P3G MODEL FRAMEWORK FOR BIOBANK ACCESS POLICY: CORE ELEMENTS (2013)

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I. BACKGROUND

In order to further its mission to lead, catalyze and coordinate international efforts to optimize the use of biobanks, the Public Population Project in Genomics and Society (P^3G) has updated its 2008 "Sample and Data Access Core Elements".[1] The 2008 core elements were based on a study of the sample and data access policies of P^3G members, in addition to the access policies and material transfer agreements of several biobanks and international consortia.[2] In order to verify the continued relevance of these core elements and to ensure the utility of its online tools, P^3G undertook a revision of the document using a similar approach. An analysis of the access policies of 42 studies contributing to the P^3G Access Catalogue,[3] in addition to the policies of current P^3G biobank members,[4] was conducted. Relevant literature and emerging issues were also considered. Based on this analysis, new core elements were identified.

The following presents the core elements to be included or at least considered when drafting an access policy for a population biobank. This generic list provides biobanks with guidance to create access policies specific to their needs that adequately address access issues, irrespective of geographical location. Biobanks are thus free to pick and choose, or add other items, depending on their needs, while having a checklist of elements to consider. These core elements of access cover both samples and data. Thus, if unspecified, "access" refers to access to samples and data. It will be up to the biobank to pick and choose clauses specific to its needs. Moreover, this list should be read in conjunction with the ***P^3G Generic Access Agreement for Population Genomic Studies***,[5] as the drafting of an access policy and access agreement go hand in hand.

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[1] Susan Wallace, "P3G Sample and Data Access Core Elements" (2008), online: P3G < http://www.p3g.org/biobank-toolkit/p3g-sample-and-data-access-core-elements>.

[2] *Ibid;* Sabrina Fortin et al, "'Access Arrangements' for Biobanks: A Fine Line between Facilitating and Hindering Collaboration" (2011) 14:2 Public Health Genomics 104.

[3] P3G, online: <http://www.p3gobservatory.org/access/list.htm>.

[4] P3G, online: <http://www.p3g.org/membership/institutional-members>.

[5] P^3G International Steering Committee et al, "A P3G Generic Access Agreement for Population Genomic Studies" (2013) 31:5 Nature Biotechnology 384.

II. CORE ELEMENTS TO ACCESS POLICIES

1. Preliminary Chapter

The first section of an access policy should present the biobank, define its aim and purpose, and specify the scope of the policy, including:

- The purpose(s)/aim(s)/objective(s) of the access policy, e.g.:

  - ☐ Provide a platform to support/facilitate a broad range of research, in an ethical manner;
  - ☐ Establish the principles, policies and procedures according to which access may be granted;
  - ☐ Enable efficient collaboration, at a national and/or international level;
  - ☐ Encourage fair, rapid and transparent access for research purposes.

- The different categories of authorized users, e.g.:

  - ☐ Researchers from the academic sector (e.g., universities, research institutes);
  - ☐ Researchers from the public sector (e.g., public institutions conducting research such as ministries, government agencies, hospitals);
  - ☐ Researchers from the private sector (e.g., private institutions such as industrial or commercial businesses);
  - ☐ Researchers from whose research project has received approval by a recognized research ethics board.

    However, there may be limitations, such as:

    - ➢ Geographical limitations (e.g., access limited to researchers within the country of the biobank); and/or
    - ➢ Limitations based on the type of research (e.g., investigators conducting health-related research).

- The type of the data/samples that can be accessed, e.g.:

  - ☐ Data:
    - ▪ Responses to self-administered or interview-assisted questionnaires;
    - ▪ Physical measurements;
    - ▪ Data derived from samples;

- Data linkage.

☐ Samples/biospecimens:
  - Blood;
  - Urine;
  - Saliva;
  - Red blood cells;
  - Serum;
  - Plasma;
  - DNA from buffy coat;
  - Toenails.

