BBMRI-ERIC®

The European research infrastructure
for biobanking and biomolecular
resources in health and life sciences

Public and Patient Involvement and Engagement (PPIE) in Biobanking

CONTENTS

INTRODUCTION

Constant dialogue with patients, caregivers, and the public is a key guiding principle in biobanking, however, public and patient involvement, often referred to as research participant engagement, has not yet become the usual practice in many biobanks[1]. When participants are engaged, it is often limited to one-way communication, with participants being informed rather than involved.

Public and Patient Involvement and Engagement (PPIE) in research is defined as "*research being carried out 'with'* or *'by'* members of the public rather than *'to,' 'about'* or 'for' *them*"[2]. Valuing the opinions and experiences of patients, caregivers, and the public in all kinds of research activities will bring about meaningful insights that will ultimately benefit the whole biobanking community. It is without a doubt that countries across Europe and worldwide have already increased efforts to involve the public, patients and caregivers in their consultation and decision-making processes in one way or another across the health-care sector. In addition, strategies

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[1] Goisauf et al., 2019

[2] Health Service Executive Research and Development. *Knowledge Translation, Dissemination, and Impact: A Practical Guide for Researchers. Guide No 8: Patient and Public Involvement in HSE Research.* https://hseresearch.ie/wp-content/uploads/2021/12/Guide-no-8-Patient-and-Public-Involvement-in-HSE-Research.pdf (2021).
There is another definition by Harrington et al. 2020: "The active, meaningful, and collaborative interaction between patients and
researchers across all stages of the research process, where research decision making is guided by patients' contributions as partners, recognizing their specific experiences, values, and expertise".
Harrington R.L., Hanna M.L., Oehrlein E.M., Camp R., Wheeler R., Cooblall C., Tesoro T., Scott A.M., von Gizycki R., Nguyen F., Hareendran A., Patrick D.L., and Perfetto E.M. (2020) Defining patient engagement in research: Results of a systematic review and analysis: Report of the ISPOR patient-centered Special Interest Group. *Value in Health*, **23**(6):677-688. https://doi.org/10.1016/j.jval.2020.01.019

of public engagement in biobanking have been a key subject in scientific discourse for over a decade, emphasising that considering public attitudes towards biobanks at early stages is crucial[3].

This document puts forward principles that will help guide biobanks in developing activities for involvement and engagement of patients, caregivers and the public.

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[3] Goisauf & Durnová 2018

Benefits of public and patient involvement and engagement (PPIE) in biobanking

Biobanks are strongly encouraged to engage with patients and the public in order to:

Improve transparency and trust: There is evidence[4] that the more people understand about science, the more trust they have in scientists. Trust – not only from patients, caregivers and the public, but also society as a whole - is important to ensure ongoing contribution of samples and data for research.

Also, PPIE provides the opportunity to express the needs, expectations and interests of research participants. Importantly, the rights of the participants[5] are defined in Art. 1 of the Oviedo Convention, which protects the dignity and identity of all human beings and guarantees everyone, “without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine”.

Strengthen research quality and relevance: Public understanding about biobanking activities may contribute to its legitimacy, which as a result can help to improve enrolment

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[4] Luna Puerta, L., et al. (2020). The reported impact of public involvement in biobanks: A scoping review.

[5] Oviedo Convention and human rights principles regarding health. The European Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine (ETS No. 164) of 1997, or the “Oviedo Convention,” promotes the protection of human rights in biomedicine at a transnational level. The Oviedo Convention is a framework instrument meaning it contains general principles intended to be translated into domestic law by signatories.

of participants and enhance research quality based on general principles 6 and 7 of the Declaration of Helsinki[6].

Obtain different perspectives: Involvement can make a big difference in the efficiency of biobanking: it has been observed[7] that the full integration of PPIE in the governance, design and conduct of biobanks has had an impact on the biobank itself, the people, and the wider research community through new policies and regulations, new recruitment strategies and materials, education of communities and lasting and trusting research partnerships.

Ensure sustainability: Participant and public support is needed to ensure the sustainability and longevity of biobanks with regards to continuous funding and resources.

Increase recognition of PPIE: To understand the needs, expectations and concerns of the participants and various categories of the public, PPIE may serve as a platform for exchange between different actors. Engaging with the public is increasingly being recognised as a strength and in recent years, it has also been progressively required by research funding organisations.

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[6] WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants . Paragraph 6 now includes: "Meaningful engagement with potential and enrolled participants and their communities should occur before, during, and following medical research. Researchers should enable potential and enrolled participants and their communities to share their priorities and values; to participate in research design, implementation, and other relevant activities; and to engage in understanding and disseminating results."

[7] Luna Puerta, L., et al. (2020). The reported impact of public involvement in biobanks: A scoping review.

