

Policy for access to samples and data stored in Tropica Biobank

The procedure for access to biological samples and data for research purposes requires the applicant (Principal Investigator, PI) to submit a project proposal (see the template attached to this document), which will be evaluated by the biobank's scientific committee. The scientific committee will evaluate the scientific quality of the proposal and the compliance with the purposes specified in the informed consent signed by the donors. The committee may propose a meeting with the PI to discuss the details of the project.

If the project proposal will be approved by the scientific committee, the following procedure will be applied:

- the study protocol must be submitted to the relevant EC, in accordance with the EC's procedures in force at the time of submission. A contract agreement will also be drawn up between the IRCCS Sacro Cuore Don Calabria and the requesting body, regulating their relationship regarding the project. The samples and associated data may be sent to other centres purely for the purpose of scientific collaboration or for the performance of certain activities (e.g. particular analyses), also for technology transfer with commercial purposes, excluding the sale of the samples themselves.
- A material and data transfer agreement (MTA/DTA, see the relevant link to the document on the website) will also be agreed and signed, in which the conditions for the shipment will be specified and in particular
 - o The definition of the biological material and its possible derivation.
 - o The conditions governing intellectual property (IP) on the material and the research that will be carried out on it.
 - o The conditions that regulate the use of the biological material and in particular it will be indicated that it will not be possible to further transfer, or make available, the material or part of the material to recipients that are not indicated in the approval document.
 - o The management of publications and any commercial and intellectual exploitation that may arise from research on biological samples and the return of the data to the biobank when possible.
 - o The management of data confidentiality.
 - o The guarantees of any financial reimbursement or research collaboration envisaged.
 - o Relevant legislation and jurisdiction.
- Samples and associated data shall be transferred without financial compensation. The biobank may, however, provide for a reasonable reimbursement to cover its own costs for handling the sample request and shipping. In the case of requests for additional analyses conducted by IRCCS Sacro Cuore Don Calabria, these will have to be discussed and formalised in the contract between the two institutions.



IRCCS

Istituto di Ricovero e Cura a Carattere Scientifico

Sacro Cuore - Don Calabria

Ospedale Classificato e Presidio Ospedaliero Accreditato - Regione Veneto

Dipartimento di Malattie Infettive - Tropicali e Microbiologia (DITM)

Direttore: Prof. Federico Giovanni Gobbi

Tropica Biobank

Responsabile: Dott.ssa Chiara Piubelli

Access to biological samples and data for research purposes will be requested from the following contacts:

Scientific Secretariat, email: segreteriaScientificairccs@sacrocuore.it

Dipartimento di Malattie Infettive - Tropicali e Microbiologia (DITM)

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Applicant Information and Project Proposal

Applicant/Principal Investigator (PI):

PI Institution/Department and address:

PI contacts (email, phone)

Title of the Project:

Background and Hypothesis:

Aims:

Methods:

Requested sample type and size:

Expected results:

Planned duration of the project:

Has an Ethical Committee already approved the study? Please indicate the competent Ethics Committee, date of clearance and protocol number.

Submit the Applicant Information and Project Proposal to: segreteriaScientificairccs@sacrocuore.it