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GCAT DATA ACCES AGREEMENT

This agreement governs the terms on which access will be granted to the data generated by the GCAT Project

The purpose of this Agreement is to establish the terms and conditions under which GCAT shall provide the Material to User for its use in connection with the activities detailed in whereas and for the sole purpose of the development of the Project, which has been positively evaluated by the Scientific and Ethics Committee of GCAT.

In signing this agreement, You are agreeing to be bound by the terms and conditions of access set out in this agreement.

This Barcelona, [date] (hereinafter, the “**Effective Date**”)

For the sake of clarity, the terms of access set out in this agreement apply both to the User and the User’s Institution (as defined below). User Institution and User are referred to within the agreement as “You” and “Your” shall be construed accordingly. **User** and **GCAT** shall be collectively referred to as the “**Parties**”, or individually as “**Party**”.

Whereas

1. **GCAT means** the GCAT Project, a group of IMPPC-IGTP-funded investigators, a list of which can be found on the study website www.gcatbiobank.org. GCAT is interested in providing and / or give access to User to GCAT Data.
2. **Data means** all and any human genetic / biological / health related data obtained from the Project, including the know-how and all proprietary information in relation thereto, which are described in **Annex 1** (hereinafter, the "Data").
3. **Data Subject means** a person, who has been informed of the purpose for which the Data is held and has given his/her informed consent thereto.
4. **User means** a researcher whose User Institution has previously completed this Data Access Agreement and has received acknowledgement of its acceptance. User is interested in receiving the Data for the sole purpose of using it in the project which is detailed in **Annex 2** of the Agreement (hereinafter, the "Project").
5. **User Institution means** the organization at which the User is employed, affiliated or enrolled.
6. **Publications means**, without limitation, articles published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research.

Now therefore, in consideration of the mutual promises, covenants and conditions set forth herein, the Parties have agreed on the subscription of this Agreement (hereinafter, the "Agreement") in accordance with the following:

1. TERMS AND CONDITIONS

USE OF THE DATA

1. Prior to the transfer of Data, and according to the Project described in the **Annex 2** of the present Agreement, a supply of [...] data shall be carried out by User, as specified in the Request Form attached as **Annex 1**.
2. **User represents and warrants** that it shall use the Data for the purposes established in the present Agreement, and User agrees that it shall not be entitled to carry out any other analysis of the DATA for any other purpose (commercial or non-commercial) without GCAT's prior written consent.
3. **Samples and related information will be sent codified**, so User shall not be able to directly identify the donors of such samples / data. The Parties undertake to comply with existing legislation to protect the identity and privacy of the subjects of the biological samples.
4. **If the donor withdraws its authorization towards** the use of his/her samples, GCAT shall notice User of such circumstance and User shall immediately stop using the samples of such donor. The results already obtained shall not be affected by the donor's consent withdrawal.

IN SIGNING THIS AGREEMENT YOU:

1. You agree to use the Data only for the **advancement of medical research**, according to the consent obtained from Data Subjects.
2. You agree to **use the data for the approved purpose and project described** in your application; use of the data for a new purpose or project will require a new application and approval.
3. You agree **not to use** data from the GCAT to carry out any other analysis for any other purpose (commercial or non-commercial) without GCAT's prior written consent.
4. You agree **not to use Data from the GCAT** to carry out any other analysis for any other purpose (commercial or non-commercial), or transfer to third parties without GCAT's prior written consent.
5. You agree to **preserve, at all times, the confidentiality** of information and Data pertaining to Data Subjects. In particular, You undertake not to use, or attempt to use the Data to compromise or otherwise infringe the confidentiality of information on Data Subjects and their right to privacy.
6. You agree **not to attempt to link the Data provided under this agreement** to other information or archive data available for the data sets provided, even if access to that Data has been formally granted to You, or it is freely available without restriction, without specific permission being sought from the relevant access committees.
7. You agree **not to sell, license, transfer or disclose the Data**, in whole or part, or any identifiable material derived from the Data, to others, except as necessary for data/safety monitoring or programme management or is required by law or court order.

Should You wish to share the Data with a collaborator out with the same Institution, the third party must make a separate application for access to the Data, and agree to be bound by the terms and conditions of access.

