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

Sara Casati [1], Antonio Aglione[2], Elisabetta Iannelli[2], Renza Barbon[3], Annalisa Scopinaro[4], Eva Pesaro[5], Marialuisa Lavitrano [1]

[1] BBMRI.it and BBMRI-ERIC Milano Bicocca University, [2]FAVO, [3] Uniamo 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 ELSI Action

a collaborative process and a participatory pact between all of the actors involved

co- producing

ELSI matrices **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**

diffuse information environment based on different information sources and multimedia options

biobanking proposal; making information available

Communication stage - also on-line - from preliminary stage to individual choice

Final documented decision – expression of consent

An interaction path understandable and accessible

contacts
website
newsletter
reporting

to communicate and interact with the biobank and/or the Principal Investigator

in the light of the decision to collaborate in biobanking for research

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 **Why is the biobanking for research useful in the field of oncology/ genetic diseases/ population diseases/…?** **Why is my participation important?** **What is the biobanking that is proposed?** **What kind of research will be developed?** **Is it possible to change the research scope?**	–Justify 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) 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 …* ·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.
correlation between any diseases I have and the biobanking	**Needs reported by patient representatives, in particular for people with rare genetic diseases.**
Rights & e responsibilities. Implications of participation **What are my rights? What are the implications?** **What does my participation in biobanking imply/entail?**	·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; ·inform people about different implications in terms of exercising rights depending on whether biological materials and related data are pseudo-anonymized or anonymized; ·inform people about what is at stake between the recognized rights and responsibilities characterizing a participation agreement;
return and use of results **How will I be informed of the research results?** **What results will be returned to me?** **Who can I contact for clarification or information about the research 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. ·Inform people if and how results will be returned: a. Individual results, b. General results, c. Incidental or secondary results. ·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. ·Inform people of the public way in which the biobank will disseminate the results, as well as the methods and timing of biobank reporting.
governance of the biobank (cross-content)	- 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 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

For Info: sara.casati@unimib.it
www.bbmri.it