ELSI GCAT

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MODIFICATIONS FROM THE PREVIOUS VERSION

Revision	done by	Date	Modifications
1	R de Cid	15/07/2013	First version
1.1	R de Cid	1/03/2014	Genomic Research policy + Genetic Counselling Units

1. ELSI Policy for the genomics research for GCAT

In order to carry out research in the field of Genomics of Human Disease wide access must be granted to genomic data, medical records and biological samples stored to shed light on and understand the role of genomics in health and in the development and treatment of disease. This requirement raises issues and must be treated specifically.

The constant appearance of and improvement in powerful new genomics techniques has allowed for the discovery of results that were unimaginable just a decade ago. This power of the technology, together with the general use of biospecimens destined for research has magnified the unsolved problem of consent given in anticipation of research before the possible consequences of any information discovered are known, so they cannot be evaluated at the time of giving consent.

Knowledge generated by these techniques is giving rise to unforeseen consequences, which push us to establish a regulatory framework for the Ethical, Legal and Social Implications (ELSI) as a central part of our activities. Alternatives, such as the de-identification of genomics data is not a solution to avoid the breach of confidentiality given that identification must be maintained for medical procedures by legal requirement (at least 10 years) and for the purposes of investigation it is preferable to be able to follow up individuals.

The exploitation of genomic data for research raises two principal concerns, which must be covered by the regulatory framework of the GCAT.

- Management of integrated information generated by genomic analysis: information which could put the ethical integrity of the individual at risk
- Management of data shared with other scientists for the purpose of research, which was not included in the initial consent

1.1. Ethical Research at the GCAT

The GCAT project has a firm commitment to participants and researchers to establish, develop and promote research that will benefit health, wellbeing and society. This commitment is shown by the observation of and compliance with an ethical-legal framework for its activities. The ELSI GCAT refers to the Ethical, Legal and Social (ELSI) aspects implied by or derived from the activities of the GCAT project and are used to guide its activities and those of the GCAT Biobank.

The custody of material and use of data will follow the ethical scientific principles under the guidance of experts in ethics and science in order to carry out ethical biomedical research for the good of society. This policy has been defined with the international framework for biomedical practice and in particular following the Charter of Principles of the *Public Population Project in Genomics and Society Project* (P^3G), which includes the following basic ethical principles:

- **Respect for people**
  An obligation to respect the autonomy of the participants in the research and protect people with reduced capacity. The respect for autonomy implies supplying sufficient information to participants in the study in order to obtain their free informed and voluntary consent.

- **Benefit /Not harm**
  The obligation to maximise net benefits for participants in the research and for society in general while advancing our knowledge and the obligation to minimize and prevent harm to the participants in the research.

- **Fairness or Reciprocity**
  The obligation to promote trust between researchers and participants in the research.

The scope of this document extends to all the collections of samples and data that have been deposited in the GCAT Biobank to carry out biomedical research and included under the biobank rules. The collections deposited in but not subject to the legal regime of the biobank will be guided by this policy, but it will not be binding.

1.2. Types of collections under GCAT-IMPPC Custody

1.2.1. GCAT

The GCAT is a collection of samples and data of the GCAT Cohort. This includes biological samples derived from blood, physical measurements, epidemiological and health data for 50,000 individuals of the general population of Catalonia.

The objective of the GCAT is to study the genomics and epigenomics of chronic diseases in the general population. The GCAT has a wide biobank permit and is regulated according to the biobank regime (LIBM, 2007).

1.2.2. Non GCAT_ under the biobank regime

Apart from the GCAT collection, other collections of biological samples and data destined for biomedical research can be kept. These collections come from different sources:

- Samples taken for diagnostics and destined for research
- Samples specifically for biomedical research

These collections have an associated wide biobank consent, regulated according to the biobank regime (LIBM, 2007).

1.2.3. Non GCAT_ outside the biobank regime

This category corresponds to other collections outside the scope of the biobank. These collections are collections of biological samples and data destined for biomedical research, but not assigned to the biobank. These collections can be of different categories:

- Samples taken for diagnostics and destined for research
- Samples specifically for biomedical research

These collections have an associated specific consent and are regulated by the Law of Biomedical Research outside the biobank regime (LIBM, 2007).

