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

darmah MARKET RESEARCH

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.

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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

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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?

A Table consensus at a glance

Is the level of information & detail appropriate	Too little ✘ **Enough** ✓ Too much ✘
Do some sections need to be 're-worded'	**No** ✓ Yes ✘
Any specific language that should be changed	**No** ✓ Yes ✘
Any omissions that might improve the document	**No** ✓ Yes ✘
Is the image effective in describing the process	No ✘ **Yes** ✓

B Comments & discussion points

- The general view was the document was **clear and easy to understand**, the glossary of terms up front was considered very useful;
- The document was considered **quite long** and it may be helpful to have a short summary version upfront as a type of 'executive summary' followed by the long document;
- The discussion agreed on the importance of **simple language** and the fact that circa 1 in 6 of the population is **non-national**. Also the point was made that language should be appropriate for people with basic reading ability. Thus font size is important while sentence length and paragraph length should be short. Overall the document was considered appropriate in these aspects;
- Patients expressed concern about the **security of data,** in particular the risk of information leaks to insurance companies. Hence patients require confidence that data security is strong;
- Patients emphasized the importance of the document being accompanied with **a verbal explanation**. The role of a HCP* in explaining patient consent and the value in patients donating samples & data for research.

C Some recommended changes

- It was suggested that the **'benefit**' piece should be presented ahead of the 'risk' piece within section 1;
- The opinion being it was better to present the positive first, as stating the risks first might deter the patient and dampen their openness to the benefit case;
- There was some discussion on the word **'forever'** with the suggestion for a more meaningful term. No suggested alternative was provided but probably the audience were thinking of data / records being archived or data being retained for x number of years;
- The group was concerned that choice of text creates a tone which is vague. The preference is for **tone to be reassuring and assertive**, e.g. in relation to risks the document states "a small chance that something could happen" – the patients asked that the language needs to give confidence that appropriate steps are taken to mitigate or reduce risks.

*HCP: Healthcare professional

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

A Table consensus at a glance

Happy with all parts of the consent form	No ✘	**Yes ✓**
Should it be a simple choice to participate, rather than a complex range of options	No ✘	Yes ✘ **Uncertain ✓**
Should patients be able to choose from different options for participation	No ✘	Yes ✘ **Uncertain ✓**
Would patients be happy to be re-contacted about their choice in future	No ✘	**Yes ✓**

View from patients regarding how best to present a choice to patients regarding participation in a study?

B Comments & discussion points

- The view was the **consent form was easy to follow,** with all parts reasonable. Patients found the form and information to be acceptable;
- In terms of choice and offering, patients should have control over the level of participation they choose, the view was this could be complicated. While choice may be a good thing, the view was that **information overload may pose problems** at a time when patients are overwhelmed with news of a diagnosis;
- Two aspects were identified as important, namely:
  - Consideration to **the timing and sensitivity** to the patient's needs and emotions at a time of immense distress;
  - Appropriate **training** for the person seeking the consent. It should be acknowledged that the process of seeking consent requires empathy, understanding and experience.
- The **timing of the consent request** and the nature of the **engagement with the patient** needs to be handled with care. It is not a case of quickly filling a form and getting the boxes ticked.

C Some recommended changes

- The benefit case should be strengthened by referencing that today's patient benefits from **the science learnt in treating patients** from the past. Thus need to dial up the extent to which patient outcomes are a function of the study of **previous patient groups and new patient groups** in the discovery of knowledge to improve outcomes for patients in the future;
- Need to emphasize that participation in the Biobank fosters **benefit for society**;
- Despite the definition of '**coded data**' and '**identifiable data**' in the glossary, confusion remains as to the difference between the two;
- It was suggested that the difference in 'coded' and 'identifiable' data be repeated in clause 2 of section 2 under heading "what type of data will be collected". This might **reassure that data source is not disclosed**;
- It was suggested the length of the document could be reduced **with more images /visuals** used;

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?

