Alberta's Tomorrow Project
Access Guidelines and Procedures

Version Date:
15 September 2026

Alberta's Tomorrow Project
Cancer Care Alberta
Arthur J.E. Child Comprehensive Cancer Centre
3395 Hospital Drive NW
Calgary, Alberta, Canada
T2N 5G2

Email: ATP.Research@cancercarealberta.ca

Alberta's Tomorrow Project acknowledges that our work takes place on historical and contemporary Indigenous lands, including the territories of Treaty 6, Treaty 7 & Treaty 8, as well as the homeland of the Métis Nation within Alberta and 8 Métis Settlements. We recognize the enduring presence and stewardship of Indigenous peoples on this land, which we all share, celebrate, and care for. By making this acknowledgement, we hope to illustrate our commitment to reconciliation.

Alberta's Tomorrow Project Access Guidelines and Procedures

1. Purpose and History of Alberta's Tomorrow Project (ATP) 3
2. Authorization and Scope of Access Guidelines and Procedures 4
3. Glossary of Terms 4
4. Letters of Support 9
5. Access Process for Data Only 9
6. Access Process for Biosamples with Data 13
7. Access Process for ATP and ACRB Biosamples 19
8. Access process for ATP staff members 19
9. Accessing ATP Data for CanPath approved projects 19
10. Linked Data held by ATP 20
11. Linked Data not held by ATP 20
12. Access Fees 21
13. Denial of Access 22
14. Access Limitations 23
15. Application Confidentiality 24
16. Execution of Agreements 24
17. Transfer of Data and Biosamples 25
18. Data Protection 26
19. Modifications After Approval 27
20. Publications and Other Outputs 31
21. Project Completion 35
22. Intellectual Property (IP) 36
23. Audits 38
24. Incidental Findings 39
25. Compliance with the ATP Access Guidelines and Procedures 39
26. Disclaimers and Limitations of Liabilities 40
27. Ancillary Studies 41

References 42

Appendix 1: ATP Authorship Guidelines for Publications 44

Appendix 2: ATP Conflict of Interest Considerations 46

1. **Purpose and History of Alberta's Tomorrow Project (ATP)**

The purpose of Alberta's Tomorrow Project (ATP) is to provide a high quality infrastructure platform, based on a prospective population-based cohort design that supports innovative and inter-disciplinary research to advance cancer control and the study of the etiology of chronic diseases. Researchers are invited to apply for access to the ATP Resource to undertake projects that align with the purpose of ATP.

ATP was launched in 2000 to determine the feasibility of establishing a longitudinal cohort of adults in Alberta, to study the etiology of cancer and other chronic diseases. Full details describing participant recruitment and enrollment to ATP are described elsewhere (Bryant et al., 2006). In brief, Albertans aged 35 to 69 years, able to complete written questionnaires in English, and with no personal history of cancer other than non-melanoma skin cancer at the time of enrollment, were recruited to ATP. Between 2000 and 2008, random digit dialing (RDD) was used to recruit participants. Adults recruited by RDD were mailed a Health and Lifestyle Questionnaire (HLQ) and a consent form. In addition to providing consent to complete questionnaires, participants were invited to provide their personal health numbers to facilitate linkage with administrative databases. Approximately three months after completion of the HLQ, participants were asked to complete a past year food frequency questionnaire (C-DHQ I; Csizmadi et al., 2007) and the Past Year Total Physical Activity Questionnaire (Friedenreich et al., 2006). Follow-up surveys on health and lifestyle characteristics were administered in 2004 and 2008.

In 2008, ATP became a collaborator in a pan-Canadian cohort currently known as the Canadian Partnership for Tomorrow's Health (CanPath; formerly known as the Canadian Partnership for Tomorrow Project (CPTP)) (Borugian et al., 2010). ATP partnered with four other Canadian regional cohorts (BC Generations Project in British Columbia; Ontario Health Study in Ontario; CARTaGENE in Quebec; Atlantic Partnership for Tomorrow's Health (Atlantic PATH) in Nova Scotia, New Brunswick, Prince Edward Island, Newfoundland and Labrador) in a harmonized protocol that included questionnaires, physical measurements, and the collection of Biosamples (blood and urine). Saliva samples were collected from participants at the time of CanPath consent who could or did not want to attend a Study Centre and thus did not contribute blood or urine. ATP invited existing participants and recruited additional Alberta residents aged 35 to 69 years to take part in CanPath. At time of recruitment completion in 2015, a total of 54,932 participants had joined ATP and 39,959 of those had also consented to participate in CanPath. Of the 39,959 CanPath participants, approximately 30,000 had donated samples of blood and urine, and had completed a battery of physical measures. Saliva samples from an additional 9,691 participants were collected for the purpose of extraction of DNA. In 2018, the Manitoba Tomorrow Project (MTP) also joined CanPath as the sixth cohort, and in 2020 the Healthy Future Sask (HFS) joined as the seventh cohort of CanPath.

ATP is currently hosted in Cancer Care Alberta (CCA), which resides in the Acute Care Alberta provincial health agency along with Alberta Health Services (AHS).

2. **Authorization and Scope of Access Guidelines and Procedures**

This document outlines the various procedures and requirements for accessing ATP's resources. It is authorized under AHS Research Information Management Policy (Document #1146, effective October 16, 2019). It should be noted that all CCA and AHS policies referred to herein may be amended from time to time in the future.

ATP is committed to sharing data and Biosamples with the national and international scientific communities, to the principles of transparent and facilitated access to ATP Resources by bona fide researchers, and to efficient release of data and Biosamples to approved users. ATP data and Biosamples include responses to self- and interviewer- administered questionnaires, physical measures, data derived from responses to questionnaires, data derived from physical measures and Biosamples, data associated with those Biosamples, Linked Data, and other meta-data.

Release of Data and Biosamples to Approved Users will occur following review and approval of the Research Proposal, and successful execution of the Access Agreement. Upon the completion of any approved research project, all Results and/or Data generated must be returned to ATP to encourage ongoing use of the ATP resource by the research community.

ATP will not discriminate between Research Proposals on the grounds of whether the Applicants are based in Canada or in other countries, or whether they are based in public, academic or private research institutions conducting scientific health-related research that advances knowledge in cancer and the etiology of chronic diseases.

These ATP Access Guidelines and Procedures will be reviewed by ATP staff annually and updated as necessary. Any major amendments must be approved by ATP's Scientific Steering Committee with advice from additional experts as required. Minor amendments must be approved by ATP's Scientific Director. In the case of approved amendments, a revised version of the ATP Access Guidelines and Procedures will be made available. Researchers are directed to contact ATP for the most recent version by visiting https://myatpresearch.ca or by emailing ATP.Research@cancercarealberta.ca.

For a high level overview of the access process, please see Figure 1 and Figure 2.

3. **Glossary of Terms**

Access Agreement: document including but not limited to: a Data Disclosure Notice (DDN), Data Transfer Agreement (DTA), or Material Transfer Agreement (MTA), as relevant to the data and/or Biosamples requested for the Approved Research Project, that describes the responsibilities of the Approved User to comply with relevant legislation, CCA/AHS (ATP) policies and procedures and any conditions imposed by CCA/AHS (ATP) specifically to the Approved Research Project.