2. Aspects of ELSI for GCAT partners

2.1. Recruitment of individuals

Participation in the GCAT is non-discriminatory and is carried out bearing in mind the following criteria:

- **Scientific**. The call to participate does not represent discrimination, it is limited by scientific criteria and the initial economic resources of the project
- **Autonomy**. Participation in the GCAT project is voluntary. This criteria is reflected in the process of informed consent specifically established for the study. Accepting to participate means agreement and explicit consent on the part of the participant to cede a biological sample and the data required for the study; that is the personal data and data related to health required by the study.
- **Non-discrimination**. The information campaign to call for participation does not represent any form of discrimination and is open to the whole population of Catalonia. Possible participants will be contacted through the communication and information network of the donors of the Blood Bank in Catalonia with no previous selection.

The criteria for recruitment of other collections destined for biomedical research are defined in the project associated and approved by the corresponding Research Ethics Committee. In any case the collections in custody will follow protocols approved by the appropriate supervising committees.

2.2. Consent of participants

In general, participation in a research project is undertaken by participants who have been informed and given explicit consent.

- The procedure for informed consent is defined explicitly in the project
- The consent is given by a signature on the consent form
- Acceptance of the terms of consent will be applied during the duration of the study, unless the participant voluntarily withdraws his or her consent
- The person responsible for the study must be sure that the participants have understood the terms of the agreement

The consent procedure complies with the Spanish Laws LIBM 2007 and RD 2011 and must include the following items:

Clear identification of the purpose of the project
Precise identification of who is running the project
Identification of who is financing the project
Clear description of what material and data is asked for
The voluntary and altruistic nature of the donation
Description of the risks of participating
Description of the participants' rights
Explicit explanation of the right to know and the legal limitations
Explicit explanation of the right NOT to know and the legal limitations
The possibility that samples and data be ceded to third parties for biomedical research
Description of the scope of the consent to carry out biomedical research
Identification of the physical destination of the material and data given
Description of the security measures and protection of confidentiality for the data deposited

The collections held in the biobank will always have an informed and detailed protocol approved by the corresponding accredited committees.

2.2.1. Informed Consent for GCAT

The genetic nature of the GCAT research makes it impossible to identify future health research uses and accordingly, the GCAT consent asked for is wide-ranging to cover genomics health research (of the biobank type). Participation in the GCAT offers the opportunity to contribute to a unique study that in the future will help to improve the health of people and society in general.

The GCAT has implemented a type of consent that follows the rules of the Spanish National Network of Biobanks. This model has been approved by the ethics committee of the Spanish National Institute of Health (ISCIII) and conforms with current legislation (LIBM 2007).

The GCAT model of informed consent (CI) has been positively evaluated by the Research Ethics Committee of the Germans Trias i Pujol Hospital (HGTiP), Badalona (see DOC-0).

The consent form explicitly asks for consent for:

- Donation of a blood sample for genomic analysis
- Taking of body measurements (weight, height, waist, hips and blood pressure)
- Collection of epidemiological data on lifestyle and healthy living
- Access to available electronic health data
- Follow-up of state of health during the length of the study

Additionally the GCAT Model explicitly covers the wishes of the participant regarding:

RECONTACTING personally if it is necessary, whether it be for a new request for a donation of a sample or data or for other information related the project. This renewed contact does not imply consent to any new request; at any point the donor can refuse new petitions.

The **RIGHT NOT TO KNOW** on the part of the participant, who is free to choose the possibility of being contacted to communicate relevant results (see the section on confidentiality and returning results in this document).

EXCEPTIONS to the consent for the use of materials donated for certain types of research

CONTINUITY of the consent for GCAT, which means that until instruction to the contrary and within the exceptions freely available to the participant, the consent for the use of samples and data and access to electronic health data is long-term.

2.2.2. Models of CI available for the GCAT biobank

The GCAT has implemented models of informed consent in line with its policy, destined for the inclusion of samples and data for use in research deposited in a biobank according to the guidelines of the Spanish National Network of Biobanks and complying with the current legislation (LIBM, 2007).

