STREAMLINING PATIENT PARTICIPATION IN HEALTH RESEARCH BIOBANKS

WORKSHOP REPORT.

The Biobank Participant Information Leaflet/Informed Consent Form Working Group & Patient Voice in Cancer Research.

Maryborough House Hotel, Cork. 9th October 2019



Background, Acknowledgements and Glossary of terms

The Biobank PIL WG is a subgroup of the National Biobank Working group. The group was established with the aim of developing a template PIL/ ICF document which combines the experience of biobank researchers with the perspectives of patients and patient advocates.

The authors of this document wish to acknowledge the following for their support and assistance:

- The Patient Voice in Cancer Research (PVCR) facilitated and hosted the workshop. "The Patient Voice in Cancer Research" is supported by Irish Cancer Society research grant PVCR19MCC and the Mater Foundation, Mater Misericordiae University Hospital (MMUH).
- Biobank Ireland Trust provided funding for writing of this report;
- Rachel Lynch MIACP, EUPATI Fellow designed the summary graphic in the Participant Information Leaflet.
- "HRB IRC TCD PPI IGNITE", provided funding for the design of the summary graphic in the 'Participant Information leaflet'

Glossary of terms / acronyms used in this documents

PIL – Participant information leaflet, WG – Working group, HCP – Health Care Professional, ICF – Informed consent form,

NCRI - National Cancer Registry of Ireland



SUPPORT BY:

























Agenda

- 1) Introduction
- 2) Key findings
- 3) Table discussions in response to the thematic questions



Introduction

Overview and main objective

Overview

 The purpose of this paper is to summarize the key findings which emerged from round table discussions with patients and the public regarding a draft Participant Information Leaflet and Informed Consent Form created by the National Biobank working group.

The approach

- The draft documents were discussed by groups of patients and the public with the assistance of a facilitator;
- The working session was structured so that different groups would focus on specific themed questions;
- Hence the workshop was set up with tables of participants, each table had a facilitator and a scribe, with each table discussing a different question;
- In total 8 questions / themes were discussed

Questions asked at the tables

- 1. Is it easy to understand the document?
- 2. Would you be happy to consent to all parts of the consent form?
- 3. Do you understand why samples and data need to be stored for long periods, is it clear why samples / data are retained for a long time?
- 4. Does the document explain why samples / data may be shared with researchers around the world

- 5. Do you understand why samples / data may be shared with commercial companies? Is It important for you to have an option?
- 6. Would you like to receive information on research projects in the Biobank?
- 7. At present there is no national agreement on how research results which affect health are returned to participants, how do you feel about this?
- 8. Does the document explain what genetic research means?



Key findings (1 of 3)

- The document is easy to understand helped by the glossary of terms and the use of simple language;
- Participants feel having trained and experienced personnel discuss research participation with them is vital.
- However the tone of the document needs to be more assertive and reassuring. On occasion the document uses phrases such as 'could'/ 'a small chance'/ 'forever' such terms are disliked by patients and seen as vague and 'non-committal. Patients prefer for the position to be definitive and seek certainty;
- While patients like simple language, it is important that the tone does not become too colloquial / common. Participation in Biobank through the donation of samples/data contributes to scientific research and plays an active role in the discovery of new treatments with improved outcomes for patients in the future. Hence patients treat participation as an important and sensitive issue and thus seek good and clear explanations with appropriate terms used;
- Patients expect that appropriate measures are in place to manage data security. In the event of there being a data breech, patients require they are notified of any such lapses in a timely manner;
- Patients expect that the Biobank and associated hospital labs in Ireland and abroad have procedures and processes in place which mitigate and reduce risks. Related is that ethical standards are followed with a strict policy of adherence and appropriate governance/oversight in place;
- In general patients are happy to sign the consent form, they need time and proper explanations communicated with empathy, and considered the sections within the form to be acceptable;
- While the glossary explains the difference between 'coded data' and 'identifiable data' patients were concerned the terms were interchangeable in the document. Patients would prefer if the document was **more explicit regarding when and where the records are held as 'identifiable data'**. It was unclear if it was 'identifiable data' or 'coded data' which was held by "health-related companies". Also patients were unclear if the 'identifiable data' was only held by the hospital. A suggestion was to use the graphic to highlight the incidence of 'identifiable data' and 'coded data';
- Patients suggested that the benefit case for participation should be stronger. In particular the role in improving outcomes for patients in future generations and the overall benefit to society should be emphasised;



