



OPEN LETTER

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Harmonising the human biobanking consent process: an Irish experience [version 3; peer review: 2 approved]

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V3 First published: 01 Sep 2021, 4:96
<https://doi.org/10.12688/hrbopenres.13384.1>

Second version: 15 Sep 2021, 4:96
<https://doi.org/10.12688/hrbopenres.13384.2>

Latest published: 13 Jan 2022, 4:96
<https://doi.org/10.12688/hrbopenres.13384.3>

Abstract

Biobanks are repositories of human biological samples and data. They are an important component of clinical research in many disease areas and often represent the first step toward innovative treatments. For biobanks to operate, researchers need human participants to give their samples and associated health data. In Ireland, research participants must provide their freely given informed consent for their samples and data to be taken and used for research purposes. Biobank staff are responsible for communicating the relevant information to participants prior to obtaining their consent, and this communication process is supported by the Participant Information Leaflets and Informed Consent Form (PI/ICFs). PILs/ICFs should be concise, intelligible, and contain relevant information. While not a substitute for layperson and research staff discussions, PILs and ICFs ensure that a layperson has enough information to make an informed

Open Peer Review

Approval Status

	1	2
version 3		
(revision)	view	view
13 Jan 2022		
version 2		
(revision)	view	view
15 Sep 2021		
version 1		
01 Sep 2021		
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Éidín Ní Shé , RCSI University of Medicine		

choice to participate or not. However, PILs/ICFs are often lengthy, contain technical language and can be complicated and onerous for a layperson to read. The introduction of the General Data Protection Regulation and the related Irish Health Research Regulation presented additional challenges to the Irish biobank community. In May 2019, the National Biobanking Working Group (NBWG) was established in Ireland. It consists of members from diverse research backgrounds located in universities, hospitals and research centres across Ireland and a public/patient partner. The NBWG aimed to develop a suite of resources for health research biobanks via robust and meaningful patient engagement, which are accessible, General Data Protection Regulation/Health Research Regulation-compliant and could be used nationally, including a PIL/ICF template. This open letter describes the process whereby this national biobank PIL/ICF template was produced. The development of this template included review by the Patient Voice in Cancer Research, led by Professor Amanda McCann at University College Dublin and the Health Research Data Protection Network.


Keywords

Biobanking, Translational Research, Genetic Research, Clinical Research, Participant Information Leaflet, Informed Consent Form, Public and Patient Involvement, Data Protection.

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Any reports and responses or comments on the
article can be found at the end of the article.

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Competing interests: No competing interests were disclosed.

Grant information: Health Research Board [HRB-TMRN-2017-1].

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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How to cite this article: O'Sullivan L, Carroll TP, Clarke N *et al.* **Harmonising the human biobanking consent process: an Irish experience [version 3; peer review: 2 approved]** HRB Open Research 2022, 4:96 <https://doi.org/10.12688/hrbopenres.13384.3>

First published: 01 Sep 2021, 4:96 <https://doi.org/10.12688/hrbopenres.13384.1>

REVISED Amendments from Version 2

Protocol V3 includes amendments and clarifications which were suggested by the reviewers. These included citing some relevant literature to support the rationale for this project, clarifying the nature of the patient/public involvement in the development of the participant information leaflet/informed consent form template and providing more information about the background of these patients/members of the public.

Any further responses from the reviewers can be found at the end of the article

Abbreviations

ICF: Informed Consent Form; NBWG: National Biobanking Working Group; PIL: Participant Information Leaflet;

Disclaimer

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Background

In the context of health research, biobanks are managed repositories of human biological samples and associated health data, which are collected, stored and used to facilitate scientific and medical research¹. Biobanks are an important component of clinical research in many disease areas and often represent the first step toward innovative treatments^{2,3}.

