The HeLEX Centre, University of Oxford

Response to the Nuffield Council on Bioethics Consultation

'Give and Take? Human Bodies in Medicine and Research'

From

The HeLEX Centre

(Centre for Health, Law, and Emerging Technologies at Oxford)[1]

Introduction

The HeLEX Centre welcomes this opportunity to comment on the Nuffield Council on Bioethics Consultation on 'Give and Take? Human Bodies in Medicine and Research'. We hope that our comments will be helpful. We provide some general comments, and specific responses to particular questions of the consultation document set out below.

General Comments

The Council has announced this public consultation to collect views on whether more people should be expected to donate organs, eggs and sperm and, if so, how far it is ethical to encourage them to donate. The Council has invited views on best ways to respond to the current demand for organs, sperm, eggs and other human material for use in medical treatment and research.[2]

In this consultation, the Council is interested in a number of questions, including:

1. How far should we as a society go in encouraging or even incentivising people to provide material?
2. What control should a person providing material have over its future use?
3. Can useful comparisons be made with people taking part in 'healthy volunteer' clinical trials where people 'give over' their body for a short time for research purposes?

The Terms of Reference of the Working Party are stated to be as follows:

[1] The HeLEX Centre is an interdisciplinary research centre, based at the Department of Public Health at the University of Oxford. The centre specialises in the investigation of the relationships between law, ethics, and practice in the area of emerging technologies in health. Its main research focus is on genomics and genetics, with developing interests in other disciplines including synthetic biology, nanomedicine, and stem cell research. Research at HeLEX will increase understanding of how the use and impact of innovative technologies in health can be accommodated within existing legal and governance frameworks, and the extent to which such frameworks may need to evolve. The centre's current research focuses on genomics with an emphasis on biobanks, privacy, data-sharing frameworks, global governance, and translational research, http://www.publichealth.ox.ac.uk/helex/

[2] http://www.nuffieldbioethics.org/go/ourwork/humanbody/page_1027.html

1. To identify and consider the ethical, legal and social implications of transactions involving human bodies and bodily material in medical treatment and research.

2. To consider, with reference to different forms and purposes of donation or volunteering, what limits there should be, if any, on the promotion of donation or volunteering, including consideration of:

a. the role of payment and any other form of remuneration or exchange;
b. the role of consent;
c. the question of subsequent use, ownership and control of donated materials;
d. the role of those acting as intermediaries between donors and recipients; and
e. the cultural and international perspectives, including regulatory differences.

3. To draft a Report and make recommendations on these issues.

We question whether this consultation does sufficiently take into account all pertinent factors in addressing the issues at hand. We have identified at least two conceptual gaps at the outset of the consultation document. We discuss these to be as follows:
In its introduction, the consultation document places within its remit any form of bodily material that may be provided 'for the benefit of others' and announces that it seeks to address relevant issues that influence individuals' decisions to 'provide bodily material' 'or volunteer for first in-human research'. The consultation document gives direct reference to the Council's 1995 report on 'Human Tissue: Ethical and Legal Issues'.[3] Back in 1995, this report was considered as the starting point for future policy formation.[4]More recently, it was criticized for its exclusive reliance on altruism as the sole motivation for participation in research, among other reasons.[5] For the purposes of this consultation, it would be extremely productive to examine further the reasons for its scope being bodily material that may be provided for the benefit of others'. The current phrasing excludes other relevant considerations that individuals may bear in mind when becoming involved in research. These include an element of mutual obligation when conceptualising the different ways of volunteering, and other ways of giving, in human research.[6] Examples of such an element include regulatory awareness of the different circumstances that apply in blood donation, organ transplantation, and genetic research; consideration of empirical evidence as to whether individuals agree to participate in research solely for charitable purposes, true acknowledgement of interests other than charitable ones; reflection on the risk of existing altruistic rhetoric being seen as an exploitative device, at the expense of the interests of individuals.[7]