These models are freely available on the GCAT website (www.GCATbiobank.org)

- GCAT Biobank model of informed consent for biobank research
- GCAT Biobank model of informed consent for biobank research using samples remaining from diagnostic

2.2.3. Access to electronic health data by the GCAT

The GCAT cohort requires tracking of health data of the volunteers enrolled in the study. This tracking will be carried out with a regular check using personal health questionnaires (electronic or in person) and by quarterly updating of data from the electronic health record registers.

Access to electronic health data (diagnostics, treatments etc) is one of the most powerful aspects of the project. The GCAT will collect data from the public health system (family doctor, hospital admissions, prescription registers, analysis, medical procedures etc) and other relevant systems (cancer register) using a collaboration agreement with the Catalan Health Ministry within the framework of the program VISC+. The contract between the GCAT-IMPPC and the Ministry of Health is in Annex 2 at the end of this document: *Annex 2. Conveni GCAT-IMPPC-Departament de Salut.*

Regarding the data in the register on causes of death, this update will be carried out using a regular agreement with the "Institute of Health Information - Ministry of Health, Social Services and Equality of Spain."

Access by GCAT to health data (eSalut) will be carried out using a controlled codification process with the colaboration of the Ministry of Health, who takes the role of "trusted partner" and intermediary between the BST and the GCAT (see figure 1). The access and update protocol for the data in the electronic health registers, apart from Cat Salut is detailed in the document in Annex 3; *Annex 2. Conveni GCAT-IMPPC-Departament de Salut.*

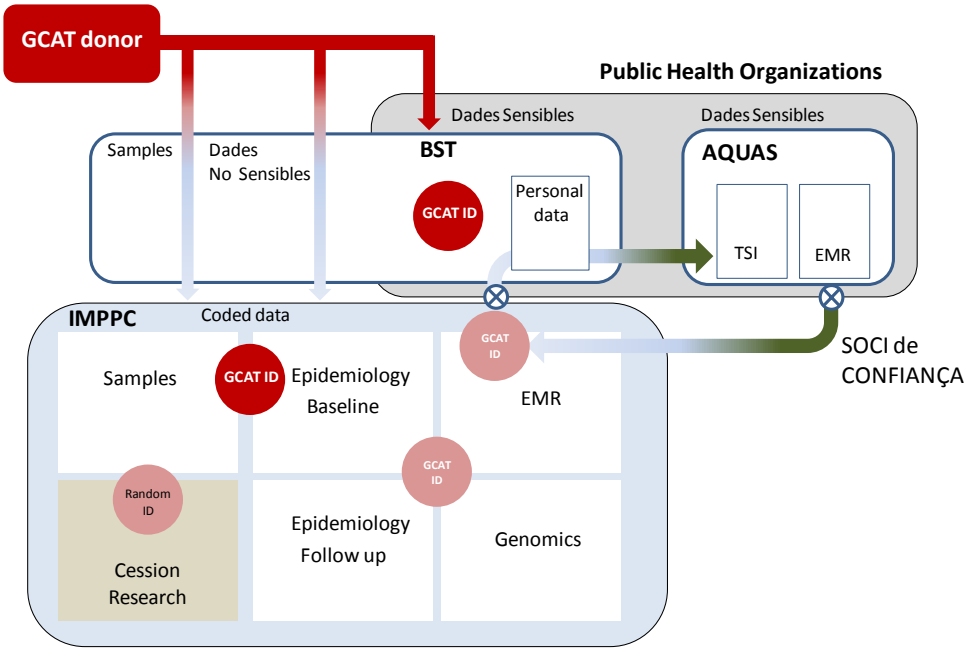

Figure 1. Exchange of data between groups participating in GCAT

In the GCAT consent process the participants are informed about the access to electronic health registers. At the moment of recruitment it is not possible to say which data from these diverse registers will be required by the GCAT study. GCAT will always communicate the possible changes in access to different types of registers. Although consent covers complete access to these registers, usually only partial access to data will occur. Access to different electronic health registers will be determined by the evolution of the project and the implementation of centralized electronic health registers.

