

Patient organizations as a partner in rethinking of both informed consent and governance in research biobanking

Sara Casati¹, Antonio Aglione², Elisabetta Iannelli², Renza Barbon³, Annalisa Scopinaro⁴, Eva Pesaro⁵, Marialuisa Lavitrano¹

¹BBMRI.it and BBMRI-ERIC Milano Bicocca University, ²FAVO, ³Uniamo F.I.M.R. onlus, ⁴ APW Italia onlus, ⁵ AISP onlus
on behalf of National ELSI Working Groups with Rare Disease and Cancer Communities

Towards a good practice in biobanking for research



2 peer working groups with the Rare Disease and Cancer communities, including patient and caregiver representatives, as a pillar of the [BBMRI.it](http://www.bbmri.it) ELSI Action
a collaborative process and a participatory pact between all of the actors involved

ELSI matrices

co-producing

ELSI consensus

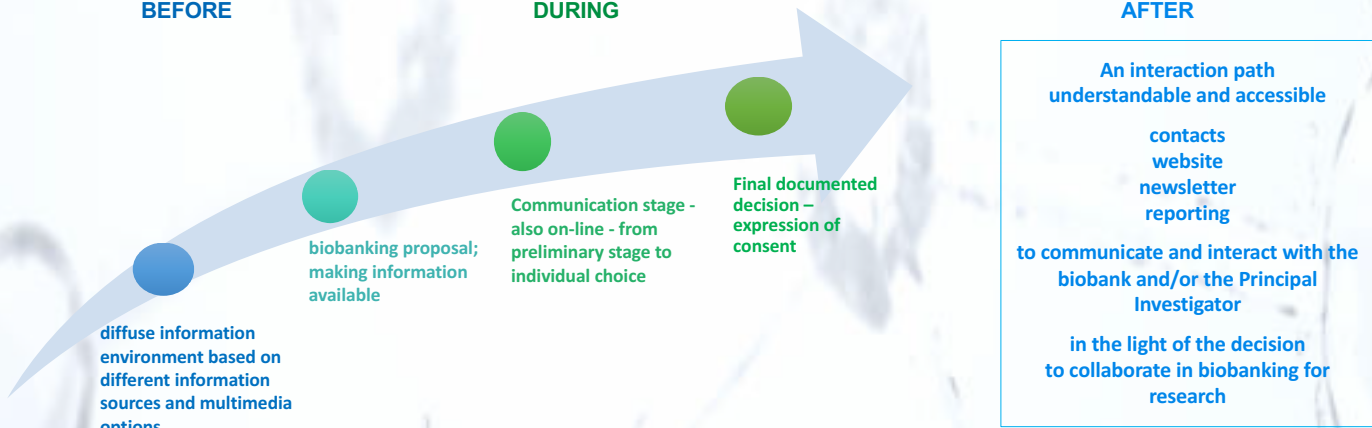
a path of validation & public sharing

A MATRIX FOR THE INFORMED CONSENT IN THE BIOBANKING FOR RESEARCH, AS A PROCESS

BEFORE

DURING

AFTER



DOCUMENTS AVAILABLE FOR THE INFORMED CONSENT PROCESS, in a headed paper with clear contacts & references

- ✓ **Opinion of the research ethics committee**
- ✓ **Code of ethics / policy** - rules for accessing and transferring data / samples and returning results
- ✓ **Material / data transfer agreement** (agreement defining and formalizing the conditions for the transfer of biological materials and / or data)
- ✓ **Statute of the biobank**

INFORMATION KEY- CONTENTS

shaped starting from the patient/citizen's information needs

reasons, purpose & nature of the biobanking that is proposed	<ul style="list-style-type: none"> -Justify <ul style="list-style-type: none"> a.The benefit of the biobanking b.The need to biobank samples associated with data (specify the type of data) c.The proposal to collaborate/participate in biobanking -Specify the scope and mode of the biobanking (non-profit or profit making) <ul style="list-style-type: none"> i.e.1 "...in the CCC Cancer biobank to develop research... The CCC Cancer biobank is a non-profit structure with a public role/function ..." i.e.2 "... in the DDD entity to develop research ... DDD is a profit-making organization ... 	return and use of results	The return of the results, regardless of the direct benefit to health, is considered by patients to be an essential step Clarify the difference between expected results and incidental findings - secondary results.
Why is the biobanking for research useful in the field of oncology/ genetic diseases/ population diseases/...?		How will I be informed of the research results?	Inform people if and how results will be returned: a. Individual results, b. General results, c. Incidental or secondary results.
Why is my participation important?		What results will be returned to me?	Inform people that the results will be published or discussed in scientific contexts in an aggregated and anonymous form, i.e. without any possibility of tracing the participant's identity.
What is the biobanking that is proposed?		Who can I contact for clarification or information about the research results?	Inform people of the public way in which the biobank will disseminate the results, as well as the methods and timing of biobank reporting.
What kind of research will be developed?	Inform people about the possibility of further contact for the expression of a new consent in the event that the research scope is changed, unless the participant has expressed otherwise and does not wish to be contacted again.	governance of the biobank (cross-content)	<ul style="list-style-type: none"> - Rules for access and use. - Rules for the transfer of material/data. - Rules relating to the cessation of the biobank. - Ways of returning and sharing results. - Ways of involving citizens and patient communities
Is it possible to change the research scope?			Understanding the governance of the biobank and what is at stake in the biobanking process is core to the informed consent process. The governance information hubs correspond to some of the main information hubs. It is essential to make available all of the institutional documents and information that help a potential participant
correlation between any diseases I have and the biobanking	Needs reported by patient representatives, in particular for people with rare genetic diseases.		
Rights & responsibilities. Implications of participation	Share the provided rights, in a framework of respect, recognition and self-determination, with a particular focus on the new rights established by the GDPR, the right to erasure (to be forgotten) and the right to portability and their effective sustainability in the development of sample/data-driven research;		
What are my rights? What are the implications?	Inform people about different implications in terms of exercising rights depending on whether biological materials and related data are pseudo-anonymized or anonymized;		
What does my participation in biobanking imply/entail?	Inform people about what is at stake between the recognized rights and responsibilities characterizing a participation agreement;		