HTA

NHS
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Consent to use human tissue and linked health data in health research

A Public Dialogue for Health Research Authority and Human Tissue Authority

Ipsos

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Executive Summary

In May 2017, Ipsos MORI was commissioned by the Health Research Authority (HRA) and the Human Tissue Authority (HTA) to undertake a public dialogue to explore views of consent to use patient data linked to human tissue in health research. The dialogue findings will inform new HRA and HTA guidance for consent procedures that will maintain public trust, support informed consent, and facilitate better health research.

The public's starting points

In order to understand the public's aspirations for and concerns about the linking of tissue samples to health data, we must first understand their start points.

Understanding of health research

Participants thought that health research is invariably done under the auspices of the NHS. They have limited knowledge of other actors involved, meaning that they assume that all data and tissue is handled with a duty of care, is for non-profit, and that there is accountability and safeguards in place. There is therefore an implicit trust that this process is happening now.

As they heard from specialists about health research and its intended impact, participants were very supportive of it both in principle and when thinking about their personal stake in research as donors and tax-payers.

Understanding of health data and tissue donation

There was limited knowledge of the value of health data in medical research. Participants starting point was that researchers would be focussed on individual health records, rather than looking for trends in a dataset. They didn't understand how statistical data might be used, or how a hypothesis is built and tested in scientific research generally. Participants were more concerned about their own identifiability than the process of some research (using aggregate data) would warrant.

Participants conflated tissue donation with blood or organ donation. Once this was explained, participants said they would be more inclined to donate, as they would prefer their excess sample used to benefit medical research, rather than for it to be wasted.

The process from tissue donation to research study

Few participants had heard of biobanks before, but there was a great deal of interest in what purpose they serve, and how they operate. Many were surprised that consent is needed at all for the donation, storage, and usage of human tissue samples. They acknowledged the integral role biobanks have in facilitating health research and were keen to support such research and biobank sustainability.

Many assumed there was more linking of human tissue and health data than currently exists. After being shown the video from a Biobank representative and MedConfidential, participants were satisfied that specialists together with "lay-experts" ought to make the decision but also because they worried the public might make a decision that would hinder research.

Overall participants were supportive of research being undertaken with their tissue and data. They therefore wanted a clear and robust consent process to ensure that research can continue and avoid donated tissue being wasted.

Common reactions to broad and hybrid consent forms

Participants' most common red lines were no access for commercial companies like insurance companies or marketing companies using data to sell a product. There were some who did not want pharmaceutical companies to have access to their data, but after their role in research was explained, almost all felt less strongly about this. Some participants also had red lines around the types of research they objected to – there were a few mentions of animal research but they didn't know what this would look like. Some added open-ended consent and tissue being accessed by researchers outside of the UK.

As a result, the idea of choosing to consent to certain things but not others (e.g. some uses like animal research and / or users like commercial companies) seemed to appeal initially, but after thinking this through participants agreed that it might turn out to be just more complex information to assimilate. Moreover, after speaking with researchers and representatives from biobanks, they realised that choosing some uses could hinder the health research their donation was supposed to support. As a result, they recognised they would be opting out in an uninformed way, given they didn't understand the implications for healthcare and as a result most felt less strongly about having absolute red lines, and instead called for the following reassurances.

Informed consent vs. information overload

Given the key concerns outlined above, participants called for more transparency about the process and the safeguards in place, however the tension remained in terms of giving people more information which they might not digest and the need for informed consent. There are six key tests which may help the HRA and HTA respond to this challenge:

1. Who can access tissue and data – this would entail providing examples of the different types of organisations / individuals that can access the research findings, how likely this would be and whether there are any associated risks with such access e.g. detected conditions affecting a donor's lifestyle.
2. Data- de-identification – information should make it clear what de-identifying means, making it clear that only de-identified data will be shared with researchers, and explain both the interest in aggregated and individual level health data.

3. How will donated tissue and data be used – information should make it clear the different types of research the tissue and data can be used in; as it is not always possible to be exact the public called for some direction in terms of listing the possibilities of things which might be found out.
4. Who can access the findings at an individual level – information should make it clear all parties which could access the research findings at an individual donor level and the likelihood of this changing in the future.
5. How will the donor be protected? – as genetic data was seen as more personal and sensitive, there was the perception of a greater risk of identification, and more opportunities for the data to be looked at, the role of safeguards took on more prominence. The public want independent scrutiny of the entire process, with published information about the decisions taken by bodies who do this.
6. Sharing the research findings – participants understood that it would be difficult to feedback research study results to the participants that supplied their tissue and data but thought that it would be feasible for the study results to be made available by Biobanks / Researchers which participants could access.

Dynamic consent

There was a great deal of interest in the concept of dynamic consent[1] when it was introduced by dialogue facilitators. The technology was viewed as a way to gain greater control of consent, the provision of feedback on the use of their tissue and potentially its impact was seen as a real plus, and it removed the perceived pressure of having to make a consent decision when in a stressful situation i.e. prior to a biopsy (beyond consent for the storage of tissue).

However, as discussions with other participants as well as specialists progressed, participants cooled on the idea.

They questioned whether they had the capacity to actually make sensible, informed decisions given that research projects are very technical and complex. They saw fewer projects going ahead as a real problem, which undermined their desire to support medical research. Similarly, others were worried that donors would select cautious settings on the basis of a misunderstanding of linked data usage.

Overall, participants thought the ideal would be both online and face-to-face due to concerns about a "digital divide" so that people with lower digital-literacy were not excluded. There was also a feeling that it should be possible to trace where samples have gone. It seemed this desire for feedback was based on an underlying need for transparency to go both ways. On balance participants felt that although dynamic consent offered a range of benefits, they did not want to engage with a more complex consent process. The priority for the HRA and HTA points towards getting broad consent right as this is seen as less demanding for both the donor and researcher.

[1] A dynamic approach can complement face-to-face consent, allowing a donor the ability to tailor their consent permissions after they have donated and consented.

Acknowledgements

This project was co-funded by the Health Research Authority (HRA) and the Human Tissue Authority (HTA), and by the Sciencewise programme[2]. The authors would like to thank the HRA and HTA for their support and advice in delivering this research and the HRA/HTA's appointed Oversight Group for their input during the scoping stage.

We would also like to thank all the public participants, specialists and OG members who attended the dialogue events and were willing to discuss their views of tissue and data linkage in biomedical research.

[2] Sciencewise is funded by the Department for Business, Enterprise, Innovation and Skills (BEIS). The Sciencewise programme aims to improve policy making involving science and technology across Government by increasing the effectiveness with which public dialogue is used, and encouraging its wider use where appropriate to ensure public views are considered as part of the evidence base. It provides a wide range of information, advice, guidance and support services aimed at policy makers and all the different stakeholders involved in science and technology policy making, including the public. Sciencewise also provides co-funding to Government departments and agencies to develop and commission public dialogue activities.

Foreword

It feels particularly appropriate to be talking to the public about their view of data and research in the year that the UK celebrates 70 years of the National Health Service. Few other institutions are so intrinsically built by public contributions; for all the deserved praise for the work of doctors and nurses, the advances and great successes the NHS has made and had are founded on the contributions of everyone who made research possible.

Included on that list are those who have donated tissue and data to biobanks. Biobanks have a crucial role in health research; by providing access to crucial tissue and blood samples, DNA, and data, they are supporting research that improves our understanding of health and disease.

Despite the crucial role of biobanks, however, the value of their stored tissue diminishes when it cannot be linked to patient health data. This gap between current and potential performance is the motivation behind the Health Research Authority (HRA) and the Human Tissue Authority (HTA) working together on this project, supported by Sciencewise and The Department for Business, Energy, and Industrial Strategy (BEIS). We wanted to better understand the public's awareness of the importance of donated tissue being linked to patient health data, and to learn what reassurances the public may need in order to provide their consent.

It was reassuring that, from the start, participants clearly placed a strong value on health research, appreciating its contribution to improving our collective understanding of diseases. However, it was clear too that their understanding of health research remains limited, particularly of research beyond the NHS, and how the public and private sectors work together. This reflected the results of previous work, notably the HRA and National Institute for Health Research's (NIHR) public perceptions research published earlier this year.

In that context, it's no surprise that understanding of the value of health data in research was low, and so too was awareness of how biobanks and the wider system operated. Many participants were surprised that consent was needed at all for the donation, storage, and use of human tissue samples; they assumed that greater linking of tissue and data already existed. Once aware of the current situation, participants were supportive overall of looking at how consent could ensure donated tissue wasn't wasted.

Anyone familiar with health research will understand that consent is not a straightforward concept. Participants recognised the tension between patients being properly informed and the danger of giving people more information than they might easily digest. They identified some important aspects to be addressed, notably the need to spell out that consent must consider future uses of data rather than simply a snapshot of existing data. The consent forms created by Genomics England were well regarded in the focus groups, and can be used as exemplars of good practice for future work on consent.

The concept of dynamic consent was also discussed, with an acknowledgement that they risk creating overly complex systems that would create excessive demands on people's time.

It is clear that consent is an evolving area, and the participants were quick to identify this. People's attitudes to how their personal data is used and shared are changing, and aspects such as the General Data Protection Regulation (GDPR) and the national opt out (offering patients in England the opportunity to choose not to have their data used for planning and research purposes) bring further change. There is a clear challenge around how to future proof consent in an uncertain world.

What is not uncertain is that the dialogue we had with participants in this research project has identified a need for clarity on the uses of tissue and data, and the requirement to provide a straightforward and accessible consent process. That work falls to us, as the relevant authorities, to address. We will be bringing together key voices in this field later this year, with a view to creating new guidance on linking patient data with donated tissue for research, and also developing good practice standards for access committees.

Allan Marriott-Smith, CEO
Human Tissue Authority

Teresa Allen, Interim, CEO
Health Research Authority

1 Introduction

In May 2017, Ipsos MORI was commissioned by the Health Research Authority (HRA) and the Human Tissue Authority (HTA) to undertake a public dialogue to explore views of consent to use patient data linked to human tissue in health research. The dialogue findings will inform new HRA and HTA guidance for consent procedures that will maintain public trust, support informed consent, and facilitate better health research.

1.1 Background to the research

Biomedical researchers want access to the human tissue samples held by biobanks[3] and to link it with health data. Samples linked with health data can better support detection of the biological, genetic or behavioural factors which influence health outcomes and as result allow researchers to understand how diseases develop. Tissue in biobanks is currently underused however, as it can be unclear whether the necessary consent permissions are in place to allow the linking of human tissue and health data. This dialogue has looked at what the public think constitutes informed consent and whether current consent forms need to change in order to achieve this.

Alongside the traditional, face-to-face way of seeking consent using paper-based forms, dynamic consent provides opportunities for donors to give ongoing consent for their tissue and data to be used for specific purposes on an ongoing basis. Another aspect of this dialogue was to examine whether current consent is suited to emerging technological developments like genome sequencing[4], and whether this can be future-proofed given the aspiration to roll-out more widely.

Ultimately, HRA and HTA are looking to augment their current guidance to ensure that the best consent procedures are in place, so that donated tissue has the greatest benefit.

1.2 Types of consent

The types of consent explored in this research are as follows:

Broad consent: consent taken at the point of donation. It records consent for a range of unspecified future research projects; in some instances, the intended use will be stated e.g. genetic analysis.

Dynamic consent: intended to give donor's greater control and ownership of their consent. The theoretical concept is usually associated with an online platform where donors can consent to specific research on an ongoing basis. In theory, is also creates an opportunity for researchers to provide feedback to the donor.

[3] Is a large collection of biological or medical data and tissue samples, amassed for research purposes.

[4] A genome is the unique sequence of DNA in an organism. Genome sequencing is the process of determining the structure of an organism's DNA. It is hoped genome sequencing will lead to better understanding of disease and ultimately, more effective, personalised medicine.

Hybrid consent: simultaneously seeking a dual consent for use of tissue in both research and treatment – for example, for research findings to be fed back to clinical teams and potentially inform a donor's treatment. This form of consent is used in the genome sequencing project run by Genomics England and the NHS, 100,000 Genome Project which has clinical and research aims.

1.3 Aims and objectives

The overall aim of the dialogue was to understand the public's views on consent for linking tissue samples and health data for use in research. Specifically, the dialogue considered:

- The information that should be included in broad consent and hybrid consent;
- What needs to be in place (e.g. accompanying information, assurances etc.) so that those donating tissue and sharing their data feel comfortable with that decision; and
- Attitudes to electronic dynamic consent for linking patient data to tissue with the opportunity to update consent on an on-going basis.

1.4 Methodology

A public dialogue approach[5] was considered the best way to explore this topic. It helps participants to learn about the topic and allows them the freedom to express the issues that are salient to them and develop their views in light of discussion with other participants and specialists

1.4.1 Approach and overall methodology

The design of this dialogue was informed by an Oversight Group (OG). The group initially met to refine objectives and scope for the project; for a second time, to develop the dialogue materials, and for a third time to discuss the findings of this dialogue and this report. Some OG members attended the events where they answered participants' questions and helped present some of the key concepts. [6]

Reconvened public dialogue workshops were held in London, Sheffield and Birmingham between 26th September and 21st October 2017. A reconvened approach allowed participants enough time to digest the information they received on the first day, and reflect on the topic outside of the workshop setting.

In total 75 participants were involved in the dialogue. They were recruited on-street using quotas for gender, age, socio-economic group and ethnicity, to ensure participation of individuals from a range of backgrounds reflective of the areas they came from and the broad diversity of the UK population. The demographic breakdown of participants is included in the appendix of this report.

[5] The dialogue approach deployed in this study was informed by the Sciencewise programme: guiding principles (2018) – these principles can be found at https://www.gov.uk/government/publications/sciencewise-programme-guiding-principles.

[6] Details of Oversight Group members are included in the appendix to this report.

As a thank you for their time, and to cover any expenses incurred through attending the workshop, such as travel or childcare, participants were provided with an incentive payment: £50 for taking part in the first workshop, a further £80 for returning for the second event, and £20 for taking part in the online community (a total of £150 for taking part in all three).

There were 2-3 specialists at each of the events (information about their area of work and which events they attended is included in the appendix of this report). The specialists described their work, answered participants' questions, and engaged in discussions about tissue donation, linking this with patient data, different consent procedures and biomedical research. The dialogue with specialists played a key role in helping participants to understand the different actors in the current system e.g. biobanks and researchers, the different issues at stake and the possible implications of their discussions.

Facilitators followed a discussion guide throughout the two events to ensure that the same topics were covered in all locations. All materials were reviewed by the OG at an early stage, and signed off after several iterations by the HRA and HTA. All research materials used in this dialogue are included in the appendix of this report.

1.4.2 Materials and data collection

The first event aimed to frame the issues presented by tissue donation and data linkage. In between, participants were able to discuss the information and ask questions of the specialists. In order to engage participants in these discussions, they were given the following information[7]:

Information given to participants	When / how information given	Function of information
Introduction to biomedical research and the different actors in the biomedical system	After capturing participants' awareness and understanding of biomedical research at the outset of Event 1, there was a presentation from Ipsos MORI and a quiz on biomedical research.	Participants understand the possible uses of donated tissue and linked data, and that commercial companies are important actors in biomedical research. The different modes were used to account for the different ways people learn and digest information.
Overview of biobanks, and the different stages from gathering tissue to research study.	This information was given to participants through a presentation from Ipsos MORI, a film produced by a biobank[8], a filmed "talking head" of a biobank representative[9].	Participants understand the process of collecting tissue, storing it, and using it in research. The videos helped deliver key messages in a consistent way across locations.
Overview of health data, anonymization, and relevant issues	After capturing participants understanding of what constitutes health data, there was a presentation	Participants understand which data is shared with researchers and engage in discussion on the potential risks

[7] The table illustrates the type of information given to participants and in the sequence this happened.

[8] Introducing Newcastle University's Biomedicines Biobank

[9] Dr Phillip Quinlan of the Advanced Data Analysis Centre explaining the challenge facing biobanks. The video is accessible at: https://www.hra.nhs.uk/about-us/what-we-do/how-involve-public-our-work/what-patients-and-public-think-about-health-research/

like data privacy.	from Ipsos MORI on health data, the process of de-identifying it and what is then shared with researchers. After participants discussed this, they were then shown a filmed talking head from the data privacy campaign group MedConfidential[10].	and harms of sharing health data and linking it with data derived from human tissue.
Safeguards	HRA representatives presented information on data protection, regulation and ethical approval.	To identify the extent to which participants think that current safeguards are fit for purpose / need to be explained in information provided to potential tissue / data donors.