The information in the registers that identifies individuals will be dissociated, protecting the rights of confidentiality of the participant at all times.

2.2.4. Health tests during recruitment of GCAT participants

The GCAT will obtain relevant information about the state of health of the participant during the initial phase of recruitment.

Recruitment by the BST includes a number of tests to detect possible infectious diseases: checks for HIV I/II, HCV, HBsAg, Lues, Chagas, antic HBC, anti HTLVi-II and nucleic acids VHC, VIH, VHB. The results and recommendations regarding the results are communicated personally and confidentially by ordinary mail to the participants.

The procedures established by the BST require that if positive or abnormal results are obtained the donor is recommended to contact health professionals. This procedure is managed internally by the BST and will be extended to GCAT donors, although they are not habitual blood donors.

This activity is mentioned clearly in the GCAT informed consent.

2.3. Confidentiality

The GCAT is completely committed to the protection and confidentiality of data and samples in line with right to data protection as established in article 18 of the Spanish Constitution and article 31 of the Statutes of Catalonia.

The GCAT guarantees that all data and material from samples donated will be identifiable and all changes carried out during the tracking will be identified in order to maintain the chain of custody and to guarantee the confidentiality and safety of the personal data in compliance with the law (Organic Spanish Law 15/99 for Data Protection for Personal Data).

The IMPPC is the instigator of the GCAT, it is legally responsible and committed to the promotion and installation of the relevant preventative measures (IT and logistic) to guarantee safety.

- **INTEGRITY** During recruitment, the information collected about participants will be transferred in encrypted form to a safe server on the IMPPC premises using a safe route (https). Temporary files are removed daily from the IT equipment at the recruitment centres and centres and headquarters.

- **CODIFICATION** The identification data is protected in a centralized way by the BST, who acts as the guarantor of custody according to the collaboration agreements between the two entities. The samples in the GCAT biobank are codified in a reversible way, using a unique code. All the information about the data and samples of participants is identified using a code with no external significance.

- **TRACKING** The data and samples are not anonymised. The maintenance of tracking will allow 1) follow up of the health of participants, 2) elimination of redundant data (for example duplications) 3) verification of the exactitude and integrity of the data in the original registers 4) establishement of the correct links between data and 5) ability to find data or samples if the participants request their restitution. Tracking allows the project to maintain a register of participation and expression of wishes by the participants.

- **ANONYMOUS TRANSFER** During transfer to third parties the researchers will never be able to obtain identifying data on individuals. Re-identification of a participant, using the key code will only occur exceptionally in specific circumstances (eg. relevant clinical results or legal requisitions) and always restricted to GCAT personnel under the supervision of the managing bodies of the GCAT.

GCAT FILE OF SPECIFIC DATA All data managed by GCAT that identifies the person or permits his or her identification are registered in file of personal data under the legal responsibility of the IMPPC (Spanish Data Protection Agency registry number: 2131481397). The participants have the

right of access, rectification, cancellation or opposition (rights ARCO) by addressing themselves in writing to director of the study.

2.4. Management of return of results to GCAT participants

The communication of results, of knowledge generated from the collaboration and participation of individuals could generate conflict if not correctly handled, leading to a loss of trust. For this reason, the GCAT has defined a policy of action to communicate results from research carried out and especially those derived from genomic research, specifically to communicate with participating individuals.

The CI of the GCAT includes an informed declaration about the general policy for returning results. The participants in the study accept a limited return of results within the agreed terms when they give their informed consent.

The GCAT differentiates two types of communicable results:

- **Research Results of general interest**

The results of general interest (research results RR) produced by research projects within the GCAT will be communicated to all participants using the channels previously defined: webpage and electronic newsletter). These will have general information about the research and information about the goals reached or studies in which the samples will participate.

- **Research results of interest to individual participants**

The return of results of individual interest (individual research results RRI) is strictly limited to individuals for who results are produced that have an **impact on the reproductive health or state of health of the person.** The GCAT has established a procedure for taking decisions to specify, clarify and outline the duties and obligations for both participants and those responsible for the research (GCAT or third parties) when dealing with the return of results to individuals.

