

BIORESOURCE PAPER

# The ICAReB Platform: A Human Biobank for the *Institut Pasteur* and Beyond

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The ICAReB platform of Institut Pasteur provides access to human bio-resources for academic and private research teams worldwide, essentially in the fields of infection, immunity and neurosciences. More than 134,000 human quality controlled, duly annotated samples (mainly whole-blood derived products, but also stool, urine, saliva, swabs...), from both healthy and diseased cohorts with open, regulated access, are available upon request. Both clinical investigation and biobanking activities are certified following ISO 9001:2015 and NF S96-900:2011 standards, respectively. ICAReB is a member of PIBnet (Pasteur International Biobanking network), BIOBANQUES and BBMRI, the French and pan-european biobanking networks, respectively.

**Keywords:** biobanking; biospecimens; sample collection; cohort; healthy volunteers

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**ANR** (French National Research funding Agency): *OH!Ticks* project (see <https://www.ohticks.fr/> 2017–2020)

**AP/HP** (*Assistance Publique/H opitaux de Paris*): *MonaLisa* (Multicentric Observational National Analysis on Listeriosis and Listeria) and *ListeriaGEN* projects, 2009–2022 and 2015–2024, respectively

**AVIESAN** (French National alliance for Life Sciences and Health). Study of the innate immunity and the microbial flora during aplasia (*PAMPA* project, 2013–2016)

**Bioaster** (French *Investissements d’Avenir* funding, Infectiology and Microbiology platform, Lyon-Paris, 2010–2020)

**Biom erieux** (Lyon, France; cardio-vascular biomarker, 2013–2015)

**FRM** (Medical Research Foundation): *Hidradenitis Suppurativa* project (2011–2015)

**IBiSA** (Biology, Health and Agronomics infrastructure) selection of ICAReB platform in 2009

**INCA** (National Institute for Cancer research): *INECOC* project, 2009–2011

**TOTAL foundation** (*Afribiota* project on Environmental Pediatric Enteropathy, 2016–2020)

**WHO** (for The WHO *Human African Trypanosomiasis specimen Bank*, 2008–2018, 2019–).

Since three years, public-private relationships were proposed and research collaborations accepted with industrial partners, for example the Lyon-Paris ‘Technological Research Institute’ (*BioAster*) following a national *Investissements d’Avenir* program launched in 2012.

## (1) Bioresource Overview

### Project description

The ICAReB platform has been established in 2008 to provide for access of pasteurian research teams and beyond, to high-quality human bio-resources. Its main fields of interest are infectious diseases, immunology

and more recently neurosciences. Two activities were developed, hence its name ICAReB, both certified following the ISO 9001 and NF S96-900 standards, respectively. More than 134,000 samples and their associated bio-clinical data (including vaccination status, ethnicity, medical history such as chronic inflammatory diseases

and allergies) are currently collected, as well as environmental factors (lifestyle, international travels, microbial environment, dietary habits, exposition to stress and pollutants ...)

The *Diagmicoll* main cohort (Clinical trials reference: NTC03912246) affords bio-resources from healthy subjects primarily, for the National Reference Centers, so as to optimize and develop new diagnostic methods [1, 3, 4, 5, 8, 10, 13, 20, 21, 28]. The *CoSImmGEN* cohort (Clinical trials reference: NTC03925272) has been set up to take in charge more complex needs such as longitudinal studies of the immune system and other integrative (e.g. metabolic/endocrine and neuro-cognitive) systems, encompassing their genetic and environmental determining factors [11, 14, 18, 22, 23, 25, 27, 33, 34, 35, 36, 37].

In parallel with these two open cohorts, other collections have been set up for disease-oriented projects: (i) the Human African Trypanosomiasis specimen bank of the WHO [7, 15, 17, 24]; (ii) the *hidradenitis suppurativa* cohort followed up at the IP Medical Center [6, 19, 29]; (iii) a Cameroonian Mother-to-Child HIV transmission cohort; (iv) anal and oral Papillomavirus infection in the young *DyPAVIR* French women cohort; (v) the French national observational survey on *Listeria* and listeriosis (*MONALISA* [30]); (vi) Lyme-like tickborne disease (*OHTICKS*); (vi) environmental pediatric enteropathy (*AFRIBIOTA* [38], and pathogen discovery in infectious diseases (*Pathodisc/PATHO-HTS* [20, 28]). Another project aimed at characterizing Opiorphin, an anti-nociceptive molecule [2, 12, 26, 31].