Between the events, participants took part in an online community. This online platform offered participants a chance to reflect on their initial views, and take part in activities about the future of research and possible risks in tissue donation and data linkage. Exercises encouraged participants to think about particular harms or benefits which might result from different donation and linkage practices.

Activity name	Description	Function	Participation
Activity 1: Welcome discussion	Open forum reflecting on the first event.	To gather views on how the dialogue is progressing, and get participants familiar with the online community format.	114 views, 31 comments
Activity 2: 'What do you need to know when consenting?'	Prompted discussions on the following statements: - Your sample will not be accessed by commercial companies - Your sample will only be used for research conducted in the UK - What your data is linked to - Length of time the sample is kept for	To introduce participants to the types of information that might be provided on a consent form, and get them to consider what their information needs might be, in preparation for the second event.	320 views / 42 comments
Activity 3: 'What if things go wrong?	Step-board activity where participants were asked to read different scenarios that might be considered risks or concerns about the process of tissue donation/linking to data. They were then asked questions to explore their understanding of the harms involved, views of how it could be avoided, what would reassure them, and the impact on their decision to donate.	To encourage participants to think through the possible drawbacks to donating, and inform them of the possible risks involved in the process.	1760 views / 803 comments / posts across all scenarios
Activity 4: 'The future of research…?'	Open forum on what participants associate with the future of research.	To prompt participants to begin thinking longer term, and about the possible uses of tissue and data in the future.	101 views / 7 comments

[10] Phillip Booth of MedConfidential explaining some of the risks associated with sharing tissue and data. The video is accessible at: https://www.hra.nhs.uk/about-us/what-we-do/how-involve-public-our-work/what-patients-and-public-think-about-health-research/

The purpose of the second event which took place approximately 2-3 weeks after the first one, was to identify and clarify participants' requirements of different consent protocols. They were presented with consent forms to explore broad, hybrid and dynamic consent. Improvisational actors also worked with the content of the discussions to bring the debates to life in an entertaining and educational way.

Information given to participants	When / how information given	Function of information
Real world example of permissions sought / information provided in broad consent	After a quick re-cap at the start of event 2, participants were given an anonymised consent form and patient information sheet	Capturing spontaneous views, then going into detail on which issues are most important to people
Overview of DNA, the human genome, the 100,000 Genome Project which utilises hybrid consent	Participants were shown a video about the human genome[11] endorsed by Genomics England, Participants were shown a video about the 100K GP[12] endorsed by Genomics England	Participants understand genetic data and future developments in medicine which might be important in consent
Real world example of permissions sought / information provided in hybrid consent	Participants were given the consent form used in 100K GP run by Genomics England	Capturing spontaneous views, then going into detail on which issues are most important to people
Overview of dynamic consent, its underlying principles, and the technology needed to support it	There was a presentation from Ipsos MORI on dynamic consent.	Participants understand how dynamic consent could work, then being able to deliberate on its potential pros and cons.

1.5 Interpreting the findings

A public dialogue brings together public participants and specialists to explore, discuss and deliberate on issues which have moral, ethical and practical implications. The dialogue approach yields a large amount of qualitative data that the Ipsos MORI team has interrogated using a thematic analysis[13]. This report offers insight into participants' starting points in terms of their awareness and understanding of tissue donation and health data linkage and how their feelings towards the issues changed as result of interaction with information from Ipsos MORI facilitators and specialists. Owing to the relatively small sample size and the purposive nature with which it was drawn, findings from this dialogue cannot be considered statistically representative of the general public's views.

Illustrative quotes are used throughout to demonstrate the points made by participants in their own language. Where verbatim quotes are used, they have been anonymised and attributed by location, e.g. London, or from the online community.

[11] https://www.youtube.com/watch?v=sn3_FlEbe0U

[12] https://www.youtube.com/watch?v=jP45Xe9O8XE&feature=youtu.be

[13] http://journals.sagepub.com/doi/full/10.1177/1609406917733847

1.6 Structure of the report

The remainder of the report is divided into the following chapters:

Chapter 2: Initial understanding and views of the system: This chapter describes participants' views of the key issues for this dialogue including medical research, tissue donation, and health data.

Chapter 3: Expectations and needs in broad consent: This chapter discusses reactions to a broad consent form and patient information sheet – it looks at how the consent permissions and the context around consent can be improved.

Chapter 4: Risks and reassurances: This chapter looks at participant's concerns about the process and the risks they identified, as well as their views of access and ethics committees.

Chapter 5: Genomics: This chapter examines views of hybrid consent for genome sequencing and the consent permissions used in the 100K Genome Project run by Genomics England and the NHS.

Chapter 6: Dynamic consent: This chapter explores participants' views of dynamic consent. It looks at perceived pros and cons of an online consent process and the public's appetite for it.

Chapter 7: Conclusions and recommendations: This chapter sets out the key learnings for the HRA and HTA's guidance on consent.

2 Initial understanding and views of the system

In order to understand the public's aspirations for and concerns about the linking of tissue samples to health data, we must first understand their start points.

2.1 Understanding of health research

Participants conceptualised health research as the development of new medicines and cures, running clinical trials and tackling and preventing chronic conditions and killer diseases. Although health research is not something which the public usually thinks about, they do place a strong value on it and recognise it can lead to personal and societal benefits i.e. "improving the health of the nation" now and in the future. Health research was also seen as a scientific enterprise that improves our collective understanding of diseases.

"I think about cancer research, stuff like that, but I don't think it's anything I've really thought about. It's just there in the background. I know it's happening, but I've never heard of anything in particular." Sheffield

"The word that pops to mind regarding health research is advancement. Advancement in knowledge, in capabilities to protect humanity, and to advance as a human race: to develop." London

There was limited prior knowledge of public and private collaboration in health research. Participants thought that tax-payer-funded research meant public benefit and privately funded research meant excessive profits, and over-priced medicines. This is partly because they are unaware of the high cost of drug development, and the low success rates, but also because they see sensationalist and conflicting stories on healthcare in the media.

"I think [health research] is a different world. If you're in it then you understand how it works, and how these things get into people hands and whatever, but we don't." Sheffield

"I was thinking the things you hear about are the more negative and unethical things. They're experimenting with animals. A lot of what we read about are the most shocking stories." Birmingham

Participants thought that health research is invariably done under the auspices of the NHS, and have limited knowledge of other actors involved. This meant participants assumed that all data and tissue is handled with a duty of care, is for non-profit, and that there is accountability and safeguards in place. There is therefore an implicit trust that this process is happening now.

"If it's the NHS, you assume it's ethical. If it's an advert and has monetary gain, you automatically think, 'No.'" London

Knowledge of the different fields of health research is limited and therefore participants tended to speculate that it also encompasses designer babies, cloning, biochemical weapons and creating "super-humans" i.e. human enhancement. This means that information given to potential donors has to be carefully handled, and specifically provide examples of the research which tissue and data might be used in.

"I don't want it being used to develop a new military vaccine to invent super army soldiers. If it's not actually being used to create a cure or antidote it is being used unethically." Sheffield

"If in the future they developed a technique where they could clone people, if they were to use it to grow something from it in 50 years' time then I would object." London

As they heard from specialists about their research and its intended impact, participants were very supportive of it both in principle and when thinking about their personal stake in research as tax-payers.

Online community task: the future of health research

There were very few participants who posted comments on how health research might evolve (unlike other online activities on the online community). This may be because the question was too challenging, or participants didn't have time to research it. The handful that did go looking seemed genuinely amazed by new discoveries in 'blue-skies' research, new diagnostic tools, and the possibilities of clinical care using data derived from wearable technology and genome sequencing. There was a lot of positivity about these futures, with perceived benefits for patients with conditions like cancer, and at a societal level through preventative and stratified medicine. However, none appeared to make the connection between consent and the use of data driven technologies, which further supports the importance of making this clear in information given to the general public / patients.

*"I have read something on nanotechnology which can detect diseases before they even develop. They can then send alerts to our smartphones; I mean how handy is that everyone seems to have their heads stuck in a smartphone these days". **

*Quote taken from the online community

2.2 Understanding of health data and tissue donation

Few participants had any prior knowledge of the use of tissue and data in research, and public involvement in health research was conflated with organ and blood donation.

2.2.1 Understanding of health data

There was limited knowledge of the value of health data in medical research. Participants starting point was that researchers would be focussed on individual health records, rather than looking for trends in a dataset. They didn't understand how statistical data might be used, or how a hypothesis is built and tested in scientific

research generally. This meant that participants could be more concerned about their own identifiability than the process of some research (using aggregate data) would warrant.

There was more residual knowledge of the idea that data is important, with some having heard that data is increasingly important in healthcare. At the outset, "Big Data" was mentioned by a few participants when discussing the future of research.

Participants understanding of health data tended to be limited to things which they assumed are contained in a medical record, including personal identifiers, treatment history, lifestyle choices e.g. smoking, and information on children and family history. They did not realise that health data could constitute other data sources like social care, birth and death records, and were surprised that health records could be accessed by anyone other than their clinicians or that postcodes could be useful in health research.

"Name"/ "Hospital number"/ "Blood group"/ "Height and weight"/ "Date of birth"/ "Children"/ "Operations"/ "Medications"/ "Allergies"/ "Diagnoses"/ "NHS number"/ "Next of kin"/ "Smoker"/ "Drinker"/ "Previous blood test results" Sheffield

On discussing the different kinds of anonymization, the differences between identifiable, pseudonymised (anonymised data but with a coded link which would enable you to be identified) and anonymised (with no personal identifiable data) were too nuanced for many to be aware of, although 'anonymisation' was a term that most were familiar with. Despite the initial unfamiliarity with the term de-identified, the idea of removing personal identifiers before it is shared was something which participants could understand. Therefore, consent forms should make it clear which data is anonymised and which data is pseudonymised, the need for these different levels of data and which is passed to researchers.

2.2.2 Views of tissue donation

Participants conflated tissue donation with blood or organ donation. The act of tissue donation was spontaneously seen as extracting tissue for the sole purpose of donation, instead of utilising the excess material that would be discarded after a biopsy. Once this was explained by facilitators, participants said they would be more inclined to donate, as they would prefer their excess sample used to benefit medical research, rather than for it to be wasted.

"I think [tissue donation] is just a term we don't know about. I wouldn't say I'm uneducated, but it's not something I knew much about." Sheffield

Participants initially questioned whether donation would give the donor any personal benefit. There was an expectation that the research undertaken with their donated tissue might provide them with better treatments. They appeared to be unaware of terms like personalised or stratified medicine, (which might have provided a good rationale for how new treatments might benefit individuals or groups in the long term). However, upon explanation participants recognised that it would be unrealistic to expect individual benefit from a tissue donation.

"Say I have a procedure, they take samples, and my diagnosis is brilliant, there's nothing wrong. 5 years down the line, it turns out that there is something wrong with me. Is there a way that can come back to the person who took the sample?" Sheffield

As noted, there was a desire to support health research - in this context donation was seen as an altruistic act - and participants questioned why it was not publicised more widely, due to its perceived importance. The message from specialists and facilitators that without tissue donation a considerable amount of health research would not happen resonated with participants, and they acknowledged the importance of making sure health research continues.

"I think it's brilliant. You can make someone's life a little bit better but it doesn't impact on your life." Birmingham

"It's about publicising it, what the benefits are to the general public." Sheffield

2.3 Views of the process from tissue gathering to research study

Participants were given information about the context of obtaining consent in a clinical setting; the role biobanks have as the intermediary between donor and researcher; and why they, and researchers, might want to link tissue and data.

After learning about the process from tissue gathering to research study, there were lots of questions about the early stages including whether the extraction of tissue was invasive and would cause physical harm, and how it is stored and how long for. The most salient ones for participants were around what happens to the tissue after it is leaves the biobank, and in particular what it would be used for, whether this would be done in an (unspecified) ethical way, and what value it has and for whom.

"If I was at the NHS I would willingly do it. I wouldn't answer an advert for a pharmaceutical company which offered payment and it wasn't asked to meet ethical agreements. Is it going to be for the good of everybody or is it for profit?" London

There was a lack of understanding of the separation between clinical and research uses and tissue storage, and the different agents involved. Few participants had heard of biobanks before, but there was a great deal of interest in what purpose they serve, and how they operate. Many were surprised that consent is needed at all for the donation, storage, and usage of human tissue samples. Participants acknowledged the integral role biobanks have in facilitating health research and were keen to support such research and biobank sustainability.

Many assumed there was more linking of human tissue and health data than currently exists. After being shown the video from a Biobank representative and MedConfidential, many seemed to trust biobanks to make the right decisions about access. This is because they were satisfied that specialists ought to make the decision but also because they worried the public might make a decision that would hinder research. Participants were

reassured that biobanks would only ever release data if it was relevant to a study and de-identified. It was thought that information given to donors should make these things clear.

"An anonymous number code is really important because it makes people aware of what information people would have access to if a tissue donation was given." Online community

Overall participants were supportive of research being undertaken with their tissue and data, and recognised the problem biobanks are facing. They therefore wanted a clear and robust consent process to ensure that research can continue and avoid donated tissue being wasted.

Online community task: reflecting on the first dialogue event

Public participants came to the first event with limited understanding of health research, health data and tissue donation. Post event 1 reflections in the online community indicate there was a steep learning curve, and some did feel a little overwhelmed by this, even though it was delivered in line with SW good practice.

"I came not knowing much but as the first event went on, my understanding increased. I felt like it did take a long time to get to grips with the topic."

This is not really surprising as people don't usually think about these things in their day-to-day lives.

"At first, I did think it was way too complicated for me to take part in, but then after listening to all the information and what they were wanting from us, I felt more at ease."

"I thought the session helped to clarify the topic, explore the need and importance and clear up any misunderstandings and ambiguities."

However, in analysis it was evident that video footage of biobank representatives and data privacy campaigns groups was particularly helpful and ensuring engagement with the issues at stake. Indeed, after seeing the footage, many put a high value on the work carried out by biobanks and others discussed the work of biobanks with their family and friends.

"I was really surprised about how interesting I found the first session! I came into the room not knowing anything about biobanks or what they did. Since the event I have discussed it with various friends/family members who also were not aware."

"Biobanks are a very interesting topic and it is really exciting to witness how much effort is put into finding the most secure models for the future."

*All quotes taken from the online community

3 Expectations and needs in broad consent

This section discusses participants' views of information contained in an example of a real broad consent form and patient information sheet, their spontaneous concerns and suggests ways to improve these information channels to achieve informed consent.

3.1 The context of obtaining consent

Overall, participants felt that the responsibility is on the individual to inform themselves about tissue donation, but the authorities should make it as simple as possible through a variety of information channels if possible. Prior to this dialogue, very few participants had seen a broad consent form. Those who had tended to be older and described having a vague recollection of being asked to consent to tissue donation when in hospital for a biopsy.

"I had a renal biopsy. They took a sample and asked me for consent. They didn't really talk me through it, they just asked me. I gave them consent." Sheffield

"I probably had to sign stuff like this when I gave birth, but I don't remember doing it. I wouldn't even have thought about it." Sheffield

All assumed that donors would be able to discuss consent with a member of the clinical team, a biobank representative, or a researcher who would know exactly how the tissue would be used. Even after it was explained that the way consent forms are administered and the opportunities that donors have to ask questions can vary, most expected that these interactions could be repeated in case they had concerns or wanted to ask questions after consent was given. Most participants questioned whether the clinical setting was the most appropriate way to receive this information, and would prefer this was done well in advance of the biopsy.

"If you're lying in a hospital bed and there's something seriously wrong, I wouldn't want to be given a leaflet. It's not the right time". Birmingham

As noted, participants said it would help if each consent form could be as specific as it can about how the tissue and data will be used; so if it is possible to be really precise then those administering the consent form should be trained up in as much detail as possible.

3.2 Spontaneous concerns

A starting point for many participants was that a broad consent form should state exactly who would access their tissue and data, and what research would be undertaken with it.

"Personally, if I signed a consent form, I would need to understand the parameters of that consent. If it's clear, to give me an understanding of it ethically. Is it to be used for commercial use? Again, what are the parameters? Where it could end up?" London

After reviewing a real world broad consent form and as participants learned from specialists sat at their table about the different types of research that can occur, participants started to describe elements which they felt were unacceptable.

The most common red lines were no access for commercial companies like insurance companies or marketing companies using data to sell a product. Some participants did not want pharmaceutical companies to have access to their data, but after their role in research was explained participants felt less strongly about pharma having access to their data. Participants also had red lines around the types of research they objected to – there were a few mentions of animal research but they didn't know what this looked like - some added open-ended consent and tissue being accessed by researchers outside of the UK.