Access Application: full package of documents required to be submitted to ATP to formally request access to ATP's Coded Data and/or Biosamples, and includes the Application Form, Research Proposal, ethics review board application and approval, evidence of funding, and Applicant CV.

Access Committee: a group of 3-5 experts independent of ATP, but supported by the ATP Scientific Director, or designate, convened to evaluate all aspects and make decisions regarding approval of an Access Application.

Access Fee(s): cost recovery fee(s) associated with application submissions, datasets, and/or Biosamples. To be paid by Applicant or Approved User, depending on when invoicing occurs.

Access Fee Estimate: an estimate of a project's applicable Access Fees generated at the time of request.

Alberta Cancer Research Biobank (ACRB): a tissue repository operated within CCA which has Biosamples available from several types of cancers, available to qualified researchers. Some ATP participants who provided baseline Biosamples (i.e., cancer free) also appear in the ACRB.

Alberta Health Services (AHS): a provincial health corporation, established under the Alberta Health Services Provincial Health Corporation Regulation and Provincial Health Agencies Act, responsible for delivering health services in the acute care health services sector.

Alberta's Tomorrow Project (ATP): a longitudinal research platform promoting research into the etiology of cancer and other chronic diseases. CCA is the host institution for ATP and ATP is subject to CCA policies. For additional information on ATP, see the website: www.myatp.ca or myatpresearch.ca.

Alberta's Tomorrow Project Access Guidelines and Procedures: a document that outlines ATP's general principles and guidelines on access to its Coded Data and Biosamples.

Alberta's Tomorrow Project (ATP) Researcher Portal: an online portal (https://myatpresearch.ca/dashboard) on the https://myatpresearch.ca website that allows researchers to complete and submit documents related to data and/or Biosample access, such as Feasibility Inquiry Forms, Access Applications, and Post-Approval Amendments.

Ancillary Study: an investigation that involves the collection and analysis of additional Data and/or Biosamples from Research Participants beyond the scope of regular ATP follow up with Research Participants (see Section 27).

Applicant: a Canadian or international data user who wishes to conduct research relevant to ATP and who is applying for access to the ATP Resource. All Applicants must be affiliated with an academic or research Institution and be eligible to receive ethical approval from a recognized ethics review board. They should also have prior peer-reviewed Publications in a domain relevant to their Research Proposal.

Approved User's Institution: the academic or research organization with whom the Approved User is affiliated for the purpose of the Approved Research Project as outlined in the Access Agreement.

Approved Research Project: an Access Application that has been approved for access to the ATP Resource.

Approved Research Project Completion: the date of closure of the research protocol with the relevant ethics review board or 6 months post publication whichever comes first.

Approved User: an Applicant who is granted access to the ATP Resource.

ATP Resource: the combination of all ATP Coded Data and Biosamples that may be requested by Applicants.

Biosamples: biological samples including red blood cells, serum, plasma, DNA from buffy coats or saliva, and urine with associated Data from a unique, but not directly identifiable, individual made available to Approved Users in accordance with the Access Agreement. Also includes such future samples as may be collected by Ancillary Studies.

Cancer Care Alberta: representing the Cancer Care Provincial Health Corporation, created under the Care Care Provincial Health Corporation Regulation and Provincial Health Agencies Act, responsible for delivering and coordinating the delivery of cancer care services oversees and delivers treatment and services for Albertans with cancer.

Canadian Partnership for Tomorrow's Health (CanPath): a large, high quality, "population laboratory" that facilitates research in cancer and chronic disease etiology, formerly known as the Canadian Partnership for Tomorrow Project (CPTP). CanPath is made up of seven regional cohorts – Alberta's Tomorrow Project, Atlantic PATH, BC Generations Project, Ontario Health Study, Quebec's CARTaGENE, Manitoba Tomorrow Project, and Healthy Future Sask.

Co-Applicant: an individual from an academic or research Institution responsible for the supervision of a trainee (including a post-doctoral fellow) who is applying for access to the ATP Resource. Co-Applicants must sign any applicable Access Agreements along with the Applicant whom they are supervising.

Coded Data: data that have had identifiers removed and replaced by a code in such a way that linkage is only possible through a key retained by ATP and not shared with Approved Users.

Commercialization: means the transfer or commercial exploitation or any combination thereof undertaken with respect to Intellectual Property and includes, without limitation, licensing, sale or further development through a spin-off company or joint venture.

Data: the information collected from questionnaires or forms completed by Research Participants, or recorded by ATP staff during a visit by Research Participants to an ATP Study Centre, or obtained by linkage with administrative health databases.

Data Transfer Agreement (DTA): a written agreement, enforceable under law, that defines the rights and obligations of the parties in regard to the receipt of Data, that may need to be distributed for research purposes as described in an Approved User's Approved Research Project. A DTA is used to ensure that Data are used only for an authorized purpose (e.g. scientific research), and to limit further unauthorized disclosure.

Derived Data: Data generated based on questionnaire responses and analyses of Biosamples, but was not explicitly asked of Research Participants. Any Derived Data created as part of an Approved Research Project must be returned to ATP to enrich the ATP Resource.

Disclosure Notice: a document developed by CCA/AHS which informs Approved Users, CCA/AHS (ATP) and any other groups of their responsibility to comply with legislation, CCA/AHS (ATP) policies and procedures and any conditions imposed by CCA/AHS (ATP) specifically to the Approved Research Project.

Final Report: a form that the Approved User is required to complete and submit to ATP at the conclusion of an Approved Research Project.

Health Shared Services (HSS): provides services such as Human Resources, Information Technology, Finance, privacy, legal, and data and analytics to Alberta's provincial health agencies and corporations.

Intellectual Property (IP): means:

a) The intangible nature of works or creations that is unique and original;
b) Any tangible expression thereof;
c) The rights arising from the legal protection of IP, including copyright, trade-marks, patents, industrial designs, and integrated circuit topographies; and
d) Know-how and other trade secrets

IP includes, but is not limited to, technology, technical information, Data, databases, formulae, computer software, computer code, drawings, graphics, designs, concepts, ideas, apparatus, processes, research tools, prototypes, methods, techniques and all original literary, dramatic, musical, and artistic works, all print, multimedia electronic and audiovisual materials, manuals, program packages, and educational materials. IP also includes all rights and forms of protection of a similar nature or having equivalent or similar effect to any of the above anywhere in the world.

Intellectual Property Creator (IP Creator): the originator of IP who is a CCA/AHS employee, an individual working in association with a CCA/AHS employee, an individual using CCA/AHS resources (which includes ATP), or a partnership of one or more individuals or organizations.

Linked Data: coded information provided from a source outside of ATP and linked with ATP Data.

Linked ERNS Dataset: radon-related data collected by the Evict Radon National Study that has been linked to ATP participants and their associated ATP data.

