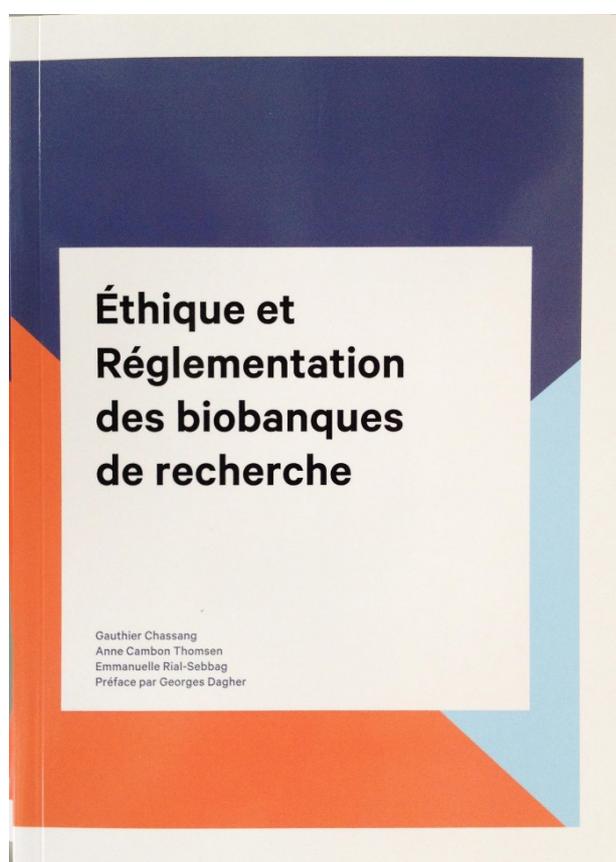


**A REFERENCE BOOK ON ETHICS
AND LAW FOR HEALTH PROFESSIONALS INVOLVED
IN THE USE OF HUMAN BIOLOGICAL SAMPLES**

What legal prerequisites must be respected to create a biobank in France? What specific rules are applicable to microorganisms? How to reuse a human biological sample for another research project than the one for which informed consent was obtained in the first place?



Written by the Ethics and Regulations Department's team of the BIOBANQUES Infrastructure - Inserm US013, the book "*Ethics and Regulation of biobanks for research*" helps all the professionals working with biological samples of human origin and associated data, for human health research purposes, to comply with the french ethical and legal requirements framing this activity.

The activity of research biobanks evolves in an ethical and legal framework

Due to their activity of collection, conservation and sharing of human biological samples, biobanks or biological resource centres have to comply with a strict and constantly changing legislation as well as with ethical best practices. This framework applies both to the protection of persons who agree to give their samples to biobanks, to the use of biological resources, and to the compliance with safety rules.

While major technological advances, such as high-throughput sequencing technologies, create new ethical, legal and social issues, biobanks are, at the same time, structuring and coordinating their practices, in application of a specific legal regime.

To accompany professionals in the respect of the french requirements, the Ethics and Regulation Department's team brought together within a unique book, the paramount ethical and legal information regarding the collection, storage, and use of biological samples.

A tool to navigate the corpus of french ethical and legal rules

The book analyzes strategic issues related to biobanking activities and presents:

- the historical components of the current framework, anchored in (bio)ethical reflections,
- the current procedures to be followed to constitute a research biobank, to make available and use the preserved biological resources (samples and associated data) for scientific research purposes,
- recent advances in the framework applicable to the activities of research biobanks in human health,
- the Ethics Charter of the national Infrastructure BIOBANQUES, tool of governance of the french network of biobanks for research in human health.

The book "*Ethics and Regulation of biobanks for research*" is addressed to the actors of biobanks, to researchers interested in the collection or use of human biological resources for scientific research purposes, and also to students attending courses in connection with health related biotechnologies.

"It is essential to keep the confidence addressed by the citizens to professionals ensuring the conduct of biomedical research activities. The respect of the ethical principles, of the will of the people involved, the protection of their personal data, including those that relate to health, are the essential requirements to maintaining that trust".

Georges Dagher, Director of the BIOBANQUES Infrastructure.

Ethics and Regulation of biobanks for research

15 euros TTC (including taxes)

To order on : www.biobanques.eu

Focus on:

Biobanks, between care and research

Biobanks [or Biological Resources Centres (BRC) and biomolecular resources centres], are unknown actors and yet inevitable in care and scientific research system in life science and human health.

Whether they are public or private, biobanks retains biological samples and related data from various sources: activities of care, diagnosis, research, etc.

Thanks to biobanks, these biological resources are maintained and made available to researchers, in France and internationally, to develop our knowledge on major complex diseases and to improve the means of prevention, diagnosis and treatment of these diseases.

The coordination Infrastructure BIOBANQUES - Inserm US013

Coordinated by Georges Dagher, Research Director at Inserm, the BIOBANQUES Infrastructure federates more than 85 Biological Resources Centres, composed of biobanks, tumor banks and Microbiological Resources Centres, spread throughout France. The Infrastructure promotes scientific collaborations with researchers and the sharing of techniques and tools with biobanks.

BIOBANQUES, it is also

- 5,5 millions of available biological samples
- 700 research teams provided with biological samples
- 800 projets de recherche utilisant les échantillons biologiques

The authors, specialists in health law applied to biobanks

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