This process is based on an evaluation for three values regarding the results:

ANALYTICAL VALIDITY The result must be independently confirmed by another technique
CLINICAL SIGNIFICANCE The result shows a risk to health
ACCIONABILITY The result must have some therapeutic benefit
Currently the importance and the scope of the three values is not totally agreed and is in a process of continuous evolution.

The same policy will be applied with the agreement of the person responsible for all the collections that are in custody of the biobank GCAT-IMPPC. Regarding collections outside the scope of the biobank, communication of results is the responsibility of the person in charge of that collection and the GCAT will only make recommendations based on its own internal policy.

2.4.1. Management of accidental findings in genomics research of the GCAT

The GCAT project aims to carry out sequencing using high performance sequencing techniques (WGS/ES). The potential and capacity of these techniques far exceeds the current on-paper knowledge of the genetic variations and mutations discovered and their effects on health.

The supervision of clinical medical genetics within the public health system is carried out specifically in reference centres, which guarantee the quality necessary for clinical practice. Normally this activity is under the supervision of the recognized and often specialized units of Genetic Counselling. In research the use of genetics is generalized and although the standard of quality is adequate, it is not applicable to personal clinical practice.

In any case genetic research on human beings requires a sharp attention to the basic ethical principles demanded by consideration of patients; assuring the capacity of decision for all that it entails (autonomy), not doing harm either on purpose or by accident (no malice) and of equal sharing of gains and risk (justice).

The consideration of these three principles is an intrinsic ethical obligation for research but it is also a legal requirement in our country.

Glossary of Terms

Patient. Participants in the GCAT, who undergo an exploration for sequencing and are competent to take their own decisions about their health.

Accidental findings. This term ha been used in the clinical context to indicate unexpected positive results. In the area of GCAT research it is not an objective of the research to evaluate a genetic condition, so any finding derived from sequencing can be considered and treated as accidental.

Medical team. The medical team who have direct contact with, or are responsible for the direct contact with the patient and the family. The medical team have to have the capacity and genetic knowledge, along with an understanding of genetic counselling, analysis and evaluation of risks in order to transmit this information to the patient.

Laboratory. Organization which takes the responsibility for the analysis, interpretation and generation of reports for sequencing. In some cases, a laboratory can generate the sequence of the data in the rough and another might evaluate and interpret the sequence, bearing in mind additional tests to confirm the emission of a medical report.

- **GENOMICS POLICY**

  The GCAT establishes its genomic policy from agreed ethical guides for activity from the Genomics Policy Centre of the international consortium Public Population Project in Genomics and Society (P3G).

  The policy refers specifically to the return of individual or accidental results of the research and the right to know and be informed of each subject undergoing genetic tests.

- **INTERNATIONAL CONSENSUS**

  The GCAT adheres to the specific recommendations agreed by the American College of Medical Genetics and Genomics (ACMG) for the management of individual and accidental results observed during research as a cause of sequencing exomes or whole genomes.

  The GCAT defines a first list of genes to be considered as a priority for special priority management with a protocol for the purpose.

  The GCAT will regularly revise the updated international recommendations to modify its own list of recommendations.

Circumstances taken in to consideration

Following the ACMG recommendations for 2013 the GCAT has drawn up a priority list of conditions associated with genes and mutations that have been clearly classified as of medical use and for which a series of preventative or therapeutic actions can be carried out to improve the health of the patient. (see Annex 1).

It is recommended to observe the following variants:

- **GERMINAL**
  Only mutations/variations of the germ line, not somatic

- **PATHOGENIC**
  Only those variants with a major probability of causing illness and those that fulfil the criteria to be defined as pathogenic should be reported. In genetic reports these are indicated as:

  - Sequence variation, which has been previously reported and is a recognized cause of an illness, or that has not been previously reported, but is of a type expected in illness

Responsibility for Management

Those responsible for the research, GCAT researchers or researchers with access to the GCAT data are responsible for managing the results.

