



Ministry of Health of Brazil

Brazil's new regulations on the use of human biological materials for research

Gabriela Marodin, Ph.D

Paulo H. Condeixa de França, Ph.D

Marcia Motta, MSc

Gyselle Saddi Tannous, MSc

Antonio Hugo Campos, Ph.D



Ministério da
Saúde



Historical perspective:



New Regulatory Framework:

PORTARIA MS Nº 2.201, DE 14 DE SETEMBRO DE 2011- Diretrizes Nacionais para Biorrepositório e Biobanco de Material Biológico Humano com Finalidade de Pesquisa

RESOLUÇÃO CNS Nº 441, DE 12 DE MAIO DE 2011 - Diretrizes para análise ética de projetos de pesquisas que envolvam armazenamento de material biológico humano ou uso de material armazenado em pesquisas anteriores

Biobank

Biorepository

Primary goal	Multiple Researches (future undefined use)	Research-driven
Holder of rights	Research subject	Research subject
Custody	Institution	Institution
Management	Institution	Researcher
Time of storage	Undetermined	Up to 10 years
Informed consent	New consent for each research OR waiver of new consent	New consent for each research

Fundamental precepts of the Brazilian guidelines:

The ICF of **Biobanks** shall:

- ❖ inform the subject that the **data provided and collected by biobanks may be used in future research**, including data derived from previous projects that had access to the samples;
- ❖ contain **reference to the types of information that can be obtained**, for purposes of aware and autonomous decision of the subject;

Fundamental precepts of the Brazilian guidelines:

The ICF of **Biobanks** shall:

- ❖ **Contain explicit guarantee of access by the research subject, including forms of contact**, so that he or she may have access to the results obtained from the using of their biological material, orientations about implications, including genetic counseling when appropriate.

Fundamental precepts of the Brazilian guidelines:

The ICF of **Biobanks** may contain:

- ❖ explicit manifestation of the research subject's regarding the **assignment of rights to the stored material to successors or others** appointed by him, in case of death or disabling condition;

Fundamental precepts of the Brazilian guidelines:

- ❖ The research subject, or his legal representative, at any time and without any cost or prejudice, **may withdraw the consent of guard and use of the biological material stored in Biobank or Biorepository**, being valid from the date of this formalization.

Fundamental precepts of the Brazilian guidelines:

- ❖ The Brazilian legislation **prohibits the patenting and commercial use** of human biological material stored in Biobank and Biorepository.

What about international collaboration?

- ❖ **Permitted**, provided that the research project has been accepted by both countries' NERBs and a formal agreement is established by the Brazilian and foreign investigators.
- ❖ **Samples may be sent abroad**, provided that the subject's privacy is secured and the samples are used only in the approved protocol.

- 1) Two mutually supporting documents on biobanking activities related to human health research.**
- 2) Insights gained from the experience in Brazil may be useful to develop national biobanking regulations in other countries.**

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2) Insights gained from the experience in Brazil may be useful to develop national biobanking regulations in other countries.

Issue to consider in the near future

❖ **The return of research results concerning biobanks.**

Thank you!



**Ministry of Health
of Brazil**

**Esplanada dos Ministérios,
Bloco G, Ed. Sede, 70058-900
Brasília - DF, Brazil**

ahcampos@hcancer.org.br