For biobanks to operate, researchers need human participants to voluntarily give their biological samples and relevant health data. In line with internationally accepted ethical standards in clinical research such as the Declaration of Helsinki⁴, in Ireland, participants must provide their freely-given informed consent for these samples and data to be taken and used for research purposes⁵. Research staff are responsible for communicating the relevant information to participants and ensuring participants understand the information they have been provided with before participants give their consent. This communication process is supported by Participant Information Leaflets/Informed Consent Forms (PILs/ICFs). PILs/ICFs should be concise⁶, intelligible⁵, and along with the conversation with the research staff, should give the relevant information so that a layperson can determine if they want to take part⁴. (For the purposes of this article, we define laypersons to be members of the public who, due to their background, may not be familiar with aspects of the research process. These individuals may have a wealth of knowledge from their lived experience but are not generally familiar with e.g., research terminology, or the role of the health research biobank. This means that these individuals may find it difficult to understand written or verbal information if it is not simple and free of jargon.) However, clinical research PILs/ICFs are becoming longer^{7,8} and in the view of the authors of this letter, are not primarily written to meet the needs of a layperson. Systematic reviews have shown that clinical research participants often have not understood important aspects of a research study they have agreed to take part in [9](#), [10](#),

particularly those with literacy challenges¹¹. While the use of visuals to explain important or complex concepts is strongly recommended^{12,13}, they are often under-utilised in clinical research PILs/ICFs¹⁴. This was identified as a limitation of current biobank PIL/ICFs in use nationally. The Irish Health Research Regulations⁵ mandate suitable and specific measures for the processing of personal data for the purposes of health research in addition to the statutory obligations of the European Union General Data Protection Regulation¹⁵⁻¹⁷. These pieces of legislation have presented additional challenges to research biobankers who aspire to provide clear, concise information which supports the decision-making of potential research participants. For example, this legislation requires that additional information about data protection measures should be provided to research participants. While we welcome research participants being provided with all the pertinent information about their data protection rights, we have found that this additional information is often provided in a format which is not well understood by laypersons. For example, legal jargon is often used and the use of the passive voice, verb nominalisations etc, can make it difficult to understand.

Biobank-based research is frequently investigative in nature, and therefore, the research aims are often broad. Biobank research increasingly yields genetic findings, the relevance of which may be unclear at the time of the analysis. These factors, among others, present additional challenges to ensure that participant consent is informed, while simultaneously ensuring that researchers have the freedom to explore and adapt their research as findings emerge, thus ensuring clinical research continues to advance, achieving the maximum possible information from the samples and data. Research staff are obliged and wish to provide information to participants in a clear and comprehensible way. However, research staff alone may not always be the best judge of what is understandable to the general public. Therefore, it is crucial that members of the general public and patients are involved in co-producing patient-facing documents, including clinical research PILs/ICFs¹⁸⁻²⁰. It can also be challenging for research ethics committees and data protection officers to ensure that all of the required information is included in PILs/ICFs due to differing templates produced and wording favoured by individual institutions.

The biobank community in Ireland came together in early 2018, prior to the application of the General Data Protection Regulation legislation and several individuals subsequently volunteered to be part of the National Biobanking Working Group (NBWG). The NBWG was established in May 2019, originally under the auspices of Clinical Research Development Ireland. The group consists of members from diverse research backgrounds who are located in universities, hospitals and research centres across Ireland, and a public/patient partner. Each member has a special interest in making information about health research biobanks accessible and understandable to members of the public. Group members are involved in maternal, infant, paediatric, adult and older adult research areas. The public/patient member is a patient advocate who doesn't have a scientific, medical or research background and is therefore

ideally placed to represent the perspectives of laypersons. The NBWG was established at a crucial juncture in the Irish health research landscape just after the implementation of new European Union data protection legislation (General Data Protection Regulation)¹⁷, Irish health research legislation (Health Research Regulations)⁵ and also the publication of the first international biobanking standard International Organization for Standardization (ISO) 20387: 2018²¹. The main aim of the NBWG was to address foreseen challenges for compliance brought about by the new legislation and to jointly work towards an improved understanding of the reshaping of the biobank landscape in Ireland.

The NBWG has developed a suite of tools and resources, including infographics, a general biobanking awareness leaflet and single PIL/ICF template specifically designed for health research biobanks, via robust and meaningful public and patient engagement, which could be adopted nationally. The group also developed a video which describes some of the research at St James' Hospital, Dublin and Trinity College Dublin: <https://www.stjames.ie/cancer/research/biobanknetwork/> This video aims to increase awareness of the importance of health research biobanks, and has been shared widely on social media and is played in multiple waiting rooms in St James' Hospital, Dublin. The NBWG also seeks to engage with members of the public and patients to increase awareness about the value of taking part in research biobanks. The inclusive and unified approach taken by the NBWG removes the need for multiple biobanks within Ireland to develop their own resources separately, a process which can be time-consuming and costly.