Material Transfer Agreement (MTA): a written agreement, enforceable under law, that defines the rights and obligations of the parties in regard to the receipt of Biosamples, that may need to be distributed for research purposes as described in an Approved User's Approved Research Project. A MTA is used to ensure that Biosamples are used only for an authorized purpose (e.g. scientific research), and to limit further unauthorized disclosure.

Microbiome: the genetic material of all the microbes such as bacteria, fungi, protozoa, and viruses that live on or inside the human body.

Microbiome Sequencing Data: DNA sequence Data derived from the analysis of the Microbiome. From the Biosamples that ATP currently holds, Microbiome analysis can be completed on both saliva and stool samples. It is important to note that DNA sequence Data generated from an individual's Microbiome does not include any of the genetic material of the individual themselves.

Net Revenue: all revenue or other considerations generated by the Commercialization of IP less all direct expenses incurred in pursuing such Commercialization including, but not limited to, any fees for protecting, marketing, manufacturing, licensing, publishing or selling IP.

Progress Report: an annual form required to be submitted by all Approved Users to describe the progress made to date on the Approved Research Project.

Publications: include but are not limited to, articles published electronically or otherwise in peer-reviewed journals, abstracts, reviews, books, posters, online reports and any other written and/or verbal presentations of an Approved Research Project.

Re-identify: the process of using Coded Data to identify a Research Participant.

Research Participants: the individuals who have contributed Data and/or Biosamples to ATP.

Research Proposal: a fulsome description of the proposed project for the use of ATP's Coded Data and/or Biosamples for the advancement of knowledge into the etiology of cancer and other chronic diseases; the Research Proposal is part of the Access Application package.

Results: any findings generated by the Approved User pursuant to the Approved Research Project.

Scientific Advisory Committee: a group of researchers and other individuals with expertise, knowledge and experience relevant to ATP who offer credible and independent advice and counsel to help guide the development and implementation of research strategies that advance the aim of ATP.

Scientific Steering Committee: a group of scientists from a range of disciplines and institutions who work collaboratively to develop and implement research strategies to advance the aim of ATP.

Significant Change Report: a form that the Approved User is required to complete and submit to ATP if significant changes will be made to the project that differ from the original Approved Research Project.

Study Centre: permanent or temporary location where Research Participants donated Biosamples and had their physical measurements taken.

4. Letters of Support

4.1.1. ATP can provide a letter of support to potential Applicants to support funding applications as well as applications to ethics review boards. Potential Applicants who receive a letter of support from ATP are still required to complete the application form and follow the remainder of the access process once funding and ethical approval are in place in order to receive Data and Biosamples.

4.1.2. ATP requires 5-10 business days to produce letters of support.

4.1.3. Potential Applicants who require a letter of support to complete funding or ethics applications must:

- Register for an ATP Researcher Portal account (Instrutions here - https://myatpresearch.ca/register)
- Submit a Feasibility Inquiry Form on the ATP Researcher Portal (https://myatpresearch.ca/dashboard). Potential Applicants must register for an account before completing the Feasibility Inquiry Form.

ATP will review the form within 5 business days of receipt and will notify the Applicant if there are any substantial issues. If there are none, or once they are resolved, a letter of support and Access Fee Estimate will be produced, and the Feasibility Inquiry Form will be approved.

4.1.4. Evidence of ethical approval for a Research Proposal is not required to receive a letter of support for funding applications.

4.1.5. It should be noted that a letter of support does ***not*** guarantee access to the ATP Resource, it does not grant exclusivity of use, nor does it reserve Data or Biosamples for any potential Applicant.

5. Access Process for Data Only

Access to the ATP Data repositories must be requested using the formal procedures described in this document and is subject to the terms and conditions of the ATP Access Guidelines and Procedures, AHS Research Information Management Policy (Document #1146, effective October 16, 2019) and the relevant Access Agreement. The access process is visually represented in Figure 1.

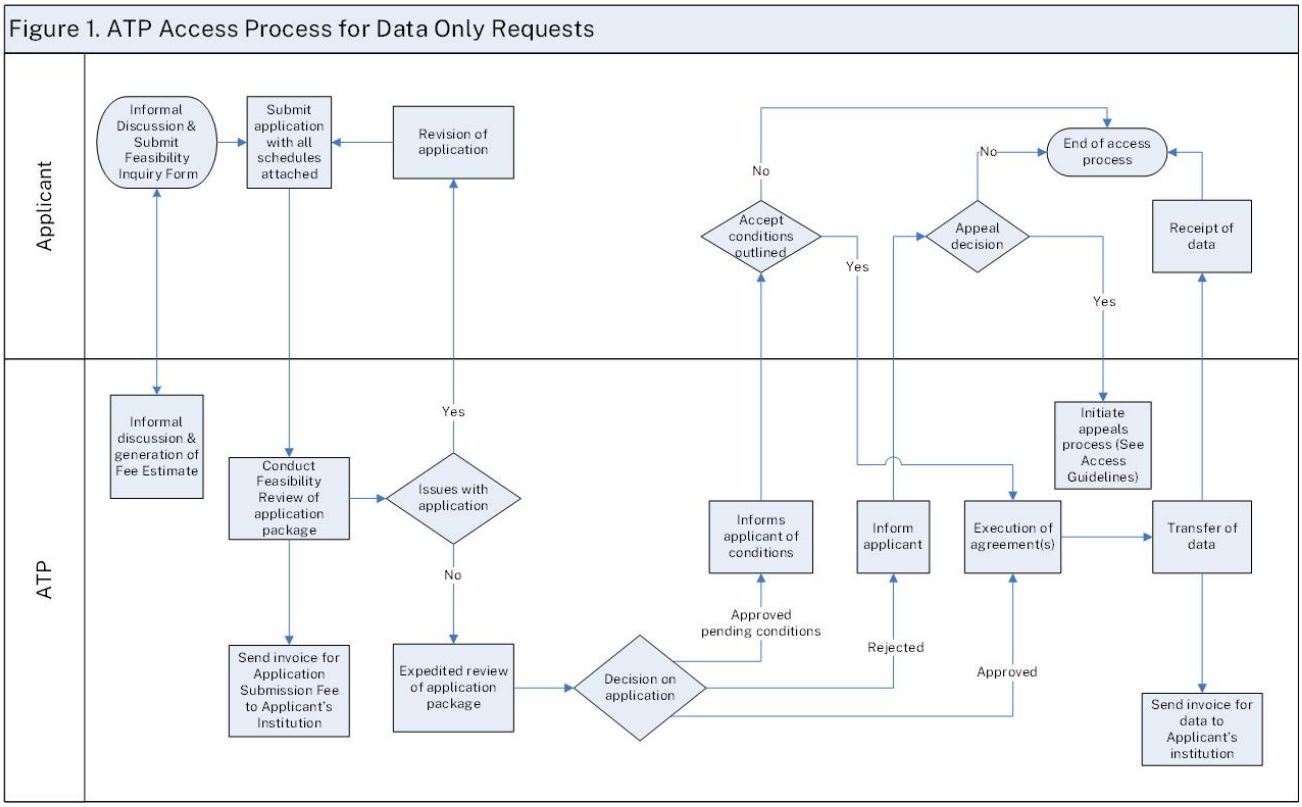


Figure 1. ATP access process for Data only requests

5.1. Data Use Disclaimers and Competing Research

5.1.1. Access to the entirety of the ATP Resource will not be granted to any one party nor will one party be given exclusive access.