2. Definition/Glossary

Including a section with definitions or a glossary in an access policy ensures clarity and consistency, as terms and meaning vary regionally. Terms to be defined include the following:

☐ Names of governing bodies of biobank;
☐ "Applicant";
☐ "Approved User";
☐ "Coded Data";
☐ "Controlled Data";
☐ "Access Registry";
☐ "Access Agreement";
☐ "Open-access Data";
☐ "Re-identification";
☐ "Participants";
☐ "Aggregated Data";
☐ "Derived Data";
☐ "Material Transfer Agreement";
☐ "General Research Results";
☐ "Individual Research Results";
☐ "Incidental Findings".

3. Open and Controlled Access

Consistent with a biobank's obligation of confidentiality towards participants, and cognizant of the potential risk of participants' re-identification, a section on the nature of access (open and/or controlled[6]) clarifies the types of datasets that may be accessed by researchers, e.g.:

- ☐ Open-access datasets;
- ☐ Controlled datasets.

4. Access Limitations

A section on access limitations outlines excluded users, the requirement of research approval, and addresses the possibility of exclusive access.

- Access to the biobank's data/samples may be expressly prohibited for some categories of user, e.g.:

  - ☐ Commercial industry groups;
  - ☐ Insurance companies;
  - ☐ Participant's employers.

- Access to the biobank's resources is limited to the dataset/sampleset for which approval was obtained, e.g.:

  - ☐ Data and/or samples cannot be used for any purpose other than the approved research project;
  - ☐ Access for non-research related purposes will not be permitted, unless required by law.

- A biobank's access policy can also address exclusive access to samples and/or data, e.g.:

  - ☐ Exclusive access will not be granted to any party;

[6] Open access means providing unrestricted access to research data, available for the use and viewing of the public at large. Open access is generally provided for data that cannot be linked with other data to generate a dataset that would uniquely identify an individual. Controlled access means regulating "access to certain more sensitive data (e.g., detailed phenotype and outcome data, genome sequence files, raw genotype calls) by requiring third parties (e.g., researchers) to apply to a body (e.g., custodian, original data collectors, independent body, or data access committee) and complete an access application that contains privacy safeguards." See Yann Joly et al, "Data Sharing in the Post-Genomic World: The Experience of the International Cancer Genome Consortium (ICGC) Data Access Compliance Office (DACO)" (2012) 8:7 PLoS Computational Biology.

- ☐ Time-limited exclusive access may be granted to investigators collecting additional data, physical measurements and/or samples from participants for an agreed period of time following data collection and cleaning. This period should be determined by parties when completing the access agreement;
- ☐ Access to samples that are limited and depletable will be controlled and coordinated. The quantity of the sample that is required will be judged against the potential benefits of the research project, with the advice from appropriate experts, as required.

5. Privacy of Participants

The section on privacy highlights the biobank's commitment to the privacy of participants, *as per* the consent form, extending these obligations to researchers requesting access. Considerations include:

- For the biobank:
  - ☐ The rights of participants to their privacy;
  - ☐ The confidentiality of participants' data and samples during storage, management and use of their samples and data;
  - ☐ The requirement for adequate security measures;
  - ☐ Applicants seeking access must assume the same obligations as biobanks towards participants.

- For the approved user:
  - ☐ Control of the transferred data and samples must be at all times retained by the user;
  - ☐ The user must not disclose, transmit or transfer any of the data to unauthorized third parties;
  - ☐ The user must not attempt to re-identify participants;
  - ☐ The user must sign a legal agreement that includes these considerations (sample/data transfer agreement).

6. Access Documents

The access policy should also include a section pertaining to the documents required to file an access request. The documents listed below are not necessarily all required, but the list reflects the array of documents currently in use:

- ☐ Registration Form;
- ☐ Preliminary Application Form;
- ☐ Access Application Form;
- ☐ Access Renewal Form;
- ☐ Access Agreement;
- ☐ Material Transfer Agreement;
- ☐ Final Project Report;
- ☐ Unanticipated Event/Significant Change Report.

