance needs to be more flexible and transparent, with streamlined access for researchers to speed up the research and development of new treatments.**
- **Regulators should do more to take into account the views of the public and patients, particularly those who have chosen to donate their data for research.**

1. The Association of Medical Research Charities is a membership organisation of the leading medical and health charities funding research in the UK. Working with our members, we aim to support the sector's effectiveness and advance medical research by developing best practice, improving public dialogue about research and science, and influencing government to ensure the best research can go ahead and be translated into new treatments.

2. Medical research charities exist because the public choose to donate their money to support research. In 2012, AMRC members invested over £1.2 billion into health research in the UK. Many medical research charities have patient groups closely allied to them and as such are able to provide a unique perspective, representing the needs of both patients and researchers.

Consultation question 1:
Do biomedical data have special significance?

3. Biomedical data are immensely valuable for researchers trying to understand the causes of ill-health and disease, for the identification of research participants and for the research and development of new medicines or other treatments. All personal information, whether of a biomedical nature or not, has inherent special significance to the individual. When a person chooses to donate their information for use in research, for example through participating in a research study, it can take on new significance, both to the individual, the researcher and society, which stands to benefit. They have participated in order to advance human understanding of health and disease. Their reasons can be manifold: they may wish for there to be better understanding of their own condition in the hope of helping themselves or others; or they may wish for the understanding of general human health and disease to be improved (as is often the case for healthy participants who see a societal good in taking part in research and sharing their data). And of course some people participate in research in return for a financial or other material reward.

4. The vast majority of patients and the public see the importance of research and wish to see their own disease or that of others' eradicated and so give researchers access to their personal information for this purpose. In a survey conducted by YouGov on behalf of the British Heart Foundation, 72% of over 2000 members of the public contacted said they would be happy to share their entire medical records with researchers under certain conditions, such as if the data were anonymised or pseudonymised.[1] And an additional 7% were happy for records to be shared with identifiable elements of the data left in. The huge value of these data for research and the public desire for new cures and treatments and willingness to share means these data also have special significance for researchers. They have a responsibility and obligation to use this gift to gain the greatest insight possible into health and disease. But also to treat it with the respect it deserves.

5. **CASE STUDY:** *Many people whose families have been touched by breast cancer feel compelled to find a way to prevent future generations going through the same ordeal. The Breakthrough Generations Study has enabled more than 113,000 women to be part of a landmark study into the causes of breast cancer. Knowing the causes will be key in helping*

[1] Total sample size was 2072 adults. Fieldwork was undertaken between 18th - 21st May 2012. The survey was carried out online. The figures have been weighted and are representative of all UK adults (aged 18+).

scientists find ways to prevent the disease. Natalie and Plaxy Matthews signed up to be part of the study after losing both their mother and grandmother to breast cancer.

6. *Plaxy says: "Having our mother and grandmother taken from us by this terrible disease means that we want to do all we can to ensure that our daughters grow up in a world free from the fear of breast cancer," continues Plaxy. "The Generations Study is an ambitious and important project and we're proud to be part of it."*

7. *"To prevent breast cancer, the causes of the disease need to be known. Natalie and I hope that our participation in Breakthrough Breast Cancer's Generations Study will help their world-class scientists to discover the causes of breast cancer and ultimately help prevent the disease."*

8. *Launched in 2004, the Study is following the lives of more than 113,000 women for 40 years to pinpoint the causes of breast cancer and costs £1 million per year to run.*

9. Genetic and genomic data, relating to individual genes or the genome as a functional whole, respectively, are not solely about the individual as genes are shared among family members. Information gleaned from analysis of these data can therefore affect others who did not choose to participate in research. This poses challenges for how these data and results arising from their use in research should be used and shared. However, this is not unique to these genetic and genomic data: a father may have high-blood pressure diagnosed whilst taking part in a trial, for example. This information might indicate that his son could also be at risk now or in the future. In many cases however the predictive power of genetics than other diagnostics and can impact on children not yet born, even for multiple generations. These data types therefore deserve special ethical and practical consideration. When deciding how genetic and genomic data are handled it is important to consider the great potential such data hold for medical research, which at the moment is inestimable.