Key findings (2 of 3)

- While the information leaflet and the form itself are important, patients emphasised that the timing of the consent request typically coincides with an emotional and difficult time for the patient. Already the patient is overwhelmed with a diagnosis and lots of new information without having to consider consent for research. Hence in this context the person seeking consent needs to have the appropriate training with the capacity to bring empathy and understanding to the situation;
- In terms of offering patients a range of options on participation with the Biobank the views were mixed. Some patients welcomed the idea of being able to choose and create their own consent to participation, while others preferred the simple straight decision to opt in to a standard approach;
- Patients want to be assured that the Biobank and researchers use samples and data with discretion. They expect that high ethical standards are adhered to and want a level of confidence that data / samples are not used for the wrong purposes. Some of the wording is somewhat 'open ended' and suggests that researchers have 'unlimited control' over samples/data. Therefore the choice of language should not convey a sense that researchers might lack discretion in their work;
- Patients raised the question of what happens in the event of a new treatment in the future and the possible requirement for the Biobank to require fresh samples at a future date. Hence patients raised how the on-going engagement for re-sampling might happen;
- Patients expressed no concern regarding the time periods and fully understood that scientific studies rely on large patient cohorts across different generations over long time periods;
- Patients were happy for data / samples to be shared with researchers around the world. There was an appreciation of the global effort in scientific research and the benefit of large numbers in the scientific community working to discover treatments;
- Some definitions need to be improved. The role of the **Biobank needs additional clarity** as does the role of the "Health-related companies". The document needs to provide a better explanation on the interface between the Biobank, public research and the private work of "Health-related companies". The path from scientific discovery through to treatment application, clinical trials, regulatory approval needs to be explained in the document;



Key findings (3 of 3)

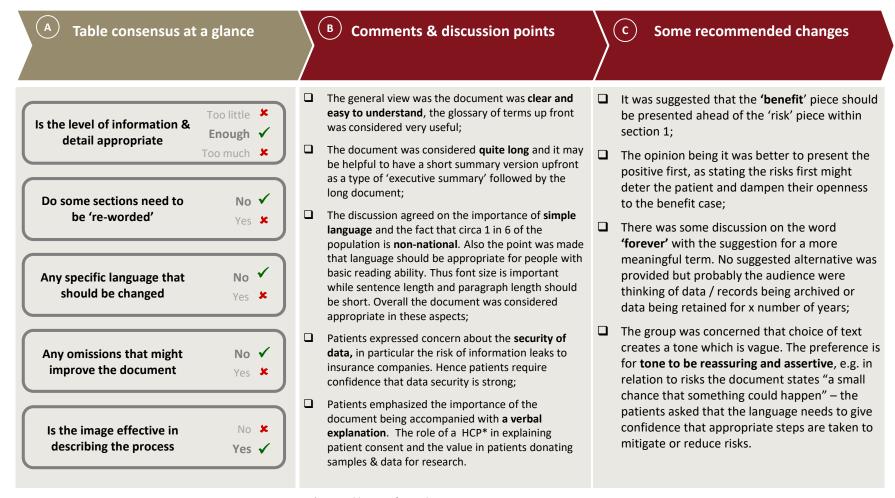
- The role of "Health-related companies" in using data stimulated a number of queries, patients felt there wasn't sufficient detail on their role and how they interface with other stakeholders. Also patients sought some clarity on the path from scientific discovery through to commercial availability of the medical innovation;
- Mixed views on information dissemination, some patients were happy to be kept informed and receive updates from the Biobank, while others were happy to donate samples / data and not require information updates. These latter group were happy to trust that the Biobank and researchers are professional and work to high ethical standards;
- It seemed that patients take a narrow interpretation on information updates and understood it to relate to findings relating to their sample / data as distinct from a more holistic approach of project progress and the pursuit of societal good in the advancement of medicine;
- The onus is to notify patients in the event of actionable results;
- Hence a clear process & structure is required when reporting actionable results. Need to respect the
 patient and therefore it is important to give information to patients with the appropriate support;
- Suggested that genetic information is sensitive and genetic counselling is important. In the absence
 of counselling, genetic data may cause anxiety to the patient;
- The document does not provide a detailed explanation of genetic research, apart from the definition in the glossary. However patients understand its role and significance;
- Awareness of the NCRI is low.

