
DOC-9-Gestio cessions de
mostres i dades GCAT

Annex 5 GCAT DATA ACCESS



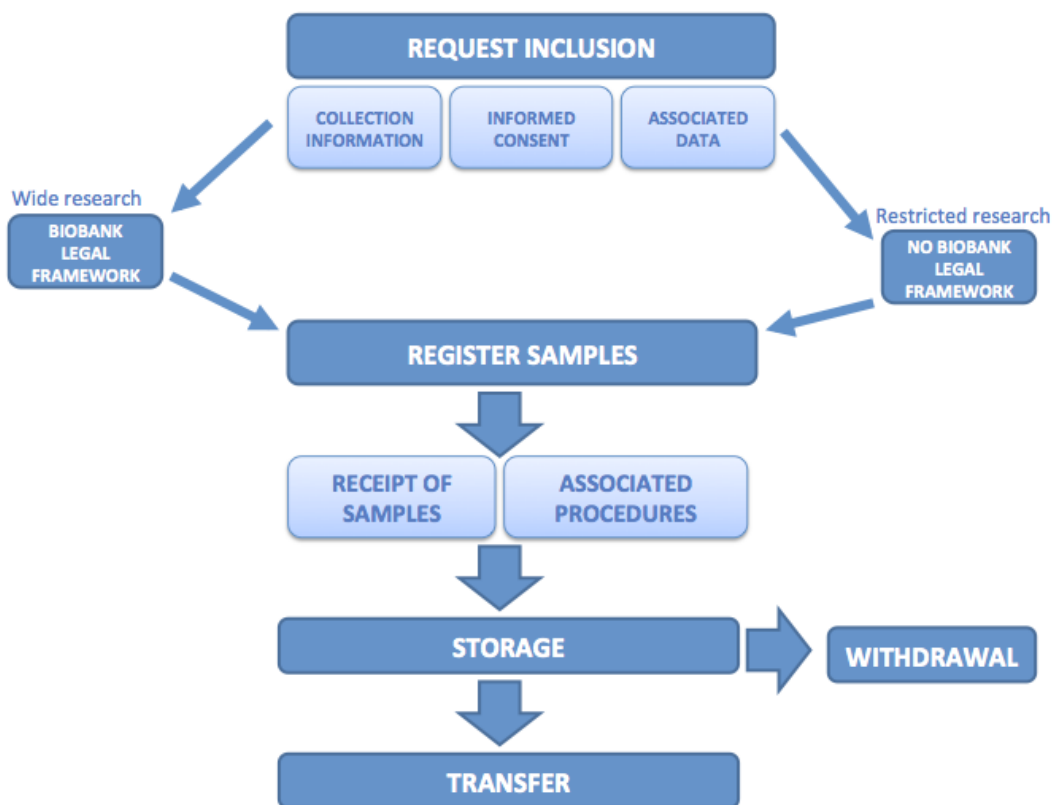
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1. MANAGEMENT OF SAMPLES AND DATA OF THE GCAT RESOURCE

The incorporation, transmission or withdrawal of samples and data given to the GCAT deposit must meet all the standards of quality, safety and traceability required by the Spanish law LIB 2007 i el RD1716/2011.

As established in article 23 of the Spanish Law RD1716/2011 the collection of samples, the deposit, conservation and later use requires the corresponding previous consent from the source donor or person legally responsible or family member. The signed consent is the end of the process of informed consent as a necessary prior step to samples being processed and conserved in the biobank.

The biobank has designed **normalized procedures to document and guarantee quality, safety and traceability of the samples included in the bank**. It has also designed all the **associated processes for their treatment and the functioning of the bank**.



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The inclusion, conservation, transmission and withdrawal of samples and data of the GCAT imply the following steps:

- Incorporation of samples and data
- Registration of samples and data incorporated
- Reception of samples and data for incorporation
- Procedures and associated services
- Storage of samples incorporated
- Transmission of biobank data and associated collections
- Application for withdrawal of samples from the biobank and resolution of the withdrawal

2. GENERAL POLICY FOR TRANSMISSION OF GCAT SAMPLES AND DATA

- The GCAT samples and data are accessible to the international scientific community for biomedical research of excellence in terms of ethical and scientific aspects
- The GCAT will make the largest quantity of data possible available to the public through its website at a general level (not at individual level). This includes a limited list of the socio-demographic and medical variables associated with the samples and the biological samples collected by the project
- Access to the samples is by payment and by a costing policy specifically defined to favour public and collaborative research. Access to the samples and data must be paid for according to the current GCAT prices.
- Access to biological samples is limited and exhaustible and will be highly controlled. The scientific and ethical committees will ensure that petitions meet scientific, ethical, technical and economic standards to give priority to excellent projects.
 - ▶ Incompatibility of the project with the consent given by the participant will be the main reason for excluding a donation.
- The GCAT guarantees anonymity and confidentiality in the transmission process by means of a methodology that guarantees the protection of the data deposited in the GCAT. Samples are always transmitted in dissociated form, with a code.
- The transmission of data is guaranteed by the signature of a material/data transfer agreement (MTA /DTA).

