Industry Research Policy

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INDUSTRY RESEARCH POLICY

PURPOSE

CanPath recognizes the value and importance of research conducted by industry as well as academics who receive funding from commercial or industrial entities. This policy is intended to layout the principles and procedures for research conducted using CanPath data and resources that is funded by industry, in contrast to publicly funded academic research which follows CanPath's standard Data Access Procedures.

CanPath participants have provided consent that allows their data to be used for research purposes or commercialization by industry, with some variation by region regarding the level of aggregation. Fees obtained by CanPath from industry are required to recover costs from the creation of source data, preparation of datasets and to support ongoing maintenance of CanPath and its regional cohorts. CanPath *does not* sell participant data to the private sector, and it is not possible for data ownership to be transferred to a commercial or industrial entity.

DEFINITIONS

Academic – Pertains to researchers that are based a university or research institution. These researchers can receive research funding from a variety of sources including government, non-profit, and the private sector.

Industry – Refers to a broad range of sectors, usually private, which are involved in some form of commerce either to make a profit or to support a business.

PRINCIPLES

The following set of guiding principles underlie any relationship between CanPath and Industry[1]:

1. Activities must be consistent with CanPath's mandate, with consents provided by participants and with legal agreements involving CanPath's funding and hosting partners.
2. Activities must provide clear value to CanPath (e.g., present a unique scientific opportunity for CanPath, provide access to financial or other resources, or to other benefit sharing prospects that will advance CanPath's goals and strategic objectives, etc.);

[1] **Source**: Adapted for Canada from guidelines of the International HundredK's Cohorts Consortium (IHCC - www.ihccglobal.org)

3. Collaborations seek to include activities/resources that build capacity for CanPath where appropriate (e.g., infrastructure development, equipment access, training for CanPath researchers, general workforce development, etc.); and
4. Transparency – CanPath will make publicly available the aim of all projects using CanPath participants, data and/or biosamples.
5. Fairness and equity – Collaborations between CanPath and industry will use mutually agreed upon, publicly documented terms for collaboration prior to engagement in the collaboration.
6. Interactions between CanPath and Industry must comply with CanPath governance, policies and procedures, including:
    - CanPath's organization and data governance are based on national standards for responsible conduct of research and for ethical conduct, as codified in Canada's Tri-Agency Framework for the Responsible Conduct of Research, and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, version 2 (TCPS-2).[2]
    - For Academic researchers, to ensure research excellence, relevance and integrity (e.g., ethics), these standards are met through responsibilities embedded in their university appointments. For Industry-based researchers, the same high standards of research excellence and integrity are required but must be demonstrated by means other than those derived from university-based scholarship.

PROCEDURES

Access to CanPath data and/or biosamples

Upon execution of a Collaboration Agreement, the Industry researcher will submit an Access Application through the CanPath Portal. Applications will be reviewed through the regular Access Process which includes an Administrative Review, Feasibility Review, and review by the independent CanPath Access Committee.

Upon approval by the Access Committee, a Data and Biosamples Access Agreement will need to be executed before data and/or biosamples are released to the industry researcher.

CanPath is able to provide individual-level information on its participants, where consents allow, directly to Industry researchers. Summary or aggregate data can be provided at a cost when analysis is performed by CanPath.

Fees

[2] **Source**: Tri-Agency Framework for the Responsible Conduct of Research = http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre; Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, version 2 (TCPS-2) http://pre.ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html)

CanPath evaluates and approves an Access Price List each year. This List is used to provide a quote/invoice to researchers for access to CanPath datasets and biosamples.

Intellectual Property (IP)

IP resulting from industry research shall be governed by the CanPath Intellectual Property Policy, which states that industry cannot make IP claims on CanPath data and/or biosamples but will own the results of their own research arising from CanPath data and/or biosamples.

Conflict of Interest (CoI)

CoI resulting from industry research shall be governed by the CanPath Conflict of Interest Policy, which is designed to ensure that conflicts of interest in all CanPath activities are managed, and for there to be transparent processes to report and mitigate potential problems that may be perceived.

Embargo

CanPath recognizes industry researchers may require exclusive access to and use of study results; however, CanPath's mission of providing a national platform for population-level health research is dependent on timely and open dissemination of research results in the public domain. Accordingly, CanPath allows for a period of *up to* one-year after an industry research study is completed before making data and results accessible to other researchers.

Return of results or derived data

Consistent with the CanPath Access Policy, Industry researchers are required to provide a copy of their derived data, along with detailed methodology and/or metadata, back to CanPath. Such data will become an integral part of CanPath data systems and will be made available to other researchers approved for access (after any embargo period has ended).

Agreements –

The following agreements are in development, to be added as appendices to this Policy:

- Collaboration Agreement for access to data/biosamples
- Material Transfer Agreement