Some concerns

- Patients have a fear that data may be leaked to insurance companies;
- Patients are anxious that cloning of cells from their tissue samples may occur in the future;
- Patients worry that samples / data may be used for the wrong purposes;
- Patients suspicious of companies in some foreign countries having access to data;
- In the future information on DNA results may be sensitive for families;
- However despite these concerns patients are happy to participate in research that leads to good future outcomes for the next generation of patients;



Table 1 - is the document easy to understand?



darmah

Table 2 – would you be happy to consent to all parts of the consent form?

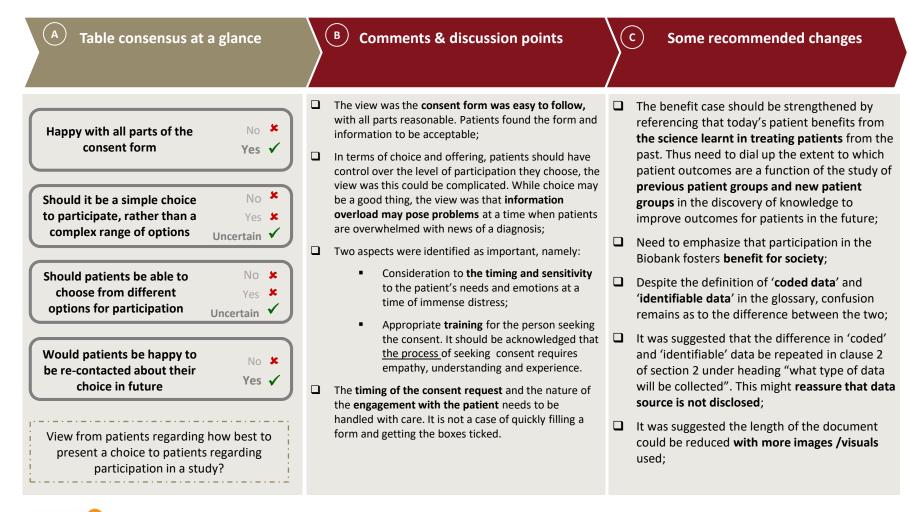




Table 2 – would you be happy to consent to all parts of the consent form?

Patients may not want choice but do want assurance that samples and data are used with discretion. Patients want trust and confidence that data/samples are used for beneficial purposes to advance the outcome for future patients.

Some suggested re-wording for the "Informed Consent Form"

- Table 2 did not have an exhaustive discussion on the merits of choice and the pros and cons of patients having a role in determining the range of uses for their samples/data;
- The broad consensus was to adopt a simple approach of a straight opt in, not get overloaded with decisions, options and additional information;
- The sense being that patients already have a lot to address without being asked to choose options regarding their preference on the the use of samples and data.
- The discussion provided a number of practical suggestions in relation to re-wording parts;
- The discussion also highlighted the importance to consider both the timing of a consent request and the appropriate training of HCPs to ensure an empathetic engagement with patients.

Section 1: clause No. 4 Consent form

- Suggested that this clause should be deleted, as it may result in unnecessary distress for patients;
- The view was the 'as-is' text would only give rise to anxiety among patients;
- Hence delete the text re. Saint James Hospital having insurance in the unlikely event of injury

Section 2: clause No. 4 Consent form

- The text "data can be used for research even after my samples are gone" was considered clumsy and should be amended
- The suggested rewording was "data can be used for as long as is useful"

Section 2: clause No. 7 Consent form

- Feeling that the language used could be interpreted as giving several degrees of freedom to researchers on the use of data and samples i.e. "permission to share my data and samples". Hence the text would seem to give unlimited control to researchers
- More appropriate text might be "give permission to researchers to act with discretion on the use of samples and data" or "carefully decide on the use of data"

Section 2: clause No. 9 Consent form

 Suggested that additional text be inserted to stress that careful consideration is taken in relation to the use and sharing of samples

Section 2: clause No. 10 Consent form

The money reference is considered inappropriate. Instead there should be a reference to the role of the research in leading to better future medical outcomes for patients



Table 3 – is it understood why samples & data are stored for a long time period?