Some restrictions can be defined in the transmission agreements for GCAT samples by the researcher responsible. These will be published to the scientific community on the biobank webpage with the information about that particular collection.

3. PROCEDURE FOR TRANSMISSION OF SAMPLES AND DATA

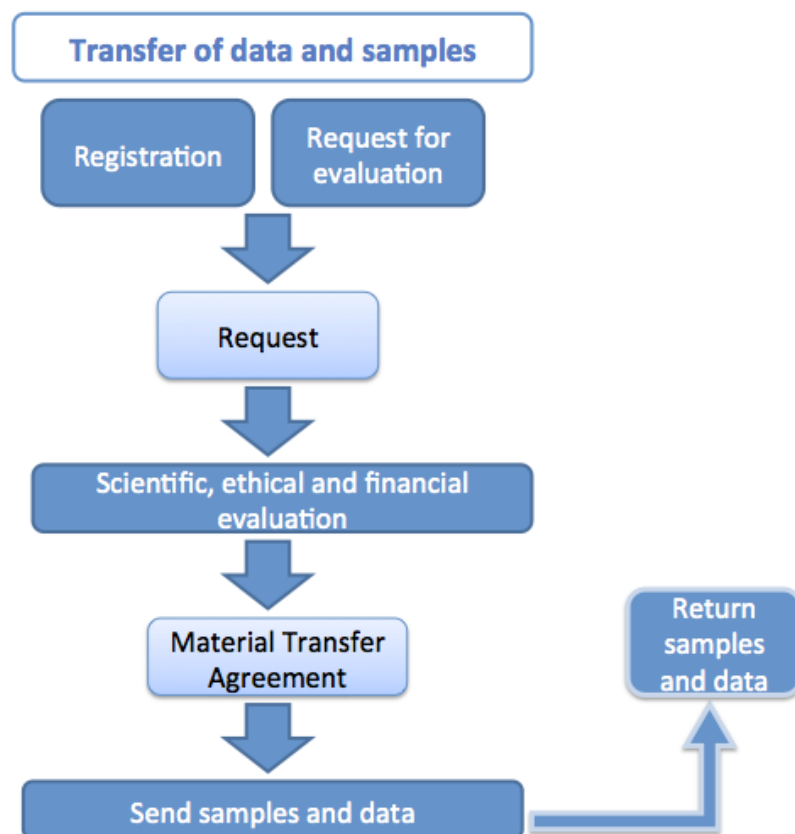
The GCAT requires researchers to make a formal petition for the transmission of data and/or samples.


The petition process is via the GCAT webpage and has three steps:

Registration and request for availability

Evaluation

Formal request and Material Transfer Agreement signature



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REGISTRATION AND REQUEST FOR AVAILABILITY

REGISTRATION

Each person that wishes to use the GCAT will have to prove his/her identity before being registered as an **authorized researcher**. Each researcher must register via web at <http://www.GCATbiobank.org/investigadors/> using the digital form.

- Research centre
- Name
- Address
- Email/Telephone
- Web-site
- CV / List of publications in the last 3 years (format pub med).


The GCAT-IMPPC personnel will take the necessary measures to confirm the identity and good faith of the researchers, and a **unique and personal registration number** is produced and sent, to identify the researcher in all the following applications.

REQUEST

The researcher should complete the formal request at (<http://www.GCATbiobank.org/investigadors/>), with complete the following information:

- Brief summary of the research project, including;
Scientific basis of the project (antecedents and data of any pilot, experimental data and design, potential calculations and expected value of the results and pertinent references)
Collaborating researchers
- Approval of the relevant CEIC to carry out the project
- Data necessary and /or the quantity and type of samples and if there is a need to re-contact with a short justification.
- Questions of viability (for example capacity for research, collaborators)
- Proposed calendar (start, duration, availability of results, presentation of publications)
Details of any publications published, en revision or anticipated
- Details of financing (or of finance applications)
- Storage protocols for the data and or samples (security of the data, physical security of the samples, capacity for resource management)

Petitioners can also send letters of support by third parties; although this is optional.

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EVALUATION AND RESPONSE

The initial request must allow the request to be verified on two levels:

Determine:

- i) The objective of their project
- ii) The availability of the data and /or samples needed for their research
- iii) An approximate cost for obtaining the data and/or samples (to see if they need to obtain funding, for example). GCAT staff may have a meeting with the petitioner, if they think this is necessary before a formal request is presented.


Evaluate:

- i) if the objective of the proposed research satisfies the criteria of excellence required (scientific and ethical approval by the external committees and by the Biobank)
- ii) if the number of exhaustible samples requested is justified scientifically (Internal Scientific Committee)
- iii) the cost of providing these data and/or samples (budget and Laboratory Manager)

One or more meetings may be needed between the researcher and the GCAT staff in order to resolve doubts on both sides.