7. Governance of Data Access

Biobanks governance structures usually establish a body to regulate access to their resources, such as a specific access committee or an existing committee entrusted by the Board of Directors with access-related responsibilities. The access committee may be internal or external to the biobank, and its composition varies. Regarding the access committee, the access policy must at least state the following information:

- ☐ Name of the committee;
- ☐ Composition;
- ☐ Mandate/Role;
- ☐ Meetings.

8. Processing of Access Requests & Conditions of Use

This section outlines the general procedure for access, as well as the criteria for review and conditions of use. It also addresses resubmission or reconsideration, when possible.

- Once a request for access is received, the following criteria may be considered:

  - ☐ Scientific merit of proposed study (clarity, novelty and scientific excellence);
  - ☐ Ethical requirements;
  - ☐ Qualifications of applicant;
  - ☐ Applicant's privacy and confidentiality policy and security measures;
  - ☐ Compatibility of proposed study with the biobank's objectives;
  - ☐ Overlapping initiatives between proposed study and studies already approved;
  - ☐ Adequacy of applicant's resources to carry out the proposed project;
  - ☐ Quantity of samples requested;
  - ☐ Impact on future uses of data and samples;
  - ☐ Impact on biobank as a resource (potential to enrich biobank).

- The outcome of an application/request for access, and the decision to be communicated to applicant, can be:

  - ☐ Application is incomplete. No decision is made and the application is sent back to the applicant. The applicant can resubmit the application, subject to certain delays.
  - ☐ Refusal of request. In such cases, the access policy must stipulate if:
    - The applicant can resubmit the application, subject to certain delays;
    - The applicant may request that the decision be reconsidered, subject to certain conditions and delays.
  - ☐ Approval of the request. Once a request is approved, the user must agree to conditions for use, which qualify the access granted and impose restrictions, e.g.:
    - Prohibition of re-identification or re-contact of participants;
    - Uses of data and samples limited to uses stated in access request/application;
    - Prohibition of data/sample sharing or selling to third parties;
    - Requirement to report any changes of circumstances or unanticipated event affecting the proposed study or the integrity of the data and samples;
    - Prohibition of patenting of data and samples;
    - Compliance with consent of participants, applicable laws and institutional policies.

9. Individual Research Results & Incidental Findings

Approved users must respect what participants initially consented to when they agreed to participate in a biobank[7], which is why the issue of return of results should be addressed in the access policy.

At its inception, a biobank must determine whether or not it will return individual research results[8] and/or incidental findings,[9] and elaborate policies and procedures on the matter (e.g. who should return the results to participants, the types of results to be returned, the role of health professionals, the duration of this obligation to return results…). Its determination should be included in the access policy, so as to inform the approved user of his indirect

[7] Biobank meaning "[a]n organized collection of human biological material and associated information stored for one or more research purposes". See P3G Lexicon, online: P3G <http://p3g.org/biobank-lexicon>.

[8] Individual research results refer to results concerning an individual participant that are discovered during the course of research and that have a potential health impact or reproductive consequences. See Bartha Maria Knoppers et al, "Population studies: return of research results and incidental findings Policy Statement", 2012 European Journal of Human Genetics 1.

[9] Incidental findings refer to results discovered in the course of research that concern an individual participant and have a potential health impact or reproductive consequences. However, these findings were unforeseen, meaning they are not within the study objectives. See Knoppers et al, *ibid.*

obligations towards participants, while the extent of approved users obligations will be detailed in the access agreement. A statement on the return of results can include e.g.:

- ☐ Individual research results and incidental findings will not be returned to participants;
- ☐ If participants have consented to the return of individual research results, material individual research results and incidental findings that are clinically significant, analytically valid, and actionable (i.e. treatable or preventable) shall be returned to participants;
- ☐ Return of individual research results and incidental findings was not considered when participants initially consented to participate in the biobank. Consequently, the issue must be referred to the appropriate ethics body to determine whether or not such results should be returned to participants in the absence of consent.