### Classification

Human

Biological samples and associated data

### Context

#### **Spatial coverage**

The healthy volunteers cohorts (*Diagmicoll* & *CoSImmGEN*) mostly originate from the regional (Ile-de-France) population:

Northern boundary: 49° 16' N

Southern boundary: 48° 8' N

Eastern boundary: 3° 32' E

Western boundary: 1° 31' E

The *CoSImmGEN-F* ancillary cohort on Familial Adenomatous Polyposis originates from France.

The *MonaLisa* and *ListeriaGen* patients come from all over France.

The *Hidradenitis suppurativa* patients come from the whole country and occasionally, from abroad. Others collections originate from African countries: Cameroon for the Mother to Infant HIV transmission collection; Chad, Democratic Republic of Congo, Guinea, Malawi, Tanzania and Uganda for the WHO Human African Trypanosomiasis specimen bank.

### **Temporal coverage**

Since 2003 (except 1994 for the Cameroonian Mother-to-Infant HIV transmission cohort) to present, on-going with a regularly reviewed expiry date.

## (2) Methods

### Steps

#### **Investigation methods**

The main asset of our platform is represented by two large volunteers' cohorts. The healthy individuals are recruited during ambulatory clinical consultations organized at the ICAREB platform by our staff. Those volunteers actively participate in research protocols on human beings (including pathophysiology, immunology, genetics, epidemiology...), and their samples and associated data presently compose the biorepository available for research purposes. The *Diagmicoll* cohort includes approximately 250 volunteers in the active file whereas the *CoSImmGEN* cohort is comprised of around 180 volunteers regularly followed up, from which genetic and environmental data are available.

Besides the recurrent work with pasteurian teams, ICAREB also builds partnerships with numerous external public and private institutions (research teams, hospital-based staffs and clinical investigation centres, other biorepositories centres, and companies) and is also developing a collaborative framework with European and international organizations. ICAREB is an active member of the French (membership number BB-0033-00062, see specific website: <http://www.biobanques.eu/en/professional>) and European (BBMRI under reference AO 203, website [www.bbmri.eu](http://www.bbmri.eu)) biobank networks.

#### **Sample management**

All the laboratory methods are based on standard operating procedures (SOP) and guidelines established within a quality management policy organized at the scale of the *Centre de Ressources Biologiques de l'Institut Pasteur* (CRBIP) structure, with a full access to the latest up-to-date documents. The individual data records are pseudo-anonymized according to the European (GDPR directive) and French (CNIL) laws in order to protect the participants' privacy. Sample quality controls are regularly performed following a biospecimen research schedule [8, 18, 23].

#### **Data management**

The ICAREB platform uses a BRC-dedicated LIMS for the bioresources management (MBioLIMS, ModulBio, Marseille France). In addition, in-house bioclinical databases have been constructed within a pre-formatted, web-based framework (Voozano, Epiconcept company, Paris). More recently we have introduced an alternative web-based framework (RedCap, Vanderbilt university, Nashville, USA) hosted by the informatic center, IP. Only authorized staff members can manage the bioresources, samples and data.

#### **Stabilization/preservation**

The following methods and containers are used for the collection and conservation of biological samples:

- Tubes with Z serum clot activator for the collection of serum
- DTA (ethylene diamine tetra acetic acid), hirudin, lithium- or sodium-heparin and sodium citrate tubes
- DMSO (dimethyl sulfoxide) or PBS tubes for storage of plasma or peripheral blood mononuclear cells (PBMC), after Ficoll purification
- Whole blood, in DMSO medium before freezing
- Red blood cells packs, after Ficoll centrifugation
- Paxgen blood DNA tubes and RNA tubes for storage of DNA and RNA
- Empty tubes for the collection of urines
- Swabs (with and without glycerol or physiologic serum-based conservatives possibly on nitrocellulose strips) for the collection of nasopharyngeal samples, tears (Whatman 41 strips, Schirmer Plus, GECIS, France) and saliva.
- Glycerol- or physiologic serum based liquids, in addition to empty tubes, for the storage of stools. Ethanol-fixed stool smears.