On transmission of data to third parties by GCAT the codification of samples allows for confidential tracking of the identify of the GCAT collaborator, who if it is necessary, can be contacted by the corresponding medical team, always under established protocols.

For the agreement of transmission of samples, all investigators who have access to the samples of GCAT collaborators are obliged to communicate to the person responsible for GCAT any unexpected discovery.

Obligations of the person responsible for the research

The person responsible for the research should establish the right conditions to ensure coverage of the recommended targets during the global analysis of the genome, or specifically during the analysis of one of the regions listed as susceptible to containing communicable results.

All this includes a series of costs (economic and logistic), which must be covered by the person responsible for the research and have to be clearly explained and acknowledged in the signing of the transfer.

- Express analysis of determined regions
- Technical checking of results
- Initiating the communication procedure to the patient once a variant is identified

Communication to the patient

The responsibility of managing incidental findings is handled through the doctor and patient and coordinated by the Genetic Counselling Unit.

The return of individual results counts on the collaboration of and guidance by a group of experts from the Transversal Clinical Genetics Advisory Committee (pTAGC) of the Germans Trias i Pujol University Hospital.

The communication with a patient is always managed via an agreed GCAT protocol.

- The GCAT presents a report of the incidental findings to the genetic counselling authorities who evaluate the medical use and the actionable component of the finding
- The GAT, via the recommendation of the genetic counselling unit proceeds to evaluate the ethical competence of the finding at the CEIC HGTiP (hospital medical ethics committee)
- The genetic counsellor can define the conditions identified by the genetic counselling unit or the medical team; any incidental finding for a patient must be seen in the light of personal and family antecedents, physical examination and other relevant findings

Genetic Counselling Units

The genetic counselling unit accompanies the patient through the genetic counselling process:

- Interpretation of family and personal history to evaluate the risk of occurrence or recurrence in a particular family
- Education about inheritance, genetic tests, prevention, resources and research available
- Offering of appropriate assessment to promote informed decisions and an adaptation to the risk or condition
- Offering, if it is available, the corresponding diagnostic or predictive genetic study

2.5. Management of ARCO rights for GCAT participants

The transmission of samples and data is subject to the data protection law. Participants who give their personal data acquire the rights to know, access, rectify or cancel them, the so-called rights of ARCO.

2.5.1. Description of ARCO rights

2.5.2. Right of access

The right of access consists of the ability of a person to know or want to know his or her personal data in the possession of somebody responsible for or with the ownership of personal data following the procedure which data they have and how they were obtained.

- **Right of rectification**

The right of rectification consists of the ability of a person, once they know which data is in the possession of the person responsible or owner, to request a rectification of a datum in particular or of all of them (for example change of address, incorrect name or old telephone number etc.) if they are not correct or complete.

- **Right of cancellation**

The right of cancellation consists of the ability of a person, once they know which data is in the possession of the person responsible or owner, to ask for data that is not necessary or is not relevant to the reason for creating the file to be cancelled. The data will be blocked, this means identifiable and reserved to avoid its treatment. Using the right of cancellation inexact data can be blocked and cancelled in a particular file.

- **Right of opposition**

The right of cancellation consists of the ability of a person, once they know which data is in the possession of the person responsible or owner, to oppose the use of data in a file being used or treated in any way.

2.5.3. Exercising ARCO rights

The ARCO rights refer to the data included in the biobank files. Any other data that is not consented is not stored. This data has to be collected with the express consent of the participant given with the signature on the Informed Consent form, this applies for the GCAT collection and other collections in the biobank.

The data included in these rights are regulated data declard to be in the biobank file and available to the biobank.

- Personal data included voluntarily and with consent
- Data obtained as derived from health files or electronic health registers by consent
- Data derived from an update with consent from the epidemiological GCAT data
- Data derived from experimental research with consent (eg. Genomics)

In order to exercise the ARCO rights participants must address themselves to the people responsible (or delegated) for the file in question, that is to say, the Scientific Director of the biobank and/or the person responsible for taking care of the ARCO rights.