5.1.2. There will be no exclusivity of access for Data-only Access Applications or Approved Research Projects.

5.1.3. Prospective Applicants are strongly encouraged to contact ATP at ATP.Research@cancercarealberta.ca and check https://myatpresearch.ca/approved-research-projects in order to determine if comparable research is already underway.

5.1.4. ATP's Data Access team will inform a potential Applicant if their proposed project may be similar to another previously Approved Research Project. However, for Data only applications, ATP will not consider the issue of potential overlap between Access Applications and/or Approved Research Projects during the Application Review Process. If similar Access Applications are received concurrently by ATP, each will be evaluated separately.

5.2. Feasibility Inquiry

5.2.1. All potential Applicants are required to complete an online Feasibility Inquiry Form (https://myatpresearch.ca) on the ATP Researcher Portal prior to submitting an application. Potential Applicants must register for an account at https://myatpresearch.ca/register before completing the Feasibility Inquiry Form. The Feasibility Inquiry Form is required to determine the feasibility of any potential access request, to generate an Access Fee Estimate and to determine if comparable research is already underway.

5.2.2. Please allow a minimum of 5 business days for any preliminary analyses (e.g., sample size estimates) to be run.

5.2.3. When the project is deemed feasible, the Feasibility Inquiry Form will be approved in the system and the Applicant will receive an email to submit a full Access Application.

5.3. Submission of Access Application

5.3.1. Access Applications must be completed on the ATP Researcher Portal. Once the Feasibility Inquiry Form has been approved, the Applicant can begin the formal application form.

5.3.2. Access Applications may be submitted at any time and are reviewed on an ad hoc basis.

5.3.3. It is highly encouraged that a potential Applicant contact ATP at least 1 month prior to submitting their application, to allow for an Access Fee Estimate (see Section 12) and to ensure the project is feasible. ATP can review the Research Proposal prior to formal submission.

5.3.4. It is highly encouraged that a potential Applicant contact ATP prior to submitting for ethics approval, to ensure all relevant details are included. ATP can review the ethics application prior to formal submission to the ethics review board.

5.3.5. For a complete Access Application, Applicants are required to submit:

i) a completed application form,
ii) a Research Proposal specific to ATP,
iii) ethics review board application and approval,
iv) evidence of funding, and
v) Principal Investigator's CV.

5.3.6. ATP will acknowledge receipt of the Access Application within 5 business days of submission. In exceptional circumstances, ATP may accept Access Applications without ethics review board approval if an application to the ethics review board

has been submitted. However, the Access Application will not be fully approved, and Data and/or Biosamples will not be released, until the ethics review board approval has been submitted to ATP.

5.3.7. For Access Applications with any objectives that are focused on **Indigenous participants**, Applicants will also be required to submit evidence of Indigenous partner engagement. Please contact ATP (ATP.Research@cancercarealberta.ca) for more information on this process.

5.3.8. For Access Applications that include **artificial intelligence or machine learning** methods, Applicants will be required to also complete a supplementary form to provide additional details on these methods. Please contact ATP (ATP.Research@cancercarealberta.ca) for more information on this process.

5.3.9. After the submission of an Access Application, Applicants will be charged an application submission fee (see Section 12).

5.4. Application Feasibility Review

5.4.1. After an Access Application is submitted, ATP will conduct a Feasibility Review. This review will check the following:

i) Completeness of the application form (e.g., is the sample size/power calculation completed and correct)
ii) Availability of the Coded Data for release, and the applicability to the research question
iii) Clarity of the descriptions of all data elements required, with a justification for each element
iv) Inclusion of the Research Proposal that relates directly to the submitted application form
v) Inclusion of evidence of funding
vi) Status of the ethical approval for the specific Research Proposal being submitted
vii) Consistency between the ethics review board application and approval, the Research Proposal, and the information provided on the application form
viii) Affiliation of Applicant with an Institution and prior Publications in domain relevant to their Research Proposal

5.4.2. Should any issues be identified during the Feasibility Review, ATP will advise the Applicant. The Applicant will be required to address any issues identified, to the satisfaction of ATP, before the Access Application will be advanced to the Expedited Review.

5.5. Application Expedited Review

5.5.1. The Expedited Review process will be undertaken by an internal Access Committee of reviewers including, ATP's Scientific Director, Data Access Research Associate and Data Manager or designates. The following areas will be examined:

i) the Applicant's qualifications
ii) the detail and scientific robustness of the Research Proposal
iii) whether the Applicant has sufficient resources and the 'fit' with ATP's purpose.

5.5.2. Additional external reviewers may be invited to review the application depending on the focus and scope of the application (e.g., advanced analytical methods such as artificial intelligence or machine learning). Applications requesting data from the Linked ERNS dataset will be reviewed by the Evict Radon National Study.

5.5.3. A decision regarding access will be communicated to the Applicant within 1 week after the successful completion of the Expedited Review. ATP will send a letter to the Applicant outlining the decision regarding access (approval, approval pending conditions or rejection) and, if appropriate, the conditions which would permit approval of the Research Proposal.

5.5.4. The Applicant will have 3 weeks to agree to and/or address the conditions proposed by ATP and if agreeable, access will be granted. ATP will then move forward with execusion of an Access Agreement (see Section 16).

5.5.5. If agreement cannot be reached, access will not be permitted. The Applicant can submit an appeal (see Section 13). Otherwise, a new Access Application must be submitted and a new application submission fee paid.

6. Access Process for Biosamples with Data

Access to the ATP Resource must be requested using the formal procedures described in this document and is subject to the terms and conditions of the ATP Access Guidelines and Procedures, AHS Research Information Management Policy (Document #1146, effective October 16, 2019), and the relevant Access Agreement. The access process is visually represented in Figure 2.