The aim of this open letter is to describe the process whereby a national template for a biobank PIL/ICF was co-produced by the NBWG, with public-patient partners from the Patient Voice in Cancer Research. While we recognise that regulatory and research governance requirements, and cultural perspectives will vary between countries, the process may be of interest to other countries seeking to develop a national template.

Development of the PIL/ICF template

The NBWG initially convened via teleconference in May 2019. One significant challenge raised during this inaugural meeting was the lack of a standardized PIL/ICF template that could be used by all biobanks throughout Ireland. As informed consent is the cornerstone of all research, including biobanking, the group decided to prioritize this development.

To undertake this task, it was determined that the NBWG would meet on a bimonthly or monthly basis, initially in person, and subsequently via videoconference due to COVID-19 pandemic restrictions. As a starting point, the group collated and reviewed more than eight research ethics committee-approved biobank PIL/ICF templates in use at that time across Irish universities and hospitals. A PIL/ICF developed by Cancer Trials Ireland, the leading cancer research organisation in Ireland was also reviewed ²². Based on the review process, it was agreed to divide the template PIL into three sections deemed most important (explained below). The group then reviewed and

amended each section, using an iterative process, ensuring that the resulting template was applicable to a broad range of biobank research, disease areas and research environments (hospitals, academic institutions, not for profit organisations etc) within Ireland. The NBWG's public-patient member was involved in every stage of the development and review process and in particular advised on whether language was understandable and relevant to research participants. The three sections were as follows:

1. **Section A: Taking part** – This section explains what a health research biobank is and invites individuals to take part. It outlines that participation is voluntary, that consent can be withdrawn, the benefits and risks of taking part, the procedure for biobanking and what will happen to participants' health data should they choose to take part. The NBWG public-patient member was particularly passionate about giving the most practical information at the start of the document, with further detail relevant to data protection to follow.
2. **Section B: Biobank Management** – This section describes the security and compliance measures in place for participants' data, details of the biobank funding, and ethics committee approval.
3. **Section C: What does the biobank do with my healthcare data?** – This section outlines what kind of data will be collected and stored, the rationale for this and the participants' rights.

These three sections of the PIL are followed by the ICF, which is divided into two sections.

Best practice guidelines for communicating clearly with laypersons, including the National Adult Literacy Agency (NALA) guidelines²³ were incorporated. For example, sentences were written in the active voice; plain, commonly used words were included whenever possible, and the section headings were posed as conversational-style questions to prompt pre-processing of information. Guidelines for optimal layout were also incorporated, such as using adequate line spacing and font size. Bold font was used for section headings as it is more accessible for dyslexic readers and those with literacy challenges, rather than underlining and all-capitals²⁴⁻²⁶. The group valued input from all members, but particularly from our public-patient member to ensure that the language and content was understandable and relevant to research participants. The group informally shared the PIL/ICF with a selection of friends and family members who are neither medical professionals nor currently attending a hospital. It is important that personnel without regular medical contact or a previous diagnosis can understand the PIL/ICF, as individuals are often presented with the option of joining a biobank prior to confirmation of disease diagnosis.

The group decided to include a glossary of key terms at the beginning of the PIL/ICF template to which readers could refer. Terms which laypersons may not be familiar with, such as 'coded data' and 'identifiable data' were included. To assess how well the template worked, the group decided to apply it

to a well-established biobank at St James's Hospital, Dublin; biobank-specific and site-specific information was added. Once the provisional content was decided, the group invited a professional graphic designer to design an infographic (see [Figure 1](#)) to explain how a health research biobank works. The graphic designer is a graduate of the Irish Platform for Patient Organisations, Science and Industry (IPPOSI) Patient Education Programme²⁷. The graphic was created with the participant at the centre of biobanking and highlights the benefits to the participant and the wider society. A larger infographic was also developed which included some relevant facts about biobanks and health research (see *Extended data: Supplementary File 1*²⁸).