A Table consensus at a glance

Do you understand why your samples/data may need to be stored for a long time	No ✘ **Yes** ✓
Is it acceptable that patients consent to store samples & data forever	No ✘ **Yes** ✓
Do the reasons outlined in the document explain the need for long term storage	No ✘ **Yes** ✓
Is there a need to 're-word' the explanations on duration in the document	**No** ✓ Yes ✘

Other concerns:

- Are there regulatory controls
- Could samples be used for cloning
- Where is the Biobank / physical location

B Comments & discussion points

- ❑ All participants **understood the need to store** samples and data for a long period;
- ❑ Also the universal view was the **document was easy to read** with the explanations simple and effective;
- ❑ Participants were **happy with the reasons** as to why samples and data are retained in storage for long time periods;
- ❑ The participants in the group discussion stated they would be **happy to sign a consent** form based on the information provided;
- ❑ Overall positive view of the Participant Information Leaflet and the Informed Consent Form.

'It is a crying shame that samples are taken in and not used again. Such a waste"

C Some recommended changes

- ❑ Some of the participants were interested as to the physical location of the Biobank and where samples were stored;
- ❑ A number of concerns were raised, namely:
  - Patients would not be happy if data was shared **with external parties such as Insurance** companies;
  - Some apprehension in relation to **future developments in cloning** and the possibility that cells can be cloned from 'my DNA';
  - Related is the questions as to what regulatory body is in place or what controls / ethical oversight is available to ensure **no abuse of samples / data** occurs;
  - Patients are happy to participate in research that leads to good future outcomes. However they are conscious that ethical standards need to be maintained and abuse avoided.

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

A Table consensus at a glance

Are patients OK with sharing data & samples with researchers worldwide	No ✘ Yes ✓
Does the document explain why it is necessary to share data to advance research	No ✘ Yes ✓
Is there a need to re-word some of the text / sections	No ✘ Yes ✓
Any phrases or language used which is unclear	No ✘ Yes ✓
Do you want to know when data/samples are shared with researchers?	No ✘ Yes ✘ Mixed ✓

B Comments & discussion points

- Patients have **no issue in sharing data** with researchers worldwide as long as the ethical standards and use of the data is appropriate;
- The view is that **'trust**' is important and patients expect that trust is not compromised;
- Patients recognize the value attached to global research networks and the **benefit in leveraging knowledge across research groups** for the purpose of advancing science;
- Patients acknowledged that there is no point in researchers reinventing the wheel, a benefit in sharing data/samples and disseminating knowledge across research teams globally;
- While the role of **Health Research Companies** in commercializing scientific knowledge is explained, the document should give clarity as to how the patient data is used and give assurance that certain protocols are followed when these companies use knowledge stemming from patient data;
- Some patients would like to know when samples are shared with researchers, while others are happy to consent once at the start. Hence **views are mixed** regarding being notified every time data is shared.

C Some recommended changes

- There is concern regarding the following:
  - The term '**web-portal**' is not understood, patients did not understand the meaning of a 'Biobank Information Management System being linked to a Web Portal to support researchers;
  - Patients were **unaware of the NCRI** and expressed surprise/concern that the NCRI holds data on cancer patients. The NCRI needs to create awareness of the NCRI and the importance of the NCRI's work;
- Patients asked that the document be **more explicit in stating that 'no identifiable data' is shared outside of the hospital**. Once data is shared outside of the hospital it is 'coded data' only and no 'identifiable data' is possible outside of the hospital;
- Also if there is **any breach with identifiable data** emerging outside of the hospital then the **patients should be informed**.

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?

A Table consensus at a glance

Are patients happy to share data with commercial companies?

No ✘
Yes ✓

Should patients have an option to share data with commercial companies

No ✘
Yes ✘
Uncertain ✓

Does the document explain reasons for sharing data with commercial companies

No ✓
Yes ✘

Other concerns:

- Lack of trust for the role of non-EU companies in commercial research;
- Need appropriate controls/safeguards in relation to genetic sampling;
- Need much more detail on the role of commercial companies in medicine;
- Document needs to better explain the value of 'societal good'

