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GIENS WORKSHOPS 2017 / Clinical research

Collection of human biological samples for research purpose: Key challenges and patients' perspectives

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KEYWORDS

Biological samples; Biobank; Biological resource center; Medical research;

Regulation; Education; Ethics; Valorisation Summary The development and the access to collections of human biological samples is one of the major challenges for health research. In recent years, biological resource centres (BRCs) have developed in such a way that they provide all activities relating to the handling of samples. In this context, France is undoubtedly a pioneering country, because most of the biological collections available were created on the basis of themed research projects, which involved a particular donor phenotype. The round table was an opportunity to emphasise the persistence of some pitfalls particularly in relation to ensuring the consistency of different regulatory pathways. It also gave the opportunity to question and make recommendations on aspects of governance of biological collections and the BRCs, to state the challenges linked to scientific and economic valorisation and to consider the place of patients and the general public. The development of specific education in public health and research is essential to underline that these initiatives are necessary for developing new diagnostic and therapeutic procedures.

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Abbreviations

ANRS French national agency for research into AIDS

and viral hepatitis

ANSM French national agency for medicines and health

products safety

BBMRI biobanking and biomolecular resources research

infrastructure

BRC biological resource center

BRIF bioresource research impact factor

CEREES Expert committee for research, studies and eva-

luations in the healthcare field

CNIL National commission for data protection and

liberties

CNRIPH National commission for research involving the

human person

CODECOH preservation of human body elements
CPAM Regional health insurance agency
CRPC Clinical research patients' committee

CPP Committee for the protection of persons (ethic

committee)

CSP Public health code HCP healthcare products

INDS National institute for health data

LEEM French pharmaceutical companies' association
MESR Ministry of higher education and research

OECD Organisation for economic co-operation and

development

RIPH research involving the human person

SNIIRAM National health insurance cross-schemes infor-

mation system

Introduction

The development of biomedical research needs more access to important collections of biological resources and clinical and biological databases in all fields of medical science (genetic, genomic, transcriptomic, proteomic). Therefore, the samples collected must be subject to complete traceability to ensure their conformity with researchers' expectations, leading to the development of infrastructures dedicated to collections of samples for research [1]. In France, as in many countries, biological resource centres (BRCs) or biobanks have been created and are responsible for the reception, preparation, preservation and provision of biological resources consistent with regulatory, ethical and technical restrictions. The purpose of the BRCs is to facilitate access to varied collections, which are highly characterized and of great quality so that the (inter) national scientific community can develop research projects more quickly. Ten years after the publication of good practice guidelines by the Organisation of economic cooperation and development (OECD) [1], the biobank community is recognised as a key factor in research by means of regulatory

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