Institution: UNIVERSITY OF BIRMINGHAM

Unit of Assessment: D32 Philosophy

Title of case study: Shaping the Ethics and Governance of UK Biobank and Genetic Research Practices

1. Summary of the impact (indicative maximum 100 words)

Widdows has shaped policy-making in areas of genetic ethics and especially biobanking. She has had impact:

- As a full member of the Ethics and Governance Council (EGC) of UK Biobank (UKB)
- As a key member of the IP and Access Sub-Group of the EGC
- As a keynote speaker at the 2013 World Medical Association Conference feeding into the redrafting of the Declaration of Helsinki (the code governing research globally)

In these arenas her work on consent, trust and genetic governance has shaped understandings of genetic ethics, which has created new policy:

- Nationally in the development of the policies and processes of UKB (especially with regard to understandings of consent and trust)
- Internationally, as the processes and lessons of UKB are taken up by other biobanks – demonstrated by the interest in UKB as the first of its kind from international consortia (such as the P3G - Public Population Project in Genetics).
- Internationally, in her impact on the revision of the Declaration of Helsinki in the explicit mention of biobanks in the current draft.

2. Underpinning research (indicative maximum 500 words)

Widdows' research on genetic ethics and governance, especially biobanking, began in 2000. It includes a monograph, a co-edited collection and a journal special issue, and over ten single and co-authored journal articles and book chapters. The impact of her research is global as biobanks are being developed nationally and regionally, and new and appropriate methods of ethics and governance for genetic data and biobanks are urgent necessities (informed consent is ineffective for biobanking ethics and governance).

Widdows' research begins with issues of genetic ethics, property and the body generally (from 2000 onwards) and develops a more focused concern for the emerging phenomenon of biobanking and population genetics (from around 2005 and continuing). The research was carried out through individual research and production of papers and chapters – highlighting the inadequacy of current ethical frameworks to address the issues of the genetic era, particularly those which are emerging in biobanking – as well as in collaborative projects. The key collaborative research emerged from two EC-funded projects (details below). Widdows was PI of the first project, PropEur, which focused on alternative models of governance, with a focus on the genome, then Co-I on the second project, Tiss.EU, responsible for the theme of 'biobanking'. Both projects involved stakeholder groups and spanned the theory, policy and practice spectrum. Participants in the project workshops included academics from many disciplines as well as policy-makers, members of NGOs and activists in order to ensure that recommendations and conclusions were as relevant and practical as possible. Appropriate ethics for biobanks, and for genetic data, is a focus throughout this body of work and in the latest publication *The Connected Self* (see R1 below).

Research findings:

- that current frameworks of ethics and governance are inadequate in the genetic era, as are current 'gold-standard' practices of informed consent and confidentiality.
- that while problematic in general in genetic ethics, consent and confidentiality are particularly problematic when it comes to biobanking. This is for two main reasons: first, consent is 'one-off', and cannot address the future-orientated and long-term nature of biobanks; second, consent can never meet the criteria to count as 'informed' (as required by policy documents such as the *Declaration of Helsinki*) as at the time of consent it is not known what research will be undertaken using the participants' samples and data.
- that alternative frameworks such as the 'Trust' model (being put into practice for the first time in UKB), should be trialed, tested, and amended as possible alternatives to informed consent.
- that to understand why it is difficult to introduce new frameworks one must understand the

dominance of the 'choice model' (the reliance on the practice of consent) and the 'fear of paternalism'.

This research speaks to a current fault-line in contemporary public ethics, that of how to balance individual rights against public goods, for instance in the security debate (civil liberties v. security) and the environmental debate (future generations and sustainability v. individual freedom). This research questions these dichotomies and suggests that if one uses alternative frameworks, such as trust, then there is less conflict between individual rights and common goods.

All this work was conducted while Widdows was a full time member of staff at Birmingham University (she took up a post in 2000 as a Research Fellow, became a lecturer in 2003, as SL in 2005 and a Professor in 2009). Other Birmingham staff were post-doctoral research fellows (details below).