All the samples are stored in barcoded tubes. The storage systems are equipped with alarm systems and monitored 24/7 throughout the year.

#### Type of long-term preservation

Freezing of aliquots is made in manual freezers ( $-80^{\circ}\text{C}$ ) or liquid nitrogen cryo tanks.

A new room-temperature storage method (Imagene, Genopole campus, Evry, France) using laser-seal capsules (DNA shells® and RNA shells®, for DNA and RNA, respectively) is currently used for long-term preservation, after being tested in the context of a pilot study.

#### Storage temperature

The storage temperature ( $-196^{\circ}\text{C}$  liquid nitrogen,  $-80^{\circ}\text{C}$ , and room temperature) depends on material type and research project criteria.

#### Shipping temperature from patient/source to preservation

For the Diagmicoll and the CoSImmGen cohorts, the sampling is directly managed at the ICAREB platform. For others cohorts, the storage temperature depends on material type and research criteria.

#### Shipping temperature from storage to research use

The shipping temperature ( $-80^{\circ}\text{C}$  (on dry ice),  $-20^{\circ}\text{C}$  (on ice),  $+4^{\circ}\text{C}$  or room temperature) depends on material type and research criteria.

#### Quality assurance measures

Being a doubly affiliated entity (to CTS for clinical investigation activity and to CRBIP for biobanking), the platform is doubly certified: following the ISO 9001:2015 and the NF S96-900 (French norm) standard, respectively.

#### Source of associated data

For healthy volunteers on one hand, the associated data are obtained at the first inclusion visit and include: complete medical history, vaccination certificates and possible

medical or laboratory records. In addition, some questionnaires may be used to meet the specific research projects criteria (for example: lifestyle, depression scale, cognitive status ...).

Associated data may also originate from care entities, when patients are recruited outside the Institut Pasteur.

#### Ethics statement

All research projects have previously received both institutional and external – so-called *Comité de Protection des Personnes* – ethical committee approval, some of them going in addition through an institutional review board (IRB) agreement.

ICAREB works in conformity with the ethical guidelines of the OECD (CIOMS 2017) and the French law. The Diagmicoll and CoSImmGen healthy volunteers collections have been declared to the French Ministry of Research (DC-2008-68, DC-2009-1067 and DC-2012-1698 statements).

Following the present European guidelines for Responsible Research and Innovation, the ICAREB platform is organizing an on-going, two-way communication process at all steps, *i.e.* during and after the research studies themselves [9, 16]. Recent colloquia in 2016, 2018 and 2020, in the IP historical amphitheater, allowed the meeting of healthy volunteers, patients, physicians and researchers (see at the bottom of our homepage). This initiative is interpreted as an observational investigation on volunteers/patients-centered health interaction project [32], which is unique in this academic context.

### (3) Bioresource description

#### Bioresource name

Clinical investigation and Access to Research Bioresources platform, Institut Pasteur.

#### Bioresource acronym

ICAREB

#### Bioresource location

The bioresources are located in dedicated rooms on the site the Institut Pasteur, Paris, France (see <https://www.pasteur.fr/en>). This research institute is a non-profit private institution, managing an interface with 32 institutes (the so-called International Network of Pasteur Institutes).

#### Contact/URL/identifier

ICAREB platform  
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 25-28 rue du Docteur Roux  
 F-75724 Paris Cedex 15. France  
 Phone: (33-0)140613885  
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 Website: <https://research.pasteur.fr/en/team/biobanking-icareb> (link to CTS).

<https://www.pasteur.fr/en/public-health/biobanks-and-collections/clinical-investigation-and-access-biore-sources-icareb> (link to CRBIP).

### Bioresource type

ICAReB is an Infectiology, Immunology and Genetic biobank, located within an international research campus (Institut Pasteur, Paris, France).

### Type of sampling

As a central research infrastructure, ICAReB is implicated in many research projects requiring high quality samples for their experiments. Most of the samples (134,211 on 2018, December report) are collected within the platform during a succession of follow-up visits as long as accepted by the healthy volunteers. 28,742 aliquots are available (end of 2018) from the *Diagmicoll* or *CoSImmGEN* cohorts, the later comprising in addition genetic and environmental criteria.

