



**PUBLIC POPULATION PROJECT IN GENOMICS and
SOCIETY (P³G)**

**POPULATION STUDIES: RETURN OF RESEARCH
RESULTS AND INCIDENTAL FINDINGS**

POLICY STATEMENT

THIS POLICY STATEMENT IS A P³G-CPTP (CANADIAN PARTNERSHIP FOR
TOMORROW PROJECT) COLLABORATION

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1. INTRODUCTION

A. The Public Population Project in Genomics and Society (P³G): Overview

P³G is a not-for profit international consortium with members from more than 40 countries. Its objective is to lead, catalyze, and coordinate international efforts and expertise in order to optimize the use of population studies, biobanks, research databases and other similar health and social science research infrastructures so as to improve the health of individuals and populations.

To achieve this, the Consortium is committed to:

1. Providing global perspectives and strategic approaches to the optimization of data access and use;
2. Catalyzing multidisciplinary and international scientific expert input;
3. Engaging studies, cohort and biobank resources/infrastructures and their users in a dynamic knowledge-based exchange;
4. Disseminating and valorizing knowledge relevant to the mission of P³G; and
5. Serving the needs of the P³G Programmes and their Platforms.

P³G brings the genomics, epidemiology, social science, ELSI/policy-making and information technology communities together. Through its network of experts and platforms, P³G offers access to large-scale infrastructures (biobank and population studies recruiting significant numbers of participants).

The topic of Return of Results has been discussed by the members at several meetings. At the P³G March 2010 Annual Meeting in Montreal, the Centre of Genomics and Policy (McGill University) presented a *Points to Consider* document addressing the emerging approaches to the return of research results and their implications for population studies. Then, in October 2011, the participants at the joint P³G/Making Connections meeting discussed a draft of the current document,. P³G would like to acknowledge the contribution of all P³G Members and participants who provided comments as well as the CPTP (Canadian Partnership for Tomorrow Project) ELSI task force. This Policy Statement is the result of this collective input.

B. Context and Scope

This *Policy Statement* considers the issue of return of results in the specific context of population genomics and addresses possible modalities for such return.

The question of return of results presents unique characteristics when viewed through the lens of population studies. In general, participants in population studies are making a free and informed choice to contribute to future, yet unspecified, research hypotheses that will contribute to the advancement of science. Population-based studies serve multiple research hypotheses over a long period of time. Despite the anticipation of their eventual contribution to the health care systems, they cannot be seen as a



substitute for health care functions. The objective of these resources is to support research. Any confusion concerning their goals could jeopardize their existence due to the creation of unreasonable expectations.

Population studies operate in heterogeneous contexts. This affects the chain of custody in the collection, conservation and use of the data and samples. The notion of ‘population based studies’ includes a variety of different kinds of ‘architectures’ which impacts on the capacity or appropriateness of returning results. Several actors are involved in this chain of custody: the biobank, the ‘host institution’, the participants, and the users (the researchers) with their own local Ethics Review Boards. What obligations are created and how they percolate through the chain of custody takes different forms.

Finally, the consent given by participants is an opportunity to create reasonable expectations for participants that are both consistent with the notion of maximizing benefits for future generations while recognizing their altruistic contribution to science. The presence of ongoing communication by the population study with participants is essential. Any return of results should be part of a mutual consensus between a population study and its participants.

This *Policy Statement* first defines the terms used throughout the document. It then presents its objectives and guiding principles before addressing the issues associated with:

- feedback at assessment and from laboratory analyses prior to storage;
- the modalities of returning general results to participants; and finally,
- the conditions and modalities of returning individual research results and incidental findings.

*Note that countries may have legal requirements concerning the return of research results and incidental findings, as well as access to personal data. Population studies and researchers should be aware of these obligations.

2. DEFINITIONS

Actionability: a finding is actionable if there are recognized therapeutic or preventive interventions or other available actions that have the potential to change the clinical course of a disease or condition.

Analytic Validity: an analytically valid finding is one that accurately and reliably identifies a particular genetic characteristic, such as a nucleotide sequence or a gene expression profile.

Baseline Assessment: includes measurements such as blood pressure, lung function, bone density, height, weight, fat, etc.

Clinical Significance: a finding is clinically significant when it is both analytically valid and reveals a well-recognized and significant risk of a serious health condition.

General Results: aggregate results drawn from the analysis of data and samples of a group of research participants.



Incidental Findings: unforeseen findings concerning a research participant that have potential health or reproductive importance. They are discovered during the course of research but are outside its objectives.

Individual Research Results: results discovered during the course of research, which concern an individual participant and have potential health or reproductive impact.

Lab Analyses: analyses carried out on biological samples prior to storage.

Population Studies: include population biobanks, longitudinal cohorts, social science and genetic epidemiology research serving as a resource for future unspecified research.

Participants: individuals contributing their data and samples to a population study.

3. POLICY STATEMENT: OBJECTIVES

The objectives of this *Statement* are to:

1. Delineate the particular characteristics of population studies;
2. Distinguish the circumstances surrounding access by researchers to such studies; and,
3. Develop a framework for the return of research results and incidental findings.