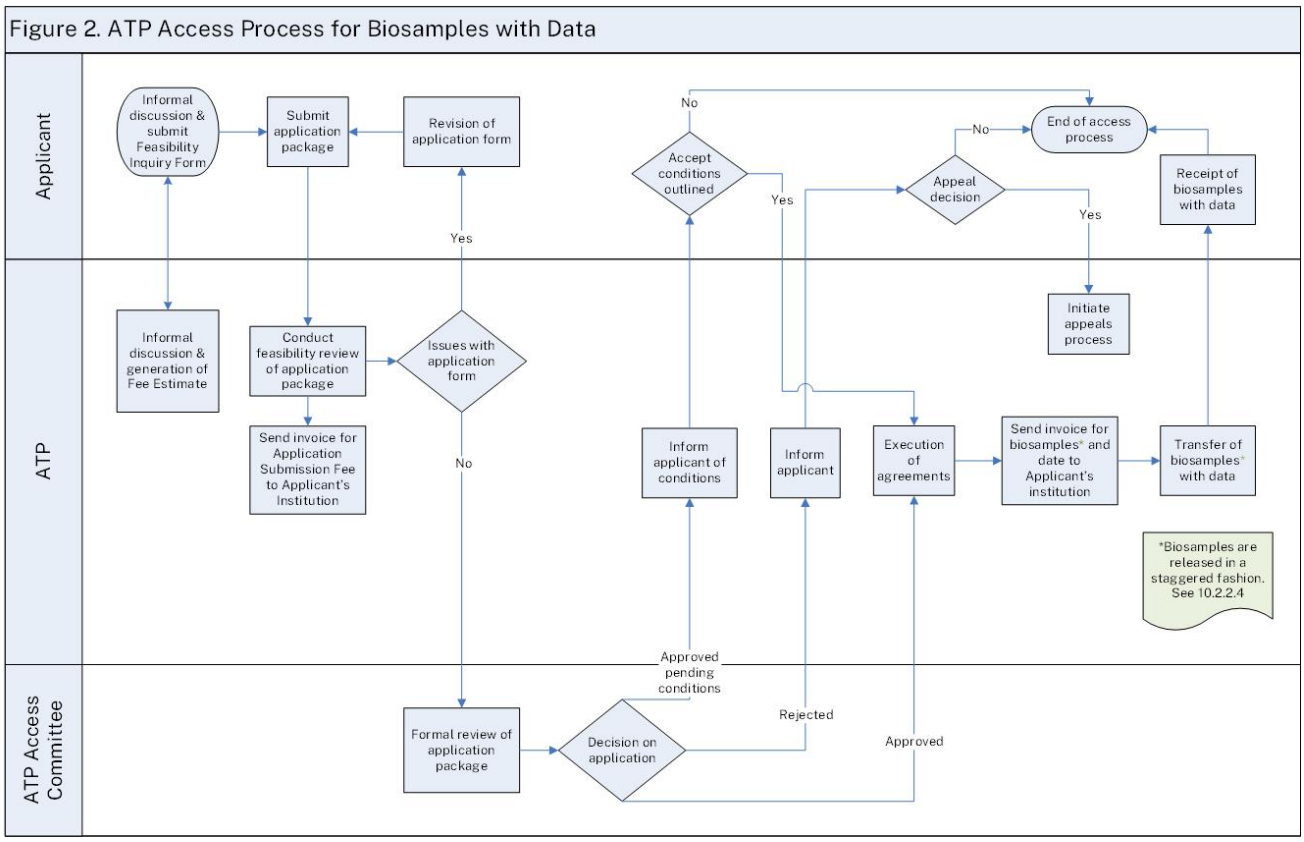


Figure 2. ATP access process for Biosamples with Data

6.1. Biosamples Use and Disclaimers

6.1.1. In general, applications will not be approved for accessing Biosamples to test methodologies, test laboratory/analytical equipment, to perform pilot studies, or for other activities that do not sufficiently justify use of the ATP Biosamples, which are a finite resource and where Biosamples from other sources may be more appropriate, and/or where the objectives are not consistent with the goals of ATP. Discovery research may be permitted if the justification for using ATP Biosamples is sufficiently robust, and will be evaluated on a case-by-case basis.

6.1.2. Applications for access to Biosamples will be subject to a minimum number of samples in order to ensure Research Participant confidentiality and to maintain the integrity of the Biosamples. Applications that may compromise Research Participant confidentiality will not be approved.

6.1.3. A proportion (25%) of the Biosamples will be reserved for up to 25 years from collection date. These guidelines will be reviewed regularly to ensure adequate Biosamples remain to support future research.

6.1.4. Access to the entirety of the ATP Resource will not be granted to any one party nor will one party be given exclusive access.

6.1.5. Approved Users must acknowledge that the Biosamples provided by ATP may contain viruses, latent viral genomes or other infectious agents. An Approved User undertakes to treat such Biosamples as if they are not free from contamination and to ensure that all Biosamples are handled by appropriately trained personnel under laboratory conditions that incorporate adequate biohazard containment. From the time of receipt, the Approved User is fully responsible for the safe and appropriate handling of the Biosamples. It should be noted that ATP has not tested any of the Biosamples for viruses, latent viral genomes or other infectious agents.

6.1.6. An Approved User or their Institution is not permitted to use the Biosamples in any experiments involving humans and cannot use the Biosamples in contact with any cells or other materials to be infused into humans. Biosamples will not be released for use in animal research or research with recombinant DNA.

6.2. Competing Research

6.2.1. Prospective Applicants are strongly encouraged to contact ATP at ATP.Research@cancercarealberta.ca and check https://myatpresearch.ca/approved-research-projects in order to determine if comparable research is already underway.

6.2.2. ATP's Data Access team will inform a potential Applicant if their proposed project may be similar to another Approved Project already ongoing.

6.2.3. As the amount of Biosamples is limited, ATP may suggest collaboration between Applicants submitting similar Access Applications concurrently. By encouraging collaboration between Applicants, the Biosamples can be used more efficiently. If the Applicants are not willing to collaborate, each Access Application will be evaluated separately.

6.2.4. If an Access Application closely resembles an existing Approved Research Project, ATP may suggest a collaboration between the Applicant and the Approved User. However, if collaboration is not possible, the Applicant submitting the Access Application will be required to provide additional robust justification to warrant access to the Biosamples, and the proposals may be compared against each other.

6.3. Feasibility Inquiry

6.3.1. All potential Applicants are required to complete an online Feasibility Inquiry Form (https://myatpresearch.ca) on the ATP Researcher Portal prior to submitting an application. Potential Applicants must register for an account at https://myatpresearch.ca/register before completing the Feasibility Inquiry Form. The Feasibility Inquiry Form is required to determine the feasibility of any potential access request, to generate a fee estimate and to determine if comparable research is already underway.

6.3.2. Please allow a minimum of 5 business days for any preliminary analyses (e.g., sample size estimates) to be run.

6.3.3. When the project is deemed feasible, the Feasibility Inquiry Form will be approved in the system and the Applicant will receive an email to submit a full Application.

6.4. Submission of Access Application

6.4.1. Access Applications must be completed on the ATP Researcher Portal. Once the Feasibility Inquiry Form has been approved, the Applicant can begin the formal application form.

6.4.2. Access Applications may be submitted at any time and are reviewed on an ad hoc basis.

6.4.3. It is highly encouraged that a potential Applicant contact ATP at least 1 month prior to submitting their application, to allow for an Access Fee Estimate (see Section 12) and to ensure the project is feasible. ATP can review the Research Proposal prior to formal submission.

6.4.4. It is highly encouraged that a potential Applicant contact ATP prior to submitting for ethics approval, to ensure all relevant details are included. ATP can review the ethics application prior to formal submission to the ethics review board.

6.4.5. For a complete Access Application, Applicants are required to submit:

i) a completed application form,
ii) a Research Proposal specific to ATP,
iii) ethics review board application and approval,
iv) evidence of funding, and
v) Principal Investigator's CV.