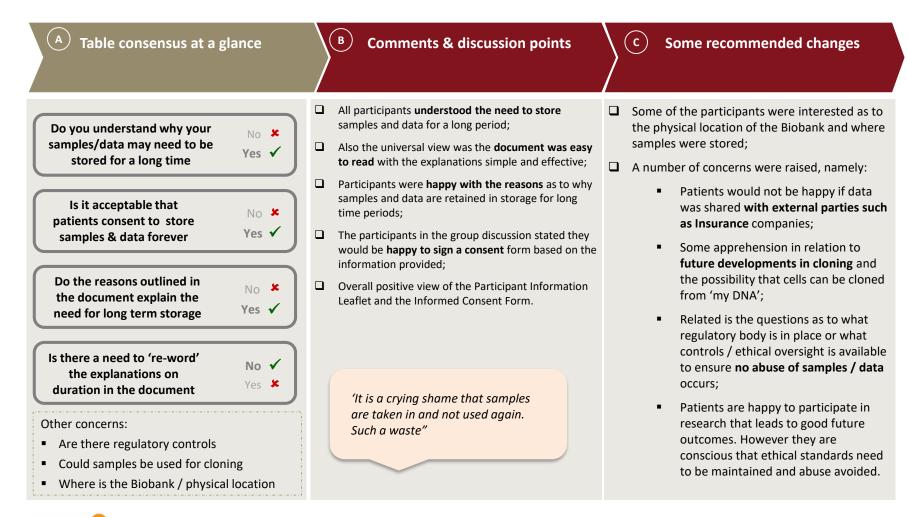




Table 4 – does the document explain why data/samples may be shared with researchers around the world?

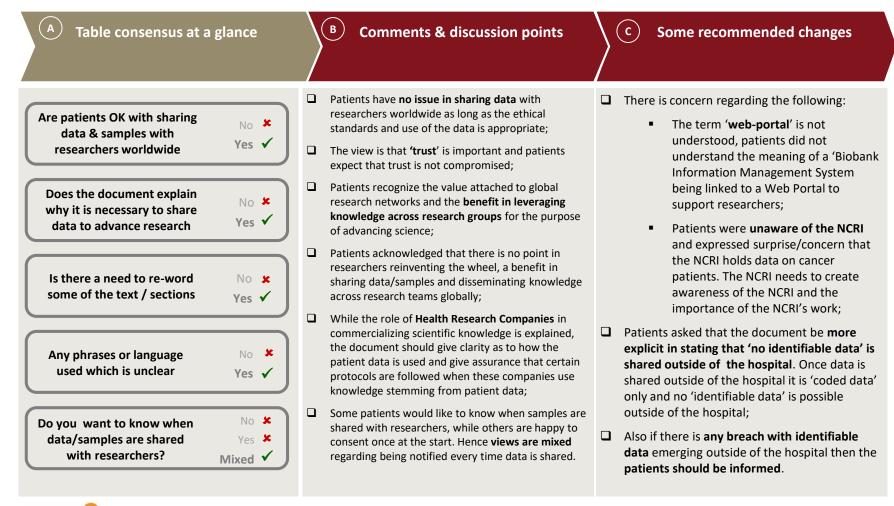




Table 4 – does the document explain why data/samples may be shared with researchers around the world?

Some suggested "re-wording"

Section 2: clause No. 5 What are your rights?

- Suggested that the wording "in so far as is possible" needs to be replaced
- This type of language does not give an assurance that appropriate efforts to protect data are in place
- The document needs to give a commitment that data security is a priority

Section 2: clause No. 6 Extra information the Biobank has to give you

- The reference to the Biobank being "responsible for deciding what data will be collected and how it will be used" was not seen as favourable by patients
- Patients felt this created uncertainty and was considered as a type of 'open clause' providing scope to extend the range of uses over time
- Some patients are happy to give consent at the start and not be notified when samples are shared, while others would like to be notified when data and samples are shared;
- There is some confusion on the sharing of data. While patients are happy for data to be shared, they want clarity as to the measures taken to ensure data security. The document should specify that only coded data is shared with Healthcare companies

Recap on comments

- Appropriate controls in place to ensure data / samples are shared for the right reasons;
- ☐ There should be no abuse of data/samples;
- Patients should be alerted if there is a data breech;
- ☐ The document needs to be really specific / explicit on who has access to 'identifiable data';
- Awareness of the NRCI is very low;
 - Patients were surprised the NCRI had data on cancer patients;
- The role of data controller needs to be explained, there was concern the current document is written with scope for future flexibility. Hence patients are interpreting that some language avails of 'open clauses' with some degrees of freedom as to how to use data. Thus this type of vagueness raises a level of concern for patients. Patients would prefer more definitive details and better clarity on the range of use and the controls / ethical standards to be followed.