10. **Case study:** *In September 2012, members of Parkinson's UK local groups (people with Parkinson's, their friends, family and carers) came together in 7 locations across the UK to talk about the charity's research work. 94% said that NHS patient data should be made available to researchers. When asked whether they thought it should be available to industry researchers to buy, 50% said no, 30% yes and 20% did not know. Some people questioned how profits from this would be used, suggesting that they should be reinvested into the NHS. They also wanted more information on how the data would be used, by all parties.*

11. **Case study:** *In July 2013, the Wellcome Trust commissioned CM Insight to conduct qualitative research to understand the general public's attitudes to different types of personal data and data linking. The research looked at whether health data are viewed differently from other types of data, and what are the perceived risks and benefits, to the individual and society, of linking different kinds of data for research purposes and other purposes.Overall the results suggest the public does not seem particularly sensitive about who conducts research involving linking of health data, providing the objective is to*

increase knowledge around the causes and cures of ill health. There were however reservations about wider use by commercial organisations.[2]

12. We have followed with interest recent developments that aim to make best use of biomedical data for research (both academic and private) whilst protecting individuals' wishes for confidentiality and protecting against inappropriate use of their data. These include the establishment of Genomics England and the Clinical Practice Research Datalink (CPRD). Using NHS patient data for research is not new – what is new is the scale of the ambition. An ambition which will see an evolution from a cottage industry where researchers mined a specific set of data for a specific research project, into a Ford-like process where the collection and manipulation of these data is automatic, large scale, mechanised and slick. If the proposed scheme is a success then all our medical data will be stored securely in a central repository and made available, in non-identifiable form, for approved researchers to elucidate important health questions. It is essential these organisations put in place robust and transparent governance paired with public awareness-raising campaigns to allow people to feel confident in the safe and secure use of their data.

Consultation question 2:
What are the new privacy issues?

13. Advances in technology raise new challenges for those tasked with collecting, handling, storing, distributing and analysing personal data. As stated in the consultation document to this inquiry, it is becoming increasingly apparent that there are ways to identify individuals even in so-called anonymised datasets. No system can be 100% secure and breaches, often through human error, can happen. It is important that researchers, participants and the wider public are aware of and understand the capabilities of data technology that could affect their confidentiality so that they can make informed decisions. Where anonymity cannot be assured and consent is sought for the use of someone's data, the person affected must be made aware of this. The decision for the individual and for society on whether to share data and to what extent must always come down to an informed balancing of the risks verses the benefits.

14. There are circumstances when use of potentially-identifiable data should be permitted, even when consent cannot be obtained. This may be where the risk to the individual is low and the potential benefit to society is greater. There are legal and regulatory safeguards in place (Section 251 of the NHS Act 2006 and the Health Service (Control of Patient Information) Regulations 2002) to ensure that this is only permitted where this risk:benefit ratio is significantly in favour of benefit to the public and the research worthwhile. It is important that these permissions exist to maintain public trust through a transparent system and allow potentially valuable research to go ahead.

15. Technology is also changing the way people think about and treat their data. Social media enables the sharing of great amounts of personal information, often with varying degrees of awareness on the part of the user. In some cases this has led to a blasé attitude and in others it has increased privacy concerns. These changes in public attitudes impact greatly on research that depends on people's voluntary donation of their personal data. Medical research charities have an important role in advocating to the public the responsible

[2] http://www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_grants/documents/web_document/wtp053205.pdf

sharing and use of personal data for research. But the government, regulators and pharmaceutical industry must also play their part to maintain public support and trust. Charities and industry are increasingly partnering to speed up the development of new treatments for patients. This is increasing awareness among their supporters of the important role of pharmaceutical companies in bringing new drugs to market; this may lead to changes in the public's attitude to industry and growing acceptance of sharing data between sectors.

16. Patients, particularly those with rare conditions, are keen to donate their data to research for reasons already covered above. They are also willing to accept higher risks when taking part in research and can have very different perceptions of risk:benefit ratios than healthy people and regulators. This conscious and understandable acceptance of risk should be taken into account when deciding whether to allow research to go ahead and when obtaining consent. New online platforms such as *PatientsLikeMe* and the *Personal Genome Project* enable patients to share their data on a much greater scale than ever before. While people keen to help in this way should be free to do so, it is crucial for their own protection and the maintenance of public trust for research, that they do so fully informed.