"Stating that commercial interests not related to NHS or medical research will not be allowed access would be very important to me, as I am all for medical advances but not for promoting commercial success." Online community

"I would donate on the basis of enhancing medical research, not for the profit of commercial companies as I think companies profiting from tissue donations made in good faith is unethical." Online community

As a result, the idea of choosing to consent to certain things but not others (e.g. some uses like animal research and / or users like commercial companies) seemed to appeal initially, but after thinking this through participants agreed that it might turn out to be just more complex information to assimilate. Moreover, after speaking with researchers and representatives from biobanks, they realised that choosing some uses could hinder the health research their donation was supposed to support. As a result, they recognised they would be opting out in an uninformed way, given they didn't understand the implications for healthcare and as a result most felt less strongly about having absolute red lines, and instead called for the following reassurances.

3.3 Meeting donor's information needs

Participants want to have sufficient information, either included in the form itself or available online, that would help "a reasonable person" to understand the process and the implications of their consent. In terms of what constitutes a "reasonable person test", there are a number of information needs which the biobank and the research projects need to ensure are met.

3.3.1 Information about who can access tissue and data

Participants were surprised to learn from facilitators and specialists that tissue and data could go to a private company, so this has to be made clear in the information given to potential donors. However, as private companies are distrusted and are seen as somehow undermining the NHS, just telling them is likely to deter consent. Therefore, people need to be informed that a range of different, approved researchers can access a

donor's tissue, and donors need to be told what is meant by "medical research companies", by providing examples of uses e.g. development of new surgical equipment.

"When asking people to donate their tissue and data match they must have a full and clear explanation of how it will be used, by whom, now and possibly in the future so they can determine whether to agree to the donation." Online community

Participants' discussions about commercial companies in healthcare often resulted in them asking specialists and facilitators about a right to benefit if profits are made, for themselves e.g. a new treatment brought onto the market, or for the NHS. Ultimately, donors need to be told that they themselves would not directly benefit from donation, but rather give examples of what biomedical research with aggregated data could lead to e.g. understanding genetic mutations in cancer so that treatments become more specific / effective. A key facilitator of consent seemed to be that people with similar conditions could benefit in future.

"It's an issue of who owns those genetic rights…Who actually owns the sample? If something came out that was worth a fortune, who owns it?" London

3.3.2 Information about the use of tissue and data

As noted, there was limited understanding of the different fields of health research that tissue and data might be used in. While participants were very comfortable about the idea of tissue and data advancing science and improving the health of the nation, these abstract terms don't resonate and don't tell donors what will be done with the tissue and data, meaning they are not informed.

The idea that it is not possible to specify exactly how the tissue and data will be used in research was a difficult concept for many; so, if it is not possible to provide specific examples of projects then information should provide examples of types of research e.g. cancer research, as this will give them more of an idea of what could happen.

3.3.3 Information about datasets and de-identification

After reviewing the broad consent form people tended to think that researchers will always be looking at individualised data and thinking about the donor's clinical history, rather than typically looking at trends in data. This led some to think that donation was invasive and it appeared that this lack of understanding could deter consent.

"My biggest question would be about data protection, my personal information that's attached to it. Age and 'white, English person' would be ok. If they wanted to know my details, where I live, then no. There are different levels of consent." Birmingham

"Many people would like the idea of being able to help improve the health of others but if that meant their own personal data was available for others to see then I think this would prevent them giving a tissue donation." Online community

The consent form should therefore make it clear that individual data and tissue forms part of a big database containing hundreds or thousands of donor records, and provide examples or images of what this looks like, as well as make clear why researchers are most interested in data trends. That said, it should also state that researchers will have to look at particular records to understand why these trends occur.

"I think it is important to have reassurance that it would be an anonymous code that could not easily be linked to you by outside agencies in case it fell into the wrong hands". Online Community

Similarly, consent forms need to go further than to provide statements around abstract concepts like data protection and anonymity, because these are only understood when they are explained. Instead, the information made available to donors must provide specifics of how the data is de-identified, spelling out that the biobanks add a unique identifying number, which itself was a great reassurance. The consent form should also specify if the prefix of a donor's post code could be accessed by researchers and indicate why this would be desirable e.g. to study the effect of geography / location on health.

"I would accept that information such as [DOB, height, weight, post code, medicines taken and diagnosis] can be useful, but with detail such as the post code along with the rest is almost as good as having my name attached to the data. I would need confirmation that only the combined results of the anonymous data were published and the details withheld in a confidential manner." Online community

Participants were initially concerned that it might be possible to work backwards from de-identified data to identify the donor. An example explained to participants by a specialist was a researcher who had identified a person suffering from a rare disease by pooling together pieces of de-identified data such as their age, ethnicity, gender, etc. Once they understand this context they felt less strongly about the possibility of being identified. Despite seeing the likelihood of this risk as low, they called for these risks to be made clear in information given to donors. A much greater risk was perceived as identifiable data ending up in the "wrong hands" (e.g. hackers), a risk they perceive to be growing due to the increasing use and sharing of data.

3.3.4 Information about health data and additional information that researchers can access

As noted, there is a limited understanding of the different data that can be held in a person's clinical record, with most assuming it is limited to their medicines and treatments, and medical history. Participants were also unaware that researchers can access a number of different aspects of the record. As such, information to donors should provide examples of types of data the researchers might ask for and make it clear that researchers can access additional information (e.g. lifestyle or physical activity data), but only if these data sources are judged by the access committee as relevant to the research.

There were lots of questions about whether research findings could go back on the donor's clinical record. Participants were keen to know whether it was possible for this information to be obtained by insurance companies as they were worried about this affecting their premiums, or being targeted by marketing. As such, the information made available to donors should clarify that this could never happen without the individual's explicit consent.

"In the consent form I would withdraw my consent if insurance companies knew about it." Birmingham

3.3.5 Information about the right to withdrawal and what is meant by this

Having the right to withdraw consent as stated in the consent form shown to participants was a key reassurance. However, discussions about the right to withdraw revealed a nervousness about a future unknown, usually perceived as a world with different values, ethics, and laws, so withdrawal was felt to somehow offer protection. Similarly, in a world where science and medicine is perceived as developing quickly and there is a continuous access to future data withdrawal gave donors a sense of control.

"I like the fact you can withdraw your consent at any time. I'd be quite happy for it to carry on, but for a lot of people it's important." Birmingham

In terms of the form itself, it should continue to make clear that withdrawal is a key feature of consent, but it should go further and provide clarity around what is meant by withdrawal, including what the biobank does with the donated tissue and data, and that the donor's data might have already been used by researchers which cannot be taken back.

3.3.6 Information that consent is open-ended

Participants conceptualised consent for data linkage as a snapshot of time – taken at the point of donation and linked to their data at that single point of time. They did not consider that they would be consenting to access to their future data. After this was explained by facilitators, participants stared calling for specific timescales to be placed around consent, usually arbitrary periods of 10, 15, 20 years. After hearing from specialists it is possible that tissue and data might not be accessed for decades and that introducing a time limit on consent could hinder health research, people were comfortable with the idea that they had the ability to invoke their withdrawal.

"Could you not have consent with a 10-year time limit, or something? Then you can re-sign if you want to after 10 years. I can't see it being a problem just consenting again. It's a 2-minute conversation." Sheffield

3.4 Implications for the HRA and HTA

After deliberating on the moral, ethical and practical implications of broad consent, participants tended to feel that broad consent - as it had been shown to them - would be sufficient for biobanks to use to link tissue and data. There are however a number of implications for the HRA and HTA.

3.4.1 Providing detailed background information

There is a clear need to provide potential donors with some examples of the possible uses of tissue and data, and the processes that tissue and data goes through, on the consent form, or through the wider information provided to patients either verbally or in writing. The reassurance that the unique identifier provided participants, that identifiable data would not be provided to researchers is a good example of this – and

suggests that the more information that could be provided to the public would be beneficial. Of course, there is the risk of over complicating the consent form / patient information sheet.

Information given to potential donors should also make it clear which kind of commercial companies might have access to tissue and data and the benefits of this, the approval process they must first go through, and given the widespread distrust, briefly explain the counterfactual i.e. the implications of commercial companies not being involved in medical research. Though it will not be possible to provide an exhaustive list of all these companies, examples of the types of companies that have accessed data and tissue in the past may help donors become more informed about the possible uses of their tissue and data.

3.4.2 A need for digestible information, multiple communication channels and feedback

There was a tension between the need for a greater understanding of tissue and data, which manifested itself as a requirement for extra, more specific information, against a recognition that not all information in the consent form and patient information sheet (PIS) would be read or could be specified in advance given that some future uses were unknown. While quantity of information was a perceived barrier to donors digesting information they are given, another was the way the information was presented. Participants asked for a number of improvements:

Improvements to design, tone and language

- Design – the reading text in the broad consent form and PIS was seen as very dense and off-putting. It was felt that, the use of diagrams, graphic imagery and using themes to break up the text could help donors digest the information. Diagrams such as demonstrations of how the data and tissue went from patient to biobank to researcher would be appreciated.

- Tone – participants felt that the consent form / PIS was trying to pitch or sell consent, which made them suspicious about the motivations of those wanting consent. They called for a tone which was clear and positive and not too persuasive.

- Language and terminology – the language must be in plain English, simple and clear so that a lay person is able to understand the text. Jargon and technical language must be avoided, but if descriptors are necessary then they must be explained. For example, what is a tissue bank, access committee, research ethics committee, private medical company. The information should talk about samples used for research rather than donations as this gets confused with organ/blood donation.

- Examples of research – As participants had such a low base knowledge of health research generally, some across the workshops suggested that the PIS could contain a couple of examples of typical projects. Participants were aware these would just be examples and would not comprise the full range of projects in which their tissue might be involved.

Information channels

Even with changes to design, tone, language, participants were worried that potential donors preoccupied with their biopsy would be discouraged from reading the consent form and PIS. Some called for materials to be circulated to potential donors prior to their biopsy and online information should be available in order to complement this. It was felt that this could alleviate the concern about feeling pressured to consent, and provide an opportunity to digest the information at their own pace.

"At what point are these forms given out? In the post? The pre-op assessment? Someone would be worried if it was the day before the operation. They need it earlier so they can think about it." Birmingham

Participants also want the opportunity to ask questions about tissue and data so the person administering the forms and PIS will continue to have a really important role. They need to get people up to speed on tissue and data, provide reassurance that withholding consent will not affect treatment, while ensuring they do not overwhelm and confuse. This person needs to help potential donors to understand the implications of consent in order to avoid knee-jerk reactions and as result choose not to consent.

The person helping to explain consent, of course, is likely in practice to be a range of different people at the clinical interface. The HRA and HTA could consider reviewing best practice in terms of the guidance/training that these people are given and recommending a checklist of the key elements of the consent (time bound, where the tissue goes, and so on). This would help the person helping the patient, and ensure they are all clear that the key elements have been understood.

Donor transparency

There was interest in having feedback on what has been done with tissue and how it has been used, although this tended to be based on the misconception that researchers are looking at individual records, rather than a dataset. Even after it was accepted that it would not be possible to have this, there was some appetite for information about the overall study results.

While participants recognised that it may not be practical to let each individual know about the research that had been conducted with each sample, they suggested that they would be interested in knowing generally about what research is being conducted with multiple samples. It was suggested that biobanks could do more to promote the research that was being carried out – for example, by providing summaries on a website – allowing donors to understand what ways their tissue had been used.

"My argument would be if you make a breakthrough on two million tissues are you going to make two million phone calls? No. They need to do a collective thanks. Obviously, you'll know that it's helped." Sheffield

"I may never know how it's used or know the outcome of any studies happening out of a biobank. We just thought it would be nice to know if it helped anybody." Sheffield

The HRA and HTA should therefore consider how biobanks and researchers can publicise the research that is being conducted with tissue and data and, importantly, the learning and impact derived from these studies. Some suggest that the clinical record ought to contain how many times the donor's sample has been used, or the types of projects it has been involved in, without realising there could be time and resource implications of data linkage working both ways.

Online community task: What do you need to know when consenting?

This task asked participants to discuss what would they need to know when deciding whether to consent. Ipsos MORI researchers prompted with: samples not being shared with commercial companies; donations only being used for research within the UK; an anonymous code linking samples to patient data; and a limit on the amount of time a sample is held for.

The comments posted by participants emphasised the importance of making it clear that commercial (profit-making) companies could access their data – as this could deter some to consent, donors will need to be told what types of companies they are, and that it is hoped this sharing will result in better health research and, as a result, clinical care.

Participants were less concerned about samples going outside the UK than they were about possible access by commercial companies. However, as discussed in the workshops public acceptability was contingent on their data being used in ethical research and having safeguards and accountability in place.

A unique identifier (anonymous code) was a key reassurance that it would not be possible to identify individual donors, which supported workshop findings. There was no consensus on whether donors would need to know how long a sample would be kept to encourage consent – it was more important to know who would have access to health data and how it would be used.

On the sample not being used by commercial companies: *"This would be very important to me as I would donate tissue for the purpose of developing health care to help benefit others. My aim would not be to benefit commercial companies."* *

On the sample not going outside of the UK: *"For me this would not be a big factor. I would rather know what my sample was being used for rather than where."*

On the anonymous answer code: *"Protecting your identity is important for trust when donating. Safeguards need to be in place to protect people's information."*

On stating a maximum term that the sample is kept for: *"I would like to know this information but it wouldn't stop me donating if I didn't have it."*

*All quotes taken from the online community

4 Risks and reassurance

This chapter explores the concerns that participants had about consent, and the views of safeguards in place to protect their interests.

4.1 Views of risks in linking tissue with health data

Overall, participants didn't have a clear impression of the harms which could befall them by donating tissue and it being linked with their data; nobody mentioned care.data.[14] The public are aware of scandals when prompted – for instance Alder Hey was mentioned but participants did not remember the details. Issues that concerned them in relation to data were postcode lotteries for treatments, NICE not authorising cancer drugs, and the pharma "baddies" who push up medication prices for pure profit.

"I can see the issues, but I can't think of a situation where I would object to my tissue being taken…That might be because I can't think of every possible eventuality it might be used for. Right now I can't imagine having an issue with it, though." Sheffield

"I can't think of anything that wouldn't be for good. I could only make something up. That wouldn't be plausible, though." Sheffield

They did seem to feel initially more comfortable with the idea of donating tissue for research because otherwise it would go to waste, than researchers having access to their health data. This did not extend to views about the data derived from tissue, however – which they viewed as broadly the same.

"I wouldn't be too keen on them going into all my medical information. If I give the tissue, it's gone and given, but if they start going into your medical records, that's different." Birmingham

Across the workshops as a whole, some perceived risks in sharing their data and the possibility of being identified. This group were usually older, in some instances patients themselves, but it also encompassed those who do not engage in social media, or access the internet - and were particularly worried about personal, sensitive health data being accessed by anyone other than their clinician.

"I'm not sure what could happen if someone got that information, but I think, personally, I just wouldn't want a load of people possibly knowing that particular thing about me." Sheffield

"I've got lots of concerns about giving private information out. I think a lot of it's generational. At my age, we're a lot more private than the kids over there. I give nothing away if I can help it." Birmingham

[14] Care.data was the UK government's scheme to store patients' medical information in a single database to support medical research. It was scrapped in 2014 because there were inadequate safeguards for the healthcare information it would store on every NHS patient.

Their concern also stemmed from a lack of understanding about why researchers would require access to a donor's medical history, lifestyle data and so on, and some felt more comfortable with researchers having access to limited details about the donor (through a questionnaire, for example). This raised lots of questions about donor's giving away information which they could never get back, mishandling of data, and things being done with their data which they had not given permission for.

"It is positive in that sense because you can get more of an overall picture as to why these conditions are enhanced or influenced. It just feels like a sci-fi film, full access. For me, I think it's really positive but it just freaks me out a bit." Birmingham

On the whole participant patients seemed more aware of processes and consent generally, and more positive about the system because they tended to see sharing linked data through the lens of personal benefits, especially those patients who have a rare disease. The participant patients are the most wary, too, about the potential risks of data being passed to insurers since they have had issues obtaining insurance or struggled to pay higher premiums.

Some participants – these tended to be younger, and trust private companies more - were more relaxed about sharing their data and felt that if you have nothing to hide then sharing linked data doesn't matter. They are also less concerned to trade privacy off against the health benefits for the whole of society.