[3] http://www.nuffieldbioethics.org/go/ourwork/humantissue/publicationlist
[4] Grubb, A. 'The Nuffield Council report on human tissue' 1995 Medical Law Review Vol. 3, pp. 235-236.
[5] For example, Kanellopoulou, N., 'Reconsidering Altruism, Introducing Reciprocity and Empowerment in the Governance of Biobanks' in Kaye, J., Stranger, M. (eds), Principles and Practice in Biobank Governance (2009), p. 33-52, investigates modern shifts in the value of human tissue that affect participants' willingness to contribute to research. The author questions whether it is still sustainable to regulate research on the basis that people do not see value nor retain an interest in how 'donated' samples are used.
[6] Levitt, M., Weldon, S., 'A well placed trust? Public perceptions of the governance of DNA databases' 2005 Critical Public Health Vol. 15, No. 4, pp. 311-321.
[77] Kanellopoulou (Reconsidering Altruism 2009) as above; Healy, K., Last Best Gifts: Altruism and the Market for Human Blood and Organs, (2006); Merz, J.F. et al., 'Protecting subjects' interests in genetics research' 2002 American Journal of Human Genetics Vol. 70, No. 4, pp. 965-971; Waldby, C., Mitchell, R., Tissue Economies – Blood, Organs and Cell Lines in Late Capitalism (2006); Dickenson, D., 'Consent, commodification and benefit sharing' 2004 Developing World Bioethics Vol. 4, No. 2, pp. 109-124.

Secondly, no consideration is given in this consultation document to what happens to the related information that is provided alongside human bodily materials for the various purposes stated in this document. Furthermore, no mention is made to information that is derived from their subsequent use, for the various purposes stated in this consultation document. Whilst distinct legal regimes exist for the regulation of human bodily materials on one hand and related information on the other – as a result of which the protection of information has a different treatment in law – the ethical issues raised are relevant when considering people's motivations to get involved in research.[8]

The reason for this omission on what happens to information in addition to body materials is not clear. It would be helpful if the Working Party can explain why it did not seek to include in the scope of this consultation the public views on control of information, alongside those relating to the provision of human bodily materials for research purposes. We believe that the end result of this inquiry would be greatly enhanced if such considerations became part of it.

Thirdly, this consultation document announces in its introduction that it seeks to address relevant issues that influence individuals' decisions to 'provide bodily material' 'or' 'volunteer for first in-human research'. We believe that a certain degree of confusion may be caused by the use of this conjunctive. We clarify our reasoning further in our response to selected specific questions below (under numbered section 2).

Specific Questions

1 Nature of human bodily material and first-in-human trials

Qs 1-4: Human bodily material (especially Q1)

In considering additional types of human bodily material that could raise ethical concerns, it would be useful to include in the list (p12 of consultation document) the types of material provided specifically for the purposes of human biobanking research. For example, in the first bullet-point entry on 'blood', while we appreciate that the mention of relevant purposes is not exhaustive, the purposes that feature in that first bullet-point cluster are a) donated materials that can be used for research if not needed for treatment, and b) materials collected as part of a medical investigation or a clinical trial. Blood is one of the primary types of material provided for biobanking research, and in the case of biobanking for future purposes – such as is the case of the UK Biobank – this is not given because it is not needed for treatment, and it is not as part of medical investigation or a clinical trial. In the interests of clarity, this type of use could be included under 'blood' in the list (p12 of consultation document). A mention is made to biobanking research, and more specifically to the work of the UK Biobank, in p14 of the consultation document. It would be consistent to introduce it as part of the list in p12 instead.

Q5: Participation in first-in-human trials

We remark that the use of the terminology of the 'loan', even in brackets, can be misleading especially to a member of the general public since property rights do not exist for individuals who volunteer in research. A jurisprudential antipathy to property persists in case law in the

UK, with very limited exceptions – that is, an individual may have a property right in a body part for the purposes of the Theft Act 1968 [R v Kelly 1998][9] or for the purposes of an action in negligence or bailment [Yearworth v North Bristol NHS 2009]).[10]

[8] McGuire A. L. et al., 'DNA data sharing: research participants' perspectives' 2008 Genet. Med. Vol. 10, pp. 46-53; Kaye, J. et al, 'Data sharing in genomics: re-shaping scientific practice', 2009 Nature Reviews Genetics Vol.10, No. 5, pp.331-335; Haddow, G., Cunnigham-Burley, S., 'Tokens of Trust or Token Trust? Public Consultation and 'Generation Scotland'' in Greene A. et al (eds), Trust, Health and Illness (2008).

2. Purposes of providing bodily material/volunteering in a trial

Qs 6-8 (especially Q6 and beyond)

We mentioned in our general comments that confusion can ensue by the distinction that the report makes in section 2 on 'providing bodily material/volunteering in a trial'. We find that the way that this section is structured is not clear. In p14, the inclusion of the part on the 'provision of bodily material for research' (especially the bullet-point on 'future and hence unspecified purposes' that include biobanking research) in a section with a heading that refers to 'volunteering in a trial' even partially, is confusing.