3. References to the research (indicative maximum of six references)

R1. Widdows H *The Connected self: The Ethics and Governance of the Genetic Individual* CUP (2013) – submitted to 2014 REF.
R2. Widdows H and Cordell (eds.) 'Ethics of Biobanking', Special Issue of *Health Care Analysis*. Vol. 19, No. 3, September 2011
R3. Widdows H and Cordell S 'Why communities and their goods matter: Illustrated with the example of biobanks', *Public Health Ethics*, 2011, 4 (1), pp 14-25
R4. Widdows H 'Localised past, globalised future: Towards an effective bioethical framework using examples from population genetics and medical tourism' *Bioethics,* 2011, 25, 2, pp 83-9
R5. Widdows, H 'Between the individual and the community: The impact of genetics on ethical models' *New Genetics and Society*, 2009, 28 (2), pp.173-188
R6. Widdows, H, Mullen C and Wickins-Drazilova, D *Property Regulation in European Science, Ethics and Law: Conference DVD and Survey*, EU Project Publication, 2006

The quality of outputs is shown by the number of peer-reviewed journal articles and the inclusion of leading scholars in the field of bioethics who contributed to the edited collection journal special issue (listed, R2). R6 contains part of the deliverables of the PropEur project, and a CUP edited collection (*The Governance of Genetic Information*) was a further output. R2 and R3 (amongst others) were connected to the Tiss.EU project. Taken as a body of work on genetic ethics and governance, and biobanking in particular, the research underpins Widdows' work on the EGC. The latest work (R1) draws together the academic work and the practical experience of policy making to propose a new ethical framework.

Grants:

TISS.EU (Evaluation of Legislation and Related Guidelines on the Procurement, Storage and Transfer of Human Tissues and Cells in the European Union – an Evidence-Based Impact Analysis)

EC-funded, (March 2008 – 2011). Co-I. Lead of 'biobanking theme'. Employed one post-doctoral research fellow, Dr S. Cordell. Payment to Birmingham €59 765

PropEur (Property Regulation in European Science, Ethics and Law)

EC-funded under the Science in Society programme (Jan 2004 – Jan 2007).
PI with two post-doctoral research fellows, Dr C. Mullen and D. Wickins-Drazilova. Total €780 000.

4. Details of the impact (indicative maximum 750 words)

The impact of Widdows's research is most clearly evident in her appointment and work on the EGC of UKB (2007-2013). UKB is a 30-year epidemiological study building the world's largest information and material resource in its area and has recruited half a million UK citizens (c.2% of the 40-69 eligible age group).UKB's funders include the Wellcome trust, the Medical Research Council (MRC), the Department of Health (DoH), the Scottish Government, the Northwest Regional Development Agency, Welsh Assembly Government and the British Heart Foundation. UKB is the first of its size and type and its significance is attested to by the media coverage it has received. Over 20 features by the BBC and features in most broadsheets, including *The Guardian, The Financial Times, Nature* and *New Scientist*. (Further details at: http://www.ukbiobank.ac.uk/news-releases/). It is the first biobank of its type to abandon informed consent and accordingly UKB is developing new forms of governance which are being adopted globally and as a member of the

EGC Widdows has **made major contributions to the development of the policy and practice of UKB and in the ethical practices adopted by UKB**.

As a member of the EGC Widdows has **fed directly into the policy development of UKB**. The EGC is not a 'policy commission' or an academic body or thinktank, but an independent body designed to evolve new ethics and governance appropriate to the new structures developed by UKB. It is demanding with at least 4 full council meetings a year and numerous sub-group meetings and public meetings. Widdows was selected as a member of the ECG because of her expertise and research track record in the area of genetic ethics and governance and was interviewed by representatives from the DoH, the Chair of the MRC and the Chair of the Wellcome Trust. Widdows was appointed via a rigorous selection process over many more senior academics, precisely because of her research on genetic ethics, particularly on rethinking consent, and her interest in the public good; and these matters were discussed in the meeting (research in the PropEur project, and particularly R1, R2, R4 & R5). Members usually serve for a 3 or 4 year period, but Widdows was asked to extend her membership given her pivotal role in the development of the UKB's access policies.

Widdows has had impact in the following ways:

- In the **critique of informed consent for biobanking and genetic research in general**;
- In **policy recognition that standard ethical procedures fail in biobanking**;
- In **development of new ethical models**;
- In **promoting the public good as an ethical justification**;
- In **making the public good and public interest key ethical criteria**.