In parallel, disease-based cohorts are recruited and bioresources collected in accordance with various research projects (for example, one on *Hidradenitis suppurativa* [6], one on *Listeria* infection-associated pathologies [30] and the WHO Human African Trypanosomiasis specimen biobank [7]).

### Anatomical site

Blood (whole, plasma, serum) and circulating (PBMC, neutrophils) cells

Digestive tract (feces)

Urinary tract (urine)

Skin, oral mucosa and genital mucosa (swabs, saliva, secretions and biopsies)

Eye (lacrymal secretion)

Central Nervous system (cerebro-spinal fluid)

### Disease status of patients/source

*Hidradenitis suppurativa* (the patients from the Verneuil's disease cohort, followed at the neighboring medical center of the IP, come France but also from all over the world).

*Listeria*-associated pathologies (foeto-maternal infection, neurologic form, septicemia): the patients from this multicenter observational national study on listeriosis and *Listeria* (MONALISA and *ListeriaGEN* cohorts) come from a national hospital recruitment.

For *Trypanosoma gambiense* or *T. rhodesiense* African trypanosomiasis (WHO HAT specimen bank), the patients have been recruited from 13 centers and 6 affected African countries (Chad, Democratic republic of Congo, Guinea, Malawi, Tanzania and Uganda).

*Borrelia burgdorferi* and other as yet undefined tick-borne pathogens (OHTICKS): the patients are recruited in 3 main regions in France: *Auvergne*, *Franche-Comté* and *Ile-de-France*.

Patients with infectious diseases of unknown etiology come from all over France and occasionally from abroad (Pathodisc/PATHO-HTS).

### Clinical characteristics of patients

Inclusion criteria, stage of the disease, evolution and treatment informations are collected depending on the project specifications

### Control samples

Blood samples from healthy volunteers are collected within the *Diagmicoll* and *CoSImmGEN* cohorts.

### Biospecimen type (December 2018 report)

Serum (0.25, 0.5, 1 or 3.5 mL) 6296 aliquots

Plasma (EDTA, 0.5, 1 or 3.5 mL; Lithium-Heparin, 0.4 mL, Sodium-Citrate, 0.4 mL): 10,250 aliquots

whole blood (1 mL), about 1027 aliquots

PBMC (0.4 mL) about 4404 aliquots, isolated polymorphonuclear neutrophils: 32 aliquots,

RBC: 10 aliquots

DNA and RNA extracts (1 to 2 µg): 3256 and 258 aliquots, respectively

fecal samples (1–3 g), *ca.* 1760 aliquots

Urines (1, 1.8 and 3.5 mL), 654 aliquots

Naso-pharyngeal swabs, 139 samples

Saliva (0.25 mL), 67 samples

Tears, 67 test trips

Cerebrospinal fluid: 21 aliquots

Cutaneous biopsies: 3 from healthy volunteers.

New samples may be available on demand after submission of the research project to the following address: [demandeRBH@pasteur.fr](mailto:demandeRBH@pasteur.fr)

### Size of the bioresource

ICAReB is a Institut Pasteur-associated infrastructure with no expiry date. The number of full time employees presently working is 11.

### Access criteria

ICAReB can provide bioresources from healthy volunteers (*DIAGMICOLL* and *CoSImmGEN* cohorts) to researchers worldwide, both from academic or private organisms. Inquiry forms can be obtained from its website or directly ([demandeRBH@pasteur.fr](mailto:demandeRBH@pasteur.fr)), leading to an interactive process the approval after evaluation by the scientific committee of the biobank (*CoSciB*) if no previous scientific evaluation has been performed. In this case, a reply can take about 3 weeks.

### (4) Reuse potential

As multiple aliquots are obtained from a single sample, the re-use is possible providing that the respective donors have given their informed consent to the re-use. Moreover, if necessary, consent for new specific research projects may be sought for from still active or connected healthy volunteers.

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### Competing Interests

The authors have no competing interests to declare.

**Author Roles**

S. Chaouche, L. Sangari: laboratory technicians

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M.N. Ungeheuer, *MD PhD*; biobank manager.

**Note added in proof**

The ICAREB platform has been appointed as a WHO Collaborating Center for HAT on 2020, February, 10th (under ref. FRA-138). A new member, Charlotte Renaudat, *MD*, joined the team.

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