8. You accept that **Data will be reissued from time to time**, with suitable versioning. If the reissue is at the request of Data Subjects and/or other ethical scrutiny, You will destroy earlier versions of the Data.
9. You **agree to abide by the terms outlined in the ' GCAT Publications Policy'**
10. You **accept that the GCAT, the original data creators**, depositors or copyright holders, or the funders of the Data or any part of the Data supplied:
 - a) makes **no warranties in respect of Data** and provides it “as is”, without any express or implied warranty of any kind, including any warranty as to merchantability, fitness for a particular purpose, accuracy, completeness or violation of third party intellectual property rights.
 - b) bear **no legal responsibility** for the accuracy or comprehensiveness of the Data;
 - c) accept **no liability for indirect, consequential, or incidental, damages or losses** arising from use of the Data, or from the unavailability of, or break in access to, the Data for whatever reason.
11. You understand and acknowledge that the **Data is protected by copyright and other intellectual property** and data protection rights, and that duplication, except as reasonably required to carry out Your research with the Data, or sale of all or part of the Data on any media is not permitted.
12. You recognize that **nothing in this agreement** shall operate to **transfer to the User Institution any intellectual property rights relating to the Data**. The User Institution has the right to develop intellectual property based on comparisons with their own data.
13. You accept to **guarantee at all times the availability of genetic information** that may have been obtained from the Data
14. You accept to **notice GCAT of the existence of any relevant and valid clinical data** regarding the subjects and/or their family members. Such compliance is construed in accordance with the frame established by the Act 14/2007, of Biomedical Research, and the internal GCAT regarding return of results as described in ELSI GCAT document (available at GCAT webpage).
15. You **accept that it may be necessary for the GCAT to alter the terms** of this agreement from time to time in order to address new concerns regarding GCAT Project. In this event, the GCAT will contact You to inform You of any changes and You agree that Your continued use of the Data shall be dependent on the parties entering into a new version of the Agreement.
16. You agree that **you will submit a report to the GCAT Data Access Committee, if requested, on completion of the agreed purpose**. The GCAT Data Access Committee agrees to treat the report and all information, data, results, and conclusions contained within such report as confidential information belonging to the User Institution.
17. You accept that the **Data is protected by and subject to international laws, including but not limited to the Spanish Data Protection Act 15/1999**, and that You are responsible for ensuring compliance with any such applicable law. The GCAT Data Access Committee reserves the right to request and inspect data security and

management documentation to ensure the adequacy of data protection measures in countries that have no national laws comparable to that which pertain in the EEA.

18. This agreement **shall be construed, interpreted and governed by the laws of Spain and Catalonia** and shall be subject to the non-exclusive jurisdiction of the courts of the city of Barcelona (Spain).

2. DELIVERY OF THE MATERIAL AND TRANSFER OF RISK AND FEES

1. Upon execution of this Agreement, GCAT agrees to deliver the Data to User in the term, formal conditions and with the information and/or documentation indicated in Annex 1.
2. Once provided the Data, any risk related to the Data shall be transferred to User, who shall be responsible for its use, storage and, given the case, disposal, always subject to applicable laws and regulations.
3. User must bear all reasonable expenditures fee resulting from the supply, storage and processing of data.

3. GCAT PUBLICATIONS POLICY

PUBLICATIONS AND INDUSTRIAL AND/OR INTELLECTUAL PROPERTY RIGHTS

1. The access to any Data shall not be construed as to grant an option or license to User under any patent, trade secret or other rights now or hereinafter held by GCAT, other than the non-exclusive, non-transferable, revocable right to use any Data for the purposes indicated herein.
2. User shall notice Provider of the global results obtained from the Project due to the use of Material, in accordance with what is stated in the applicable legal dispositions (Act 14/2007, of Biomedical Research and Royal Decree 1716/2011, of Biobanks). Specifically, User undertakes to send GCAT through e-mail, to the address [...], a copy of any publication based on the use of Material (or derivatives), in the term of three (3) months from the publication.
3. The ownership on the results related to Data developed by the User shall be considered on a case by case basis. In any case GCAT shall have a royalty-free, worldwide, non-transferable, non-exclusive license to use such results for research and non-commercial purposes.
4. In any event, protection of Intellectual and/or Industrial Property Rights relating to results shall observe at all times the moral rights of the inventors or authors, expressly including the right to be mentioned as inventors or authors.
5. In accordance with scientific practices, the contributions of data of GCAT, given the case, shall be expressly mentioned in all the public disclosures, both written or orally and through a co-authorship statement, regarding any research where data has been used.
6. All authors who use data from the project must acknowledge the GCAT using the following wording "This study makes use of data generated by the GCAT |Genomes for Life Project. Cohort study of the Genomes of Catalonia" and cite the relevant primary GCAT publication (details of which can be found on the GCAT website). A full list of the investigators who contributed to the generation of the data is available from www.gcatbiobank.org. Users should note that the GCAT bears no responsibility for the further analysis or interpretation of these data, over and above that published by the GCAT.

