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**Authors:** Wiskott K, Gilardi F, Michaud K, Augsburger M, Castiglioni C, Carminati A, Grabherr S, Thomas A, Fracasso T

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# Creation of a *Forensic Pathology Biobank* in Switzerland. Which issues and research opportunities?

K. Wiskott[1], F. Gilardi[4], K. Michaud[3], M. Augsburger[2], C. Castiglioni[3], A. Carminati[3], S. Grabherr[5], A. Thomas[4,] T. Fracasso[1,3]

[1] Forensic medicine unit, University Center of Legal Medicine, Rue Michel-Servet 1, 1205 Geneva, Switzerland
[2] Forensic toxicology and chemistry unit, University Center of Legal Medicine, Rue Michel-Servet 1, 1205 Geneva, Switzerland
[3] Forensic medicine unit, University Center of Legal Medicine, Chemin de la Vulliette 4, 1000 Lausanne 25, Switzerland
[4] Faculty Unit of Toxicology, University Center of Legal Medicine, Chemin de la Vulliette 4, 1000 Lausanne 25, Switzerland
[5] Direction, University Center of Legal Medicine, Chemin de la Vulliette 4, 1000 Lausanne 25, Switzerland

Corresponding author: kim.wiskott@hcuge.ch

## Abstract

A biobank is a collection of biological material associated with health database. The field of biobanking has significantly developed over the past thirty years. Research based on biobank material gives access to data of a large number of people and can often significantly accelerate the understanding of disease and improve the quality of the care.

In the University Center of Legal Medicine Lausanne-Geneva, samples collected during autopsies are used for forensic investigations. The legal and ethical framework to use these samples for research is often complex and confused, which is unfortunate given the potential of these biospecimens. Indeed, forensic samples are valuable for research because they originate in part from young (including pediatrics cases) and healthy people who are poorly represented in worldwide institutional biobanks. In this context at the beginning of the year 2019, the Forensic Pathology Biobank was created.

Creation of a forensic pathology biobank is the best way to standardize local conservation practices and improve personal data management, thus providing a very valuable biological material for scientific projects. Its development gives rise to many questions about technical standards, ethical and legal issues but also many research opportunities.

**Keywords** : biobank, forensic, data management, research, ethics

## Introduction

A biobank is a collection of biological material associated with health database (1, 2). Biobanks may pursue several purposes such as research, diagnostic or therapeutic goals. Research based on biobank material gives access to data of a large number of people and can often significantly accelerate the understanding of disease and improve the quality of the clinical care. The field of biobanking has significantly developed over the past thirty years and is currently implemented from the academic laboratories to institutional government supported repositories such as population wide biobanks (3). The vast majority of biobanks collects samples from adult individuals and includes mainly blood (and derivatives), urine and tumor tissues. This is the case for instance for the “Biobank Graz” of the Medical University of Graz (Austria) or the “All of us” biobank of the US National Institutes of Health (4, 5), two of the largest biobanks in the world. In the forensic field, biobanks have been described in relation with forensic genetics on living donors (6) or in the context of registers of sudden infant deaths (7). Tozzo et al, underline that there is an urgent need to develop an

international collaboration between forensic institutes to improve research in the forensic field (8), the development of forensic biobanks could be a first step in this direction.

Forensic context is particularly complicated when it comes to research. In the absence of consent on deceased persons, guidelines are not always clear for the research activity (9). In the University Center of Legal Medicine (Lausanne-Geneva), many biological samples are routinely collected during each autopsy. A big part of them is used for forensic investigations (histopathology, toxicology, microbiology, clinical chemistry and genetic) in the medicolegal context and is destroyed at the end of the medicolegal procedure, after a delay of three years. The legal and ethical framework to use these samples for research is complex and confused, which is unfortunate given the potential of these biospecimens. Indeed, forensic samples are valuable for research because they originate in part from young (including pediatrics cases) and healthy people who are poorly represented in worldwide institutional biobanks. Moreover, we collect at each autopsy a panel of extremely precious tissues that are not easily accessible in healthy living patients, such as brain or heart. These samples are a great resource but must be used in accordance with the ethical considerations.

Against this background, it was decided to carry out research within a juridical and ethical framework in our center. In this context, a research biobank has been created in our medico-legal institute at the beginning of the year 2019.

The creation of a biobank improves the preservation of the samples and the data traceability, thus increasing the quality of the research and promoting legislative and ethical regulation while ensuring the accomplishment of forensic investigations requested by the justice. It gives rise to many questions about technical standards, ethical and legal issues but also many research opportunities that will be discussed below.

No mention of another biobank of forensic biological tissues and liquids was found in the literature.