6.4.6. ATP will acknowledge receipt of the Access Application within 5 business days of submission. In exceptional circumstances, ATP may accept Access Applications without ethics review board approval if an application to the ethical review board has been submitted. However, the Access Application will not be fully approved, and Data and Biosamples will not be released, until the ethics review board approval has been submitted to ATP.

6.4.7. Justification for the use of ATP Biosamples must be considered sufficiently robust to permit partial depletion of limited resources.

6.4.8. Should Applicants have specific Biosample processing requirements, ATP must be informed of such. For example, if the Biosamples requested must be frozen within two hours of collection to enable use by a specific assay, Applicants must inform ATP of that requirement.

6.4.9. For Access Applications with any objectives focused on **Indigenous participants**, Applicants will also be required to submit evidence of Indigenous partner engagement. Please contact ATP for more information on this process.

6.4.10. For Access Applications that include **artificial intelligence or machine learning** methods, Applicants will be required to also complete a supplementary form to provide additional details on these methods. Please contact ATP for more information on this process.

6.4.11. After the submission of an Access Application, Applicants will be charged an application submission fee (see Section 12) .

6.5. Application Feasibility Review

6.5.1. After an Access Application is submitted, ATP will conduct a Feasibility Review. This review will check the following:

i) Completeness of the application form (e.g. is the sample size calculation complete and correct)
ii) Clarity of the descriptions of all Data elements required, with a justification for each element
iii) Clarity of the descriptions of the Biosamples required, with a justification for the number and volume needed, for each type of Biosample (if multiple types required), as well as for use of the ATP Resource
iv) Availability of the Coded Data and Biosamples for release, and the applicability to the research question
v) Inclusion of the Research Proposal that relates directly to the submitted application form
vi) Inclusion of evidence of funding
vii) Status of the ethical approval for the specific Research Proposal being submitted
viii) Consistency between the ethics review board application and approval, the Research Proposal, and the information provided on the application form
ix) Affiliation of Applicant with an Institution and prior Publications in domain relevant to their Research Proposal

6.5.2. Should any issues be identified during the Feasibility Review, ATP will advise the Applicant. The Applicant will be required to address any issues identified, to the satisfaction of ATP, before the Access Application will be advanced to the next step in the access review process.

6.6. Application Formal Review by ATP Access Committee

6.6.1. The ATP Access Committee consists of 3-5 members of ATP's Scientific Steering Committee and/or external subject matter experts, is chaired by ATP's Scientific Director (or designate) and supported by the ATP Data Access team and ATP's Bioresource Advisor. The Committee convenes on an ad hoc basis to evaluate all aspects of an Access Application. A minimum of 3 members will evaluate Access Applications according to the Terms of Reference, which are available upon request. The following aspects will be evaluated:

i) Relevance of the Access Application to the vision and aim of ATP
ii) Experience and qualifications of the Applicant, particularly with respect to the proposed methodologies
iii) Scientific merit of the Research Proposal (considering reviews from the external peer reviewers, if applicable)
iv) Adequacy of resources to support the Research Proposal and to protect the integrity/security of the Coded Data and Biosamples
v) Justification for use of the Biosamples, and potential impact on future uses of ATP's Biosamples
vi) Enrichment potential for the ATP Resource
vii) Evidence of ability of Applicant to obtain access to all other Data or Biosamples required for the Research Proposal (e.g. if the Research Proposal is for ATP 'control' samples, the Applicant should indicate how they plan to access 'case' samples)

6.6.2. The application materials will be sent to the Access Committee. Members will complete the Biosample with Data Review Form for Access Committee within three weeks. The Committee members will indicate if the Access Application is either approved, rejected or approved pending conditions.

6.6.3. In the case of unanimous approval or unanimous conditional approval, ATP will notify all Access Committee members to assess consensus as to whether or not further discussion is needed. If so, a meeting will be held. If not, email communication may be used to formulate feedback for the Applicant. ATP will send a letter to the Applicant outlining the Access Committee's decision (e.g., approval or approval pending conditions) and the conditions which would permit approval of the Access Application (if applicable).

6.6.4. If a unanimous decision is not reached, a meeting (either in person or by teleconference) will be convened with the Access Committee and the Chair, where the Committee will reach a decision and formulate feedback for the Applicant. ATP will send a letter to the Applicant outlining the Access Committee's decision (approval, rejection, or approval pending conditions) and if appropriate, the conditions which would permit approval of the Access Application.

6.6.5. The Applicant will have 3 weeks to agree to and/or address the conditions proposed by the Access Committee and if agreeable, access will be granted. ATP will then move forward with execusion of an Access Agreement (see Section 16).

6.6.6. If agreement cannot be reached, access will not be permitted. The Applicant can submit an appeal (see Section 13). Otherwise, a new Access Application must be submitted and a new application submission fee paid.

7. Access Process for ATP and ACRB Biosamples

Applicants interested in obtaining Biosamples from pre-cancer diagnosis and at-cancer diagnosis timepoints may want to submit a joint ATP and Alberta Cancer Research Biobank (ACRB) Access Application. Contact atp.research@cancercarealberta.ca and bio.bank@cancercarealberta.ca for more information.

8. Access process for ATP staff members

8.1.1. ATP staff members seeking access to Data only will undergo the same process as external researchers (see Section 5), with the only difference being the review process. A condensed review process will be conducted by the ATP Data Manager and the ATP Data Access Team only.

8.1.2. ATP staff members seeking access to Biosamples and Data will undergo the same process as external researchers (see Section 6).

8.1.3. ATP staff members who are the principal investigators of an Access Application are exempt from fees but remain bound by all other policies including the conflict of interest considerations as outlined in Appendix 2.

9. Accessing ATP Data for CanPath approved projects

9.1.1. Applicants of CanPath-approved projects may request additional regional Data from ATP (e.g., Data that CanPath does not hold, such as the Alberta Cancer Registry dataset or Data collected by ATP prior to the formation of CanPath in 2008) by submitting an Access Application to ATP.

9.1.2. CanPath's approval will be honoured, however a condensed review will still be conducted by the ATP Data Access Team and the ATP Data Manager to ensure feasibility and to identify any regional Data required.

9.1.3. An Access Agreement is required for the Data obtained directly through ATP.

9.1.4. ATP will also honour CanPath's annual Progress Reports, and will not make requests for additional reports.

10. **Linked Data held by ATP**

For information about the linked Data held by ATP, please visit https://myatpresearch.ca/data-dictionaries.

10.1. Alberta Cancer Registry (ACR) Data

10.1.1. Applicants may request access to a select number of variables from the Alberta Cancer Registry (ACR) that has been linked to ATP participants and which ATP holds and can distribute.

10.1.2. If the Applicant requires additional Data from the Alberta Cancer Registry, a separate application to the relevant department will be required. ATP can provide support with the application process.