10. Re-contact & Ancillary Studies

The issue of re-contact should also be addressed in an access policy. The possibility of re-contact depends on the nature of participants' consent. Generally, researchers cannot directly re-contact participants. However, the biobank may re-contact participants for additional information or ancillary studies on behalf of studies, if this was consented to. These considerations can be included in the access policy, so as to inform the approved user, e.g.:

- ☐ The participants have consented to be re-contacted and initial re-contact should always be undertaken by the biobank, if appropriate;
- ☐ Approved users should not contact participants without prior approval by the biobank;
- ☐ The participant did not want to be re-contacted, and thereby re-contact is not permitted;
- ☐ Re-contact was not considered when participants initially consented to participate in the biobank and the issue must be referred to the appropriate ethics body to determine whether or not re-contact is possible.

11. Derived Data

In order to enrich the value of a biobank, approved users may be required to return their derived data to the biobank, e.g.:

- ☐ Approved users must send their derived data to the biobank at the end of their research project;

- ☐ New data collected by the approved user as part of an ancillary study must be sent to the biobank;
- ☐ Derived data is to be included in the biobank and made available for future studies;
- ☐ A delay may be allowed before approved users must return their derived data to the biobank.

12. Linkage

The growing issue of linkage should be addressed, whether it be in the biobank's access policy or in a separate policy on the subject, e.g.:

- ☐ Participants have consented to linkage of biobank data with administrative health data;
- ☐ Participants have not consented to linkage of biobank data with administrative health data;
- ☐ Linkage with other databases requires the approval of the entities in control of these databases.

13. Duration of Access

While not necessarily a separate section, the duration of access must be indicated in the access policy. Access is provided for a limited time, after which an approved user must either reapply or return the data and samples, and comply with all formalities required by the terms of the access policy and agreement, i.e.:

- ☐ A uniform time limit may be stipulated (*e.g.*, one year);
- ☐ Access may be granted for a period commensurate with the scientific aims of the project, as determined by the access committee;
- ☐ Subsequent annual renewals may be possible (or not).

14. Confidentiality of Access Requests/Applications

A statement should also be included as to the confidential treatment of the access requests, and the public nature of some information, e.g.:

- ☐ Information on research projects will be kept confidential;
- ☐ If access is granted, specific information will be added to the public access registry (*e.g.*, title of approved study, names of investigators, lay summary of the study…).

15. Custodianship/Ownership

Custodianship or ownership of the data and samples may also be addressed within an access policy. Generally, custodianship, ownership or stewardship, as referred to by some, remains with the biobank. However, it is essential to remember that participants may retain certain rights and powers over their data and samples, such as a right to withdraw, e.g.:

- ☐ The biobank remains the custodian of the data and samples;
- ☐ The funding organizations of the biobank are the owners of the data and samples;
- ☐ The scientists or the principal investigator (PI) are the custodians;
- ☐ The biobank remains the owner of the data and samples.

16. IP Policy

Access policies should contain intellectual property policies, which may be contained in a separate document. These policies seek to avoid the appropriation of the biobank's data and samples by users, and ensure collaboration and sharing to ultimately enhance scientific knowledge, while providing sufficient incentive to encourage discoveries. Such policies generally provide for types of licensing, e.g.:

- ☐ Approved users may not make intellectual property claims on the biobank's primary data and samples;
- ☐ Approved users may obtain intellectual property rights on subsequent innovations and discoveries arising from the use of the biobank;
- ☐ The need to protect intellectual property or pre-publication results may result in constraints on public disclosure;
- ☐ Approved users are granted limited licenses to use the data and samples to conduct the approved research project for a limited period of time. These rights are not assignable or transferable and cannot be the object of any sub-license.

17. Publication Policy

Access policies generally contain publication requirements, which may also be contained in a separate document. A publication policy is aimed at encouraging researchers to share their results and acknowledge the contribution of the biobank, while others may seek to reward creativity. Publications and acknowledgements are also meant to increase a biobank's visibility within the scientific community.