Scientific Director GCAT. Dr. Rafael de Cid
rdecid@imppc.org
Person Responsible for ARCO rights GCAT. Mireia Vilardell
gcatbiobank@imppc.org

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There is a procedure to ensure the correct execution of the ARCO rights (see DOC-5). The principles are regulated by the IMPPC Security of Information Plan.

3. Aspects of ELSI for GCAT researchers

The GCAT has a protocol for the use of and access to data and samples as well as for the publication of results by researchers.

3.1. Access to data and samples

The samples and data of the GCAT project can be used for biomedical research by universities, public institutions and charitable and profit-making private companies. This shared use of the biological samples is one of the objectives of the GCAT.

Because of the limited and exhaustible nature of the samples and the strategic nature of the associated information, which is the principle added value of the collection, access and transmission will be strictly controlled by specific access committees (Executive Committee and Evaluation Committees).

Access will be admitted according to the following criteria:

- **Transparent access.** The GCAT will publish its policy and procedures for access to the samples and data and their use in research.

  The GCAT will maintain total control of access and use of the data and samples of the project in line with its commitment to public use of the collection and within its own regulations.

  The Executive Committee will continually revise the policy for use of its samples to ensure that that it is used, above all, for the general benefit of the public.

- **Acceptance of the policy of use of GCAT.** Access will be defined in the terms and conditions established and agreed by the GCAT participants in their consent.
- **Adaptation of GCAT strategic lines**. The projects will be in line with the scientific objectives of the GCAT Project.
- **Checking of the project**. Access to data and/or samples will be allowed after a scientific and ethical evaluation of the research.

  All proposals will be revised by the scientific and ethical evaluating committees to ensure that they are in line with the consent given, that they have the ethical approval required and that they are up to the desired scientific standards of excellence. As the resource is being developed, the first data and samples will be used to validate and improve the methodology for compiling data and carrying out analysis.

- **Fees**. Fees will be charged for access, with the option of higher charges for organizations hoping to obtain financial profit from their use of the resource.

- **Protection of Intellectual Property**. Access and transmission of data implies an acceptance of intellectual property generated by the GCAT or the researcher

- Protection of confidentiality. The samples and data together available to the public will always be transmitted in an unidentifiable form (anonymised).

- **Single protocol.** The GCAT has established a global policy and the detailed conditions of access (DOC-5 Management of entries and drop-outs) has been and will continue to be developed with equal rights and transparency of decision-making, a correct management of possible conflicts of interest and priorities in mind.

The administrative procedures for access are laid out in the document.

3.1.1. Non GCAT Data

In this case, although in line with the general guidelines laid down by GCAT, access and the conditions for transmission of samples and data have to be previously submitted for approval or not of the person legally responsible for the collection and this will be reflected in the transmission agreement to be signed.

In the case of collections out of the scope of the biobank, responsibility for their use and access lies completely and solely with the promoter and/or principal researcher of that project. The biobank will be limited to advising on decisions to promote shared use of resources.

3.2 Data publication

The publication of data derived from the research carried out on the samples and data is a desirable outcome for the GCAT Project. Publication of research results will raise the value of the project and the collection and will help to ensure more benefits and repercussions for public health across disciplines.

1. **General results**. General conclusions and access to journals/servers where results are published

2. **Individual results.** Individual results for GCAT participants will be incorporated in the GCAT
The following general criteria will be applied to the publication of GCAT data:

   Strategy. They must be in line with the GCAT strategy
   Value of results. Results must be considered to be scientifically and ethically appropriate, published in journals of proved scientific impact and evaluated by independent committees of scientific prestige

   Guarantee of intellectual property. The results must be usable beneficially for the owners of intellectual property.

   Latency period. There will be a latency period for the publication of data subject to the right of intellectual property of its promotors. Researchers are permitted to maintain results confidential for a reasonable period of time to guarantee intellectual property (eg. preparation of publications, patent applications or other methods of obtaining a reasonable competitive advantage over competitors.

   Transfer agreement. The commitment to publish will be explained as a requirement for the transmission of GCAT data. All researchers using the data must publish the results in the public domain whether they are positive or negative.

El GCAT will keep all its policies on use and publication of results updated to guarantee the rights to intellectual property on one hand and public access to data on the other.