17. **Case study:** *The Welsh Institute for Health and Social Care, University of Glamorgan, supported by Genetic Alliance UK, convened a group of patients with serious and/or rare conditions and family members of someone with a serious and/or rare condition.*[3] *They explored the risks and benefits of hypothetical case studies and heard from a number of expert and advocate witnesses about how the regulatory system currently works, its strengths, and its potential weaknesses. The findings demonstrated that people with serious conditions are willing to take greater risks for the potential cure or improvement of their condition.*

18. **Case study**: *PatientsLikeMe is an online data-sharing platform that allows patients to share their own information and learn from real-world, outcome-based health data. For more information see http://www.patientslikeme.com/about.*

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

Answered in combination with:

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

19. The increasing availability and applications of biomedical data have had a significant impact on the medical research funded by charities. Indeed, many AMRC members have helped to catalyse these developments (and continue to do so) by funding research and development in information technology, funding and building infrastructure needed for advanced research using data, and creating strategic partnerships, including linking the needs of patients, clinicians and researchers. They have done this in collaboration with or complementing the work of the NHS and public and private research funders.

[3] http://www.geneticalliance.org.uk/docs/citizens-jury-report.pdf

20. Medical research charities are trusted sources of information for the public. With their strong patient links, charities have helped to recruit patients to data registries, some of which are directly run by charities themselves, to help support care delivery and medical research. Charities are also active participants in addressing barriers to research and communicating the importance of data to the public. For example, in June 2012 the British Heart Foundation published *Clear and Present Data: how access to our medical records can help life-saving science.*[4] This report identified problems faced by researchers and produced a number of recommendations for the government on how to tackle them. Medical research charities do this because they are driven by a single purpose: to find new and better treatments to improve and save lives.

21. **Case study:** *The Arthritis Research UK Epidemiology Unit is a unique research institution internationally, in terms of its major focus being understanding the epidemiology of the major rheumatic and musculoskeletal disorders. The Unit receives substantial core funding from Arthritis Research UK of approximately £2.7 million. The Unit also receives financial support from The University of Manchester and the major grant receiving bodies such as the Medical Research Council, The Wellcome Trust, Department of Health and other funding agencies. These resources support approximately 100 individuals working on a wide variety of different programmes and projects.*

22. There is great potential in linking data from many different sources to be able to answer new and more complex research questions. There is a need to future-proof consent models to enable linking in ways or on scales that are not currently possible or even conceived. Research is also an internationally-collaborative endeavour and there will likely be many times when data must be shared between different countries. Consent models need to also take this into account, considering that which countries or organisations will need access to the data might not be known at the outset when consent is first sought. This is difficult as people who have gifted their data may have different conceptions of who should be a beneficiary of that gift. It is nonetheless an important barrier to overcome. Charities, with their close links to those affected by ill-health and disease, are keen to remove as many barriers to research as possible whilst maintaining public confidence in the way in which their data are handled, now and in the future.

23. **Case study:** *A trial funded by Cancer Research UK piloted a consent model that permits generic research on surplus biopsy material, and linkage to clinical outcomes enabling further research and cohort identification. Patient acceptance exceeded expectations, with 5393 patients agreeing to participate by the end of September 2012. 96% of the patients approached (range 89-100% by centre) consented to take part in the study. 12% of patients dropped out of the study after consent, mainly due to ineligible tumour type for the study or benign tumour.*

24. **Case study:** *In 1997, an audit of 6,115 facial injuries presented in UK hospitals recorded the types of injury and the events surrounding them. Results showed a strong link between excessive alcohol consumption and serious facial injuries, assaults or road traffic accidents (RTAs). Those aged between 15 and 25 suffered the greatest number of facial injuries.*

[4] http://www.bhf.org.uk/patientdata

25. *A second audit following the same protocol was undertaken by the National Facial and Oral Research Study Centre in 2008. It found alcohol-related RTAs and alcohol-related assaults in the under-16 and 16-25 year old age groups had increased since 1997.*

26. *These audits provide a snapshot of facial injury levels in the UK and the reasons why they occur, allowing healthcare teams to monitor trends and allocate resources accordingly. However, current information governance issues create significant red tape and can prevent clinicians from contacting patients. In this instance, a valuable opportunity to conduct research on treatment outcomes for use in the appraisal of oral and facial surgery was lost. Both audits were funded by the Facial Surgery Research Foundation - Saving Faces.*