10.2. Canadian Urban Environmental Health Research Consortium (CANUE) Linked Data

10.2.1. Applicants who are based in an academic institution may request access to environmental Data from the Canadian Urban Environmental Health Research Consortium (CANUE) that has been linked to ATP participants. If the Research Proposal is approved, the Approved User must complete CANUE's Data Sharing and Use via Approved Third Party Agreement as well as the Access Agreement. As per CANUE's policy, there will be no fee for access to this dataset, however ATP will recover costs incurred to prepare the linked dataset for the Approved User.

10.3. Evict Radon National Study (ERNS) Data

10.3.1. Applicants can request data from the Evict Radon National Study that has been linked to ATP participants ("Linked ERNS Dataset"). As a condition of use, the Approved User must agree that they will **not** use the Linked ERNS Dataset to generate maps of radon exposure.

- This includes performing classic colorimetric, geospatial radon mapping – such activities are explicitly prohibited.
- The reason for this is that it violates participant consent and data governance policies that are foundational to the Evict Radon National Study.

11. **Linked Data not held by ATP**

11.1.1. An Approved User may seek to apply for additional Data from an external source to link with ATP Data if ATP approves them for access. These Data may be collected from external organizations from whom the Approved User applies for access. If Linked Data is required for an Approved User Research Project, the Approved User

may be required to apply to the external organizations on their own whereas in other instances ATP will be responsible for applying for the Data.

11.1.2. An Approved User may seek to link their own Data to ATP Data if ATP approves them for access. This request would need to be stipulated in the Access Application and is subject to review by the ATP Data Manager for privacy and security. If the linkage is deemed to be a risk for potential participant identification, the request will be denied. If the request is approved, ATP and the Approved User will enter in negotiations on integrating the Data into the ATP repository, and an embargo period.

12. **Access Fees**

ATP's Access Fees are based on efforts to pursue a cost recovery model to support long-term sustainability of the platform. The fees reflect partial recovery of expenses associated with the access process, including administrative cost for reviewing applications, executing agreements, retrieving and processing Data and Biosamples for release, and upholding excellent Data and Biosample quality and management. Access Fees are set in accordance with CanPath and CCA/AHS, and are subject to regular review.

Information on the current Access Fees list can be obtained by contacting ATP.Research@cancercarealberta.ca.

12.1. Access Application Submission Fee

12.1.1. There is a fixed application review fee for each Access Application for Data Only requests and for Biosample requests. This is to help defray ATP's initial costs for the administration of the review process for the Access Application. This charge will be invoiced for upon submission of the Access Application.

12.2. Dataset and Biosample Access Fees

12.2.1. Please contact ATP to determine Access Fees prior to the submission of the Access Application.

12.2.2. Generally, ATP's access fee structure is in alignment with CanPath's cost-recovery access fees.

12.2.3. Generally, Applicants based in non-profit and/or academic institutions will be charged subsidized Access Fees. Applicants based in commercial and/or for-profit institutions will be charged non-subsidized Access Fees.

12.2.4. Access Fees for Data-only requests will be invoiced for when the Approved User receives their dataset from ATP.

12.2.5. Access Fees for Biosamples will be invoiced for prior to release of Biosamples and datasets. In the case of staggered release of samples (see Section 17.2.4) the Approved User will pay for each release separately.

12.2.6. Approved Users will be responsible for covering any costs related to packing and shipping Biosamples to meet the conditions outlined in the Access agreement.

12.2.7. Approved Users will also be responsible for any costs relating to securing permits, licenses or other documentation required to ship the Biosamples. Any taxes levied will also be covered by the Approved User.

12.2.8. ATP periodically reviews the fee guidelines and, as a result, fees may change. Potential Applicants should contact ATP to ensure that they have up to date information on current Access Fees.

13. **Denial of Access**

13.1. Access denial

Access to ATP Coded Data and/or Biosamples may be denied for several reasons, for example:

13.1.1. The ability of the Applicant to execute the Research Proposal is in doubt or aspects of the Research Proposal are considered inadequate or problematic by the ATP Expedited Reviewers or Access Committee. The Applicant will have to show evidence of expertise, resources, financing and the ability to execute the Research Proposal to its successful completion.

13.1.2. There are ethical or legal issues with the Research Proposal, including, for example, when the proposed use is not consistent with the specified purpose of the Biosample collection in the original informed consent, or is in contradiction of ATP's mission, scope and goals. It should be noted that receipt of ethical approval from an ethics oversight board/committee does not guarantee access to ATP Resource.

13.1.3. The Research Proposal does not comply with ATP's Access Guidelines and Procedures, Alberta's Health Information Act and/or all other applicable CCA/AHS policies.

13.1.4. The requested Biosample volume is deemed to be too large in the context of the specific Research Proposal, it will compromise the future scientific value of the ATP Biosample collection, or the available volume held by ATP is insufficient to fill the request.

13.1.5. Justification for the use of ATP Biosamples is not considered sufficiently robust to permit depletion of limited resources.

13.1.6. There is a conflict of interest in relation to the Research Proposal, in the view of the ATP Expedited Reviewers or Access Committee (see Appendix 2 for the ATP Conflict of Interest Guidelines).

13.2. Appeals

13.2.1. Any Applicant who wishes to appeal the decision of the ATP Expedited Reviewers or Access Committee can apply to ATP for appeal consideration by ATP's Access Committee. Appeals must be made in writing with a self-contained and fully documented description of all the relevant background and a formal justification for triggering the appeals process.

13.2.2. The process for appealing a decision concerning an Access Application is as follows:

13.2.2.1. Within 2 months of ATP issuing a notification denying access, the Applicant may choose to submit a self-contained written request and justification for an appeal. Appeal requests received more than 2 months following notification of denial will not be accepted;

13.2.2.2. Within 4-6 weeks of receipt of such a request, ATP's Access Committee will review it along with the original Access Applciation (and any other information that it considers pertinent) and make a recommendation. ATP will provide the Applicant with a written explanation of the relevant committee's recommendation;

13.2.2.3. If considered necessary, ATP's Access Committee may seek additional advice (e.g. from scientific or other experts), in which case the Applicant will be advised by ATP of any revision to the timetable for review.

13.2.3. If, following reconsideration under the appeals process, the recommendation is to deny access, the Applicant will not be able to submit the same Access Application again. However, if the recommendation to ATP is to grant access, ATP will abide by the recommendation and the access process will continue with the execution of Access Agreement(s) and any subsequent steps. The relevant committee may also choose to recommend access be granted subject to conditions being met. In the latter situation, the Applicant will have 3 weeks to agree to the conditions proposed and if agreeable, access will be granted. However, if agreement cannot be reached, access will not be permitted and a new Access Application will have to be submitted.

14. Access Limitations

Requests to access the ATP Resource at the individual Research Participant level for non-research related uses including by law enforcement bodies or governmental agencies, will be considered in

consultation with the CCA/AHS Legal and Privacy portfolios and in accordance with Alberta's Health Information Act, the Access to Information Act, and the Protection of Privacy Act.

15. **Application Confidentiality**

15.1.1. All information on Access Applications (including Research Proposals) submitted to ATP will be kept confidential during the submission and review process.