Table 5 – do you understand why samples are shared with Health Related companies?

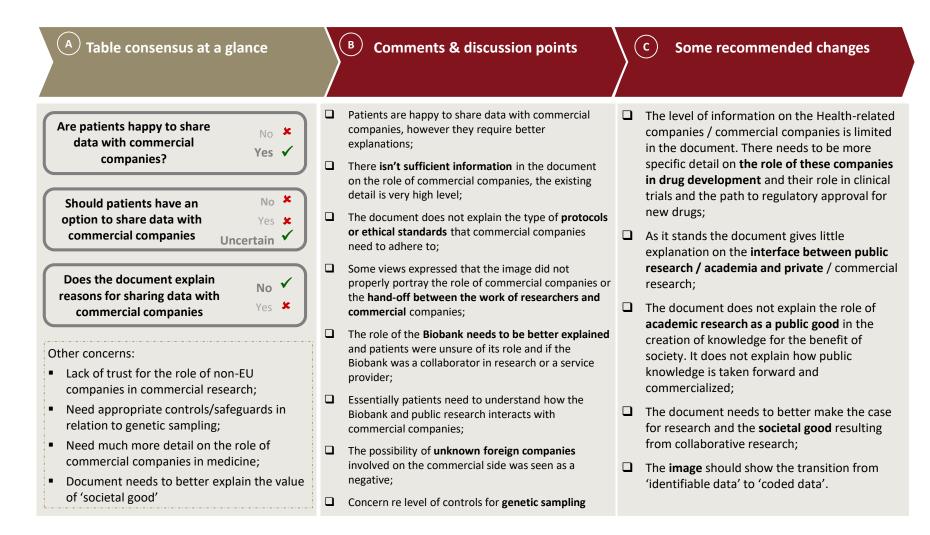




Table 6 – are you interested in updates on projects supported by Biobank?

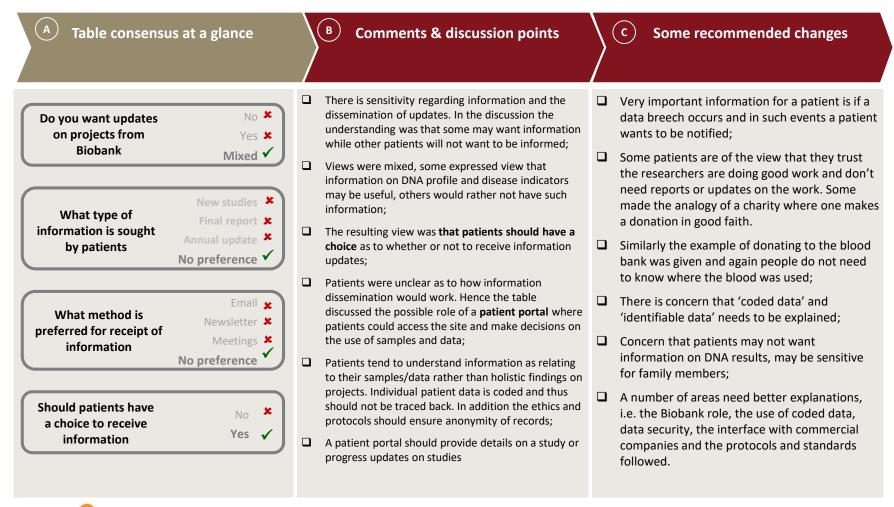




Table 7 – There is no national agreement on how research results which may affect your health should be returned to you , how do you feel about this?