"I was struggling to come to something you wouldn't want to pass on. STDs and things, why wouldn't you be happy passing that information on… It's not going to the Evening Post, you know?" Sheffield

"Surely no one cares enough, who cares that I had that illness? With bank details they can take your money, but medical information, why do I care?" Birmingham

The different perspectives on sharing linked data means that all information given to potential donors will need to respond to the different needs of the various groups.

4.1.1 Usage by commercial companies

The most salient concern across the workshops was around how to manage the role of private companies in the process. It was thought they would make excessive profit from research findings from linked tissue and health, that there would not be universal access to treatments, and that donor information would become a commodity and sold to marketing and insurance companies. These views tended to be driven by a knee-jerk distrust of profit-making companies in a health context, misunderstanding about the role of private companies in health research, a lack of understanding about how treatments are made available by the NHS, and lack of understanding about donor protections.[15]

[15] Other recent studies on general publics' views and acceptability of commercial companies accessing public's health data are: Ipsos MORI (2016) public attitudes to commercial access to health data for Wellcome Trust Available at: https://wellcome.ac.uk/sites/default/files/public-attitudes-to-commercial-access-to-health-data-wellcome-mar16.pdf; and patient and public engagement project Assessing views on sharing anonymised patient level data where there is a potential mixed public and private (commercial) benefit HRA (available on request from HRA)

"Obviously I've been more trusting with the NHS having my details, because they're around and they already have it, but a private company could be worrying" Birmingham

"You as the donor could be harmed not in a physical way but emotionally due to worry and stress over corporations holding your personal data." Online community

4.1.2 The risk of identification

There was an initial tension between participants' desire for privacy and a desire to support medical research. Initially participants were uncomfortable about health data being shared with anyone other than their clinical team, and as they thought of specific types of health-related data – for example, abortions, adoptions, mental health, or STIs – they became concerned about the emotional distress and consequences identification would have for their day-to-day lives. However, once the process of data de-identifying was explained by specialists, participants seemed willing to trade off a degree of privacy in order to support biomedical research. Others did not perceive identification as a significant risk, provided the process happened as it should; for them, the key issue was not being contacted by those who had looked at or used their data.

"I'd want to remain anonymous. My sex, my age, my ethnic group, and the background on why the tissue was taken. I wouldn't want any of my details connected to it." Birmingham

2.4.3 Tissue and data leaving the country

There was an initial pushback against the idea that a donor's tissue and data could end up being accessed by researchers in other countries, which prompted some participants to name check the countries they felt it was unacceptable for their tissue and data to go to. Concerns were raised about other countries not having the same governance arrangements and safeguards used in the UK, and the risk of unethical practices with tissue and data. However, when examples were given of how data was shared abroad, the approval processes in place, participants' fears seemed to be allayed.

"If there is a crime committed across country barriers, but in that jurisdiction, it's not illegal, how does that then weigh up? They might then think differently or release information because their laws are very different." Birmingham

Therefore, the form should make it clear that it is possible that tissue and data could leave the country, but that this would only happen if approved by research ethics committees and access committees. These forums themselves need explaining, which is discussed below.[16]

[16] This is already happening in practice: specialists involved in the dialogue explained that tissue or data given to some specific biobanks was routinely shared with specific countries and where this was known, it should be possible to supply this information in the supporting information supplied with the consent form.

"I think this would help to reassure many donors if they know where their sample is going and what it will be used for. This would allow the donor to make a more informed decision as to whether they want to donate or not." Online community

With the inclusion of these additional pieces of information and extra clarity in the consent form, the majority of participants are very relaxed about de-identified data being shared and linked.

4.1.3 Feedback to the donor on research findings

There was interest in whether tissue donation would benefit a donor. Typically, this was based on a common assumption that a researcher would be able to report back any health conditions they had detected when undertaking their research – which can happen although it is rare. Participants felt that some kind of feedback ought to be a condition of donation, especially if there was a possibility of private companies benefitting from the research, which a donor had contributed to.

"I would like to know the end results. If I did have a disease and it was removed, I'd like to know the end results, and know whether they found anything." Birmingham

However, there were concerns about how biobanks would be able to manage this process while keeping a donor's details anonymous. For some, getting individual feedback on research increased the risk of being identified or private information being leaked. Detail about what information is fed back to the donor (if any), and how, should therefore be clearly spelled out at the point of consent.

4.1.4 Future-proofing consent

Participants wanted reassurance about the use of their tissue and data in an uncertain future, where they perceived that ethics, and attitudes to data sharing may be may be re-defined. Leaving the EU was given as an example of an imminent societal shift that might impact how public and private companies use patient tissue and data. Participant's concerns included Brexit changing the context in which consent forms are interpreted, how ethical research is defined, allow private companies to gain greater access to patient data, or legalise the selling of data. Another risk was data going abroad where safeguards and oversight are likely to be different

"The issue here is you don't know what you don't know. You have an opportunity to ask questions, but in the future, it's so out of your control, and you're hoping for the best, and it's a matter of trust, but you don't know what could go wrong." London

"Say we all consent today to the NHS, and then in 5 years' time the NHS gets sold off. Who then has our information?" Sheffield

The HRA and HTA should consider how to ensure that the wording used in consent forms/ PIS is future proofed can reassure future donors. It will also be important to ensure this wording will be accepted by health care organisations asked to share patient data at a later date. For example, consideration will need to be given

to the concerns of the groups (e.g. GPs) that might turn the consent down and work out how to make sure they are answering their concerns.

4.2 Views of safeguards

A recurrent theme throughout the dialogue was the high level of trust in the NHS, and participants tended to assume that the process was authorised by the NHS. They therefore believed that all data and tissue is handled with a duty of care, without a profit objective, and under the same accountability and safeguards that clinicians work. Thus they assumed a trusted process is happening now.

Participants also assumed that researchers will have signed confidentiality agreements, and that they are properly trained and signed off. This reassured them that their tissue and data would be used only for the purposes of medical research.

"The only people that are going to see my name are the people at the medical centre…they have to sign a thing. I worked at a bank and I had to sign a thing to say if I saw something about someone I knew I had to come straight off it." Sheffield

4.2.1 The role of access committees

Access committees ensure that health-related research is in the public interest. When it reviews an access application from researchers, it may ask for further information from applicants about the aims of their proposed research or for guidance from relevant experts (e.g. scientific, legal, ethics). An access committee will need to be satisfied that a research application meets the requirements outlined by the consent given by individuals and also meets any conditions set out by the Research Ethics Committee as a condition of approval of the Research Tissue Bank. Participants were given this information in a presentation from a specialist.

Participants saw access committees as a key reassurance. They were happy to trust them to decide whether and how the sample should be used, usually on the basis that they themselves claimed not to understand the subtlety of consent issues. Access committees were, therefore, seen to have a critical role between the interests of the specialist researcher and the common-sense interests of the donors.

"I felt enlightened by it, and reassured that they had that committee to discuss things before the tissue is released. That can only be a good thing. There's a safeguard in place." Sheffield

Participants asked specialists and facilitators a lot of questions on the composition of access committees, their responsibilities, powers, and how they operate. After specialists answered their questions. participants called for greater representation of lay people. Some wanted ethicists and lawyers involved given the perceived complexity of the issues. These comments, however, were usually made without realising how these changes could delay decisions around access and therefore potentially stifle the research which consent was supposed to support. The call for greater lay representation really reflected the desire among participants for reassurance that the access committee would be diverse, impartial, and take transparent decisions on the consent permissions included in the consent form.

"It's about who should be on the committee, there should be a commitment for patient participation that's anonymous so they don't know who they're getting on board." London

"They might be able to put a different spin on the ethics. If you're a scientist, you've got that scientific mind, whereas a member of the public might see a bigger picture." Birmingham

The things which participants called for are summarised below:

- Transparency: participants want the access committees to prove their impartiality, and to demonstrate on what basis decisions are made. They called for minutes of access committees and lay summarises of research to be published in the public domain.
- Standardisation: they also wanted access committees to be standardised so that the composition and role of the group is consistent across the country, and decisions would therefore be made in a consistent way.
- Practical considerations:
    - Representation: there was a need for access committee members who have no vested interests in research or at least for conflicts of interest to be noted. Some went further and wanted no biobank representative in the committees, as they saw cost recovery as a potential conflict of interest. There was support for continuing to have "lay-specialists" involved in decision-making, and some suggested the need to mandate one-third lay membership as less than this was seen as tokenistic.
    - Setting: there was perhaps an unrealistic expectation that the access committees should always meet face-to-face. Specialists explained this could add delay to the approval process, but participants felt such forums would support better debate and scrutiny.
- The consent form / PIS: Given the perceived significance of the access committees in the system, participants asked for the forms to have more detail about how they work and who is represented on them. This was a key requirement in terms of helping to build trust in the system.

Finally, participants recognised that the access committees would have both donor-driven motives and science-driven motives but they felt that implementing their suggestions would better protect the integrity of consent while at the same time help to facilitate biomedical research.

4.2.2 The role of research ethics committees (RECs)

Research Ethics Committees exist to safeguard the rights, safety, dignity and well-being of research participants. RECs review research proposals and give an opinion about whether the research is ethical. They also look at issues such as the participant involvement in the research. The committees are entirely independent of research sponsors (the organisations responsible for the management and conduct of the

research), funders and the researchers themselves. This enables them to put participants at the centre of their review. Participants were given this information in a presentation from a specialist.

Participants were keen to see reassurances that the research with their tissue would be ethical. For example, there were significant concerns that that samples and data wouldn't be used to benefit everyone. They did not want their tissue being used for research into drugs that wouldn't be accessible to everyone. They pointed out that despite the drug being developed using their tissue they might not be able to afford it.

"If it's about pharmaceutical companies doing research for profit, that Joe Bloggs can't pay for, then it's not actually benefitting humankind. Those morality issues bother me, in the back of my mind." Sheffield

However, ethics committees provided participants with the reassurance that there would be oversight of these issues, and that these things would be taken into account once a donation had been made. Although participants were unware what constitutes a research ethics committee, the fact that they are involved in the process was a key reassurance to many and some called for more transparency on the decisions they make. Ethics committees were interpreted as guarantee that research would be undertaken in an ethical way, and that all this would be done by an independent body.

"The Review Panel says it's, 'Made up of Doctors and Scientists and which has Medical Research Ethics Committee oversight.' It sounds official to me. To me, it sounds ethical and secure and something I have confidence in." Birmingham

4.3 Guidance for stakeholders

It was difficult for participants to spontaneously identify any harms associated with tissue and linked data. This raises the question of whether the information supporting consent forms needs to be more explicit about the potential harms, set against the benefits in order to support informed consent while not deterring consent.

However, as it seemed to be that clinicians, privacy groups, researchers and academics are simply more concerned about the risks than the public, the HRA and HTA therefore will need to ensure the consent process and the structures around it are completely transparent and the guidance they issue places this as a key principle.

This research could also serve to reassure stakeholders that the public do, in fact, trust them as specialists to make decisions about tissue and data linkage if strong safeguards are upheld; and that they can perhaps afford to be less risk-averse when using the consents which exist currently.

Online community task: perceived risks in linking tissue and data

The online community continued a discussion about possible risks involved in the use of linked data in health research, and the concerns people have about this. In order to help participants to engage with the concept of risks they given the following hypothetical scenarios: the sample being sent to the wrong place; a large amount of personal data being linked to samples; commercial use of tissue and data; tissue samples not being used due to concerns about data security; and the risk of no one donating due to anxieties about data breaches.

The online community was a useful triangulation tool as a number of reassurances participants called for were repeated including the importance of data security and confidentiality; what happens to linked data, who has access to it, information which should be given to potential donors in a clear and digestible way. There was some new insight in terms of participants wanting data processors and users to adhere to up-to-date guidance which is something that HRA / HTA are currently working on.

The issues flagged by participants on the online group also included the risk of tissue being wasted because the right procedures are not in place, the risk of being identified, and the use of tissue and data for profit or uses they have not consented to.

*"If it is a genuine error and the sample is not used I don't see any issue with this, However, if it happens on a large scale it could be considered wasteful." **

"Cross referencing such a broad range of data could lead to fairly easy identification of the donors. This could lead to the donor's personal information being used by others that is against the interests of the donor."

"I feel that the individual that is donating the tissue sample is being harmed by having their own tissue sample and personal data utilised for the benefit of an entity to market their own products/services."
"If there was an information leaflet that concisely told me what data would be passed on and who would see it and what the data would be used for, this would give me a bit more reassurance."

"The only [reassurance] would be an air tight document (consent form) which allows me to feel knowledgeable about what will happen to my tissue once donated."

"A diagram/illustration of all the entities my tissue would go to and touch potentially along with explanation encompassed into the consent form."

"Once people are assured that everything will be properly handled then people would be less reluctant to make a donation."

*All quotes taken from the online community

5 Views of genome sequencing and hybrid consent

This chapter starts with participants' views about the field of genetics and genomics, and the current use of genome sequencing and in the future. The aim was to gather views on 'hybrid consent', which combine patient care and research participation.

The 100,000 Genomes Project run by Genomics England and the NHS. recruits c.70,000 eligible NHS patients with cancers and undiagnosed rare diseases, combining diagnostic (healthcare) and research/biobanking aims. Participants' views were sought of the consent form used in the 100,000 Genomes Project to understand ways this information can be improved to increase transparency and help people feel better informed. We note they were not shown the Information Sheet for the Project, which gives information some of the issues raised as requiring more detail to be offered.

5.1 Views of genome sequencing and 100,000 Genomes Project

Participants had a very limited understanding of genes, the genome, DNA code and the genetic similarities in people e.g. 99 per cent of genes are the same. The videos shown in this dialogue[17], had an important role in helping participants engage in discussions about genome sequencing and hybrid consent, with an exemplar offered for discussion of the consent form used in the 100,000 Genomes Project run by run by Genomics England and the NHS in England, Wales and Northern Ireland, with an analogous project in Scotland.
There was very low awareness of genome sequencing and the 100,000 Genomes Project. After being shown the videos, people expressed genuine surprise that this technology existed, and that it had not been publicised more widely. They were surprised to learn that this technology could benefit patients with various health conditions, including infectious diseases, and not just those who have a rare disease or cancer, but there was consensus that it was right to focus on these groups first, given the perceived seriousness of these conditions. Participants were really interested in the technology, the aspiration to roll-out more widely, and the hope that it could lead to new treatments of inherited, genetic disorders, or obtain learning to correct mutated genes.

"I'm guessing the bigger picture of all of this is to develop it so that we're curing people, in the future. So they might find a fault with me, but not know how to fix it, but the long term aim is to find cures for particular diseases, or lifestyle changes?" Sheffield

Participants felt the hybrid consent form was a significant improvement over the broad consent, mainly because it was clear how their tissue and data would be used. However, it was only after clarification from facilitators and specialists that they realised the forms serve two very different purposes.

[17] Two videos were presented to participants: explaining the human genome to provide background to discussion genomics research produced by Great Ormond Street Hospital, and a REC-approved recruitment video introducing the 100,000 Genomes Project, which uses hybrid consent.

"There's a certain amount of trust and altruism because it's beneficial to us as a species. Obviously, like anything, there's the potential for it to be building a master race, or whatever, but maybe not. Outside of that it could help someone with quite serious illnesses". London

Despite the sense that genome sequencing is a good thing as it could lead to researchers having a better understanding of cancers and rare disease, lead to new and better treatments, as well as the prevention of certain genetic disorders, participants did express some concerns. There was a sense of worry about researchers having access to genetic code as it was seen as more personal and sensitive data than data derived from tissue or a health record and some saw this level of understanding as invasive. There was, as a result, a call for better education about the technology, more transparency around the project and a desire for reassurance, especially around who has access to genetic code.

"It's a bit scary because the level of information you can get, it's like a computer code, and that's what's really overwhelming, but I think it's exciting because we can accelerate how much we know and how much we can treat". Birmingham

For some, this technology was genuinely risky; it was seen as effectively "playing God", which if it was allowed to run its course and encompass all citizens then it could have dangerous repercussions on society. Some saw this future as the UK having a huge data profile of society's genetics that allows the population to be segmented, profiled, and therefore some groups suffer harms. These harms included a "eugenics society", in the worst case scenario, designer babies, or giving vast market advantage to a company that citizens may not want to help. For example, the consent somehow shifts the way healthcare is delivered in the UK in a way that citizens might not personally have voted for.

These issues are not necessarily about individual points of consent, but about what might happen to society if everyone consents, and there are unintended consequences. The HRA and HTA may need to start thinking about these concerns now.