Evaluation of the draft PIL/ICF template Patient Voice in Cancer Research Workshop

The group felt it was critical that the understandability and usability of the PIL/ICF template be evaluated by a wider independent group of laypersons. The Patient Voice in Cancer Research, led by Professor Amanda McCann at University College Dublin, is an initiative that positively impacts on cancer research and outcomes for patients by actively engaging cancer patients, cancer researchers and other interested parties (patient advocates, families, carers, healthcare professionals, policymakers and those with an interest in cancer research) in discussions and decision-making processes^{29,30}. The Patient Voice in Cancer Research and the NBWG co-hosted a workshop in Cork on 9th October 2019 to develop public input into the draft template. To facilitate a critical appraisal of the documents, the workshop attendees were assigned to nine different groups of approximately 10 people each. Round-table discussions on an

assigned topic were led by experienced facilitators. The topics were as follows:

- Is the PIL/ICF easy to understand? (two groups were assigned this topic as this was the main purpose of the review)
- Would patients be happy to consent to all parts of the consent form?
- Is it understood why samples and data are stored for a long time period?
- Does the document explain why data/samples may be shared with researchers around the world?
- Is it clear why samples and data may be shared with commercial companies?
- Are patients interested in updates on projects supported by the Biobank?
- 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?
- Do you understand from this document what genetic research means? Do you have any concerns?

A report from the roundtable discussions was prepared by Ms Yvonne D'Arcy of Darmah Market Research (see *Extended data: Supplementary File 2*²⁸). Overall, the event participants agreed that the PIL/ICF template was accessible and user-friendly, and that the glossary of key terms and images were extremely helpful. Patient Voice in Cancer Research



Figure 1. Infographic from the PIL/ICF template – *How a biobank can help future patients.*

attendees also provided informative feedback on content highlighting where it could be improved, including:

- clarifying the meaning of some of the key terms.
- emphasising the benefits to society in the future.
- clearly stating security measures in place for participant data.
- keeping General Data Protection Regulation information clear and concise.

There were mixed views on whether potential participants should be offered the option to consent to some aspects but not others and whether ongoing updates should be provided to participants. The feedback was incorporated into the draft template.

Review by the Health Research Data Protection Network and the Data Protection Commission

The Health Research-Data Protection Network was established in December 2018 to harmonise the approach of data protection officers working in health research environments in Ireland. The PIL/ICF template developed by the NBWG was sent to the Health Research-Data Protection Network in 2020, the resulting feedback was discussed and the documents were amended per the feedback. The PIL/ICF template was also submitted to the Data Protection Commission for their review and the group awaits this feedback.

The final template PIL/ICF is included as Supplementary File 3 (*Extended Data*²⁸).

Implementing the PIL/ICF template

Some research groups have adopted the template PIL/ICF and it has been submitted for approval to various local research ethics committees. Established biobanks have also requested the documents for use at their institutions. The PIL/ICF template has received positive feedback from the biobank community and the patient advocacy community. We welcome requests for use and feedback from other researchers or patient groups.

The infographic and biobank awareness leaflet (see *Extended data*: Supplementary File 4²⁸) are currently in use in Irish Cancer Society Daffodil Centres, several research centres and hospital clinics nationally.

Limitations

There are some limitations to this project. The PIL/ICF template developed by this group is intended for adult readers with the capacity to consent. Therefore, additional and/or different considerations will be needed for PIL/ICFs for children or adults lacking the capacity to give their consent. However, the process for the design and evaluation of a PIL/ICF could easily be adapted to facilitate stakeholder engagement for children and vulnerable research participants. While this PIL/ICF template was designed with the health research biobank in mind, the overall structure and much of the content could be applied to other forms of health research.

Future directions

The experience of the NBWG members is that the standard data protection information included in biobank PILs is often too complicated, lengthy and poorly understood by research participants. For this reason, the group attempted to use easy-to-understand language and to explain terminology, which is not in common use. To receive feedback on this aspect, the group intends to submit the PIL/ICF to the National Adult Literacy Agency for a full review. In addition, the group hopes to receive feedback from the Data Protection Commission on the accuracy of the explanations of the data protection terminologies. Ongoing work, using insights gained from the patient-public partners as part of this project, is focused on the production of a video version of the PIL/ICF specifically aimed at making the information more accessible to individuals with literacy challenges. The NBWG welcomes feedback from users of the PIL/ICF template and informal or formal evaluations of the template's effectiveness. Finally, the group hopes that the newly-developed biobank PIL/ICF template will eventually be adopted nationally as a standardised template, with the option to accordingly adapt it for specific patient groups. Ideally the group would favour a national standardised suite of documents and are willing to engage with other public-patient groups, including those representing minorities such as those with disabilities and members of the travelling community, to achieve this goal.