As explained in section 2, informed consent is not appropriate for biobanks. Widdows' critique and her work on new forms of governance (particularly in the ProEur project) contributed to her appointment to the EGC. Widdows has had distinctive impact **in showing UKB the implications of having broad consent rather than informed consent** (see [2] - publicly available minutes from meetings 18, 20 and 21). This recognition that informed consent is not appropriate for biobanking was the reason she was invited to be the UK representative and keynote speaker at the World Medical Association 'Expert Conference on the revision of the Declaration of Helsinki' (Tokyo, 2013). This Declaration is the code that governs research globally and sets ethical standards against which all researchers are judged. Widdows gave the keynote address to an audience which included the international Chair of the World Medical Association and chairs of all the national medical associations as well as significant policy lobbyists (including government representatives from Japan and US) and lobbyists from Pharmaceutical companies. She was invited to speak *precisely* because her work on revising consent and genetics (especially with regard to biobanks) is setting world agendas. **In the recent draft version of the Declaration of Helsinki (now released for consultation, see [3]) biobanks are explicitly mentioned for the first time.** The suggested revision recognises Prof. Widdows' claim that these are "exceptional situations where consent would be impossible or impractical" (Clause 32 of the current consultation document). In addition to having impact in ensuring the failure of informed consent is recognised she has had **impact on the development of new ethical models** which do not rely on informed consent, such as that adopted by UKB. Her impact in the development of these in UKB, and her insistence that UKB continue to consider alternative models such as benefit- and/or profit-sharing can be seen in the minutes of the committee (see [2] and minutes from meetings 16 and 26).

Crucial to the new governance model adopted by UKB is the **foregrounding of public good** and the role this plays as an ethical criterion when informed consent is not used. Widdows' role, as key stakeholders in the process have attested, has been pivotal in ensuring that UKB understands the extent of the public good requirement of the biobank's aim, namely that all research must be demonstrably in the public interest and that this is ascertained before access is granted (see [7] and [8]). Shown in minutes from meetings 14, 20, 21, 24, 26, 27, 28, 29 and 30 ([2]). This **impact is shown in the final access policy and processes** which require that public good criteria are met for access to be granted. Widdows' work in its development are shown in minutes from meetings 14, 19, 20, 21, 24, 26, 27, 28, 29 and 30.

Further evidence for all this impact can be attained from the respective Chairs and secretary. For instance, one former Chair of ECG states, “had she not been so relentlessly insistent about the responsibilities of both the EGC and UKB, as trustees for the interests of participants as well as being stewards for the public interest, **it is unlikely that the resulting Protocol would have been as explicit as it is in embedding these interests**”. Likewise the Secretary states, “It was Heather, with full backing of the access subgroup, that proposed an extension to this exception to include Intellectual Property Rights that are being used to restrict access to health-care unreasonably. **The proposed extension has been adopted by UK Biobank**” and “I believe that through Heather’s input the ‘public interest’ features more prominently in the access procedures than it would otherwise have done”.

Taken together Widdows has shaped policy-making both nationally and internationally:

- As a key member of the IP and Access Sub-Group of the EGC
- As a keynote speaker 2013 World Medical Association Conference feeding into the redrafting of the Declaration of Helsinki (the code governing research globally)

In these arenas her work on consent, trust and genetic governance has shaped understandings of genetic ethics, which has created new policy:

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- Internationally, in her impact on the revision of the Declaration of Helsinki in the explicit mention of biobanks in the current draft.

5. Sources to corroborate the impact (indicative maximum of 10 references)

[1]. UKB (http://www.ukbiobank.ac.uk) and the EGC (www.egcukbiobank.org.uk) websites confirm the remit, membership and activities of the Council.

[2]. EGC minutes (public): http://www.egcukbiobank.org.uk/meetingsandreports/index.html (Individuals are not specified in these but the themes of Widdows’ research and her areas of particular concern and expertise are clearly identifiable in Council discussions and in the recommendations to UKB. The identified EGC meetings, listed in section 4, show particularly clearly Widdows’ distinctive contribution and annotated versions can be provided on request and confirmation from the secretary can be attained.

[3]. http://www.wma.net/en/20activities/10ethics/10helsinki/15publicconsult/DoH-draft-for-public-consultation_annotated.pdf).

[4]. ‘Top 6’ document. This document was drawn up by the EGC to detail the Council’s main concerns – including those of the limits of broad consent and the trust model and the public good criteria. The Council Chairs and Secretary are willing to attest to Widdows’ significant and distinctive contribution and provide this if needed.

[5]. ‘UK Biobank Ethics and Governance Council statement’ in response to the public consultation (public): http://www.egcukbiobank.org.uk/assets/wtvm051562.pdf Again emphasizes public good.

Factual statements provided by:

[6]. Secretary of Ethics and Governance Council

[7]. Chair of Ethics and Governance Council (from 2011)