3.1.1 Other collections

The publication policy for data derived from the use of these collections is limited to the general communication of results obtained, their implications and a mention of the GCAT biobank as the source of material and data. Other actions will be the responsibility of the promoter of the collection in question.

3.1. Types of GCAT data and samples accessible

he list of samples and data available and accessible will be regularly revised by the GCAT to reflect the continual advances in genomics and epigenomics or other fields as the GCAT evolves.

The first list of accessible material is:

- **Biological samples and services derived**
  - Total blood
  - Serum / plasma
  - DNA
  - Viable leucocytes
  - Established cell lines
- **Diagnostics**
- **Phenotype and associate detailed information**
  - Geographical location
  - Risk habits
  - Clinical and surgical procedures
  - Medication
  - Radiation and other treatments
  - Histological nature of biopsies
  - Biochemistry
  - others
- **General molecular Informacion (not at intellectual level)**
  - Expression data
  - Methylation
  - Genotypic frequencies
  - CNVs, LOHs
  - New variants
  - others
- **Detailed Molecular information (in the second phase)**
  - Expression data at individual level
  - Rough Genotypes / rough sequencing
  - Genotypes, mutations or variants at individual level

4. ELSI Aspects and Society

GCAT has a lasting commitment to participants and this is made visible via a transparent action agreement and the inclusion of public entities from the health sector in the project.

- Blood and Tissue Bank of Catalonia
- Ministry of Health Generalitat de Catalunya.

In line with its vocation for public service for the benefit of the general population and the national and international scientific community the GCAT will be managed openly as a biobank in the service of genomic and epigenomic research. It will integrate health resources and electronic registers available for biomedical research.

4.1. Communication

One of the missions of the GCAT is to develop a dynamic system of communication between the GCAT donors, the GCAT research team, investigators and GCAT users as well as society as a whole. The GCAT will regularly communicate global results of research, research projects carried out and also it will publicize the advances that it contributes to with its activities.

The GCAT has initially established two channels of communication for people interested:

- **Web Page**. The GCAT webpage (www.GCATbiobank.org) is a space for information for the main stakeholders. It will allow information to be published quickly and respond to the needs of participants and the public in general regarding GCAT

- **Social networks**. GCAT has reserved the Twitter address @GCATbiobank this will be active within the IGTP and IMPPC social networks. Other networks will com on-line in the future

- **Electronic magazine**. The GCAT will publicize its activities regularly through and electronic magazine.

4.2. Benefits

The GCAT aims to generate and publicize knowledge to improve the health of the whole population. Any economic benefits from its activities will be reinvested in the maintenance and development of the project.

The indirect benefits of the project will come from:

- Communication of the activities taking place and the publication in international scientific and medical journals for the benefit of the research community
- Generation of a database of accumulated data destined for quality biomedical research

Direct economic benefits will be an added value of the samples and data and these will be generated during the life of the project, principally from intellectual property, patents and inventions derived from the research.

5. Approval of the ELSI Policy of the GCAT

The consideration and approval by the Management Committee of the ELSI policy has taken place on two levels:

1. INDIVIDUAL

The consideration of the questions of rights of autonomy and confidentiality of the individuals taking part has received the independent external approval from the Ethical Committee of the Germans Trias i Pujol University Hospital (CEIC HUGTP). This committee gave their approval of the ethical and legal regulations established for the development of biomedical research on human samples in April 2013.

2. RESEARCH

The treatment of matters arising from the rights and obligations of the users of the samples and data regarding the return of results, publication of results and the obligation to preserve the confidentiality during research.

The GCAT and its management bodies have the authority to regulate the uses of the GCAT and the ELSI management policy. Any modification of the ELSI policy will be carried out with the supervision of the CEIC responsible (CEIC HUGTP) of any committee decisions.

Annexes

Annex 1. DOC-2a-Annex 1.List of ACMG recommendations for reporting incidental findings

Annex *2*. DOC-2a-Annex 2. GCAT-IMPPC-Ministry of Health Joint Agreement

Annex 3. DOC-2a-Annex 3. Procedure for follow-up of electronic health data