Publication requirements vary and can include the following:

- ☐ Approved Users are encouraged to publish their research results to benefit the scientific community, in addition to society;
- ☐ Approved Users must publish their research results within a specified time period;
- ☐ Approved Users must acknowledge the contribution of the biobank in their publications or presentations;
- ☐ A copy of the document must be sent to the biobank for publication approval;
- ☐ A copy of the publication must be sent to the biobank upon publication;
- ☐ Promotion of open data sharing;
- ☐ Publication moratorium.

18. Destruction of Data or Return of Samples

An access policy or its corresponding agreement should stipulate what the Approved User must do with the data and samples once access comes to an end, to ensure the constant protection of participant's privacy and confidentiality.

- ☐ Once the Approved User's access rights have expired, the Approved User undertakes to destroy all data and copies thereof in his possession or under his control;
- ☐ The Approved User must certify that the data and copies were destroyed;
- ☐ Once the Approved User's access rights have expired, the Approved User undertakes to return all data and samples in his possession or under his control.

19. Reporting Obligations

Approved Users have various reporting obligations that will generally be outlined in the access policy and contained in the access agreement. These obligations may be specific to the end of access, like a Final Project Report, or periodic, such as an Unanticipated Event/Significant Change Report (see Access Documents above).

Upon the expiration of the access agreement, Approved Users generally have an obligation to report their general research results,[10] as a matter of transparency and ongoing communication with participants, which can be done through newsletters, websites, etc.

Examples of reporting obligations include:

- ☐ Upon expiration of the Access Agreement, the Approved User must complete a Final Project Report;

[10] General research results mean the aggregate results drawn from the analysis of the data and samples of research participants. See Knoppers et al, *supra* note 7.

- ☐ Upon completion of the study for which access was granted, the Approved User must send to the biobank a summary of its research results in lay term, which will be accessible to the public (or disseminated via newsletter, online resources…);
- ☐ Should something change in the approved study, during the term of the Access Agreement, the Approved User must submit an Unanticipated Event/Significant Change Report informing the biobank;
- ☐ If the Approved User becomes aware that the terms of the Access Agreement have been breached, he must promptly notify the biobank. The Approved User must provide, in a timely manner, any material information relating to the breach, including the date and nature of the event, the remedial measures taken and plans to avoid any further or future breach (e.g., accidental re-identification of a participant to the biobank, unauthorized access to the data and samples by a third party, etc.).

20. Compliance

Compliance mechanisms may also be included in an access policy.

- ☐ In the case of a failure to comply with the provisions of this policy, the biobank reserves the rights to undertake measures it deems necessary to rectify or sanction the Approved User;
- ☐ Notice of non-compliance;
- ☐ Approved User's rights of access are terminated/suspended and all data and samples must be returned;
- ☐ The biobank reserves its right to take legal action against the Approved User for any damages sustained due to a breach of the Access Agreement.

21. Costs

Most biobanks use a cost-recovery model, while others use a sliding scale depending on the intended use (*e.g.,* industrial vs. academic use).

- ☐ The biobank will provide access without fees. However, the Approved User must reimburse any reasonable cost related to the shipping of the data and samples;
- ☐ The biobank will supply the data and samples, as well as contact participants for ancillary studies, based on a cost-recovery basis (cost to be specified in the accompanying access agreement);
- ☐ Researchers will have to pay a fixed charge for filing an application/request for access;

- ☐ Researchers will have to pay a variable charge, depending on the amount of samples and data requested;
- ☐ Applications/request for access from commercial organizations will be charged at a commercial rate.

22. Amendments

With time, amendments to an access policy are inevitable and thereby should be provided for.

- ☐ The Access Policy will be reviewed every [x] years;
- ☐ A governing body can submit amendments for approval.

III. CONCLUSION

These 22 core elements were distilled from current access policies and material transfer agreements and reflect the existing practices of biobanks globally, They incorporate issues that are at the forefront of biobanking and need to be addressed by biobanks. Nonetheless, these core elements need to be periodically revised, to ensure their relevancy and in order to keep pace with scientific innovation. We hope that this checklist of core elements guides biobanks worldwide in the creation or revision of their access policies to respect international ethical norms, and, ultimately, facilitate international collaboration in research.

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