B Comments & discussion points

- ❑ Patients are happy to share data with commercial companies, however they require better explanations;
- ❑ There **isn't sufficient information** in the document on the role of commercial companies, the existing detail is very high level;
- ❑ The document does not explain the type of **protocols or ethical standards** that commercial companies need to adhere to;
- ❑ Some views expressed that the image did not properly portray the role of commercial companies or the **hand-off between the work of researchers and commercial** companies;
- ❑ The role of the **Biobank needs to be better explained** and patients were unsure of its role and if the Biobank was a collaborator in research or a service provider;
- ❑ Essentially patients need to understand how the Biobank and public research interacts with commercial companies;
- ❑ The possibility of **unknown foreign companies** involved on the commercial side was seen as a negative;
- ❑ Concern re level of controls for **genetic sampling**

C Some recommended changes

- ❑ The level of information on the Health-related companies / commercial companies is limited in the document. There needs to be more specific detail on **the role of these companies in drug development** and their role in clinical trials and the path to regulatory approval for new drugs;
- ❑ As it stands the document gives little explanation on the **interface between public research / academia and private** / commercial research;
- ❑ The document does not explain the role of **academic research as a public good** in the creation of knowledge for the benefit of society. It does not explain how public knowledge is taken forward and commercialized;
- ❑ The document needs to better make the case for research and the **societal good** resulting from collaborative research;
- ❑ The **image** should show the transition from 'identifiable data' to 'coded data'.

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

A Table consensus at a glance

Do you want updates on projects from Biobank	No ✘ Yes ✘ **Mixed** ✓
What type of information is sought by patients	New studies ✘ Final report ✘ Annual update ✘ **No preference** ✓
What method is preferred for receipt of information	Email ✘ Newsletter ✘ Meetings ✘ **No preference** ✓
Should patients have a choice to receive information	No ✘ **Yes** ✓

B Comments & discussion points

- There is sensitivity regarding information and the dissemination of updates. In the discussion the understanding was that some may want information while other patients will not want to be informed;
- Views were mixed, some expressed view that information on DNA profile and disease indicators may be useful, others would rather not have such information;
- The resulting view was **that patients should have a choice** as to whether or not to receive information updates;
- Patients were unclear as to how information dissemination would work. Hence the table discussed the possible role of a **patient portal** where patients could access the site and make decisions on the use of samples and data;
- Patients tend to understand information as relating to their samples/data rather than holistic findings on projects. Individual patient data is coded and thus should not be traced back. In addition the ethics and protocols should ensure anonymity of records;
- A patient portal should provide details on a study or progress updates on studies

C Some recommended changes

- Very important information for a patient is if a data breech occurs and in such events a patient wants to be notified;
- Some patients are of the view that they trust the researchers are doing good work and don't need reports or updates on the work. Some made the analogy of a charity where one makes a donation in good faith.
- Similarly the example of donating to the blood bank was given and again people do not need to know where the blood was used;
- There is concern that 'coded data' and 'identifiable data' needs to be explained;
- Concern that patients may not want information on DNA results, may be sensitive for family members;
- A number of areas need better explanations, i.e. the Biobank role, the use of coded data, data security, the interface with commercial companies and the protocols and standards followed.

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?

A Table consensus at a glance

Should it be a choice to receive research results through clinical team	Yes ✘ No ✘ **Mixed** ✓
Is it appropriate that patients are informed of actionable results	No ✘ **Yes** ✓
Why choose to receive research results which may affect future care	Drug access ✘ Intervention ✘ **Uncertain** ✓
How should results be shared, what is the most appropriate method	GP ✘ Hospital ✘ **Uncertain** ✓
Should the HSE build this into future healthcare planning and policies	No ✘ **Yes** ✓

B Comments & discussion points

- If you hold healthcare data on people, you must respond and let the participant know if there is actionable results;
- This should be ringfenced by legislation that participants are told;
- There must be a national agreement on the clinician returning results to the participant;
- Person should be able to **choose,** if they tick a box. Should be option to have the results of an actionable finding returned to the patient;
- Patients feel there is a difference between research v's clinical diagnostic, so anything non genetic related should be reported to patients e.g. high b/p, diabetes. Others felt if genetic – mandatory to report;
- Clear structures are needed to ensure it is done in an appropriate way, cannot land a bombshell on a patient, cannot give this information without providing appropriate support;
- There should be a **name/ contact point/** department that is agreed beforehand;
- Timeframe is important when results are being returned to patients. This is relevant if samples go elsewhere out of Ireland/ around the world.