Participation in biobanking research is not equivalent to participation in a trial. We appreciate that the Working Party does not intend to equate the two (it possibly seeks to learn lessons from their comparison), but this is not necessarily obvious to the untrained eye. In the interests of clarity, we believe that it would be more intuitive to structure existing section 2 in three separate sections: one discussing 'treatment', one discussing the 'provision of bodily material for research', and one discussing the 'provision of bodily materials for either treatment or research'. Such distinction would further help address the differences in the opening questions featured on the Council's website that introduce this consultation, and mentioned early in our general comments.[11]

3. Ethical values at stake

Qs 9-13

We find that the consultation document could benefit from better articulation of the ethical and social values at stake. For example, further refinement needs to be given to the concepts of 'reciprocity' and 'solidarity':

i. ***Reciprocity*** imposes on one the obligation to return a favour or resource. This obligation does not necessarily require the return of the same favour or resource; in many cases, the return can be in kind as long as it is assessed on a fair and mutual basis.[12] Reciprocity relies on a notion of exchange through which the contribution of both parties is respected – in the context of genetic research this discussion regards the recognition of the role of research participants.[13] Recent scholarship discusses the nature of this notion of exchange not as mere trade but as a continuous engagement between two or more parties, involved in a mutually beneficial relationship.[14]

ii. The concept of reciprocity relates to but differs from the notion of 'mutuality' that is often encountered in the context of sharing of (genetic) risk between family

members, as a way of pooling and spreading all known risks.[15] Mutuality requires that parties are jointly bound as regards the risks and benefits from their interaction and one's obligation of return is contingent on some benefit being received. Reciprocity not only requires that parties are jointly bound as regards the risks and benefits from their interaction but also that an equitable return exists between them to continue their collaboration. Reciprocity considerations provide a more balanced metric with which to evaluate participants' contribution in research.[16]

iii. **Solidarity** alludes to notions of mutual support within a community, as the consultation document comments. The concept can have different meanings[17] and broad historical roots. It centers on the articulation of moral obligations that bind parties who share common interests.

In the context of genetic research for example, it would be useful for the purposes of this inquiry to articulate examples of such interests, both on the part of research volunteers as well as intermediaries, other actors, and stakeholders in medicine and research. This exercise is important because previous notions of 'special moral relationships' and related possible 'moral duties' in research participation have been proposed by advisory bodies in the UK,[18] but have not developed in tandem with mechanisms to recognise research participants' contribution.[19] In the interests of consistency, any opportunities to refine the concept of 'solidarity' in this area would be welcome and could really benefit from a commitment to building frameworks that promote transparent, equitable benefits and obligations for all parties involved.[20] This is especially topical since two of the questions in this section of the consultation document seek views on a 'moral duty' – to provide human bodily material, and to participate in first-in-human trials.

iv. A further definition of the term ***duty*** and its ramifications would be of benefit in this context. Overall, we would like to encourage a shift in the Council's thinking that seems to no longer conflate solidarity with altruism and instead considers the two concepts of solidarity to be connected (see also glossary entries these two terms, in pp. 36-37 of the consultation document). We welcome and would be committed to pursue further conceptual work in this area so as to contribute to the development of robust, sustainable ethical research frameworks in the UK and abroad.

[9] Mason J.K., Laurie J.T., 'Consent or property? Dealing with the body and its parts in the shadow of Bristol and Alder Hey' 2001 Mod Law Rev Vol. 64 No. 5, pp. 710-729.
[10] Hawes, C., 'Property interests in body parts: Yearworth v North Bristol NHS Trust' 2010 Mod Law Rev Vol. 73, No. 1, pp. 130- 140.
[11] http://www.nuffieldbioethics.org/go/ourwork/humanbody/page_1027.html
[12] Kanellopoulou (Reconsidering Altruism 2009), as above.
[13] Knoppers, B., Chadwick, R., 'Human genetic research: emerging trends in ethics' 2005 Nature Reviews Genetics Vol. 6, pp. 75- 79.
[14] Kanellopoulou (Reconsidering Altruism 2009), as above.

v. As far as the definition of ***altruism*** is concerned, we would like to add a concise definition that we have found useful from previous scholarly work that refers to altruistic action as 'an action in the interests of another or the disposition to act in the interests of another'.[21]

[15] Knoppers & Chadwick, as above.
[16] Kanellopoulou (Reconsidering Altruism 2009), as above.
[17] Knoppers & Chadwick, as above.
[18] Human Genetics Commission (UK), Inside Information: Balancing Interests in the Use of Personal Data (2001).
[19] Petersen, A., 'Securing our genetic health: engendering trust in UK Biobank' 2005 Sociology of Health & Illness Vol. 27 No. 2, pp. 271-292.
[20] Capps, B. et al, Access to the UK Biobank Resource: Concepts of the Public Interest and the Public Good (2008).
[21] Birks, P., 'The content of fiduciary obligation' 2000 Israel Law Review, Vol. 34, pp. 3-38.