When the revision of the request has finished, the GCAT will formally communicate the researcher:

- Rejection by the GCAT of the request giving a short explanation of the reasons. The PI requesting can then opt to:
 - (i) Clarify or modify the request
 - (ii) Withdraw the request
 - (iii) Ask for a reconsideration
- Conditional approval with some pending issues (for example, concession of financing), which must be completed within a specified time
- Approval subject to acceptance and signature of a standard DTA/ MTA transfer form: http://www.GCAT_biobank.org/investigadors/

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The evaluation process will be managed by the Internal GCAT Committee, which will carry out a series of standard controls and ask for advice for specific applications if necessary.

The director of the GCAT will ask for recommendations for each request according to his criteria and they will be subject to approval by the External Ethical and Scientific Committee (conditions of access are detailed in the document Management of GCAT ELSI (in Catalan)).

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FORMAL REQUEST AND MATERIAL /DATA TRANSMISSION AGREEMENT – MTA/DTA

For approved requests the materials transfer agreement must be signed and the conditions of payment accepted and the budget paid.


The GCAT will send the standard MTA/DTA to the PI requesting for checking and acceptance by his/her institution.

Formal request data and Standard MTA/DTA forms are available at <http://www.gcatbiobank.org/investigadors/daccess-documents/>

The MTA will be considered as signed when the GCAT receives a signed MTA from the PI making the request by ordinary mail.

After accepting the MTA a brief summary of the research project will be posted on the GCAT webpage (any confidential information will be removed) so the participants and the public can see which studies the GCAT resources are being used for.

If a researcher breaks the MTA agreement, there could be an immediate withdrawal of the licence to use the resources. It could also lead to other actions, such as informing the host institution of the researcher and/or financing bodies, or regulatory bodies and prohibition of the host institution from having access to the resources.

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4. SENDING DATA AND SAMPLES

A.DATA

Data will be made available to the petitioners by sending a hyperlink and password by email, where the relevant data can be consulted and downloaded. The link and password will be unique to each request and only valid for a short time.

Regarding large data sets, of which download is not a practical option, other methods will be found, for example access on site, or other solutions that will be paid for by the petitioner.

The GCAT guarantees anonymity and confidentiality of the samples. When the data are given to the researchers all practical measures will be taken to remove direct and indirect identifications that enable the identification of the individual participants (reversible dissociation or codification). Researchers will accept in the MTA signed with the GCAT that they will make no attempt to identify participants.

It is prohibited to transfer data outside the institution requesting it without the consent and approval of the GCAT.

B. SAMPLES

The GCAT will provide petitioners with three types of samples: DNA, serum and plasma. The three types will be kept in the installations of the biobank at a temperature of -80°C.

All samples requested will be sent by urgent mail (delivery in 1 or 2 days) with dry ice and the cold chain guaranteed at all stages.


The despatch of samples will be registered by the IMPPC reception personnel electronically, as defined in the GCAT Security Document - Despatches register.

Unless otherwise indicated in the request form, samples will be sent in 0.5ml polypropylene tubes codified in 2D en racks of 96 samples.

Despatch will be carried out under the following conditions:

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- The GCAT will notify the researcher when the samples are ready to send
- The receiving researcher will notify the GCAT of the details and exact address for the delivery of the samples. The time of despatch will be Monday to Friday from 09.00 to 16.00 (avoiding despatches on the day before public holidays)
- The GCAT will give the delivery to a transport company certified to carry biological samples. Transport will be in the appropriate packaging for biological samples, (foam-padded pouch to protect the tubes) and addressed to the researcher.
- Within one day of reception the receiving researcher will confirm their arrival

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5. RETURN

A. RETURN OF UNUSED REMAINDERS OF SAMPLES

Once the samples have been used for the project requested, the researcher must return the remaining material to the Biobank as stated in the MTA.

To do this, the researcher must contact the GCAT again. The samples must arrive in their original tubes with identification. If this is not possible, it must be indicated to the GCAT and samples must be sent in identified containers.

Sending will be done under the following conditions:

The researcher will indicate to the GCAT when the samples are ready to send and which samples are being sent by email.


The GCAT will notify the researcher of the dates and place to deliver the samples. The time of despatch will be Monday to Friday from 09.00 to 16.00 (avoiding despatches on the day before public holidays)

- The cost will be covered by the researcher, who will give the delivery to a transport company certified to carry biological samples. Transport will be in the appropriate packaging for biological samples, (foam-padded pouch to protect the tubes) and addressed to the researcher with the chain of cold guaranteed at all times.
- The GCAT will notify the researcher of the arrival within one working day of reception.

B. RETURN OF RESULTS

General Information

All publications derived from the use of data/samples from the GCAT must include the acknowledgement "This research has been carried out using the resources of the GCAT|Genomes for Life. Cohort Study of the Genomes of Catalonia" and an express reference to the webpage (www.GCATgenomesforlife.org) from which it will be linked, when possible to the research tools such as PubMed or MEDLINE.

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Individual Information

According to the terms of the MTA the individual information will be communicated to the Biobank and incorporated as part of the GCAT, as described in the ELSI policy document of the GCAT, DOC-2-GCAT ELSI (in Catalan).

As regards individual information that can be acted upon, following the ethical guidelines the finding of such results will activate the protocol for contacting patients, as described in the ELSI policy document of the GCAT, DOC-2-GCAT ELSI (in Catalan).