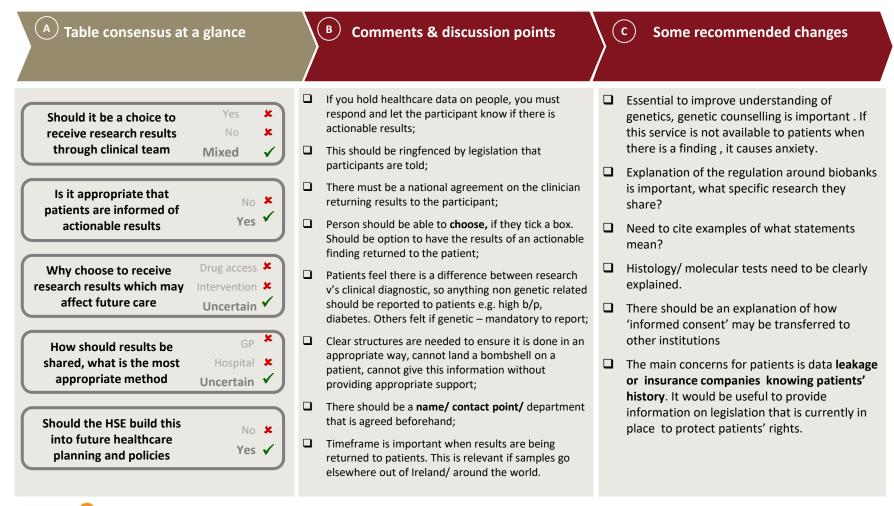




Table 8 – do you understand from this document what genetic research means? Do you have any concerns?

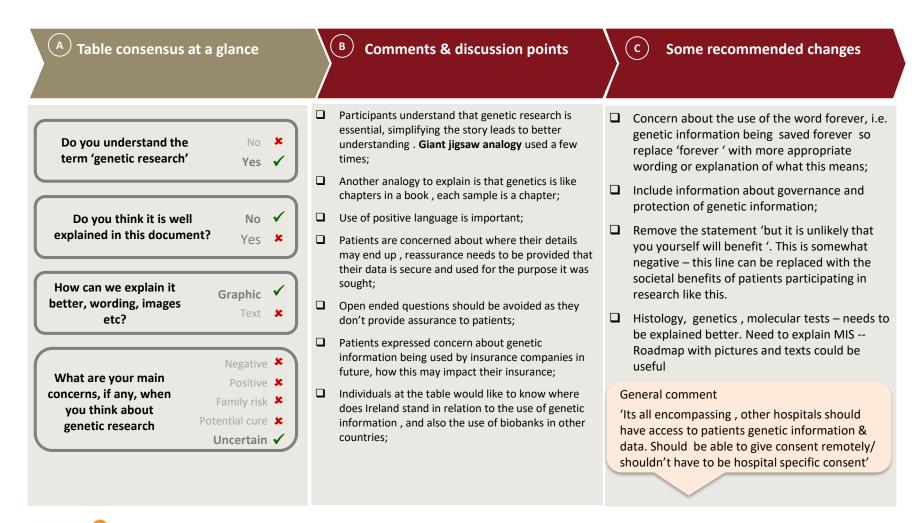
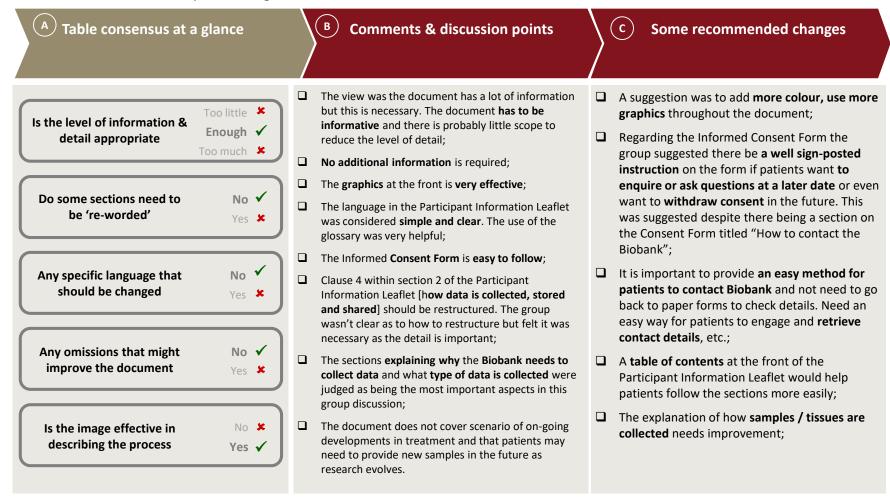




Table 9 – is the document easy to understand?

Table 1 discussed the same questions as this table. Views were consistent across the 2 tables. Like table 1 this table also believed terms such as "forever" require editing.





Appendix

The Biobank Participant Information Leaflet Working Group:

Suzanne Bracken, Niamh Clarke, Sarah Cooper, Ann Cullen, Blanaid Mee, Billy Mc Cann, Verena Murphy, Mairead Murray, Jackie O'Leary, Lydia O'Sullivan, Sharon O'Toole, Ciara Peters.