5.2 Salient issues in hybrid consent

There were a number of specific issues which resonated with participants after they had the opportunity to digest the information contained in the 100,000 Genomes Project consent form (please see the appendix).

5.2.1 Feedback to the donor and their family

The idea of getting feedback from genome sequencing was initially appealing to all. Spontaneously people felt this could be used to detect conditions across their family and pretty much start treatment straight away if necessary. Some misunderstanding the different function of the 100,000 Genomes Project form saw the option of feedback as correcting a perceived shortcoming with the broad consent form, while not recognising the subtle implication that there might not be an effective treatment.

Others who saw the feedback as a positive, said they would want to know if there was the possibility of their family members having a certain condition and saw this as helping them to prepare emotionally and plan for a time when the condition got worse. Some said they would want the peace of mind if nothing was detected.

"It can be positive, in the sense of, 'Right, we're going to aim towards providing more research in this area,' but also, 'I'm looking forward to my child enjoying their 20s, because of this illness, that they don't have." Birmingham

There were a number of concerns about research findings being reported back to the donor; it was felt the donor would incur undue stress if they were told they or a family member had a condition for which there was no effective treatment. Similarly, some were worried about emotional distress if they were given additional findings on top of the condition which they were already aware of. However, these concerns seemed not to be as important as the benefits of genome sequencing.

"You know, the anxiety, because you've already got one diagnosis, which has rocked your world, and then there's this as well." Sheffield

Overall participants felt that the 100,000 Genomes Project form made it clear that findings may or may not be reported back and that it was clear there was an option to have additional findings on request. However, participants called for the form to provide an indication of the time it could take to receive such findings given the emotional distress of waiting for results.

5.2.2 Sharing with commercial companies

There were lots of questions about which type of private companies could have access to the genetic code. In terms of the form, participants felt uninformed by the term "private (profit) companies" and wanted the form to provide specific examples. The voluntary moratorium on access to records by insurance companies wasn't seen as a reassurance because it was felt this could be revoked at any time and many worried about the implications this could have on their day-to-day lives, and their employment prospects. The belief that donation to this project was worthwhile seemed to make participants accept this as a consequence of participation, but nevertheless they wanted more clarity about the moratorium, its voluntary nature, and examples of the types of health data which could be accessed if it did not exist.

5.2.3 The perceived risk of identification

There were lots of reasons why there seemed to be more interest in the genomics form; partly it was because it was easier to conceptualise the research and perceive the benefits from participation. It was also because there was genuine interest in the potential of linking data with other forms of data which they had not previously considered i.e. genetic data. However, because genetic data wasn't seen as "anonymous" as other data sources, it seemed that more people would be looking at the data (Genomics England, study monitors, and clinicians), and it was thought that more data sources would be accessed, and as a result the perceived risk of identification became more significant.

5.3 Pros and cons of 100,000 Genomes Project consent form

There was some confusion after participants looked at the 100,000 Genomes Project consent form because they didn't grasp that more detailed information can be found in the 100,000 Genomes Project patient information sheet, which goes along with the consent form. They were not shown both as it was felt that this could lead some to disengage from the discussions.

Despite this, participants went on to discuss ways to improve the current genomics form, as well as the statements and information which they saw as a reassuring and helpful if they were making a decision about consent.

5.3.1 Elements of the form seen as useful

The wording was seen as simple, and positively constructed, and it was felt this would help donors to digest the information, and have a reasonable understanding of what consent would involve. Participants liked the fact the form listed different types of health data which can be accessed but they wanted clarity on whether this was an exhaustive list. They also like the discrete sections but some were unaware of two key implications of the information which they contained. First, that potential donors have to agree to research findings being fed back to the clinical record, and, second, that research findings might not be known in enough time to inform treatment decisions.

The table below provides more detailed feedback on statements and information which were seen as useful in the context of consent:

Statement / information	Why it was useful	Suggested improvement	Included on PIS?
Section 1: taking part			
I can decide to join the project, or not	Voluntary nature of participation; withdrawal not affecting ongoing or planned treatment / care a key reassurance for consent	N/A	
If I can join, I can withdraw at any time	Withdrawal at any point, especially important due to the number of data sources which can be accessed because this made the act of donation more personal / sensitive.	People called for the form to provide information on how they would have to request withdrawal e.g. who they would have to tell; some wanted to know whether or not tissue and data would be permanently removed by the biobank.	Yes

Statement / information	Why it was useful	Suggested improvement	Included on PIS?
Section 2: samples			
The different types of tissue samples which might be used	The clarity around the different type of samples But still some confusion around why it might be necessary to have bone marrow	Give reasons why specific samples might be needed depending on the type of cancer. Provide examples of research using the different samples	Reasons for specific samples for certain types of research is provided e.g. use of bone marrow used for whole genome sequencing.
Section 3: data			
	The clarity around the different types of datasets which could be accessed	People questioned whether or not this was an exhaustive list so this needs explaining.	Yes
Section 4: my results			
Information about how results can be used	This is seen as a key determinant of informed consent		Yes

5.3.2 Statements / information which caused concern / confusion

Statement / information	Issue with statement / information	Suggested improvement / Comment	Included on PIS?
If you agree to take part in the 100,000 Genomes Project, please initial boxes 1,2,3, and 4	Some were unsure whether not doing would exclude them from the project	More clarity that this is a requirement of participation.	Yes. A healthcare professional is also available to answer questions.
Section 1: taking part			
You at Genomics England	Ambiguity of "you at Genomics England"	Form needs to provide examples of who at Genomics England would have access to donor's data.	Yes

Statement / information	Issue with statement / information	Suggested improvement / Comment	Included on PIS?
Section 2: samples			
I understand that there might be new ways of doing things in the future	Vague, led to more questions being asked, and concerns about what might happen	Remove/ reiterate that donors can withdraw at any time/ provide examples of what may change	Withdrawal is included
My samples or DNA could be sent to approved organisations outside the UK for processing or analysis	Some were unconformable about samples / DNA leaving the UK, as they feel DNA is more personal and there is greater scope for mis-use.	Need to inform by explaining why there might be a need to do this; can reassure by providing examples of approval process, e.g. adhere to certain rules / standards / legislation to protect identifiable data/ no identifiable data shared outside the UK	
Section 3: data			
I agree that the project can access and collect electronic copies of my past and **future** health records	Some felt uncomfortable with open ended access to their records	Form should re-iterate that donors can withdraw at any time/ reassurance provided by access committees	
To get this data, the project will need to send some details about me to approved organisations	Ambiguity of "approved organisations"	Provide examples of approved organisations	
It [data} can be collected at any point in my life and collected after my death	Some felt uncomfortable about data being accessed after their death, however participants were not shown a copy of the genomics England Patient Information Sheet which would have accompanied a consent form and might have allayed their concerns.	This is clearly a very sensitive area, but for transparency it was felt this must be included and could be touched on appropriately in the consent discussion. The end of the 100,000 Genomes Project consent form, at participant request, now also offers participants the chance to nominate another person to receive their results (if there are any) e.g. 'If you are not able to receive results that are	Yes The 100,000 Genomes Project Participant Information sheet was developed with patient/participant feedback, as was the consent form. It offers some information as to why data is potentially accessed for life, including after a participant's death.

		relevant to your family, is there anyone else who you would want your clinical team to try and give them to?' Participants are then asked to fill in their details.	
Statement / information	Issue with statement / information	Suggested improvement / Comment	Included on PIS?
Approved individuals from Genomics England, the NHS and other study monitors can look at this information	Ambiguity of approved individuals, the NHS study monitors and what constitutes "this information"	Form needs to provide examples of who at Genomics England / the NHS, study monitors would have sight / use of this data e.g. researchers, clinicians. Form needs to include detail of what is shared with clinician, what isn't	
May include commercial (profit) companies	Ambiguity of this statement led to many asking whether or not private companies would have access, the circumstances in which this could happen and the type of private companies	Acceptance that it may not be possible to say with certainty, so in the absence of this people called for the form to provide examples of different types of private companies/ provide reassurance that private companies may be working in collaboration with the NHS.	Yes
Additional contact details (optional)			
If you are unable to receive results that are relevant to your family, is there anyone else who you would like the clinical team to try and give them to	Many did not appreciate that this is an opportunity to add additional contact details in case the donor dies before the results are known	The form should make it clear the reason why this question is asked.	Yes – although without examples

6 Views of dynamic consent

This chapter explores participants' perceptions of dynamic consent. A dynamic approach can complement face-to-face consent, allowing a donor the ability to tailor their consent permissions after they have donated and consented. This brief chapter sets-out participants' views of dynamic consent and the extent to which there is appetite for more flexible consent and a more participatory relationship with researchers.

6.1 Views of dynamic consent

There was a great deal of interest in this concept when it was introduced by Ipsos MORI facilitators in a brief presentation. The technology was viewed as a way to gain greater control of consent, because participants envisaged using it to give their consent to some types of research and not others – things which they had said they were initially uncomfortable with such as research conducted by private companies, and requests for certain types of research and their health data.

The provision of feedback on the use of their tissue and potentially its impact was seen as a real plus, as it was felt this addressed a key shortcoming of more traditional consent mechanisms. It was also liked because participants felt that it removed the perceived pressure of having to make a consent decision when in a stressful situation i.e. prior to a biopsy (beyond consent for the storage of tissue). They imagined a donor being able to spend a considerable amount of time thinking about their options, and do some research before making their decision, but didn't realise an extended period of deliberation could slow down the research process.

"It sounds good; it gives you an option to decide what sort of research you want to get involved in." Sheffield

However, as discussions with other participants as well as specialists progressed, participants cooled on the idea.

They questioned whether they had the capacity to actually make sensible, informed decisions given that research projects are very technical and complex. They saw fewer projects going ahead as a real problem, which undermined their desire to support medical research. Similarly, others were worried that donors would select cautious settings on the basis of a mis-understanding of linked data usage.

"If you were to let people opt in and out, smaller things will miss out on [tissue] samples because people won't be bothered unless it's something big." Sheffield

Tailored dropdown settings did initially appeal, but after it was explained that a donor's tissue and data could be used in many projects, most felt it was rather unrealistic to think that they would constantly change their own restrictions, especially if there was no prompting email or reason to check the site.

Participants thought that dynamic consent would require a high level of engagement and participation from the donor, which was something they did not think they would be willing or able to dedicate the amount of time necessary for it to work.

"If you've given consent and there are updates…you've got to use your time again…if its big and its 30 pages I don't want to do that." Birmingham

Overall, participants thought the ideal would be both online and face-to-face due to concerns about "digital divide" so that people with lower digital-literacy were not excluded. There was also a feeling that it should be possible to trace where samples have gone. It seemed this desire for feedback was based on an underlying need for transparency to go both ways.

"Kids have all gotten very good at computers, but old dears like me wouldn't be able to do it". Sheffield

However, there was some who rejected the idea of this approach. They questioned whether the time spent giving feedback or answering questions would distract researchers from doing actual research, and the cost of maintain such a system; others rejected it on the basis of the technology and called instead for an app due to convenience.

"It's not only the set-up costs it's the maintaining it as well, if people are constantly changing their minds it could be a massive task." Sheffield

6.2 Implications for the HRA and HTA

In order for dynamic consent to work effectively for donors, the HRA and HTA and other research organisations will need to think carefully about how different research projects are presented to the public. This will need to happen in a way so that donors can make an informed decision, but also guard against too many people not providing consent for certain projects if they do not see an explicit benefit for themselves or wider society.

On balance participants felt that although dynamic consent offered a range of benefits, they did not want to engage with a more complex consent process. The priority for the HRA and HTA points towards getting broad consent right as this is seen as less demanding for both the donor and researcher.

That said, the online aspect of dynamic consent was well received by participants as a way of providing more information about the process of tissue donation, data linkage and research. As discussed in chapter 3, more information about medical research, data and tissue could be valuable in helping patients think through the implications of tissue donation and data linkage, and ensure they are able to make an informed decision (wherever face to face information provision is not possible). It was also seen as a tool to communicate to donors how tissue samples are being used, and the types of research that is being carried out. This was seen as a positive step, and the HRA and HTA might want to think about how this element of dynamic consent can be adopted into broad consent – for example, by providing more examples online about what types of research are carried out using tissue samples.

7 Conclusions and recommendations

7.1 Informed consent vs. information overload: six key tests

The public participants called for more transparency about the current system and the safeguards in place, however the tension remained in terms of giving people more information which they might not digest and the need for informed consent. There are six key tests which may help the HRA and HTA respond to this challenge:

1. Who can access tissue and data – this would entail providing examples of the different types of organisations / individuals that can access the research findings, how likely this would be and whether there are any associated risks with such access e.g. detected conditions affecting a donor's lifestyle.
2. Data- de-identification – information should make it clear what de-identifying means, making it clear that only de-identified data will be shared with researchers, and explain both the interest in aggregated and individual level health data.
3. How will donated tissue and data be used – information should make it clear the different types of research the tissue and data can be used in; as it is not always possible to be exact then the public called for some direction in terms of listing the possibilities of things which might be found out.
4. Who can access the findings at an individual level – information should make it clear all parties which could access the research findings at an individual donor level and the likelihood of this changing in the future.
5. How will the donor be protected? – as genetic data was seen as more personal and sensitive, there was the perception of a greater risk of identification, and more opportunities for the data to be looked at, the role of safeguards took on more prominence. The public want independent scrutiny of the entire process, with published information about the decisions taken by bodies who do this.
6. Sharing the research findings – participants understood that it would be difficult to feedback research study results to the participants that supplied their tissue and data but thought that it would be feasible for the study results to be made available by Biobanks / Researchers which participants could access.

This dialogue identified a need for absolute clarity on the uses of tissue and data, the need to future proof consent processes, and the requirement to provide a straightforward and accessible consent process. These are described in more detail below.

Conclusion	Recommendation
Educating potential donors:	
Participants only had a basic understanding of what constitutes biomedical research, or how tissue and data might be used in research.	There is a clear need to provide potential donors with information on tissue, biobanks, medical records, health data, and how these are used in research. The processes that tissue and data goes through should also be included on the wider information provided to patients at the point of consent. The HRA and HTA could consider including a glossary of terms, or case study examples of uses of tissue and data in research to educate potential donors.[18]
Defining how health data might be used in research in the present and future:	
Participants did not have a detailed understanding of what constitutes health data, why researchers would be interested in it, and how data might be used. For example, there was low awareness that individual data and tissue forms part of a big database, or what types of data would be included on medical records. Furthermore, it was difficult for them to grasp that they were being asked to consent to open-ended access to their records, rather than data taken in a snapshot of time.	There is a need to provide further detail and reassurances about the types of data included on the medical record and what researchers might be interested in. Consent forms/information sheets should therefore provide examples of types of data researchers might ask for. The information should also provide specifics of how the data is de-identified, spelling out that some biobanks add a unique identifying number before passing anything on to a researcher. Consent forms need to be clear that a tissue sample may be linked to current health records, and a donor's health records at any time in the future, including after they have died.[19]
Transparency on who can access tissue and data at an individual level:	
Clarity about who will be using tissue and data was a priority for participants, particularly the role of private companies in the process.	Information given to potential donors should provide detailed information on the range of different researchers who can access a donor's tissue/data and the role of access committees in overseeing this process. The information should

[18] The understanding patient data project has examples of good practice.

[19] Examples of where this has been done before are available on the 100,000 Genome Project website.

	also provide detail about what is meant by "private research companies", as well as be explicit that data and tissue will not be sold for profit. [20]
Transparency on sharing overall research findings with participants:	
Clarity about whether study wide summary research findings will be shared with participants or will they just be able to access all published research findings on the tissue bank website.	Sharing all research study findings with the specific participants who donated their tissue and data is likely to be unfeasible to implement. However, it is possible for tissue banks to share top level research findings on their website and to make this known to participants.
Specifics on the harms arising from tissue donation and data linkage:	
It was difficult for participants to spontaneously identify many of the harms associated with tissue and linked data. Moreover, it seems that clinicians, privacy groups, researchers and academics are more concerned about the risks than the public are.	The consent process and the structures around it need to be completely transparent. It might be beneficial for PIS to be more explicit about the potential harms to donors to ensure they are providing informed consent.[21]
Reassurance provided by the access:	
Mention of access committees in the consent forms provided reassurance that research (and researchers) would have to go through rigorous processes before projects could go ahead. Participants particularly would like to see lay membership on access committees.	Information materials should explain the different roles of access and ethics committees as they do now, possibly providing signposts to further information in wider material about how they are selected, who sits on them, and how they make their decisions. Emphases on their neutrality – particularly how vested interest is avoided is of particular importance, and making decisions transparent would also provide further reassurance. The HRA and HTA should look at whether national standards for access committees could be introduced with regard to composition and transparency to provide further reassurance to the public and potential participants.