27. Linking data also allows patients to be invited to take part in research that is appropriate to them. This is particularly important for patients being treated in hospitals or primary care settings that are not research active in themselves. *Our vision for research in the NHS* calls for all patients to be given these opportunities, including that clinical teams should consider every patient's suitability to take part in research as part of their care.[5] Linked datasets and national information technology systems in the NHS are an efficient way of realising these ambitions. Patients want these opportunities. In 2011 an AMRC-, British Heart Foundation- and Breast Cancer Campaign-funded MORI poll found that 72% of those asked would like to be offered opportunities to be involved in trials of new medicines or treatments if they suffered from a health condition that affects their day-to-day life.[6] And in a separate study, of 1.2 million UK women contacted to take part in the UK Collaborative Trial of Ovarian Cancer Screening, only 32 complained they had been contacted and almost three quarters of those eligible to join the trial attended a recruitment meeting.[7]

28. The importance of making data available and reporting outcomes following the completion of research should also not be forgotten. Proper dissemination is essential if we are to reap the full benefits of developments in data science and information technology. Data generated through research and the findings of that research can be incredibly valuable to other researchers who can build upon them. There are some useful models emerging from both the industry and academic research sectors on how to do this. GlaxoSmithKline for example has established a register of all its clinical trials and the data generated from them so that researchers can apply to be given access. By controlling access in this way, they aim to protect participant confidentiality. Proper dissemination also includes ensuring that those who have contributed their data to research are informed of the findings. This is part of the unwritten moral contract between the researcher and the participant. It is therefore important that effort is made to maintain contact details for donors and participants. This will become increasingly difficult as data linking becomes ever more common and complex and as technology advances allow research to take place over longer time periods. This is an important challenge to consider.

29. Datasets for research, which have appropriate consent and controls to protect confidentiality, are most valuable if they are made available to as many researchers as possible, including researchers in the private pharmaceutical and biotechnology industries. Ensuring efficient and secure access to high-quality datasets will allow the greatest benefit

[5] http://www.amrc.org.uk/publications/our-vision-research-nhs
[6] http://www.ipsos-mori.com/researchpublications/researcharchive/2811/
[7] http://www.ncbi.nlm.nih.gov/pubmed/19008269

to be derived for patients, fulfilling the obligation to the donor to make best use of their gift. There are however challenges as data are shared between different jurisdictions. Medical research is internationally-collaborative and so there is a strong need for a joined-up international approach to data protection, governance and regulation.

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

30. There are many and increasing instances when data being used in a clinical setting to monitor the health of patients or in other aspects of their care are simultaneously being used for medical research. For example, real time monitoring of the effects of medicines, including side-effects, is useful for clinicians but also for researchers who are looking to judge real-world safety and improve the efficacy of medicines. This is especially important as the medical research and regulatory community move towards more adaptive licensing models which allow faster access to medicines where there is a high unmet need and the full effects of the treatment are not fully understood. Real-world monitoring will be essential for this.

31. **CASE STUDY:** *The UK Cystic Fibrosis (CF) Registry, funded and coordinated by the Cystic Fibrosis Trust, has over 10,000 people with CF registered and in 2012 had 90% complete data. This data comes from 59 regional CF centres and 90 associated network clinics. The registry is used to assist in improving care and standards for people with CF by producing national reports on clinical outcomes; providing data for the current Cystic Fibrosis Trust / British Thoracic Society Peer Review process; producing reports for Phase IV pharmacovigilance studies ensuring safety of newly licensed medications for CF; producing data for research grants to improve standards of care and for the production of bandings for the department of Health national mandatory tariff of CF disease severity. The registry is the frontrunner in providing this work and from the annual data recorded by the care centres/clinics the 5 severity bands of CF can be calculated. The UK CF Registry is now key in ensuring patients with Cystic Fibrosis receive "gold" standard care.*

32. Data collected during care and data that are processed and analysed as part of research are both valuable to inform health care commissioning decisions. For commissioners to make the best use of evidence to inform care they need access to both. This should be considered when designing information sharing and consent systems.

33. A core challenge if we are to capitalise on biomedical data collected during routine care is ensuring the quality of the data is compatible with research downstream and that information systems are interoperable for the purposes of linking (able to talk to each other). Furthermore, data should be gathered from all points of delivery of care. This increasingly includes both social and primary care and the interfaces between them. There is also a need for greater consideration of rarer conditions where data are not routinely collected or the quality is too low to conduct meaningful research. The quality of data input by healthcare professionals should be reviewed and improved where necessary to achieve this. Support and training opportunities for health care professionals where needed should provide the skills and demonstrate the value of patient data in providing better care and the value of research opportunities for patients.