How to identify public and patient representatives to include in your activities

Engaging representatives requires acknowledging that diversity exists not only among patients and other participants, but also among different patient and public groups representing the same condition. In terms of public representatives for PPIE activities, biobanks should consider non-affiliated literate persons with no specific qualification with respect to biomedical research, medicine, or health care in the last 5 years who can represent the local community and are aware of the local language, cultural and moral values of the community[8].

Choosing suitable representatives is therefore key for any activity in order to balance different perspectives[9]. Biobanks can engage members of the public through activities such as scientific fairs, open science days, media and social media, webinars, and educational materials. For example, BBMRI.NL provides a manual on how to organise an interactive public outreach day designed for increased public engagement and participation[10].

Another meaningful form of engagement is to create a formal partnership with patient organisations and civil societies.

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[8] Guide for Research Ethics Committee Members, Council of Europe: https://www.coe.int/t/dg3/healthbioethic/activities/02_biomedical_research_en/guide/Guide_EN.pdf

[9] Tackling Representativeness: A Roadmap and Rubric, https://nationalhealthcouncil.org/wp-content/uploads/2019/12/Representativeness%20in%20Patient%20Engagement.pdf

[10] BBMRI.nl. (2020). PUBLIC OUTREACH FOR BIOBANKS Enhancing knowledge, gaining trust and increasing citizen participation.

Biobanks can also consult with the BBMRI-ERIC Stakeholder Forum Patients’ and Citizens’ Pillar to engage members of the public to develop their PPIE activities.

KEY PRINCIPLES FOR PPIE

BBMRI-ERIC recommends the following principles to be considered when biobanks develop their PPIE activities:

1. Co-create clear objectives and scope of PPIE activities

Biobanks are encouraged to *co-create PPIE activities with patients, caregivers and the public*, rather than *for* and *about* them, discuss the joint objectives and agree on their purpose and expected outcome.

2. Enable engagement and involvement in different levels of biobank governance

Biobanks should engage and involve different research participants in the existing governance structures of the biobank, such as the Biobank Steering Committee, Scientific and Ethics Oversight Committee, Data and Sample Access Committee or Lay Advisory Panel/Community Advisory Group[11,12]. Research participants can act in an advisory role in all of these committees, or when relevant, have decision-making rights along with other members of the body.

3. Ensure diverse representation of patients and the public

Biobanks should strive to involve diverse groups of patients, caregivers and the public into their PPIE activities, especially underrepresented groups when possible[13]. They should offer easy, accessible ways to get involved, clearly explain roles and set up mechanisms to support meaningful participation (e.g.,

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[11] Mendy, M., et al. (2017). Recommendations for biobanks.

[12] Snapes, E., et al. (2023). Updating International Society for Biological and Environmental Repositories Best Practices,

[13] Guidelines on how meaningful representativeness can be obtained can be found here: https://www.sciencedirect.com/science/article/abs/pii/S0277953617302794?via%3Dihub and https://nationalhealthcouncil.org/wp-content/uploads/2019/12/Representativeness%20in%20Patient%20Engagement.pdf

https://vivobiobank.org/ppi). Everyone participating should have a chance to express their opinion in a respectful and trustworthy environment where all voices are heard and valued.

4. Provide training and support

Biobanks should provide training and support whenever necessary to help both the biobank staff and the research participants to contribute effectively to the PPIE activities. The aim is to ensure that everyone has the same level of understanding of the objectives and expected outcomes of the PPIE activity.

5. Create conditions for compensation or reimbursement whenever possible

Whenever possible, biobanks should discuss with the patients, caregivers and the public appropriate ways to fairly compensate their efforts and contributions (monetary or non-monetary) to the PPIE activities, especially when they are directly involved e.g., participating in developing and evaluating biobanking related documents or involvement in governance structures. Often, biobanks and their umbrella organisations will have regulations that determine the modalities of compensation and reimbursement, as is the case, for example, with ethics committees.

6. Make contributions visible

Biobanks should recognise and value the expertise of patients, caregivers and public representatives. This involves acknowledging and including their contributions to the PPIE activities and outcomes in a transparent way (e.g., co-authors on reports, publications, project summaries, reflection of their involvement in governance on the websites).

7. Assure sustainability of involvement and engagement

PPIE should be considered a continuous collaboration and not a one-time exercise. Biobanks should plan for sustained public engagement throughout the biobank's lifecycle, regularly seeking input, providing updates and adapting the PPIE based on feedback and evolving needs. We recommend conducting annual meetings with the patients/public representatives to gather feedback and review the PPIE activities.