Data availability

Underlying data

No data are associated with this article.

Extended data

Open Science Framework: Harmonising the human biobanking consent process: an Irish experience, <https://doi.org/10.17605/OSF.IO/5M8FP>²⁸.

This project contains the following extended data:

- Supplementary File 1: Infographic
- Supplementary File 2: Patient Voice in Cancer Research Workshop Report
- Supplementary File 3: Template information leaflet and consent form
- Supplementary File 4: Infographic and biobank awareness leaflet

Data are available under the terms of the [Creative Commons Zero "No rights reserved" data waiver](#) (CC0 1.0 Public domain dedication).

Acknowledgements

The authors gratefully acknowledge the following:

- The Patient Voice in Cancer Research, led by Professor Amanda McCann at University College Dublin, supported by Irish Cancer Society research grant PVCRI9MCC and the Mater Foundation, Mater Misericordiae University Hospital, for co-hosting the workshop.

- HRB PPI IGNITE at Trinity College Dublin, for providing funding for the design of the summary graphic in the PIL/ICF.

- The HRB for funding the making of the video which describes some of the research at St James' Hospital, Dublin and Trinity College Dublin as part of the KEDS-2018-015 grant.

- Biobank Ireland Trust for providing funding for the preparation of the report following the Patient Voice in Cancer Research workshop reviewing the PIL/ICF.

- Ms Rachel Lynch, support group facilitator with FibroIreland, accredited psychotherapist with IACP, European

Patients' Academy on Therapeutic Innovation (EUPATI) Fellow and member of Teaching council of Ireland for designing the summary infographic used in the template PIL/ICF.

- Ms Yvonne D'Arcy of Darmah Market Research for preparing the report following the Patient Voice in Cancer Research workshop.

- Health Research Data Protection Network for reviewing the sample PIL/ICF.

- To each individual who generously shared their input, thoughts and opinions on this initiative at many stages along the process.

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Open Peer Review

Current Peer Review Status:  

Version 3

Reviewer Report 28 February 2022

<https://doi.org/10.21956/hrbopenres.14709.r31236>

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Thank you for this clarity and for providing the additional literature.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Ashfaq Chauhan- Consumer engagement, co-design, patient safety, ethnic minorities Laurel Mimmo – pediatric healthcare quality and safety, consumer engagement, co-design, inclusive research, intellectual disability

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 24 February 2022

<https://doi.org/10.21956/hrbopenres.14709.r31237>

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I have one more suggestion for the authors: Figure 1 may be referred to in several presentations or used as a reference if it has a higher resolution.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Human research ethics; Informed consent; Biobank research.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 2

Reviewer Report 22 November 2021

<https://doi.org/10.21956/hrbopenres.14617.r30795>

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This open letter describes the developmental process of the national biobank informed consent template in Ireland. Overall, the manuscript is sufficient in general, however, there are some issues that need to be addressed.

1. The title of the two sections is not representative of the content provided therein. For example, "Joining a health research biobank" does not represent "the benefits and risks of taking part". For another example, "details of the biobank funding" is not related to anything about "what does the biobank do with your healthcare data?" In addition, the content in the manuscript seems to be inconsistent with the template (in Supplementary File 3). In Supplementary File 3, there are 3 sections: Section A (Taking Part), Section B (Biobank Management), Section C (What does the biobank do with my healthcare data?)
2. In Figure 1, what is the meaning of the arrow from "7" to "1"? I do not understand the link between "For future patients better tests, treatments, drugs or medical devices" and "Participant".
3. In Supplementary File 3 (the template), only the participant's signature box is available. What if the participants cannot read and write? The authors should explain or discuss the implementation of the template as well. Whether or not the template is limited to those who can read, write, and sign consent. Or, whether or not the template must be modified to suit particular scenarios, and how to modify it?