[20] Examples of where this has been done before are available on the 100,000 Genome Project website: https://www.genomicsengland.co.uk/the-100000-genomes-project/data/current-research/ which sets out data use in the Project and https://www.genomicsengland.co.uk/the-100000-genomes-project/data/research/ which lists current projects that are approved for access to the 100,000 Genomes Project data.

[21] Again, the 100,000 Genomes Project has examples of how this can be dealt with in the PIS: *Are there any risks?*

Future-proofing consent:	
Participants had trust in the system as it is now. They pointed out that they might be happy to sign a consent form today, but the ethical and legal context in which that consent is interpreted might change. Subsequently, there was concern that guidelines on access to tissue and what is deemed ethical research may change as well.	The HRA and HTA should consider ways to futureproof consent processes, to reassure donors that the uses of their tissue and data will remain ethical. The wording used now in consent will also have to remain acceptable by health care organisations when they are approached to share patient data 10-15 years down the line. HRA/HTA will also need ensure that any future guidance and suggested templates have regard for the GDPR.
Making consent easy to understand and use:	
Participants suggested how consent forms could be improved. Importantly, participants did not want to engage with a complex consent process – they wanted something that was straightforward, easy to understand, and convenient. They therefore felt on balance that dynamic consent was too involved for it to be viable, though it offered advantages like the ability to adjust consent according to research projects.	It will be important for consent to be accessible and engaging, by avoiding dense language, and using plain English. One of the main ways researchers could ensure suitability for the potential participant group would be to engage with the relevant patient group and seek their views on appropriate content and language. Checking the overall length of consent forms and participant information documents, producing Easy Read versions, making available translations and interpreters, seeking Plain English Campaign advice would also help with ensuring the information is accessible. Participants also wanted consent forms and information sheets to be informative, without being too persuasive in tone. The use of diagrams, graphic imagery and themes to break up the text could encourage donors to read the information, as well as providing tangible examples of types of research, and the approval process that it goes through, using lay terms to help with comprehension.
The administration of consent:	
The timing of consent was an important consideration for participants. Participants were concerned that they might be asked to donate at a	It will be important to ensure potential donors have time to consider and digest the information provided to them as part of consent. For example,

stressful time – for example, after they had received a cancer diagnosis. They also noted that there would be a lot of information to digest as part of the consent process, which would take time to consider properly. They questioned whether a hospital appointment would be the right time to consider consenting to tissue donation, and they also did not want to feel pressured to consent – which they might do if consent was administered at the same time as their treatment.	circulating the consent form in advance of a procedure would give them time to think about the request. Providing REC- approved information online that donors could return to at their convenience could also resolve the issue of providing too much dense information in one sitting. Participants were also keen to have the opportunity to ask questions about tissue and data so the person administering the forms will continue to play an important role, and it will continue to be good practice to add contact details for researchers in case of any questions arising from information sheets and consent forms

8 Appendix

The appendix to this report contains the following:

- Members of Oversight Group involved in this public dialogue
- Demographic breakdown of public participants
- Research materials: discussion guides, plenary slides,
- Broad consent form and patient information sheet; hybrid consent form used in 100K Genome Project.

Members of Oversight Group

Name	Job title	Organisation
Amanda Hunn	Joint Head of Policy	HRA
Clive Collett	Ethics Guidance & Strategy Manager,	HRA
Catherine Blewett	Research Ethics Service Manager	HRA
Christopher Birkett	Head of Regulation	HTA
Dr Philip Quinlan	Chief Technology Officer - Advanced Data Analysis Centre	University of Nottingham
Phil Booth	Coordinator	MedConfidential
Sam Smith	Representative	MedConfidential
Dr Natalie Banner	Policy Advisor	Wellcome Trust
Laura Riley	Head of Ethics	Genomics England
Maggie Wilcox	Independent Cancer Patients' Voice	N/A
Dr. Victoria Chico	Lecturer in Law/HRA Data Advisor	University of Sheffield
Kirstin Goldring	Principal Scientist: Human Biological Sample Strategy and Governance	AstraZeneca
Suzannah Lansdell	Dialogue and Engagement Specialist	BEIS / Sciencewise
Alec Weir	Public Engagement and Media; Science and Skills Engagement Team	BEIS / Sciencewise

Demographic breakdown of public participants

Quota	London	Sheffield	Birmingham	Total
Age	6 x 18-30 8 x 31-44 8 x 45-64 6 x 64+	7 x 18-30 13 x 31-44 5 x 45-64	7 x 18-30 5 x 31-44 9 x 45-64 5 x 64+	20 x 18-30 26 x 31-44 22 x 45-64 11 x 64+
Employment status	19 employed 9 unemployed	19 employed 6 unemployed	21 employed 5 unemployed	59 employed 20 unemployed
Social grade	10 AB 8 C1C2 10 DE	8 AB 10 C1C2 7 DE	5 AB 12 C1C2 9 DE	23 AB 30 C1C2 26 DE
Gender	14 Male 14 Female	11 Male 14 Female	12 Male 14 Female	37 Male 42 Female
Ethnicity	11 White 17 BME	19 White 6 BME	11 White 5 BME	41 White 28 BME
Total	28	25	26	79

Dialogue materials: discussion guides / plenary slides

Event 1 discussion guide

Time	Exercises
6-6.15pm	**Welcome and introduction to the dialogue**
	Public facing dialogue question on posters around the room. Blank flipcharts also around the room for points/questions/issues we can return to during the dialogue. **PLENARY** **Welcome and introduction** • *Introduce self and Ipsos MORI* • *Thank participants for their involvement so far.* • *Introduce clients, Sciencewise, evaluators, and experts – researchers, clinicians* **Slide 1- 6:** Information about public dialogue question and approach, interactive sessions, dialogue sponsors, how results used, evaluation; then introduce themselves. ***How should researchers seek permission to link health data and human tissue for use in biomedical / health research?*** *You will need to thing about several aspects of this.* • ***What exactly does the consent form give permissions to do?*** • ***What assurances do people want when donating tissue and your health data?*** • ***What safeguards / protections are needed?*** **Thing to think about:** o What kind of permission or consent are we talking about? We'll be talking about the kinds of things the consent should contain, and what information the person consenting should be given about the linkage to health data. o We're thinking about 'health e.g. medical record, or a social care record, which may or may not have bits removed e.g. post code, DOB o You'll need to think about this from your own perspective, but also thinking about what's best for everyone. • *Explain discussion group ground rules: respect each other/ ask not to talk over one another/ might need to move the conversation on*

	• *Explain confidentiality and MRS guidelines.* • *Remind about, video – transcribe for quotes, no detailed attribution.* *NB – explain to participants that we are working on behalf of the HRA/HTA who want such research to go ahead as it currently does i.e. in a way that is already carefully* monitored, laws and safeguards exist and we'll hear more about these. For the purposes of the discussion, we are assuming that research is a good thing! However - the HRA/HTA know that it's only with the support/confidence of the public that they can do anything, so we need to find the solutions for consent that would help the public trust the process of linking data and human tissue. Your job today is to think of the solutions that are best for public and best for biobanks and research teams. Housekeeping – timings, plenary and break out groups, mobile phones off / silent
6.15-6.30pm	**Introduction to biomedical research**
	TABLES *Table facilitator introduce themselves then introductions around the table:* • What's your name? What do you do? • Why do you think you're here today/ what are your expectations of today? **What do you think of when I say 'health research'?** • What do you hope health research will be able to do in the future? • Is there anything you're worried about? NB No right / wrong answers – really interested in what you think! **PLENARY** **Slide 8 -10:** • Brief introduction to health research (to the room): How does hearing this make you feel? Have you heard about biomedical research before? • Types of research (to the room): How does hearing this make you feel? Have you heard of these types of research? Now we're going to a quick quiz!
6.30-6.45pm	**Quiz: Basic information about tissue, data, and biobanks**

	Handout B: *Quiz sheets to participants.* First, a quiz to introduce the issues we're going to discuss and for a bit of fun! **SPLIT TABLE INTO SMALL GROUPS** In pairs / threes write down your answers from the multiple choices. Do discuss what you as a group think is the correct answer and try to reach a consensus if you can. It's a bit of fun, there is a prize for the top 3 teams though. *Top 3 teams get a bunch of celebrations sweets.* **IN PLENARY** **Slide 12-18:** Facilitator to ask teams to shout out answers. **Slide 19:** Summarise what's in/out of scope for the dialogue
6.45-7pm	**Overview of biobanks and tissue donation**
	PLENARY **<u>Introduction to biobanks</u>** We're now going to look in detail at the process of collecting tissue, storing it, and using it in research. First, here's a short video on biobanks and the role they play: **Slide 21:** Video on the Newcastle Biobank • What do you think? How does hearing that make you feel? Any questions? Was there anything you didn't understand? **Slide 22:** How sample is gathered. This flowchart shows the process of gathering tissue samples and storing it in a biobank. **Slide 23:** The challenge facing biobanks – Phil Q video
7.00-7.15pm	**Donating a tissue sample**

BACK IN TABLES:
Anything in the films stand out for you?
Did you feel reassured / excited / worried / optimistic / interested? What was your take-away message?

Any surprises? Anything concern / reassure you about samples generally and the process itself?

Has anyone been asked donate tissue?

- If yes: What sorts of things did you consider before deciding? E.g. personal considerations: e.g. privacy/ sensitivities. Or practical considerations e.g. what would happen etc. What was your overriding consideration? Why?
- If took part: What motivated you to do so? Would you do it again? Why / why not?
- If invited but didn't take part: Why?

Imagine you were asked to donate some tissue…

- IF NECESSARY USE CASE STUDY EXAMPLES
- Would you do it if invited? Why/why?
- What would you need to know to inform that decision? E.g. who is using it? What the rules governing the process are? Anything else?
- What sorts of things would you consider? E.g. personal considerations: e.g. privacy/ sensitivities. Or practical considerations e.g. what would happen etc. What was your overriding consideration? Why?

How would you feel about biobanks and researchers also accessing your medical records?

- What would you like to know about that?

Do you understand the challenge / problem facing biobanks?
Quick check of their understanding of the problem for biobanks and researchers i.e. linking data and human tissue.
MODERATOR EXPLAINS: the biobank holds tissue and data about that tissue (e.g. the part of the body its from and how it's been stored). However, having lots of different pieces of data about the donor (e.g. medications or lifestyle) means that the tissue becomes more useful for research. Consent forms don't necessarily give the right kind of permission to allow the biobank to link data and tissue. If the two things aren't linked then the researchers can't do the research that they really want to do, biomedical research will suffer and biobanks could go out of business as they'll be underused by researchers.

- What do you think the risks are of bio banks and researchers not having access to human tissue and linked data e.g. clinical record? E.g. they can't do useful research.
- What are the risks of biomedical research not happening? (refer back to the benefits of biomedical research on slide 8)
- What do you think needs to happen to allow researchers to link tissue and data?
- What safeguards are required? E.g. to protect your privacy?

	All on table – what would you need to be told before you agreed to donate your tissue? *Capture views on a flipchart*
7.15 – 7.40	**Health data and anonymization**
	AT TABLES What kinds of HEALTH data do you give and share? *flipchart responses. If necessary, prompt on your medical record. Allow for spontaneous.* - What type of information do you think is held in your medical record? *Flipchart responses* - PROBE: demographic data/ lifestyle data (e.g. smoking/ alcohol)/ tests results/ treatments/ diagnoses/ contact details - Is some more sensitive than others? Why / why not? *Facilitator to identify boundaries of what can be collected.* - Can you think of any other personal data? E.g. name, age, address, DOB etc. *Flipchart responses.* **PLENARY** **Slide 25-30:** Data on your clinical records and anonymising data Pause at **slide 28** and ask the room: What information here identifies Robert? (Shout out) **Slide 31-34:** Providing data to biobanks and linking data **IN TABLES –** What did you think? Anything stand out for you? Did you feel reassured / worried / optimistic / interested? What was your take-away message? Does hearing this affect your views about tissue donation? And linking data with tissue samples? Why?
7.40-7.55	**BREAK**
7.55-8.30	**Implications for patients and society**
	Welcome back. **We just talked about the information on your medical records, and sharing this with biobanks and linking it to tissue samples. Thinking about this process, what might be the risks involved?** o What might the risks be to you? What about other donors? To society as a whole? *Hand out cards: a different card between 2-3 people. Discuss:* o Is this a problem? Why?

	○ How concerned are you about this issue? ○ What can be done to stop this happening? *Each group feeds back:* ○ What problem did you read about? ○ How important is this issue to you as potential donor? How important is it to society as a whole? ○ How concerned are you about this issue? ○ What can be done to stop this happening? *Facilitator notes:* • ***Researchers apply to use the tissue and patient data, but when the biobank approaches some GPs for their medical records, the GP is concerned that the permission in the consent form doesn't allow them to share the data, so the tissue and data isn't shared and the project doesn't go ahead*** ○ *Is it a problem that the project doesn't go ahead - how about if this is the case for many projects / biobanks shuts down etc?* • ***I gave my consent to donate a tissue sample 5 years ago but since then I have had other problems with my health and I might not want to share that with researchers.*** ○ *Is that just a risk we take? is it a problem for me, for any other patient, for society as a whole?*

Event 2 discussion guide

Time, Session, Materials	Exercises
10.00-10.40	**Introductions and re-cap**
Yellow highlight indicates where we are using stimulus materials 10-10.20	**PLENARY** **<u>Welcome and introductions:</u>** • *Introduce self and Ipsos MORI, thank participants for their involvement so far.* • *Re-introduce clients, Sciencewise, evaluators, and experts – researchers, clinicians. Introduce improvisational actors and videographer* • *Explain discussion group ground rules: respect each other/ ask not to talk over one another/ might need to move the conversation on* • *Explain confidentiality and MRS guidelines. Remind about video – transcribe for quotes, no detailed attribution.* **<u>Presentation: includes summary of aims / what you told us last time / revisit the core question of the day.</u>** • Revisit handout of previous session's information – it's intended as an information resource in case they have forgotten something since the last event.

10.20-10.35	**AT TABLES**
	
	Introductions at table
	Name, occupation, reflections on online community.
	Which activities have you taken part in? What did you think? What did you learn?
	
	Thinking specifically about the 'what could go wrong?' activity. In the process of seeking permission to link tissue and data, we asked you to look at some of the things that might go wrong. What do you remember that might go wrong?
	
	Would these things put you off from donating tissue and your health data?
	
	What reassurances would be needed?
	
	If the public don't come up with anything, remind them of -
	
	• Biobank error: Samples **going to the wrong place or wrong person**. *(NB this is always possible but systems are designed to minimise this, penalties are in place.*
	• Someone being **identifiable who has a rare disease** (not specifically a problem of biobanking, and there are penalties in place against this)
	• Someone **looking up the details of a friend** or a celebrity who has given this consent
	• People being **scared by the risks, and not giving consent** to link their tissue and data.
	  o *They as **individuals*** might miss out on possible health benefits that could happen via research- e.g. the linkage confirms their eligibility for a clinical trial- a very important route in terms of accessing new drugs e.g. in cancer, they also miss out on being altruistic and helping research if that was something they were interested to do.
	  o ***Everyone*** then misses out on the benefits of scientists and doctors accruing new knowledge and possibly misses out on the invention new treatments or tests that could have been developed via future research if this contribution had been made.
	  o *Patients with **similar health conditions*** to each other will miss out because less likely that scientists can spot links and patterns between e.g. their genotype and their symptoms or disease onset or progression.
	• People (at biobanks) being scared by the risks, biobanks not releasing an identifier, and **their tissue NOT being used** in research - contrary to the consent form they've signed indicating they would like this to happen.
	• People **generally in society being over-worried about the data issues** and therefore important research does not go ahead (Phil Q's point). (it might not be funded, researchers may not be drawn to work in the area, R&D and drug development is held back etc. etc. etc.)
	
	Summarise: of all the things that could go wrong, which feel most serious to participants?