8. Ensure transparent and accessible outreach of the patient and public engagement

Biobanks should share their PPIE strategy, activities and outcomes in a transparent and visible way, making the information jargon free, easy to find, understand, and access. Additionally, biobanks should promote opportunities to participate in PPIE activities through multiple channels (website, social media, events when relevant) to reach new research participants, including underrepresented groups and other audiences.

9. Measure and evaluate impact

Biobanks should implement tools to measure and evaluate the impact of their PPIE activities and communicate the outcomes with those involved and the wider community. Learnings, upcoming needs and evolving societal values shall be adopted and findings shall be embedded in future activities. Deliberative democratic methods like citizen juries or consensus conferences have proven useful for biobanking discussions and for collecting feedback[14,15,16]. Several tools are available to be used for measuring and evaluating the impact of the PPIE in research, for example the CEPPP Evaluation Toolkit[17] and McMaster University: Public and Patient Engagement Evaluation Tool[18] to name a few.

These principles reflect different stages of involvement and engagement of patients, caregivers and the public. The table on the following page shows the spectrum of patient and public participation and includes different levels, the purpose, and relevant activities that can be implemented by biobanks. The table is an adaptation of the IAP2 Spectrum of Public Participation[19].

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[14] Luna Puerta, L., et al. (2020). The reported impact of public involvement in biobanks: A scoping review.

[15] Molster, C., et. al. (2013). Blueprint for a deliberative public forum on biobanking policy: were theoretical principles achievable in practice?

[16] O'Doherty, K. C., & Hawkins, A. (2010). Structuring Public Engagement for Effective Input in Policy Development on Human Tissue Biobanking.

[17] CEPPP Evaluation Toolkit: https://ceppp.ca/en/evaluation-toolkit/

[18] McMaster University: Public and Patient Engagement Evaluation Tool: https://ppe.mcmaster.ca/resources/public-and-patient-engagement-evaluation-tool/

[19] International Association for Public Participation: The 3 Pillars of Public Participation: https://www.iap2.org/page/pillars

Additional methods for involvement and engagement can be checked in the IAP2 methods matrix, and the guide developed by University of Manitoba on "Methods of Patient & Public Engagement".

Other resources for developing PPIE activities:

- OECD template for Public Engagement Strategy: https://oecd-opsi.org/wp-content/uploads/2019/12/Draft_Engagement_Planning_Template.pdf,
- NIHR Resources and training for public involvement in research: www.learningforinvolvement.org.uk ,
- Engage with Impact Toolkit: www.evaluateengagement.ca,
- Patient and public involvement and engagement in research - a "how to" guide for researchers: https://zenodo.org/records/5017791#.YdW_M9_TUaF

THE SPECTRUM OF PATIENT AND PUBLIC PARTICIPATION

	PUBLIC/PATIENT PARTICIPATION GOAL	PURPOSE	ACTIVITIES
INFORM	Provide the public with balanced and objective information about biobanking activities and assist them in understanding the opportunities (e.g., recruitment of participants in ongoing research projects).	Inform those with an interest in participating in biobanking activities e.g., recruitment of participants in research, recruitment of patients/public in other PPIE activities.	Biobanks can participate in science fairs, organise open days, create communication materials (leaflets, one pagers, webpages, videos etc.) about biobanking activities etc.
CONSULT	Obtain feedback on relevant topics (e.g., informed consent, other ethical aspects), materials, proposals etc.	Keep the stakeholders informed, listen to the stakeholders and acknowledge their concerns and input and provide feedback on how the public input influenced the decision.	Public/patient/ethics advisory boards, deliberative exercises, ad-hoc consultation, surveys, interviews, workshops etc.
INVOLVE	Work directly with participants throughout the policy / decision making process to ensure that their concerns and aspirations are consistently understood and considered.	Work together with stakeholders to ensure that their concerns and aspirations are directly reflected and considered in the solutions developed and provide feedback on how public input influenced the decision.	Co-development of biobanking documents or projects – informed consent, information material on biobanking activities, workshops, focus groups, participatory research etc.
COLLABORATE	Partner with public/patient representatives in each aspect of the decision, including defining the issue, developing alternatives and identifying preferred solutions.	Consider the advice and feedback of the public/patient representatives in formulating solutions and incorporate their advice and recommendations into the decisions to the maximum extent possible.	Formal partnerships with patient organisations and civil societies, deliberative exercises, workshops, focus groups, etc.
EMPOWER	Place final decision-making in the hands of the public/patient representatives.	Empower the patient/public to make decisions and/or take actions. Implement what the patients/public representatives decide.	Patient/public representatives to be involved as members of governance models: biobank steering committee, scientific and ethics oversight committee, data and sample access committee etc.

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Cancer Patients Europe
EBC European Brain Council
EFA European Federation of Allergy and Airways Diseases Patients' Associations
Hellenic Cancer Federation ELLOK
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Eurohealth
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