

# “An intriguing Insubria Research Biobank model: ethical framework and opportunities for a Biobank Ethics Consultation Service (BECS)”



**Elena Ferioli, Mario Picozzi**

University of Insubria, Department of Biotechnologies and Life Science, Varese, Italy

## SETTING

For about two decades at the University of Insubria researchers have been independently collected and stored a lot of human biological samples to study the pathological mechanisms of diseases. Typically these are small research groups, probably lack of specialists in biobanking and of sufficient funds to ensure quality and safe samples storage.

In recent years, however, the University is committed to provide specific training programs in Bioethics, Applied Ethics and Clinical Ethics Consultation aimed to face to critical topics related to medicine, research and biobanking.

## OBJECTIVES

On the basis of the current situation, the primary aims of our project are: i) to design an academic “**Insubria Biobank**” as an unique key research infrastructure which must respond to high quality levels, safety and skills as required by the international community in accordance with guidelines for scientific and technological infrastructure; ii) to set up an appropriate “**Ethical Framework**” identifying sufficient and well-established ethical instruments available for regulating biobank research; iii) to create an institutional “**Biobank Ethics Consultation Services**” (BECS) to help scientists, health care professionals, patients, donors, institutional review board and policymakers, navigate ethical issues in biobanking management and research.

## METHODS

We need to reflect upon the delicate and complex ethical questions that a biobank rise and particularly: who owns the tissues and who can benefit from potential results? Which kind of informed consent is the most appropriate for experimental protocols not yet predictable at the time of tissue collection? How can data confidentiality be guaranteed also in relation to genetic analysis?

The topics were analyzed with reference to: i) the biobank research protocols submitted to our ethical evaluation, ii) the research conducted in ethics training and specialized programs (PhD and Master), and iii) the international literature.

## DISCUSSION

The ethics of biobanking is one of the most controversial issue in current bioethics and public health debate. For some biobanks offer the possibility of unprecedented advances which will revolutionize research and improve the health of future generations. For others they are worrying repositories of personal information and tissue which will be used without sufficient respect of autonomy. Considering the complexity of these issues, we believe that the **patient's trust** is the main matter.

The Insubria Biobank would become subject responsible for the **custody** and management of biological materials and the protection of data confidentiality, acting as a filter between the public and the research community. So in our biobank model the researchers would only be licensed for use and not for ownership the biological samples collected, which are an heritage of the community, according to a model of “**Charitable Trust**”, in which the donor gives his powers devices to a trustee, which has a legal duty to use them in the public interest.

This model would allow an effective balance between freedom of scientific research, individual rights and collective needs in the name of the principle of **sociality** and the “broad” informed consent model is justified precisely in this perspective.



contact: elena.ferioli@uninsubria.it

## RESULTS

We maps the key challenges and controversies of biobanking ethics.

✓ Regarding the ownership of biological samples and the intellectual property rights of the potential outputs based on the data, according to the recent literature, we approve the **concept of solidarity** which consider all samples and information at full disposal of the entire community and which indicates the biobank as the manager of the archive.

✓ The model of “**broad**” **informed consent** seems to prevail: we indicate its point of strength and weakness, considering a necessary balance among the individual autonomy, the collective interest and research requirements.

✓ Finally, regarding the **confidentiality** of all data, we need to reflect upon the right to privacy along with the possibility to use the available data for research purpose. Personal data and genetic information should be protected by coding and accessible only by authorized persons.

Ethical Framework	Options	Insubria Biobank Model
Ownership of biological samples and Intellectual Property	<ul style="list-style-type: none"> <li>• Thesis of Separation</li> <li>• Thesis of Seizure</li> </ul>	<ul style="list-style-type: none"> <li>✚ Custodianship</li> <li>✚ Open data sharing</li> </ul>
Informed Consent and information provided to the subjects	<ul style="list-style-type: none"> <li>• Copyright</li> <li>• Patenting</li> </ul>	<ul style="list-style-type: none"> <li>✚ Broad Consent</li> </ul>
Protection of Confidentiality	<ul style="list-style-type: none"> <li>• Specific</li> <li>• Limited</li> <li>• Future</li> <li>• Proxy</li> <li>• Broad</li> <li>• Blanked</li> <li>• Dynamic</li> </ul>	<ul style="list-style-type: none"> <li>✚ Identifiable data (dual coding)</li> <li>✚ Privacy right</li> <li>✚ Personal right</li> </ul>



## CONCLUSIONS

This “credit of trust” - interesting and surprising in the current historical and social context - must be fed and confirmed by the ethical choices of the biobank. Just a mistake and trust is broken. Therefore, we must ensure maximum transparency and traceability of decisions. The Insubria Biobank must be an “ethical subject” to secure public trust. This involves the definition of ethics criteria to be made public and to which the biobank will comply. In our model we identify three involved parties that can guarantee this essential credit of trust.

➤ The **Independent Ethics Committee**, to whom adequate resources and expertise must be granted, becomes the assurer entity for an ethically acceptable management of a biobank and for approving research design and implementation

➤ An **Ethics Code** that explain the principles of conduct and the purpose of the Insubria Biobank (Charter of Principles).

➤ A **Biobank Ethics Consultation Services (BECS)** to make a critical, educated and practical contribution to the ongoing dialogue and direction of biobank research.

The major ethical and professional practice challenges associated with the provision of BECS include: i) managing multiple institutional roles and responsibilities, ii) supplementing regulatory oversight, iii) managing sensitive information, iv) communicating with consultation requestors about how these issues are managed and providing a forum for deliberative exploration of ethical issues, and iv) training the researchers in ethical issues.

It is desirable that the creation of a Biobank Ethics Consultation Services (BECS) takes into consideration the possible indications given by the potential stakeholders, in addition to the experiences coming from others countries.