10.35-40	
10.40-10.55 Introducing experts	**AT TABLES** – *expert at each table* *Expert introduces themselves, explains their job, how their work is relevant to the question of biobanks needing to link data and tissue, and how their work involves issues around consent.* **Questions from participants.**

10.55-12.05	**Broad consent**
Looking at generic consent forms for spontaneous views, then going into detail on which issues are most important to people	**AT TABLES** *(with expert at each table)* **Consent Form and Patient Information Sheet A** (identifying location and other info removed) In pairs, look at this consent form. This is an approved form / represents current good practice. This information is an example of what's used to get permission to use donated tissue sample and link it to health data. Read the consent form/information sheet. Please highlight the top 3 sentences that are the most important, to you, about taking part in this process of giving tissue and data for research. The sentences that have the information which would matter most to you if you were taking part. *Then discuss as a table:* • **What are you consenting to in this form?** • **How do you think your tissue sample might be used?** • **Who would be able to access your tissue sample and/or link it to some of your information?** • **Who should decide on your behalf who should get access to your tissue sample?** *Facilitator note: if necessary say this is about the use of your consent, which the access committee makes a judgment about in the light of the request from the researcher.* o Probe: who should sit on the access committee: typically, this is academics and lay people, although good practice to include representative from patient group. • **How do you feel that your sample and tissue may not be accessed for 5 years? 10 years? 15 years?** Does this change how you feel about donating your tissue and linking this with your data? *Probe*: what if you developed a condition which was added to your clinical record and you were unsure if wanted to share that? *Then look at specific issues, looking at their top 3 issues first then others:* **Purpose: surplus tissue taken after diagnostic tests** • How is it different from diagnostic tests? What do they mean by surplus tissue? *Facilitator can explain that they have to determine if there is enough tissue to create a research sample as well as a diagnostic one. If necessary remind that we're talking about blood samples e.g. 5ml or cells etc, rather than organs.* **Data linkage: tissue sample linked to clinical record** • **Is it clear from this consent form that your tissue sample will be linked to your data? Why? How?** • **What aspects of your patient data would be accessible here? Probe: all of it e.g. clinical record, lifestyle questionnaire etc. / some of it e.g. clinical record?** *Probe on awareness of how identifiable they think this would be. Do they think their NHS number would be shared – do they see this as part of their identity? (NB HRA sees NHS number as identifier) Does it matter to you if it's identifiable or not?* • What data do you think would go along with the tissue itself?

Explain about tissue becoming data & probe awareness of what kinds of data exist. If necessary explain that biobanks / researchers don't want to hoard data or tissue, so to make them useable for researchers they need a minimum amount of data (sometimes lots of different pieces of data). Being able to combine these will make their research better / more powerful and means that the individual donation of tissue and data can be used by more researchers.

- Who is doing the linking?
  Probe on awareness that the biobank does the linkage, while researchers have a de-identified version?
- Does this affect how you feel about donating tissue?
- What benefits do you see from consenting to share your data and tissue in this way? To you / society as a whole?
- What are the risks? To you / society as a whole? (have they noticed that they are not promised that they will *never* be able to be identified as a participant? *This is the correct approach- because reidentification is usually always a theoretical possibility, but there should be a clear explanation of the checks and balances in place which will normally prevent this.*
- Would your views change if you had a particular medical condition or disability? How? Why? *Facilitator note: research indicates that people are more altruistic when they have experience of a condition themselves, or if someone they care about has. Ditto if heightened public awareness of a condition- sometimes celebrities highlight medical conditions or disabilities.*
- Are your concerns adequately covered in the information sheet and consent form? Why/Why not?
- How would you improve the information provided in the consent form/ information sheet about data linkage?

Types of research/researcher – commercial and other:

- **What types of health research could be carried out on your tissue sample and data?** Probe on whether there are types of research they would not like to take place; who they think has access, what level of access, exactly what information they think is passed to who.
- **What types of organisations can have access to your tissue sample and data?** *Probe on awareness that not only academic institutions carry out research, e.g. almost all drug development is done within the private sector. Can include academics who are publicly funded pharma companies, public and commercial working together, makers of medical equipment.* How do you feel about that? Any 'red lines'?

Finding out about the results of any research: you won't know exactly how your tissue/data has been used

- Would you expect to know this? Do you need to see on the consent form that you won't know this?
- Would it be helpful for you to know what research studies are done with the tissue and data from the biobank? *Facilitator note: a donor can find out what broad areas of research the sample and tissue has gone to, but not specifically how a person's tissue and data was used.*
- What do you think about research being listed on the website*? (some biobanks have website where their participants can log in and see more info that is not on the public website – like UK Biobank)*
  - Might you prefer not to donate your samples and info *at all*, (or you might want to withdraw) if you are worried that you could become identifiable because a biobank has allowed access to a particular study?

Ethical issues

- **We want to know if there is anything you'd definitely NOT want your tissue/data involved with? What are the trade-offs – Would you only give consent if you were able to specify (against, or for) future uses in this way? Would it put you off if these questions weren't asked as part of your consent?**

- ***Do not prompt on the below- only if nothing is mentioned then bring up examples as below.***
  - "genetic research" - what does this mean to you? What aspects, if any, make you feel uncomfortable?
  - Research on contraception -for example a male pill, new barrier method or spermicide
  - "No samples will be supplied for research involving animal models
  - 'The government' or HMRC having my data – the government funds a lot of health / biomedical research via the NHS

Right to refuse : care not affected if you do not take part – not obligatory to take part

- What reassurance do you need about the effect on your care of donating or not donating a sample? Does it make a difference if you are ill or well? *Note: it would not be ethical or legal for a health care professional to deviate from standard care for you because you hadn't wanted to take part in biobanking!*

Checking that I have understood

- When would you anticipate asking questions? Who would you want to ask? What needs to be in place for you to feel reassured about asking, confident you have all the information?
- Is there more/different checking required given that you are donating a tissue sample, than just giving permission for your patient data to be accessed?

Right to withdraw at any time, without giving a reason

- How important is this?
- What do you think this means – will they delete anything they have done so far, or simply not analyse the data any further?

Data confidentiality and safeguards *Facilitator to remind them that the researcher has a de-identified dataset but the original biobank knows how to link the sample, and the information gained from it, with other data in your medical record.*

- **Back to the first consent form: what happens to your tissue sample/data to ensure you cannot be identified?**
- **What do you need to know about this to feel reassured?**
- **How important is it to provide information on data confidentiality?**
  - Are your concerns adequately covered in the information sheet and consent form? Why/Why not?
  - How would you improve the information provided in the consent form/ information sheet about keeping your information confidential?
  - What is the harm if you were identified? *Allow for spontaneous then probe:* Not a nice feeling, embarrassment, let down, stress, worry. *NB It's never been published that someone has lost a job / mortgage as a result of being identified although this doesn't mean it hasn't happened.*

Safeguards and oversight

- **What safeguards do you think are in place to make sure that errors don't happen and people don't break the rules?** *(NB in any human system people can break rules)*
- What should the oversight be? What should access committees think about when it comes to research being well planned, in terms of consent? Probe: If you were a biobank what criteria would you use to assess a researcher's application.

	• In terms of the panel, should it include people included in the dataset or representative of the patient group, or people who have the same characteristics as those included in the dataset e.g. particular ethnicity, age etc. • Does the consent form need to mention any bigger dataset your data will be part of? *Note: most legal agreements will exclude further data linkage to prevent identification accidental or deliberate* • Are your concerns about the types of research that might be carried out with your tissue sample and data adequately? covered in the information sheet and consent form? Why/Why not? *Revisit slides on access committees/ other safeguards* • **What might 'go wrong'? What would the harm be? How can the safeguards help?** *Revisit the 'things which might go wrong' from before* o Mistakes e.g. samples going to wrong place; o someone turning out to be identifiable, e.g. any person with a rare disease; o samples processed by a commercial body who legally use the information for marketing purposes; o a researcher who re-identified someone e.g. spoke publicly or published identifiably about someone who had donated tissue + data. *Facilitator note this would constitute serious misconduct; would lose their credibility, breach of contract, lawsuits, possible breach of DPA, loss of future research funding, probably lose job if an academic etc.* • Thinking about these issues, if they happened does it make a difference if it's tissue here vs 'just' data? E.g. genetic information which could have a bearing on the lives of your children/ other people in society? • Does the consent form provide enough detail? What more information would you like? Why? • How would you improve the information in the consent form/ information sheet about the types of research that will be carried out? Summarise key things that the form should tell you, facilitator captures on a **flip chart** Each participant puts **dots** next to the most important information for them
12.05- 12.15	**Feedback and summary**
	Summarise in plenary what each group thought was most important.
12.15 – 1.00	**Lunch**
1.00 – 1.20	**Improvisers break: the improvisers share some ideas they've heard from people and perform scenes based on these**

	AT TABLES Any comments or thoughts from the morning/the improvisation show?
1.20 – 2.10	**Consent jointly for sharing information for your health and for research – 10k Genomics**
	PLENARY Now we want to talk about some of the future developments in medicine which might be important in consent. What about where your consent for research is mixed with consent for your NHS healthcare? **Show video:** **REC-approved recruitment video: (overview of 100KGP)**: 10 mins 19 secs: **https://youtu.be/jP45Xe9O8XE** What do you think? What things stood out? How do you feel hearing this? Interesting / exciting / worried / any questions? **Show video:** https://www.youtube.com/watch?v=au1EBIpk6ec&feature=youtu.be This is the **100KGP recruitment video** for **cancer patients** (REC approved and is used with patients). 4 mins 9 secs What do you think? What things stood out? How do you feel hearing this? Interesting / exciting / worried / any questions? **GOSH video 'My Genome Sequence'** is for young people (but could be fine for adults) -explaining what genomics is and why taking part in research might find new information for patients: 2 mins 27 secs **https://www.youtube.com/watch?v=sn3_FlEbe0U** **AT TABLES** **Any questions?** **Has anyone heard of this before? Where?** Experts answer questions **Consent Form C (Cancer – Genomics):** Whole consent form for adults with cancer – plus info sheet. Participants may skim rather than read the info sheet as we will look at sections of it. Hand-out post its and **in pairs** look at the information sheet and corresponding consent form. Imagine you were asked to take part in this project. Discuss - • How could this project impact you? • How could it impact your family members? **Feedback to group** **What are the most important issues around consent here? Spontaneously.** *Now looking at some of the specific issues:* **Your genomic result and main condition is reported back to the NHS clinical team who recruited you into the project** • What do you need to be told about this to be reassured? • If the research was able to indicate that your clinicians should investigate further, so they could try and diagnose if you had something you didn't know you had - would you want this research to be fed back to your doctor? Why/ why not?

- Would you want to be told about it as well? Or would you prefer to only be told about it, if your NHS care team have validated it as clinically relevant for you?
- How about in the future, if the NHS could provide whole genome sequencing as part of care; what would you need to know at the point of consent about how the NHS could use the sequence information for your diagnosis? (e.g. could tell you about conditions you might or might not get, or things which might impact your family)

In this project, you can't have your genome analysed as part of your clinical care unless you also agree to the research option. Views on this? Should the consent form say this explicitly? Would this influence your consent?

Finding out about your illness and its impact on your family

- For the people in this project, they may find out the cancer you have is inheritable, or that you have a suspected rare genetic disease which is inheritable. What information would you need to know about this? How might this impact your family? Does there need to be anything different on the consent form as research done with your tissue and data might impact your children or other relatives?
- How about if people find out they are the carrier for genetic diseases and feel under pressure not to have children – what impact do you see on society?
- How about the possibility for screening future babies for a disease you know you are the carrier for? Is this into the territory of 'designing' babies? (NB not for trivial things like eye colour)

Getting to know about additional findings

- In 100KGP it's possible to consent to being told additional findings e.g. (completely optionally!) you can ask your care team to let you know about information from your gene sequence linked to diseases where these are worth knowing about early. If you want this information to be looked for and fed back to your clinical team for them to discuss with you, if the results show a link to the disease, the NHS can give you screening or treatment earlier to avoid or lessen the impact of the disease.
  Would you want this? Would the consent form need to tell you the pros and cons of this upfront?
- Imagine if the diagnosis didn't have an effective treatment at this point – would you still want to know? Why/ why not? *Facilitator note: this happens a lot in medicine – not GS specific*. There may be advantages to your family members in knowing your diagnosis even if it is not possible to give you treatment for something- this is often a factor for e.g. cancer patients.
- Is this adequately explained in the consent form? is anything missing?

Finding out unexpected things about your genome: we estimate that between 10 and 20% of cases reveal non-paternity, e.g. children and one or other of parents not related. How big a risk is this? Should the consent form specify this?

The effect on your insurance: If you already have insurance cover in place, you do not have to disclose any further information to your insurer. This includes your participation in the project, genetic tests results, any screening, treatment, or diagnosis that you receive during or after the project, or indeed any change in your health after the policy came into effect. But if you want to take out a new insurance policy, they will be able to see the genetic information.

- That could make it difficult to take out insurance in the future – and there could be knock-on effects such as employers not giving jobs to people who are not healthy.
- Should this be made clear upfront?
- Currently, there is a moratorium on insurance companies checking such data – does the form need to make it clear that this might change in the future?

The data gathered from genome sequencing (from donated saliva or blood) might not immediately benefit you, but the information would be kept in in your medical records in case one day it becomes relevant to your treatment.

- How do you feel about that? Do you feel differently about this information being on your records as opposed to other health related data e.g. details about a hospital admission, or results from a leg X-ray? Why/ why not?
- It might not be relevant for your treatment, but researchers might be interested in your results as part of a wider study. How do you feel about that?
- Does this need to be covered in the consent form? Why/ Why not?

Looking at the data section

- What **aspects** of your patient data would be accessed here?
- What would you be comfortable with? What do you have concerns about?
- How do you feel about them **accessing your past records to make them available to researchers in deidentified form, or available to your care team in identifiable form** to compare with your genome sequence information?
- How do you feel about them accessing **your future records** for the above reasons? Why?
- Are certain types of information about you more **sensitive**? What kinds of things might people not want to be shared with researchers (where this does not identify the individual)? What about other doctors (in identifiable form?)
- What reassurances would you need to see in the consent form about this?
- Explain the sequenced genome, health data and information from the tissue of everyone who takes part in the project is compiled in to a big dataset. What do you think about letting in an **approved third party** e.g. researchers to look at this dataset? Is it different when your sequenced genome involved?

Risk of people with rare diseases being identified: should the consent form specify this?

Uncertainty - the data linkage may affect your treatment, what you know about your health and what you can do about it – or what you know about your children's likelihood of developing some specific diseases. It might be useful for research down the line However, it might not!

- What does the consent form need to say to make this clear? How important is it to be clear on this uncertainty?
- Would this encourage you or deter you from donating a sample or agreeing to be part of a research project? Why?