vi. Similarly, an additional ethical value of 'empowerment' should be included in this table of values. ***Empowerment*** as a research ethics principle places emphasis on the need to recognize the value of individual and group participants in research as proactive contributors and partners in research. For example, in the context of biobanking research, it stipulates the need for balanced evaluation of the shared role of research biobanking participants in the research process. The underlying rationale is the maintenance of an equitable balance in the interaction between researchers and participants and the recognition of their relationship as a relationship based on trust and ongoing collaboration. In offering ways to review and enhance participants' power and involvement in research, the principle of empowerment is inspired by notions of justice and fairness.[22]

4. Responding to demand

Q14: Supply and demand

No tailored response but please refer to our general comments.

Q15: Current regulatory framework

No tailored response but please refer to our general comments.

Qs 16-19: Increasing supply

Please refer to the previous section that discusses the ethical value of reciprocity. For example, in genetic research, the development of mechanisms for benefit sharing should be developed in tandem with a clear articulation of the ethical values involved, as part of rigorous ethical frameworks that also take account social values and empirical evidence from sociological research. These ethical values include reciprocity and solidarity, in a social context of growing unease with the altruistic paradigm, and the increasing emergence of equitable governance models. It is anticipated that the application of these ethical values in each case will largely depend on each particular context and on the needs

of the relevant participants' and researchers' communities. It is therefore essential that the frameworks to be developed are flexible, adaptive, and responsive to participants' needs and expectations in ways that secure and increase trust in their continuous involvement in research.

Q20: Alternatives to increasing supply

No comment.

5. The role of consent

Qs 21-22: Valid consent

In this section, it would be useful if the role of consent can be explained further especially as regards its lack of ability to provide continuous control on behalf of the participant over materials given to research. This would help explain why considerations of control have become so pertinent within literature and policy discourses on regulating medicine and research.

For example, in the context of genetic research, scepticism has been expressed on the adequacy of consent to address continuous interests of participants in controlling the use of samples and information that they provide for research purposes. This criticism refers to the logic of disempowerment that is

imposed by the traditional view of consent as a merely informational process. Critics view sole reliance on consent as a device that allows the entrenchment of power distribution in the relationship between researchers and participants, fails to make the latter less visible, and frames their relationship in unequal terms. In this view, participants are being denied a vital role in controlling the use of research materials, resources, and benefits while consent becomes a slim legitimisation device in the absence of broader visions on research governance.[23]

In an era of increasing economic and commercial value of human tissue, concerns about entrenched inequalities in the relationship between participants and researchers, obtain new significance. These concerns are manifest in scholarly attention on the question whether research participants should be provided with information about commercialisation when considering getting involved in research, or whether they should be allowed to seek a direct or indirect benefit from it, either for themselves or on behalf of their family or broader community. This issue was debated among stakeholder groups and public consultations in UK where it was revealed that prospective participants wanted to be informed of the financial and commercial aspects of biomedical research.[24] It continues to attract attention due to policy concerns on how the prospect of commercialisation affects the decision to participate in research.[25]

[22] Kanellopoulou (Reconsidering Altruism 2009), as above.

Q23: Consent for future unknown ('secondary') uses of bodily material

We refer you to our comments under the previous question.
In addition, to the extent that this consultation were to include issues relevant to control of information provided in research, it would be useful to explain the circumstances in which exemptions from consent and re-consent provisions may apply for research purposes.[26]

Q24: Role of families: living donation
No comment.

Q25: Role of families: donation after death
No comment; HeLEX researchers are developing an interest in the legal, social, and ethical questions raised in this area.

6. Ownership and control

Qs 26-28: Property rights
Q29: *Control*

As regards conceptual issues about 'control', in existing frameworks, the logic of 'disempowerment' that we referred to earlier in our response to section 5 of this consultation document on consent, is nurtured by enduring assumptions of altruistic surrender in research. These are exemplified in the recommendations of the Medical Research Council Working Group on the use of human biological samples in research, that 'donated material' is to be construed as a 'gift', in the sense of a free and voluntary transfer with no expectation of return.[27] This policy model sees the transfer of samples solely as a question of 'altruism', an approach which erroneously imports the blood donation paradigm to the realm of genetic research where no same circumstances apply; it relies on the false premise that potential research participants act exclusively out of charitable inclination and denies other interests that research participants may have; arguably, it becomes a dangerous rhetoric that invites exploitation.

