

## A Participatory Survey: the open ELSI priorities from Italian biobanks perspective

Sara Casati ☆, Barbara Parodi \*, Luciano Milanese ◇, Marialuisa Lavitrano ☆

☆ Milano-Bicocca University, Milan, \* IRCCS A.O.U San Martino – IST Ist.Nazionale Ricerca sul Cancro, Genova, ◇ CNR-ITB, Milan

### A premise

During HandsOn: Biobanks 2015 the Italian node promoted a participative workshop open to the entire community of biobanking (POs, biobanks, patients, professionals and researchers): 165 were the participants. The brainstorming was focused on the most problematic ELS issues, in order to identify priority courses of action and shared good practices; in this way emerged pre-defined areas on the basis of which to set up a **qualitative survey among the Italian signatories biobanks of the BBMRI partner-charter**. The national common service ELSI launched the survey based on 28 specific items, gathered in six main areas:

**in-formation**      **patient-citizen engagement**  
**interaction with Research Ethical Committees**  
**establishment of a biobank**      **data treatment**  
**access**

### Responded 33 biobanks out of 65.

In more than half of biobanks surveyed, the inter-relations between the biobank and REC were reported as problematic and in need of a common policy. Most of the biobanks stressed the need of

- developing specific guidance and training for Research Ethics Committees
- considering at least one REC member expert in biobanking / biobank.

It was highlighted the usefulness of a policy agreement between biobanks, POs and Healthcare Units.

**Strong are the awareness and the request to promote a public information program and cross-cutting engagement addressed to citizens and specific communities of patients.**

**A key point: Access of data / results to the patient/the citizen** and the identification of to make accessible research data and results.

### On-going courses of actions

- Contact and involvement of the National REC network to face needs and critical issues in order to share good practice for ethical review
- European Biotech Week 2016 as a concrete horizon to promote public information and engagement in biobanking and infrastructures
- General data protection Regulation and WMA Declaration on health databases and biobanks debates as a common and systemic good practice training ground for data governance

PRINCIPAL OPEN ISSUES	COMMENTS
67% Data/results ownership	<ul style="list-style-type: none"> <li>Who owns the biobanked data? Who owns the results of the research carried out by those data?</li> <li>focus on sponsored study</li> <li>Public availability of the results</li> </ul>
65% ELI requirements for biobanking samples collected during a trial	<p>Asking for:</p> <ul style="list-style-type: none"> <li>an agreement template between Biobanks and Principle Investigators</li> <li>Insertion of the requirements for biobanking in the Protocol</li> <li>Specific training of the operators and stakeholders</li> </ul>
65% Good Practice for Informed Consent (Logics and articulation of contents, informative process, informed consent matrix)	<ul style="list-style-type: none"> <li>Provision of informed consent models (Information &amp; consent expression) to: <ul style="list-style-type: none"> <li>biobanking from clinical study</li> <li>use by private companies</li> <li>industrial use for genetic research</li> <li>use of historical material</li> <li>patentability</li> <li>mature teens and young adults</li> <li>vulnerable subjects</li> </ul> </li> <li>Modeling "return of information to the patient"</li> <li>Specific training of physicians and other health professionals</li> </ul>
65% Using biobanking samples without informed consent: how to proceed	<p>For many biobanks a cogent problem since they originated from ancient collections.</p> <ul style="list-style-type: none"> <li>The shift from collection to biobank</li> <li>Consensus on use policies</li> </ul>
65% Education and empowerment	<ul style="list-style-type: none"> <li>Ongoing and systematic ELSI training, empowerment workshops for all the involved stakeholders (citizens, technical health professionals, researchers) in biobanking, research and related health policy.</li> </ul>