C Some recommended changes

- Essential to improve understanding of genetics, genetic counselling is important . If this service is not available to patients when there is a finding , it causes anxiety.
- Explanation of the regulation around biobanks is important, what specific research they share?
- Need to cite examples of what statements mean?
- Histology/ molecular tests need to be clearly explained.
- There should be an explanation of how 'informed consent' may be transferred to other institutions
- The main concerns for patients is data **leakage or insurance companies knowing patients' history**. It would be useful to provide information on legislation that is currently in place to protect patients' rights.

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

A Table consensus at a glance

Do you understand the term 'genetic research'	No ✘ **Yes** ✓
Do you think it is well explained in this document?	**No** ✓ Yes ✘
How can we explain it better, wording, images etc?	**Graphic** ✓ Text ✘
What are your main concerns, if any, when you think about genetic research	Negative ✘ Positive ✘ Family risk ✘ Potential cure ✘ **Uncertain** ✓

B Comments & discussion points

- ❑ Participants understand that genetic research is essential, simplifying the story leads to better understanding . **Giant jigsaw analogy** used a few times;
- ❑ Another analogy to explain is that genetics is like chapters in a book , each sample is a chapter;
- ❑ Use of positive language is important;
- ❑ Patients are concerned about where their details may end up , reassurance needs to be provided that their data is secure and used for the purpose it was sought;
- ❑ Open ended questions should be avoided as they don't provide assurance to patients;
- ❑ Patients expressed concern about genetic information being used by insurance companies in future, how this may impact their insurance;
- ❑ Individuals at the table would like to know where does Ireland stand in relation to the use of genetic information , and also the use of biobanks in other countries;

C Some recommended changes

- ❑ Concern about the use of the word forever, i.e. genetic information being saved forever so replace 'forever ' with more appropriate wording or explanation of what this means;
- ❑ Include information about governance and protection of genetic information;
- ❑ Remove the statement 'but it is unlikely that you yourself will benefit '. This is somewhat negative – this line can be replaced with the societal benefits of patients participating in research like this.
- ❑ Histology, genetics , molecular tests – needs to be explained better. Need to explain MIS -- Roadmap with pictures and texts could be useful

General comment

'Its all encompassing , other hospitals should have access to patients genetic information & data. Should be able to give consent remotely/ shouldn't have to be hospital specific consent'

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.

A Table consensus at a glance

Is the level of information & detail appropriate	Too little ✘ **Enough** ✓ Too much ✘
Do some sections need to be ‘re-worded’	**No** ✓ Yes ✘
Any specific language that should be changed	**No** ✓ Yes ✘
Any omissions that might improve the document	**No** ✓ Yes ✘
Is the image effective in describing the process	No ✘ **Yes** ✓

B Comments & discussion points

- The view was the document has a lot of information but this is necessary. The document **has to be informative** and there is probably little scope to reduce the level of detail;
- **No additional information** is required;
- The **graphics** at the front is **very effective**;
- The language in the Participant Information Leaflet was considered **simple and clear**. The use of the glossary was very helpful;
- The Informed **Consent Form** is **easy to follow**;
- Clause 4 within section 2 of the Participant Information Leaflet [h**ow data is collected, stored and shared**] should be restructured. The group wasn’t clear as to how to restructure but felt it was necessary as the detail is important;
- The sections **explaining why** the **Biobank needs to collect data** and what **type of data is collected** were judged as being the most important aspects in this group discussion;
- The document does not cover scenario of on-going developments in treatment and that patients may need to provide new samples in the future as research evolves.

C Some recommended changes

- A suggestion was to add **more colour, use more graphics** throughout the document;
- Regarding the Informed Consent Form the group suggested there be **a well sign-posted instruction** on the form if patients want **to enquire or ask questions at a later date** or even want to **withdraw consent** in the future. This was suggested despite there being a section on the Consent Form titled “How to contact the Biobank”;
- It is important to provide **an easy method for patients to contact Biobank** and not need to go back to paper forms to check details. Need an easy way for patients to engage and **retrieve contact details**, etc.;
- A **table of contents** at the front of the Participant Information Leaflet would help patients follow the sections more easily;
- The explanation of how **samples / tissues are collected** needs improvement;

Appendix

The Biobank Participant Information Leaflet Working Group :

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