This approach reinforces a significant paradox because in law, a gift presupposes an underlying property right.[28] To the extent that existing guidance stipulates that 'any proprietary rights that the donor might have in their tissue would be transferred with the control over the use of the tissue to the recipient of the gift' and that [the donor] 'surrenders all interests', the question is left open. The current legal position implies that property interests exist and this is awkward because when debating who has control over the transfer and use of research material, one needs to know what rights can be asserted, by whom and to what extent.

[23] Laurie, G.T., Genetic Privacy: A Challenge to Medico-Legal Norms (2002).
[24] Shickle, D. et al, Public Attitudes to Participating in UK Biobank: A Public Consultation on Issues Relating to Feedback, Consent, Withdrawal and Access (2001).
[25] Kanellopoulou, N., 'Reciprocity, Trust and Public Interest in Research Biobanking: in Search for a Balance' in Lenk, C. et al, (eds), Human Tissue Research - A Discussion of the Ethical and Legal Challenges from a European Perspective (In Press, Forthcoming 2011), pp. 197-218.
[26] Curren et al, 'Identifiability, Genomics and UK Data Protection Law' 2010 European Journal of Health Law Vol. 17, No. 4, pp.329-344 (In Press).

By leaving this issue open, the tension about whether participants can attain some degree of control in research is unresolved in existing UK frameworks. Current guidance does not resolve this problem and could cause great unease towards participation, especially on a long-term basis. For example, in social empirical research from Generation Scotland, the ELSI (ethical, legal, social issues) research team considered the language of 'property' and 'ownership' that was used by publics as metaphors for 'control' and as part of efforts to minimise the effects of private profit on recruitment.[29] We believe that it is important to build mechanisms premised not necessarily on whether participants who agree to give biological material for research purposes can have property rights over samples but, mainly, whether, and how, better control can be secured for participants over the use of samples, as well as possible other claims such as time, effort, and resources that they contribute to research. These would include claims for the return or destruction of materials, should that be possible.[30]

7. Any other issues (Q30)

We refer you to our earlier discussion in the general comments of our response to this consultation document. It is not clear to us why the relationship between tissue samples and related data is not explored in this consultation. We find that for the purposes of an ethical inquiry into giving and taking human bodies in medicine and research, this relationship would be of great relevance for the study of individual and collective motivations for participation. We also find that the differentiated legal questions that are raised by the dichotomy between samples and data, is of ethical relevance. To scientific researchers, the data matter a great deal. More research is needed to investigate participants' attitudes and views about control of information in the context of research. We consider that its absence is, at least, a missed opportunity to address issues relating to the provision of bodily materials and information for the purposes of research on a joint and well-structured basis.

[27] Medical Research Council (MRC) Working Group on Human Tissue and Biological Samples, Human Tissue and Biological Samples for Use in Research (2001).
[28] Laurie, as above.
[29] Haddow, G. et al, 'Tackling community concerns about commercialisation and genetic research: a modest interdisciplinary proposal' 2006 Social Science & Medicine Vol. 64, pp. 272-282.
[30] Kanellopoulou (Reciprocity, Trust and Public Interest 2011), as above.

Glossary

i. For some terms such as **'reciprocity', 'solidarity', 'altruism, 'duty'**, we refer to our previous response to the questions featuring in section 3 of the consultation document.
ii. In addition, we suggest a few further terms are added, such as 'biobanking' since it is more nuanced than what applies in the work of the UK Biobank.
iii. The entry on the 'gift' on the other hand would benefit from an expansion that explains the differences between 'free gift' and 'conditional gift'. This distinction is important especially in the light of recent scholarly work as well as empirical findings that reveal the desire for models of mutual exchange in research participation, as mentioned earlier. According to this distinction, a free

(unconditional) gift can be defined as ‘a gratuitous transfer with not expectation of return’. A conditional gift involves the ‘exchange of reciprocal returns implied by ongoing collaborative interaction and dynamic relations between mutually engaged parties’.[31]

iv. An entry to explain the notion of ‘bailment’ could be included since the glossary discusses the recent case law under the entry on ‘no property rule’ (p34).

v. If considerations of what happens to information that is given for research purposes alongside bodily materials were to be adopted by this inquiry, a new entry on types of ‘data’ or ‘information’ should be added in this glossary. We refer you to earlier comments as part of our general comments for further details.

END OF RESPONSE

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[31] Kanellopoulou (Reconsidering Altruism 2009), as above.