# Technical standards

### Sampling and data management

Each year, about 500 medico-legal autopsies are performed in our center. All the samples collected during medico-legal autopsies for forensic investigations are included in our biobank (peripheral and cardiac blood, urine, interventricular septum, psoas muscle, brain, vitreous humor, liver, pericardial fluid, cerebrospinal fluid, bile, serum and adipose tissue) as well as histological samples (included in paraffin and relative slides), post-mortem imagery and antemortem samples from the hospital (Figure 1 (10)).

After collection in the autopsy room, samples are stored for few hours at 4°C. Part of them are taken out for forensic investigations. Residuals samples (at least peripheral blood, serum, urine, bile, muscle, adipose tissues, brain, septum, pericardial fluid, cerebrospinal fluid and vitreous humor) are frozen at ultra-low temperature freezers (-80°C). Qualified staff including biologists, physicians and laboratory technicians works to preserve the biological material (11, 12).

In the process, personal details (age, gender, postmortem delay, BMI, comorbidities, toxicological results etc.) of the deceased person (Table 1), in association with the biological samples, are listed and coded in a health database named SLIMS® (13). This software combines laboratory information management system and electronic laboratory notebook which means that it records all sample collection and storage information and also the future experiments and results. During the collection of medical data, research consent gathered from the regional hospital will be verified. In the event of refusal, the case will be excluded from the biobank.

### Application of technical standards

In Switzerland, decisions relative to biobanking conformed with recommendations of the national biobanking

network, known as *Swiss Biobanking Platform (SBP)* (1). This platform has been developed to help biomedical researchers. It promulgates protocols (about specimen conservation, ethical or legal requirements and consent) and delivers quality certificate. Our biobank obtained the first quality label.

## International ethical standards

Ethical standards regulate biobanking operations. They are promulgated by two declarations of the *World Medical Association*. The declaration of Helsinki (1964) lays down ethical principles for medical research involving human subjects, guided by the three principles of dignity, autonomy and privacy (3, 14). In 2016, declaration of Taipei described ethical considerations regarding health databases and biobanks (specifically collection, storage and use of biological materials as well as identifiable data) that should contribute to « the benefit of society, in particular public health objectives »(14).

## Swiss legal aspects

As mentioned before, research without consent in a forensic context on deceased people is complex. Guidelines are not always clear for this research activity.

In Switzerland, two specific articles in the Human Research Act (HRA, 2011) concern more specifically the research in the absence of consent and involving deceased persons. Article 34 (HRA) decrees that *in absence of informed consent, use of biological material or health-related personal data may be made in exceptional cases if - it is impossible or disproportionately difficult to obtain consent (…), - no documented refusal is available or, - the interests of research outweigh the interests of the person (…)* (15, 16). This article allows coded data and biological material reuse under condition. The second article, article 38 (HRA), regulates especially the research in connection with an autopsy. It decrees that *minimal quantities of bodily substances collected during an autopsy may be anonymized for research purposes without consent, in the absence of a documented refusal of the deceased person(15, 16)*. Therefore, article 38 is less permissive than article 34 and only allows the reuse of data in an anonymized form.

Swiss legislation is relatively supportive for human research and is designed to ensure the quality and the transparency of research involving human beings(15-17). In absence of consent, it allows utilization of body specimens as long as they are coded or anonymized, and subject to ethics committee approval.

### Application of ethical and legal standards:

In compliance with legal and ethical issues, the forensic pathology biobank (FPB) has a regulation that defines its purpose, operational process and organization; this allows more transparency concerning its activities. After three years from collection, samples and clinical data will be anonymized and made available to researchers. Anyone with a documented refusal of research consent will be automatically excluded from the biobank. A scientific committee of the FPB was also established. The scientific committee will position on the requests of the research groups for the use of the samples and collaborate with the respective research ethics committee. Indeed, in front of the national and international ethical challenges, creation of a forensic pathologic biobank needs to have a sound implementation.

### Perspectives

FPB opens up a whole new range of possibilities in usual forensic and clinical researches, as well as genomics, proteomics or metabolomics researches. Forensic studies are underway in our center to determine biological quality of the samples according to postmortem delay, and preliminary results show excellent

quality material. In this context antemortem samples are very attractive for qualitative and comparative studies. Furthermore, we hope that these precious biological samples of healthy young and deceased people could be a valuable asset in clinical studies, such as epidemiologic and public health studies. It is interesting to remind that these cases can also be used as negative control in oncologic cohort for example.

## Conclusion

The creation of FPB was the best way to standardize local conservation practices and improve personal data management, thus providing a very valuable biological material for scientific research. Its development must be done in compliance with national laws and international ethical guidelines. Forensic biobanking opens up a whole new range of possibilities in forensic, clinical and -omics researches.

## Declarations

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