4. GUIDING PRINCIPLES

This *Policy Statement* is consistent with P³G's *Charter of Principles*. It aims to weigh the potential benefits and harms of the return of research results and incidental findings to participants in population studies. It includes consideration of the following principles:

- **Respect for Persons** – the duty to respect the autonomy of research participants and protect those with reduced capacity. Respecting autonomy entails the provision of sufficient information to research participants so as to obtain their free, informed and ongoing consent.
- **Beneficence** – the duty to maximize net benefits for research participants and for society as a whole, while advancing knowledge.
- **Non-Maleficence** – the duty to minimize and prevent harm to research participants.
- **Reciprocity** – the duty to promote trust between researchers and research participants.

5. FEEDBACK AT BASELINE ASSESSMENT AND FROM LAB ANALYSES PRIOR TO STORAGE

Findings emanating from the baseline assessment and lab analyses prior to storage as well as any subsequent assessments conducted by the population study for the purpose of enriching the research



infrastructure are not research results. However, their return to participants constitutes a form of ongoing communication and feedback.

The description of the feedback process at baseline assessment should avoid the therapeutic misconception (i.e. participants mistaking that they will directly benefit from their involvement or that baseline or subsequent assessments are equivalent to a medical check-up). Nevertheless, there should be a health professional involved as a member of the population study to ensure appropriate medical input in the overall process.

- Findings from baseline assessments should be returned to participants as soon as possible.
- Findings from lab analyses prior to the long-term storage of samples should be returned if they reveal a serious or life-threatening condition. Other data could also be returned, prior to storage, if participants have consented.
- When findings reveal an abnormal result during baseline assessments or lab analyses, personnel should encourage participants to contact a physician. When life-threatening, critical values are found, immediate care should be provided for the participant.

6. RETURN OF GENERAL RESULTS TO PARTICIPANTS: MODALITIES

All efforts should be made to effectively communicate general results as a matter of transparency and because they serve as the primary means of communication of research outcomes.

- As part of the ongoing communication between population studies and their research participants, general research results should be made available in an ongoing fashion so as to inform participants of overall findings.
- Researchers accessing a population study should provide it with a description in lay language of their research as well as the results obtained, including negative results. Special attention should be paid by ethics review bodies to any results that may contribute to stigmatization. Researchers have a duty to actively promote the proper interpretation of research results, including their limits.
- Population studies can return general results via newsletters, websites or, other dynamic, interactive communication tools.

7. RETURN OF INDIVIDUAL RESEARCH RESULTS (IRRs) AND INCIDENTAL FINDINGS (IFs) TO PARTICIPANTS: CONDITIONS AND MODALITIES

A. No Return of IRRs and IFs

There may be population studies where the policy is not to return individual results or findings and this was consented to by participants at recruitment. This remains a viable option where appropriate.



Researchers accessing the study population and their local ethics review committee should be made aware of this policy.

In situations where participants in population studies were not consented for the return of findings but have nonetheless, consented to recontact for updates and for further questions or collection of samples, population studies could use this opportunity to explain and introduce a return of research results and incidental findings policy and accompanying procedures, if the population study so chooses and with ethics approval. Upon recontact, participants could be provided with an option to consent (or not) to such results. Moving forward, population studies with a no return policy could consider adding such an option to their consent process at recruitment.

B. Return of IRRs and IFs

i. The decision to return results

- When consent to return result is present, one should consider whether the finding poses a material risk. Findings are material if they have:

- (1) analytical validity;
- (2) clinical significance; and
- (3) actionability

- Researchers, in collaboration with their local Ethics Committee, **should** consider returning IRRs and IFs **to participants** when they determine that the following criteria are met:

- (1) The participant has consented thereto in the initial consent form or at a later time;
- (2) The findings are analytically valid – (are confirmed by an independent laboratory);
- (3) They reveal a well-recognized and significant risk of a serious health condition; and
- (4) They are actionable

- Researchers, in collaboration with their local Ethics Committee, **may** consider returning IRRs and IFs when the above criteria are not satisfied, but when the following criteria are met:

- (1) The participant has consented thereto in the initial consent form or at a later time;
- (2) The findings are analytically valid – (are confirmed independently);
- (3) They reveal an established risk of likely health importance to the participant; and
- (4) They have a likely therapeutic benefit.



- The decision to return IRRs and IFs remains the responsibility of the researchers and the local Ethics Committee. Resources should be available for this decision-making process.

ii. The communication of results

- Contact of participants for the communication of material findings remains the responsibility of the population study.
- The population study should ensure the quality of the results, as well as the timeliness and appropriateness of the information returned to a given participant (including considerations related to the number of recontacts).

C. Procedures

- Population studies should put in place policies and procedures that clarify and circumscribe the obligations and procedures arising from their return of results policy. These should be reflected in any material transfer agreements and or access policies for researchers. These policies should include the length of duration of any return of results policy and the degree of involvement of researchers. Attention should be paid to issues of feasibility and reasonability.
- Procedures should be in place in the population study for the communication of such results by a health professional.