4. The authors describe the general background about the biobank research and informed consent as well as the developmental process of the PIL/ICF template. However, the manuscript has lacked discussion on several issues. Are there any other templates in the world? What is the difference between the PIL/ICF template here and other templates? Pros and cons? Can the PIL/ICF template be applied outside Ireland? Can it be applied even outside Europe, like in the US or Asian countries? For example, in the US, there is the revised Common Rule that indicates the required elements of broad consent. Does the PIL / ICF template comply with the revised Common Rule? For another example, the CIOMS 2016 guidelines provide a guideline for the collection, storage, and use of biological materials and related data. Did the authors consider that guideline when developing the PIL/ICF template?

Is the rationale for the Open Letter provided in sufficient detail?

Yes

Does the article adequately reference differing views and opinions?

Partly

Are all factual statements correct, and are statements and arguments made adequately supported by citations?

Partly

Is the Open Letter written in accessible language?

Yes

Where applicable, are recommendations and next steps explained clearly for others to follow?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Human research ethics; Informed consent; Biobank research.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 07 Jan 2022

Lydia O'Sullivan, University College Dublin, Ireland

Thank you Prof Koonrunsesomboon for your time in reviewing our paper. We appreciate all of your comments and suggested changes. We have addressed each of the points you have raised and amended the paper accordingly.

We have now amended the manuscript so that it matches the content in Supplementary File 3.

The meaning of the arrow from “7” to “1” in Figure 1 relates to the fact that if a participant donates a biobank sample(s) and healthcare data, these can be used to develop new tests, treatments etc. These innovations will ultimately benefit research participants in the future. We explain this in the PIL (Supplementary File 3) within Section A/Point 3/What are the benefits to me? We also outline in this section that developing new tests, treatments etc often take a long time, so the benefits may not accrue to the participant themselves, but to others in the future. We recognise that no infographic/diagram will be able to explain the biobank process perfectly, but this version has been reviewed and approved by our wider public-patient partners. Our public-patient input highlighted how important it was to show a biobank as a circular process, rather than linear, which starts and ends with the participant. This is what we have tried to convey in this diagram.

Supplementary File 3/Part 1/Point 1 allows for participants who cannot read – “I have read, or had explained to me...”, but we do acknowledge the value of having a line for a witness to allow for participants who cannot write and we will consider adding this to a future version of the PIL/ICF template.

We recognise that biobank PIL/ICFs templates exist in many other parts of the world. However, since the regulatory and research governance requirements, as well as cultural perspectives, vary in different countries and jurisdictions, we feel it is important that PIL/ICF templates are developed nationally or locally in conjunction with public-patient partners. The aim of this paper was to describe the experience we had in Ireland and we feel that researchers in other countries may be interested in this experience. We have produced a PIL/ICF template which aims to be compliant with the ethical and governance guidelines which are applicable in Ireland. We have now clarified this point at the end of the Background section, after stating the aim of the paper.

Many thanks again.

Competing Interests: No competing interests were disclosed.

Reviewer Report 17 September 2021

<https://doi.org/10.21956/hrbopenres.14617.r30315>

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Éidín Ní Shé 

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Thank you for the opportunity to read this open letter. We found this very interesting and consider it a significant issue as researchers working with people with intellectual disabilities and culturally and linguistically diverse populations in Australia.

Please see below suggestions for you to consider:

1. Please provide some additional detail/examples for why the current PILs/ICFs are not suitable for layperson in the authors' view, and any available feedback or evidence of what biobank participants want to know? For example, are the suitability issues related to length, content, and/or accessibility? Is there information missing from the current PILs/ICFs that biobank participants want or ask for, but is not included?
2. Please clarify who do you mean by layperson? Our population is inherently diverse and consists of many different groups including people who are refugees, are from diverse ethnic minority backgrounds or have specific communication needs.
3. Second paragraph: last line – what additional challenges do the regulations create? This can be briefly added to give reader some context. Are these additional challenges related to length, content, etc.?
4. Third paragraph – you have established some relevant links here e.g. importance of involving patient/public in developing patient-facing documents. This can be supported by references to academic literature.
5. While the effort taken by the authors to ensure the format of the information sheets met literacy guidelines is acknowledged, the NBWG membership has multiple representatives from various research fields, however, there is only a single public-patient partner, was this an individual person or a group of people? Please consider limitations that may be posed by lack of diverse patient/public representation in the working group as you have mentioned that only one member of the group was a patient/public. You could include some detail to highlight if they belonged to mainstream population group, or how they were representative of biobank participants, what level of experience they had and how this may have affected their contribution, and what level of actual contribution they made to the process and outcome.
6. The aim statement alludes that more than one patient/public partner was involved in the process while the above paragraph mentions one member of patient/public group as a member of the working group. Please clarify.
7. Thank you for describing the process in good detail. Were the patient/public partner also involved in drafting and generating ideas for the PIL/ICF draft and subsequent versions along with ensuring that the language was understandable and relevant to research participants. The workshop conducted to collect feedback on the draft is a great approach