34. **Case study:** *Electronic Patient Records represent an important source of data for researchers. However, they are only as useful as the information they contain. When inputting records, GPs allocate specific codes to each condition, for example 'N040.00 Rheumatoid arthritis'. These codes are consistent and easily searchable when analysing large datasets. However, as clinicians are able to enter free-text that is not coded into patient records, for example 'sore hand', an unknown amount of information is invisible to both audit and research. This can lead to levels of disease being underestimated, or a delay in referring patients to specialists. Understanding how doctors record information and how software interfaces influence data input is important to ensure that all potentially valuable data are collected.*

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

35. The boundaries between different types of research are becoming increasingly blurred. Psychosocial and mental health research both contribute to biomedical research and health care; and use datasets derived from them, for example. As with biomedical research, the sharing and use of data outside of biomedical research and health care should be compatible with the original consent obtained. There is understandable concern about linking data obtained from different sources (for example shopping habits with health records) and how this information can be used, and by whom. This must be approached carefully for the health benefits to be realised without crossing a line that people are uncomfortable with regarding how their data may be linked. And, as described above, it is important that consent models are future-proofed to obtain valid consent for all uses that could help in the research and development of new and improved treatments and better healthcare. A joined up and consistent approach to data regulation and governance applicable to all data types, including beyond biomedical data, could be valuable.

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

36. The current opaque regulatory system for research and use of biomedical data has led to inconsistencies in its application and created barriers to research. Researchers need a single and consistent point of contact for obtaining approval to conduct research in order to reduce duplication and waste of time and money. And there is a high need for a more flexible and transparent regulatory system governing medical research which takes into account the views of patients and the public, including those who have donated their data to research.

37. The NHS in England currently uses an opt-out system of consent for anonymised and pseudonymised data use. Whilst we welcome a system that allows people to make their own decision on whether their data are shared, the opportunity to object in the current initiative is provided at the discretion of the Secretary of State for Health and is not enshrined in law. A statutory right for individuals to object to the sharing of their data would engender greater public trust and support for the NHS collecting and making available patient records, which are so valuable for medical research.

38. The process of opting out should also be clear and easy to enact so that the public are given a fair chance to pursue their decision, for example encouraging them to make a decision in a timely manner given that once data is in the Health and Social Care Information Centre there will be no opportunity for patients to ask for their identifiable data to be deleted from the system.

39. The NHS Constitution contains information about how each patient's records will be handled, including that the data within them will be anonymised and used for research. As discussed in previous sections, it is important that people are fully aware of how their data are used and their confidentiality protected, whatever system is in use in their jurisdiction. Public awareness-raising campaigns are an essential part of any regulatory system. The recent Caldicott Information Governance review recognised that "more could be done to increase awareness of the benefits of research, what it entails, and how health and social care information may be used to support it"[8]

40. **Case study:** *SHARE (Scottish Health Research Register) is a partnership between the NHS, government and universities in Scotland set up in 2012 to improve access to and participation in research. This novel initiative established a Register of people interested in participating in health research. It takes about a minute to sign up to the Register online. By signing up to the Register, people give permission for SHARE staff to use the coded data in their various NHS computer records to check whether they might be suitable for health research studies. When their profile matches a given study, SHARE staff contact them to see if they are interested in taking part. A user-friendly website explains the Register's benefits and confidentiality safeguards, and gives case studies on who joined the Register and why.*[9]

41. The motives for taking part in research and sharing data may be different for patients already affected by a condition than those of healthy volunteers. The latter could be considered a different sort of altruism and the motivations may be more akin to blood donation or other areas in a sense of a societal good. In all cases fully-informed consent is crucial but the information required may be different and consent models could also require a stratified approach.

42. As discussed in answer to questions three and four, consent models should be future-proofed and efforts should be made to maintain contact details for data donors. To achieve this it would be reasonable and possibly even beneficial to encourage ongoing two-way contact between research and data donors and other participants. This would allow them to have their desired level of say in how their data are used on an ongoing basis and provide opportunity to introduce new uses if required by researchers. We watch with interest the model being developed by Genomics England that aims to achieve this and would also point to previous success with UK Biobank as a learning opportunity.

[8] Department of Health, 2013, Information: To Share Or Not To Share? The Information Governance Review - https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf

[9] http://www.registerforshare.org/

If you require any further information or detail of issues raised in this response please do not hesitate to contact us.

Yours sincerely,

Sharmila Nebhrajani
chief executive, AMRC
ceoffice@amrc.org.uk