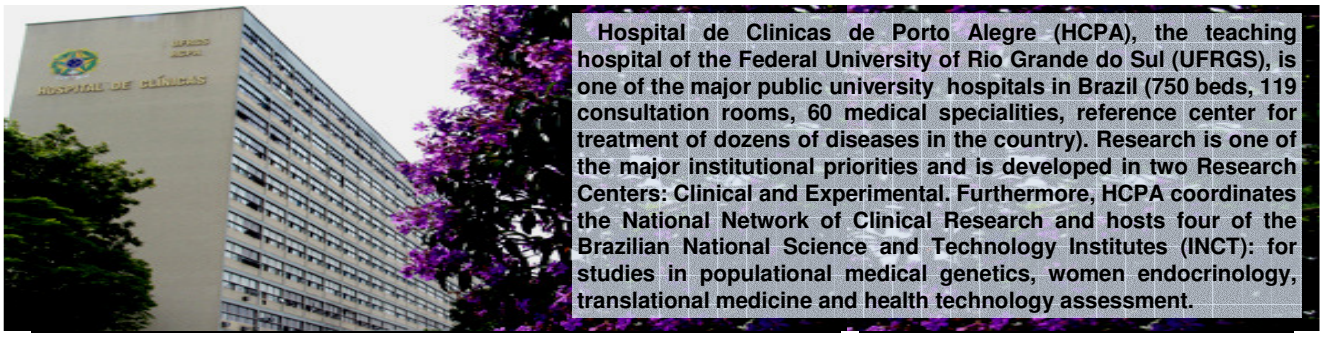
Ministério da Saúde

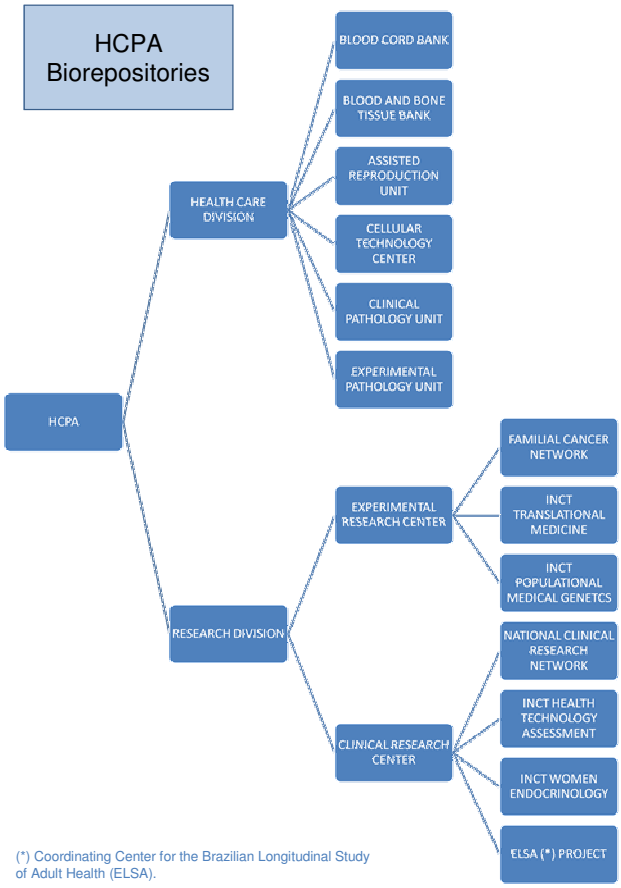
HOSPITAL DE CLÍNICAS PORTO ALEGRE- RS

Technical, ethical and legal framework for the organization of a Biobank in a Public University Hospital (Hospital de Clínicas de Porto Alegre/HCPA) in Latin America

Fernandes, Márcia Santana (BA, PhD – Bioethics Laboratory/HCPA); **Ashton-Prolla, Patricia** (MD, PhD – Experimental Research Center/HCPA – Dept. of Genetics, UFRGS); **Matte, Ursula** (BSc, PhD – Protein and Molecular Analysis Laboratory/HCPA - UFRGS); **Martins-Costa, Judith** (BA, PhD – Law School/UFRGS); **Clausell, Nadine** (MD, PhD – Research Division/HCPA - UFRGS); **Kuchenbecker, Ricardo** (MD, PhD – Health Care Division/HCPA - UFRGS); **Marodin, Gabriela** (BSc, PhD – Ministry of Health/Brazil); **Goldim, José Roberto** (BSc, PhD - Bioethics Unit/HCPA - UFRGS).



Hospital de Clinicas de Porto Alegre (HCPA), the teaching hospital of the Federal University of Rio Grande do Sul (UFRGS), is one of the major public university hospitals in Brazil (750 beds, 119 consultation rooms, 60 medical specialities, reference center for treatment of dozens of diseases in the country). Research is one of the major institutional priorities and is developed in two Research Centers: Clinical and Experimental. Furthermore, HCPA coordinates the National Network of Clinical Research and hosts four of the Brazilian National Science and Technology Institutes (INCT): for studies in populational medical genetics, women endocrinology, translational medicine and health technology assessment.



(*) Coordinating Center for the Brazilian Longitudinal Study of Adult Health (ELSA).

Background

HCPA facilities currently hosts at least 13 different biological sample repositories connected to clinical research trials and collaborative research networks. Currently, there is no legal framework for the implementation and maintenance of Biobanks in Brazil, although storage of biological samples is regulated by two documents:

- **A guideline from the National Health Council (CNS 347/05), containing minimal regulatory information about maintenance of research samples repositories;**
- **A resolution from the National Health Surveillance Agency – ANVISA (RDC-ANVISA 33/06), which specifically regulates the technical and ethical aspects of cell and germinative tissue biobanks only.**

Detailed standards of procedure (SOPs) and guidelines for sample collection, transport, annotation, storage, retrieval and distribution are not available.

Objective

Consolidate an institutional guideline for biobanking in HCPA and disseminate the resulting documents to other public health care Institutions in Brazil.

Methods

- **Task force participants: Researchers, Physicians incl. pathologists, Biologists, Bioethicists, Lawyers, Geneticists, Epidemiologists, Nurses and Patient Advocates.**

- **Focus group to formulate an institutional guideline for biobanking activities, in clinical and basic research as well as health care, transposable to other public hospitals and institutions participating in the National Clinical Research Network.**

Results

A preliminary biobank normative document was elaborated for Institutional use (HCPA) aiming at the protection and proper annotation of various human biological materials, including DNA, cells, tissues (incl. tumors), biofluids and other biological samples, linking pertinent clinical information from the patient´s medical records to the samples deposited in Central or Satellite Biobanks and using a unified informed consent. The proposal takes into consideration national and international guidelines and regulatory issues and includes SOPs for technical, ethical or legal issues common to all biorepositories and those specific to certain activities of individual biobanks.

Future Perspectives

Disseminate the guidelines and SOPs elaborated for HCPA to other public health care institutions engaged in basic, clinical or translational research and use this document as the basis to develop, in collaboration with the Brazilian Ministry of Health, an unified and comprehensive federal regulation for the proper storage and use of biological samples.

Hospital de Clinicas de Porto Alegre – Brazil
Rua Ramiro Barcelos 2350 90035-903 Porto Alegre/Brazil
Phone +55-51-21018304 Fax +55-51-21017640 e-mail gppg@hcpa.ufrgs.br