The P3G "Generic Access Agreement" is a template for use by those involved in prospective, longitudinal population genomics studies and is inspired by approaches found amongst P3G members (www.p3gconsortium.org); WTCCC (www.wtccc.org.uk); EMERGE (www.genome.gov/27540473); ICGC (www.icgc.org); UK Biobank (www.ukbiobank.ac.uk); NIH (cancergenome.nih.gov); and CPTP (www.partnershipfortomorrow.ca). This document has also been developed in conformity with the suggested principles and procedures of the "Data Sharing Code of Conduct for International Genomic Research" and the European Commission's report *Biobanks for Europe*. The Agreement integrates conditions for access to biological materials along with those for data access.

This Agreement is offered as a template to assist or inform researchers seeking access to population studies, and is not intended to be proscriptive. It is designed to indicate the elements that may be considered when creating consents, accompanying access procedures, and governance structures. Each study will necessarily need to include or delete elements according to its aims, cultural and ethical norms, and national legislation or policy. We hope this Agreement will provide a starting point and a useful guide.

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**Letterhead of (Population Genomics Study)**

**ACCESS AGREEMENT**
**[Name of Resource/Biobank/Study]***
(*collectively referred to below as "Study")

## DEFINITIONS

"Applicable Law" means the laws specified by the parties, in the section entitled **Choice of Law**.
"Applicants" refers together to the applicant institution and the principal investigator of the Approved Research Project, both of whom have signed and accepted the Access Agreement.
"Approved Research Project" means the research project with appropriate institutional and ethics approvals that seeks to access Data and Materials.
"Data" means the data supplied to the Applicants for the Approved Research Project.
"Effective Date" means [insert date].
"Inventions" means findings that are new, involve an inventive step and are susceptible of industrial application.
"Participant Identifiable Information" means any information whatsoever that identifies, or could identify, Research Participants.
"Research Participants" means individuals (living or dead) who have contributed their Data or Materials.
"Materials" means the biological tissues or samples supplied to the Applicants for the Approved Research Project.

## PARTIES TO THE ACCESS AGREEMENT

**Name of Study:** _____

**Applicant Institution:** _____

**Principal Investigator Name(s):**_____

### 1. GENERAL

The Applicants agree that the use of the Data and Materials under this Access Agreement is limited to the scope of the Approved Research Project and complies with Applicable Law and ethics approvals.

The Applicants agree to respect the policies of [Study] with respect to the handling, storage and use of its Data and Materials. These policies include [e.x. Participant Consent Forms, and Study Access, IP and Publications Policies], and are available [give web address or include as Annex]. The Applicants will be responsible for the training and conduct of all research personnel involved with the Approved Research Project. The Access Agreement is effective upon execution and receipt of a signed copy by all parties.

## 2. DELIVERY – TIMETABLE AND CONFIRMATION OF RECEIPT

[Study] will deliver the following Data and Materials to the Applicants: [insert description of Data and Materials to be delivered]. The Data and Materials will be delivered to the following address: [insert delivery address]. [Study] will use reasonable efforts to deliver the Data and Materials within [insert number] days of the Effective Date.

## 3. PRIVACY, CONFIDENTIALITY, AND IDENTIFIABILITY

The Data and Materials provided to the Applicants have been [coded or anonymized – (provide description of data treatment here)]. If the Applicants inadvertently receive Participant Identifiable Information, they will take all reasonable and appropriate steps to protect the privacy and confidentiality of such information. This may require immediate destruction of the information on request of [Study]. The Applicants agree to make no intentional attempt to re-identify Research Participants through linkage of Data, or otherwise. The Applicants will immediately report any identification of Research Participants to [Study].

The Applicants will not transfer any of the Data and Materials obtained, or any information derived therefrom, to third parties, except with the approval or on the request of [Study].

## 4. SECURITY

The Applicants will adhere to the security protocol outlined [in the Study Access Application], and employ all reasonable efforts to prevent unauthorized access to the Data and Materials in their custody.

## 5. LIMITS ON LIABILITY

[Study] will not be liable for damages related to the provision of Data and Materials to the Applicants. This includes but is not limited to damages in relation to inaccuracies, lack of comprehensiveness, or use of the Data and Materials, or any delay or break in supply by [Study].

The Applicants acknowledge that [Study] makes no guarantee that the Materials are free of contamination from viruses, latent viral genomes, or other infectious agents. The Applicants agree to treat the Materials as if they were not free from contamination, to assure appropriate biosafety training to research personnel, and to implement appropriate biohazard containment measures.

## 6. INTELLECTUAL PROPERTY

The Applicants must not make IP claims on Materials or Data derived directly from [Study]. However, the importance of downstream Inventions made with [Study] Materials and Data is recognised; patents on such Inventions are permitted. In doing so, the Applicants agree to implement licensing policies that will not obstruct further research.

The Applicants will own all results, data, and inventions which arise under the Research Project. The Applicants do however grant to [Study] a perpetual, non-cancellable, royalty-free, worldwide license, with right to sublicense, to use study results for all purposes.

## 7. RESULTS AND PUBLICATION

Upon completion of the Approved Research Project, the Applicants will send to [Study] [reports, enriched data, etc.]. The Applicants must endeavour to publish results in an academic journal or in an open access database. The Applicants agree to acknowledge [Study] in any publication or presentation on work derived in whole or in part from the Data and Materials and to supply [Study] with a copy or web address of any publication.

## 8. REPORTING A BREACH

If the Applicants become aware that the terms of the Access Agreement have been breached, they will promptly notify [Study] of such breach. The Applicants will provide to [Study] in a timely manner any material information relating to the breach, including the date and nature of the event, remedial measures taken, and plans to avoid further or future breach. In the case of a breach please contact: [Study Contact Name and Info].

## 9. TERMINATION

[Study] has the right to terminate this Access Agreement upon material breach of any term of the Access Agreement by the Applicants. The Applicants may terminate this Access Agreement at any time with immediate effect by providing written notice to [Study] of the termination.

Upon termination, the Applicants agree to destroy all copies of Data except as required by publication practices or Applicable Law, and to destroy [or return forthwith] all Materials. The Applicants will send written confirmation to [Study] detailing the destruction of the Data and Materials.

## 10. MISCELLANEOUS

**Duration of Agreement/Procedure for Renewal:** (Insert local clause)
**Choice of Law:** This Access Agreement shall be construed in accordance with the laws of [insert jurisdiction].
**Representations and Warranties**: (Insert local clause)
**Force Majeure:** (Insert local clause)
**Authority and Compliance:** (Insert local clause)
**Assignment:** (Insert local clause)
**Severability:** (Insert local clause)
**No Partnership or Employment Relationship:** Nothing in this Access Agreement creates a partnership or employment relationship between the Parties.

[*These conditions may be modified to allow for the specific needs of population studies, and negotiation between the parties.]

**APPLICANT SIGNATURE(S): [etc]**
**DATE:**