7. Funding for the project was provided by the MINECO (ADE 10/00026) and RYC 070".
4. **WARRANTY AND LIABILITY**
 1. User represents and warrants that shall use the Material in compliance with all applicable laws and regulations, including but not limited to, health and research regulations and the Protocol approved by the Ethic and scientific Committee.
 2. GCAT states that the samples have been obtained following the law and in compliance with ethical and quality requirements regarding Biological Samples (proper processing of samples and ethical-legal guarantees of these procedures).
 3. GCAT shall not be liable for any damages arising from the use, handling, storage or disposal of the Material by User.
5. **CONFIDENTIALITY**
 1. Subject to the other provisions of this Agreement, both Parties agree to treat any and all other information which is disclosed between the Parties orally, electronically, visually, or in a document or other tangible form and which is identified as confidential or which may reasonably be inferred to be confidential; and test results, error data, feedback, or other reports, in connection with the Material (hereinafter "**Confidential Information**"), with all cautions reasonably necessary and practicable to prevent its disclosure to persons other than those of their employees, agents or contractors who need to have access to the Confidential Information for the purposes of or as envisaged by this Agreement.
 2. Each Party warrants that all such employees shall be obliged to maintain the confidentiality of the Confidential Information and to use it only in accordance with the provisions of this Agreement, and each Party shall use all reasonable endeavours to avoid and act against non-compliance by its employees.
 3. The confidentiality obligations hereinabove mentioned shall not apply to:
 - Information which the receiving Party can establish by written record was in its possession before the date hereof and not obtained, directly or indirectly, from the other Party.
 - Information which is or becomes in the future public knowledge through no fault or omission of either Party, its employees or its directors.
 - Information lawfully obtained by either Party after the date hereof from a third party with the right to disclose it.
 - The confidentiality obligations contained in this Agreement shall not prevent either Party from disclosing Confidential Information as a result of an administrative or judicial order to regulatory authorities. However, the disclosing Party shall notify the other Party as soon as practicable and, in addition, shall make its best efforts to procure confidential treatment by the receiving Party or authority.

4. The obligations assumed under this clause shall remain in full force and effect even after termination of this Agreement, as long as the information remains confidential.

6. TERMINATION

1. This Agreement shall enter into force on the date of the last signature herein below.
2. The **term of this Agreement shall be one year from the application for acces to the Material / Data** ; or (ii) upon finalization of the Project according to Annex 2, whichever occurs first, without prior notice by any of the Parties. Notwithstanding the referred term, this Agreement shall remain in full force and effect indefinitely for as long as Data are secret and confidential. You accept that this agreement will terminate immediately upon any breach of this agreement by You and You will be required to destroy any Data held.
3. Any breach of this Agreement by any of the Parties may be remedied within thirty (30) days of receiving written notice thereof. Any uncured breaches or breaches which, by nature, are not capable of being remedied shall entitle the other Party to claim proper fulfillment or alternatively, to terminate this Agreement, and in any case, to be indemnified for damages resulting from the aforementioned breach.
4. Upon termination or expiration of this Agreement, howsoever caused, User will automatically discontinue its use of the Material and will, unless otherwise agreed, return or destroy any remaining Material.
5. The provisions concerning Publications, Intellectual Property, Confidentiality and Warranty and Liability shall survive this termination or expiration.

7. MISCELLANEOUS

1. Any formal notice required or permitted by this Agreement must be delivered in writing and sent by certified mail, return receipt requested, addressed to the other Party at the address shown at the beginning of this Agreement or at such other address for which such Party gives notice hereunder.
2. Should any part, article, paragraph, sentence or clause of this Agreement be deemed vague, valid or inapplicable, such part shall be eliminated and the rest of the Agreement shall remain valid and in force.
3. This Agreement may not be changed or modified in any way, orally or otherwise, unless such amendment is made in writing and signed by both Parties.
4. This Agreement may not be assigned by either of the Parties in any case without the express prior written consent of the other Party.

8. GOVERNING LAW AND JURISDICTION

1. This Agreement shall be governed by and construed under the laws of Spain.
2. With express waiver to any other jurisdiction that may correspond to the Parties, any dispute or controversy in relation to, in connection with or resulting from this Agreement shall be exclusively resolved by the courts of the city of Barcelona (Spain).

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorised representatives as of the Effective Date.

For and on behalf of User:

Name of Applicant(s):

Signature of Applicant(s):

Date:

For and on behalf of User Institution:

Signature of Institutional or Administrative Authority:

Print name:

User Institution:

Date:

WHEN SUBMITTING THIS DOCUMENT, PLEASE INCLUDE ALL PAGES OF THE AGREEMENT WITH THIS SIGNATURE PAGE



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Institut de Medicina Predictiva i Personalitzada del Càncer-Can Ruti Campus
<http://www.gcatbiobank.org/>