Subsequent research recontact: You are always free to say no to anything when recontacted to ask for extra samples or information or given a

2.00-2.10	research invitation or you can say no to being sent updates about the project or participant newsletters. • You can withdraw from the Project at any time and without affecting your normal care. • How do you feel about being recontacted in general? would be by a biobank by letter/email • Is taking part with recontact in the longer-running studies like 100k Genomes a different thing to consider taking part in than for a biobank in general- which may not include recontact? **Summarise: the top three ideas which are most important to people on each table, feedback to plenary, lead facilitator captures on flip chart.**
2.10-2.35	**Break**
2.35-2.55	**<u>Improvisation Scenes – new ideas about genomics & consent for both research and your care</u>** **Any comments or thoughts about the improvisation show?**
2.55 – 3.20	**Making consent more flexible and involved - online**
	PLENARY presentation Then AT TABLES: **This way of giving consent may become more prevalent in future** • What do you like about it? Why? What do you dislike, why? What does it add to the process of consent? • What is the most important information you would need to know if giving this kind of consent? Is this any different from what you need to know about consent in the examples we have been looking at before? • Would do you think about doing consent (information-giving and/or signature capture) via a smartphone app or online platform or over the phone instead of face-to-face. Better / worse / same. Would you feel the same about this if you were ill or had caring responsibilities or worked long hours or lived a long way away from where you were being asked to give consent? • What if the information sheet was posted to you first? Probe trust in systems vs. face to face. • What if you had to use an electronic signature in order to consent. **What things would you need to know about each research study?** • PROBE: aim of research study; who is doing it, the data your sample will be linked to? • FOR EACH: what things would prevent you from consenting? What things would you be happy to consent to? • Would you want to consent to each individual research project as they come up? • Would you prefer 'default preferences' and anything falling outside these would need individual consent? • What things would you include on your default preferences? PROBE: type of research, when the research is being carried out, type of personal information the research uses, where the research is being carried out, organisation carrying out the research. • Doing this could mean the data quality would suffer. If consenting is to help research then having such preferences could actually do the opposite to now. What do you think now? Would having a serious or life-threatening disease change the way you think about this? **Would you like to know about the overall outcome of the research that is conducted using your sample?**

	• *It would not be your individual results - Does that affect how you much you want to know about it or not?* • Would this encourage you to donate a tissue sample and consent to it being linked with your records? • What if the results were very technical? (would be good practice to give an easy-to-understand summary for the general public available wherever possible. but this isn't always possible) • Why might you want the outcome of the research if there isn't an easy to understand summary for the general public? e.g. curiosity etc. *Think about the resources required to make these results intelligible.* • *Explore appetite around feedback:* don't want any info, newsletter as and when – what are the limits? **Do you think <u>you</u> would use an online platform to amend your permissions for each research project? Why?** • How frequently would you expect to access the tool and amend your permissions? • Do you feel like this level of involvement too much / about right / not enough? • Would you want to log in and out every time your sample was used in a different research project? **Would this process for consent make you feel more reassured about consenting to data linkage?** • Why do you say this? • It could require a lot of involvement from a person, e.g. you would need to regularly check requests for use of your data and sample. Is it reassuring to constantly be asked to adapt your consent? on balance does it require a reasonable amount of participation from the person who donates samples and data? **What are the most important issues for data linkage in an online future? Feedback to plenary, lead facilitator captures on flip chart.**
3.20- 3.35	**Summarising the whole day, on tables**
3.20 – 3.45	**What are the 3 principles which should guide the HRA / HTA and others in developing consent information and forms?** **Some reminders of what's possible:** • What **level of access** to patient data do researchers/biobanks have – info about where research could be carried out in the world – what do people need to know? • Types of research e.g. **genetic research** – how far do you think people should be able to opt in or out of specific activities (within the approval of that biobank)? (Obviously people cannot give data or samples to that biobank at all, if they don't agree with the uses it lays out in the consent form/info) • **Open ended-ness** – how much restriction should people be allowed to put on the consent they give? • How consent is taken – **when is a respectful time**, what level of check should researchers/biobanks give donors on how the project is using your data? • What do you need to tell people about **possible implications for them**, their health, and future generations (e.g. if genomics discovers something about their genome)? (note: this also applies in all kinds of medical care and research though) • And - Bearing in mind some increased levels of checks might be costly, and longer forms might put people off… what's the **MINIMUM** you need to provide?

	• Is it OK to offer a minimum mandatory written info for consent or via a **video**, and then seek consent, if you also offer extra optional greater detail for patients to look up online (or they be given on paper) if they want this? • Also – what's the **IDEAL** situation? What are your aspirations for this kind of process in the future? • What kind of **governance** ought to be in place? Then return to plenary and feedback one or two ideas from each table
3.45-4.00	**Wrap up and thank-you:** Outline next steps. End of event questionnaire / evaluation process. Continue to use online community. Incentives.

Broad consent form and patient information sheet

TTB ID:

NHS Tayside and the University of Dundee

Consent form for the Collection and Storage of Tissue for Research

1. I agree that any surplus tissue removed in the course of my procedure as a necessary part of my diagnosis or treatment may be used for research provided that this does not interfere with any diagnostic tests and on the understanding that the following conditions apply:

Please initial as appropriate.

- I have read the information below, received a copy of the Patient Information Sheet (Version 6, 14 March 2013) and had an opportunity to ask any questions.
- Samples of tissue will be anonymised and kept securely. They will not be directly traceable to me or my family by researchers.
- Data relating to my clinical record will be stored and shared with other Tissue Banks. This information, but not my identity, will be made available to researchers.
- Tissue and relevant anonymous clinical data will not be sold but will be provided on a non-profit making basis to researchers within universities, the NHS and medical research companies. ☐
- Tissue samples may undergo analysis on an anonymous basis to help find out whether genetic make up has any connection with disease.
- Tissue donation will not result in any payment to me, even if my tissue is involved in research that leads to a new treatment or medical test.
- My tissue will only be used for research approved by a Review Panel made up of Doctors and Scientists and which has Medical Research Ethics Committee oversight.

2. A supplementary blood sample (up to 20 ml) may be collected as part of my participation . ☐

If you do not wish to give consent this will not adversely affect your treatment or care. You may choose to withdraw your consent at any time (See Patient Information Sheet for details).

Signed……Date……..

I have explained the request for tissue for research purposes and answered any questions the patient has asked.

Signed……Name……..Date……..
(Trained Consenter)

FOR TISSUE BANK USE ONLY:

CHI / label	Pathology Number:	
	Tissue Site(s)	
	T – N – Blood –	

One copy for Patient, One copy for Tissue Bank *Version 12 (29 November 2013)*

Page 1

NHS Tayside & University of Dundee

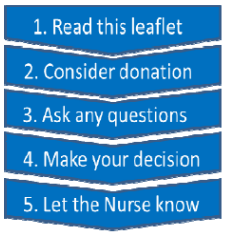
Patient Information Sheet for the Collection and Storage of Tissue for Research

We invite you to donate any tissue left over after your procedure for use in medical research. Before you decide you should understand why research using tissue is performed and what it would involve for you.

Key Points:
- **Donating tissue is entirely optional.**
- **Your decision will not affect your treatment or care.**
- **No extra tissue is taken.**
- **Your procedure will not be prolonged or altered in any way.**

Why am I being invited?

Often doctors need to remove tissue as part of your treatment, for example during a surgical operation or biopsy procedure. Doctors will not take more tissue than is needed for your care but sometimes there is surplus tissue or body fluid left over that is not required for your diagnosis or treatment. This tissue, which would otherwise be discarded, is a *valuable resource for medical research*. We ask your permission to collect, store and use any surplus tissue that may arise from your procedure so that it is available to medical researchers.



What is a Tissue Bank?

A Tissue Bank is a collection of such surplus samples that have been gifted by patients for use in medical research by doctors and scientists. The Tayside Tissue Bank at the University of Dundee stores these samples and shares resources with similar Tissue Banks. It is a founding member of the Breast Cancer Campaign Tissue Bank. Any tissue you donate may be divided between these Tissue Banks, which are maintained in collaboration with other institutions including charities.

Page 2

Have you had permission to contact me?

Yes. The East of Scotland Research Ethics Committee REC 1, which has responsibility for scrutinising proposals for medical research in Tayside, has examined this proposal and raised no objections from the point of view of medical ethics. Monitors from the University of Dundee and NHS Tayside also check that research is properly conducted, records are kept and that the interests of those taking part are adequately protected.

What would I have to do?

Read this information sheet and consider whether you wish to give permission for your tissue to be used for medical research. When you come into hospital or attend a clinic you will be asked if you wish to let your surplus tissue be used. The Nurse / Doctor will record your decision and, if appropriate, assist you in completing a consent form.

Do I have to take part?

No. Donating tissue (including blood) to Tissue Banks is entirely voluntary. *Giving or refusing consent for the collection, storage and use of surplus tissue for research will not affect your care or treatment in any way.*

What will happen if I take part?

The procedure that your doctor has planned will take place as normal (if this has already happened the samples could still be useful). After the tissue has been removed and examined by a specialist (a Pathologist) and enough kept for any further testing that may be required, a small piece of any left over tissue may be stored in the Tissue Bank. In addition, to this tissue sample the Tissue Bank may ask that a blood sample of up to 20 ml (just over 1 tablespoon) is also collected.

What are the advantages of taking part?

While it is unlikely the research will help you directly, we hope that the information that medical researchers obtain from your tissue will help improve the diagnosis and treatment of other patients in the future.

Page 3

What will happen to any tissue that is taken?

Your tissue (including blood) may be used in a number of research projects in universities, the NHS or medical research companies. It *will not be sold for profit* but may be used in research that could lead to the development of new drugs or treatments. Whilst samples are never sold to researchers, they may be asked to pay for the cost of storing and transporting any tissue samples they request. Before donated samples are released to any researcher (worldwide) they must provide a written explanation of what they intend to do with the tissue. This must satisfy a panel of doctors and scientists that the research is well planned and of medical value.

Will any genetic tests be done?

Sometimes samples are used for genetic testing which may help to identify inherited factors that influence the development of disease. No samples will be supplied for research into reproductive cloning.

What about my personal information?

We collect data relating to your medical records, such as diagnosis, treatment and demographic details (e.g. age, gender, postcode and number of children). All information that is collected is kept strictly confidential. Your name and other identifying information is removed from any records that are given to researchers so that you cannot be recognised from them. Researchers using the tissues will be given a copy of your anonymised information to help make your tissue donation as useful as possible. Should our collaborative arrangements with other institutions end, your tissue and information may be transferred to one of the research institutions or charities we work with. If your tissue and information is transferred it will be held by the Tissue Bank administrators in the same way as we currently hold it and can only be used for further medical research.

Version 6: 14 March 2013

Page 4

What will happen to the results of the research?

Results, including DNA analysis, will not be relayed back to you, your hospital doctor or your GP. Studies that are being carried out on tissue that has been gifted to the Tissue Bank are listed on our website as well as links to the scientific publications that report the results of the research.

What if I want to change my mind?

You are free to withdraw your consent at any time, without giving a reason. This will not affect your care. If you wish to withdraw consent, contact the Tissue Bank and you will be sent a withdrawal form to complete and return. On receipt of this, we will remove and safely dispose of your research samples. If consent is withdrawn after donation it is possible some of the samples may already have been issued to researchers. In this case the Tissue Bank will request the immediate return of any unused tissue from researchers for disposal. If tissue samples have been used by researchers prior to you withdrawing your consent no further action can be taken.

How can I contact the Tissue Bank?

If you have a concern or question that you wish to discuss you can contact the Tissue Bank at the address below:

Mail: Tayside Tissue Bank, Medical Research Institute, Jacqui Wood Cancer Centre, Ninewells Hospital & Medical School, Dundee, DD1 9SY

Phone: 01382 632698
Website: www.tissuebank.dundee.ac.uk

What are my rights?

If you believe that you have been harmed in any way by donating tissue you have the right to make a complaint and seek any resulting compensation through the University of Dundee who act as the research sponsor. Details about this are available from the Tissue Bank. In addition, as a patient of the NHS, you have the right to pursue a complaint through the usual NHS process by writing to:

Complaints Office, Level 9, Ninewells Hospital, Dundee DD1 9SY
or telephone: Freephone 0800 027 5507.

Thank you for taking the time to read this Patient Information Sheet

Hybrid consent form used in 100K Genome Project

Genomics england

C1

For adults with cancer (or suspected cancer)

[INSERT NHS GMC LOGO]

Crystal Mark 22290 Clarity research by Plain English Campaign

100,000 Genomes Project

Participant consent form

If you agree to take part in the 100,000 Genomes Project, please:

- initial boxes 1, 2, 3 and 4;
- initial your choices for returning the additional findings in box 5; and
- sign your name at the end of this form.

Taking part, samples and data

1 Taking part

I have read and understood the participant information sheet 'for adults with cancer' dated_____/_____/_____ (version_____). I have been able to ask questions and have these answered.

I understand the following.

- **I can decide to join the project, or not.**
  My routine medical care or legal rights aren't affected if I don't take part.
- **If I join, I can withdraw at any time.**
  I do not have to give a reason why.
  If I withdraw, I understand that some research may have already taken place using my data and this can't be undone.

I agree to the following.

- You can tell my GP and other healthcare professionals I have joined the project.
- You at Genomics England and my clinical team can contact me to:
  - ask me to donate more information for the project;
  - ask me to donate further samples if needed in the future;
  - invite me to join other research; and
  - send me general updates about the project.

If I am asked, I can say yes or no. It is my choice.

Initial here to show you agree.	

Genomics england

C1

For adults with cancer (or suspected cancer)

2 Samples

I agree to donate to the project:

- a sample of blood;
- other samples, such as saliva, if needed; and
- samples already collected as part of my medical care. This includes samples of my tumour or bone marrow depending on the type of cancer I have.

My samples can be used for:

- collecting DNA for whole genome sequencing; and
  studying my blood to find out how the DNA is working.

I understand that there might be new ways of doing this in the future.

My samples or DNA could be sent to approved organisations outside the UK for processing or analysis.

Initial here to show you agree.	

3 Data

I agree that the project can access and collect electronic copies of my past and future health records.

- This includes personal information from all of my records from the NHS, my GP and other organisations. This includes information about any illnesses or stays in hospital – even ones that appear unrelated to my cancer.
- The data is from different sets of records, including hospital or clinic records, medical notes, social care and local or national disease registries. It includes images from my NHS records, such as MRI scans, X-rays or photographs.
- To get this data, the project will need to send some details about me (for example, my NHS number and date of birth) to the organisations holding this information. This will allow them to find the health data they hold about me.
- The data may be used to study many different medical conditions, not just ones that affect me.
- It can be collected at any point in my life and will continue after my death, unless I have withdrawn from the project.
- Approved individuals from Genomics England, the NHS and other study monitors can look at this information at any time.

Genomics england

C1

For adults with cancer (or suspected cancer)

I understand that:

- all information about me held by the project will be treated as confidential;
- my data, and information from my samples will only be used by researchers in a form that protects my identity;
- research organisations accessing my data and samples may include commercial (for-profit) companies;
- researchers won't be allowed to copy or remove any of my information; and
- I will not benefit financially if research using data from the project (which includes my data), leads to new treatments or medical tests.

Initial here to show you agree.	

My results

4 I agree that:

- tests can be run on my samples and health information to look for the cause of my cancer and may also help to find ways to manage my cancer; and
- the results can be reported to my clinical team for them to discuss with me.

I understand the following.

- Information generated by this project may benefit my family members, now or in the future. If relevant, the NHS will support me in sharing this with them.
- I may not get information that will help with my medical care now or in the future.
- Results may not be returned in time to be used in my medical care.

I understand that:

- apart from my cancer and additional findings (if I have asked for these) no other information will be looked for or reported.

Initial here to show you agree.	

Genomics england

C1

For adults with cancer (or suspected cancer)

Additional findings (optional)

5 I understand the following.

- I can choose if I want certain other conditions that might affect me to be looked for in my samples ('additional findings').
- These conditions are not connected to my cancer.
- All the conditions can potentially be treated or prevented.
- My results might also be important to other members of my family.
- Even if my results seem to show that I don't have one of the conditions, I could still get it in the future.
- We may add to or change which conditions we look for. This means I might get other results in the future.
- I can change my mind about receiving additional findings at any time.

Initial your choice

Yes, I want additional findings to be looked for and given to my clinical team.	

Or

No, I do not want this information to be looked for and given to my clinical team.	

Genomics england

C1

For adults with cancer (or suspected cancer)

Carrier testing (optional)

6 The next section is unlikely to be relevant to people who are not planning to have children in future. You can initial the box below and move to the next section.

Initial if carrier testing is not relevant for you.	

I understand that:

- I can decide to be tested to see if I 'carry' a risk of passing on serious genetic conditions to my future children or grandchildren;
- these conditions may or may not be able to be cured, made less severe, or prevented using standard NHS treatment;
- I may still have a child with one of the conditions, even if the result doesn't identify the condition in my genome data; and
- you will regularly update the conditions looked for. This means I could get further reports about different conditions in the future.

Initial your choice

Yes, I want this information to be looked for and given to my clinical team.	

Or

No, I do not want this information to be looked for and given to my clinical team.	

Genomics england

C1

For adults with cancer (or suspected cancer)

Name of participant (BLOCK CAPITALS):	
Date of birth:	(DD/MM/YY)
Signature:	
Date:	(DD/MM/YY)
Name of person receiving consent (BLOCK CAPITALS):	
Signature:	
Date:	(DD/MM/YY)
Name of interpreter if used: (BLOCK CAPITALS):	
Signature:	
Date:	(DD/MM/YY)

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C1

For adults with cancer (or suspected cancer)

Additional contact details (optional)

If you are not able to receive results that are relevant to your family, is there anyone else who you would want your clinical team to try and give them to?

Name (BLOCK CAPITALS):	
Relationship to you:	
Date of birth:	(DD/MM/YY)
Address (BLOCK CAPITALS):	

When you have filled in this form:

- 1 (the original) will be kept in the adult participant's 100,000 Genomes Project records.
- You will keep a copy.
- We at Genomics England will keep a copy.

For administration use only (NHS GMC staff).

Insert local contact details here
Phone number:
Email address:
Hospital address:

Sarah Castell
Research Director
Sarah.Casetell@ipsos.com

Graham Bukowski
Associate Director
Graham.Bukowski@ipsos.com

Rachel Burkitt
Research Manager
Rachel.Burkitt@ipsos.com

Tom Rossington
Graduate Research Executive
Tom.Rossington@ipsos.com