and authors may wish to consider commenting on the diversity of patient/public participants who provided feedback on the draft.

8. In draft PILs (Section C, point 6), authors may consider adding a line that that staff can assist patient/participant to know their rights by providing them with a copy of the document if needed.
9. Is there a plan for evaluating the effectiveness of these revised forms? It would be prudent to see how they are working in practice, given the limited public-patient representation in the development. They could be tested with people from minority groups, such as those from ethnically diverse backgrounds, children and young people, and children and adults with intellectual disability. As there is limited detail on the involvement of diverse laypeople, the evaluation could include how useful the revised forms are for minority groups, and what adaptations may be necessary.
10. Infographic and use of multimedia are good but the letter lacks detail on whether they are being used by or helpful for the general public; what has been the feedback on these resources from biobank participants?
11. For question 4 our response is partly because there are many acronyms used. It is difficult to read a document with multiple acronyms, even where they are explained. We found we had to regularly go back and check some of the acronyms that are used only a few times in the letter. For example, GDPR, HRDPN, RECs. We would suggest acronyms are not used in these situations.

Is the rationale for the Open Letter provided in sufficient detail?

Yes

Does the article adequately reference differing views and opinions?

Partly

Are all factual statements correct, and are statements and arguments made adequately supported by citations?

Partly

Is the Open Letter written in accessible language?

Partly

Where applicable, are recommendations and next steps explained clearly for others to follow?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Ashfaq Chauhan- Consumer engagement, co-design, patient safety, ethnic minorities Laurel Mimmo – pediatric healthcare quality and safety, consumer engagement, co-

design, inclusive research, intellectual disability

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however we have significant reservations, as outlined above.

Author Response 07 Jan 2022

Lydia O'Sullivan, University College Dublin, Ireland

Thank you Mr Chauhan, Ms Mimmo and Dr Ní Shé, for your time in reviewing our paper. We appreciate all of your comments and suggested changes. We have addressed each of the points you have raised and amended the paper accordingly.

We have now included additional references (References 9-11) and some text in the second paragraph of the Background section, explaining that the current clinical research PILs/ICFs are written at a level that is too complex – this means that the material is not accessible to many lay individuals, particularly those with literacy challenges. We have also included some references and text to note that systematic reviews have consistently demonstrated that clinical research participants, when assessed, frequently have an inadequate understanding of the research study they have agreed to take part in. We are not aware of any formal research which indicates that biobank participants feel that information is missing from PILs.

We used the word 'layperson' to clarify that the intended audience for research PILs/ICFs are members of the public who, because of their background, may not be familiar with the research process. These individuals may have a wealth of knowledge from their lived experience but are not generally familiar with e.g., research terminology, or the role of the health research biobank. This means that these individuals may find it difficult to understand written or verbal information if it is not simple and free of jargon. Some of these individuals may be from diverse ethnic groups and have additional communication needs, as you have pointed out – the aim of our project was to create a PIL/ICF template which would be understandable to as many people as possible. We have now clarified our intended meaning of the word 'layperson' in the manuscript.

We have now added some sentences to clarify that the data protection regulations create additional challenges because they require additional information to be provided to research participants. While we welcome research participants being provided with the pertinent information about their data protection rights, we have found that this additional information is often provided in a format which is not well understood by an average member of the public. For example, legal jargon is often used and the structure of the sentences (e.g. use of the passive voice, verb nominalisations etc) makes it difficult to understand.

We have now added some references (References 18-20) to the academic literature to describe the importance of involving patients/the public in developing patient-facing documents.

One patient/public partner is a member of the National Biobank Working Group. This is noted in the following sentence in the *Background/4th* paragraph: *The group consists of members from diverse research backgrounds who are located in universities, hospitals and research centres across Ireland, and a public/patient partner.* We have also added in the following sentence: *Group members are involved in maternal, infant, paediatric, adult and older adult research areas.* We have added in a sentence to describe this public/patient partner's background and level of experience. However, the draft PIL/ICF template, once developed by the National Biobank Working Group, was reviewed and adapted, by a wider patient/public advocacy organisation – the Patient Voice in Cancer Research. This process, which is explained in the *Evaluation of the draft PIL/ICF template/Patient Voice in Cancer Research workshop* section, ensured that the template was reviewed by a larger group. The workshop was attended by approximately 90 people for 2 hours. The Patient Voice in Cancer Research group is composed of individuals from differing backgrounds including patients, family members, charities and the general public, all interested in cancer research. We have now included a reference to a paper that they have published (Reference 30), describing how they formed and how they operate. The NBWG is currently seeking more public-patient representatives to ensure a more balanced representation.

The patient/public partner was involved at every stage of drafting and generating ideas for the PIL/ICF draft and ensuring the language was understandable and relevant to research participants. We have now added a sentence in paragraph two of the 'Development of the PIL/ICF template' section to clarify this. As noted in point 5 above, we have now also added a reference (Reference 30) regarding the formation and composition of the patient/public participants at the workshop.

We will certainly consider adding a sentence about staff providing a written copy of participant data protection rights in a future version the PIL/ICF template. We do also note, in several places in the template, that prospective participants can request further information from the investigator or study coordinator.

This paper describes the first step in the process – co-developing a PIL/ICF template for biobanks with patient/public representatives. We acknowledge that it is important to evaluate the effectiveness of these form in practice and have now noted in the '*Future Directions*' section that we welcome such evaluations of effectiveness. We hope that this paper will increase awareness of this PIL/ICF template and lead to these kind of evaluations; however, an assessment of the effectiveness of the PIL/ICF template is outside the scope of this paper. We disagree that the template development process involved 'limited' public-patient representation – as noted in point 5 above and as described in the paper, the template was reviewed and adapted following feedback from ~ 90 public-patient representatives, in addition to our NBWG patient representative who has been part of this work since its inception. This amounts to over 200 public-patient hours involvement in total.

Many thanks again.

Competing Interests: No competing interests were disclosed.

Author Response 07 Jan 2022

Lydia O'Sullivan, University College Dublin, Ireland

The aim of this open letter was to focus on the development of the PIL/ICF template, which includes a section of the infographic – both of these were reviewed by the Patient Voice in Cancer Research workshop. However, we have now noted that the knowledge gained from developing the PIL/ICF template was applied to preparing the video and a biobank awareness information leaflet. We have now also included more information about the video, which highlights the importance of biobank research. We acknowledge that getting feedback from biobank participants on the video is important, but it is outside of the scope of this paper.

We have now removed the following acronyms from the manuscript:

- EU: European Union
- GDPR: General Data Protection Regulation
- HRR: Health Research Regulation
- HRDPN: Health Research-Data Protection Network
- PVCR: Patient Voice in Cancer Research
- REC: Research Ethics Committee

Competing Interests: No competing interests were disclosed.

Comments on this article

Version 2

Author Response 16 Sep 2021

Lydia O'Sullivan, University College Dublin, Ireland

Response to Prof Mark Little, Trinity College Dublin, Ireland on Version 1:

Thank you for your comment, Mark. We would very much welcome input from the DPC and have have sent the PIL/ICF to them for review. Despite several attempts to engage with them, we have not received a response to date. We will continue to strive for DPC engagement.

Competing Interests: Corresponding author of this paper.

Version 1

Reader Comment 06 Sep 2021

Mark Little, Trinity College Dublin, Ireland

Excellent paper! Really important for the biobanking community in Ireland. Formal linkage with the data protection commissioner would be a major advantage.

Competing Interests: Member of National Irish Covid Biobank steering committee