15.1.2. Once access to the ATP Resource is granted, the following information on each Approved Research Project will become publicly available and may be published in a variety of places including, but not limited to, the ATP website:

i) Title of the Approved Research Project
ii) Name(s) of the Applicant(s) involved and their academic credentials
iii) Name(s) of the employer(s) and/or Institution(s) with which they are affiliated
iv) Scientific abstract provided by the Applicant
v) Lay summary provided by the Applicant
vi) Scheduled project start date and end date
vii) Source of funding for the Approved Research Project

15.1.3. At the conclusion of an Approved Research Project, the scientific and lay summary of the findings submitted by the Approved User may also be added to the publicly available information about ATP.

15.1.4. ATP reserves the right to edit or modify any lay summaries submitted to suit the needs of ATP's website and/or other publicly available material.

16. **Execution of Agreements**

16.1.1. Upon approval of the Research Proposal, the Approved User, ATP and CCA/AHS will enter into an appropriate Access Agreement (the type of agreement will be determined by the nature of the Data and/or Biosamples requested). All parties will be required to sign the agreement(s) and representatives of each implicated Institution may also need to sign.

16.1.2. If the Applicant has also requested Linked Data from Canadian Urban Environmental Health Research Consortium (CANUE), a CANUE Third-Party User Agreement must also be signed prior to release of CANUE Data (see Section 10.2 for more information about CANUE Data).

16.1.3. Any required agreements will be signed by the ATP Scientific Director on behalf of ATP. In the event the Scientific Director is unable to sign the required agreements, theca Executive Director of Cancer Research & Business Partnerships will fulfill the role. Institutional signatures may also be required from AHS, HSS, Cancer Care

Provincial Health Corporation, or other, depending on the data and/or Biosamples requested.

17. **Transfer of Data and Biosamples**

Coded Data and Biosamples will only be released to Approved Users once all required agreements have been successfully executed.

17.1. Transfer of Data

17.1.1. Once all required agreements are successfully executed, an ATP Data Analyst will upload the Approved User's datasets to a shared folder on AHS's Secure File Transfer Protocol (SFTP) website. The Data Analyst will then email the Approved User a unique link to access the shared folder. The Approved User then will have access to the website for a maximum of three weeks during which the Coded Data files should be downloaded. The files will be provided in CSV format.

17.2. Transfer of Biosamples

17.2.1. ATP will only begin to remove Biosamples from the ATP repository and prepare them for shipping once all required agreements are successfully executed and the Approved User has secured any required permits, licenses, or other documentation for shipping the Biosamples.

17.2.2. ATP will only ship Biosamples to the Approved User after payment has been received. In the case of staggered release of samples (see Section 17.2.4) the Approved User will pay for each release separately.

17.2.3. Biosamples will be removed from the ATP biorepository and packaged on dry ice and sent to the location specified by the Approved User on their Access Application. The Approved User will be responsible for covering all costs associated with packing and shipping the Biosamples as well as ensuring the shipping address is current and a receipt process is in place. Unless otherwise agreed upon, a trial shipment of a small number of Biosamples will be done; additional trial shipments may be done at the request of the Approved User and at their cost. The Approved User is responsible for covering the costs of any taxes that may be levied. The most appropriate delivery method, as determined by ATP, will be used to transfer the Biosamples.

17.2.4. Biosamples will be released in a staggered fashion (i.e. the Approved User will not receive all of the Biosamples at once). This is to ensure procedures for preparing, shipping, receiving, and testing samples, as well as Data generation and return, are appropriately tested prior to releasing the full sample lot. ATP will determine the number and types of samples to be released in the first shipment, as well as relay the expectations for Data return and evaluation. Data returned from the staggered

release will be reviewed by the ATP Bioresource Advisor and ATP Data Manager, along with member(s) of the Access Committee or external experts as needed. If concerns are raised during the review, the Applicant may be approached for adjustments to the methodology, changes in the volume of each sample or other as required.

17.2.5. If, for any reason, the Approved User is incapable of using the Biosamples provided for an Approved Research Project, ATP must be informed of the circumstances around the incapacity and the Biosamples must be returned to ATP at the cost of the Approved User.

18. **Data Protection**

Protecting the confidentiality of Research Participants is a primary concern for ATP. As such, ATP follow the principle of least amount of information and expects Approved Users to follow additional conditions related to Data security and privacy, described here.

Ultimately, Approved Users are responsible for having the necessary technical and organizational measures in place to protect the Coded Data and/or Biosamples from unauthorized access.

18.1. Prohibiting re-identification of Research Participants

18.1.1. Data and Biosamples are coded to protect the integrity of the Research Participants and Approved Users must not attempt to Re-identify any individual from the Coded Data or Biosamples provided as part of an Approved Research Project.

18.1.2. If an Approved User believes that they have inadvertently identified any Research Participant, they must not record this, share the identification with any other person or attempt to contact the Research Participant. Approved Users must inform ATP immediately of the identification, complete an ATP Privacy Breach Notification form on the ATP Researcher Portal, and provide the details of the circumstances under which the identification occurred. Further follow-up by CCA may be initiated with the Approved User and their Institution.

18.1.3. Any Publications, reports or other public disclosures based on the ATP Resource must be done in a manner as to ensure Research Participant confidentiality is maintained. Approved Users cannot present (e.g. in presentations, Publications, etc.) aggregate information on groups of <10, unless a special request is made, which will be evaluated on a case by case basis, as defined by AHS's Privacy Standard for Non-Identifying Health Information (Standard # IPO-2013-0004).

18.2. Data linkage, sharing and publishing

18.2.1. Approved Users must not link the Coded Data or Biosamples provided with any other Data set without the prior permission of ATP.

18.2.2. Approved Users or their Institutions must not share Coded Data and/or Biosamples accessed as part of an Approved Research Project with any other individual or Institution other than those specified in the Approved Research Project.

18.2.3. If an Approved Research Project involves **Microbiome Sequencing**, the Approved User must send the sequencing Data to ATP to obtain written approval prior to any presentation or Publication of the Data, including uploading Microbiome Sequencing Data to open access repositories.

18.2.4. If an Approved Research Project produces a **machine learning or AI model** trained on ATP participant Data, the model may not be shared publicly or with any other individual or Institution other than those specified in the Approved Research Project unless granted express and written approval from ATP.

18.2.5. Approved Users may not publish sequencing or other Data on external repositories (such as, but not limited to, GitHub), without written approval from ATP.

19. **Modifications After Approval**

All Post-Approval documents can be found under the "Post-Approval Documents" menu in the ATP Researcher Portal at https://myatpresearch.ca/dashboard. For copies of the forms, please contact ATP's Data Access team at ATP.Research@cancercarealberta.ca.

19.1. Progress Reports

19.1.1. Annual Progress Reports are required from all Approved Users.

19.1.2. ATP will send reminders for submission of the Progress Report form approximately 1 month in advance of the due date, with instructions on how to complete the form in the Researcher Portal. Progress Reports will be due annually, on the date the Data and/or Biosamples were received by the Approved User.

19.1.3. Proof of a current annual renewal from the relevant ethics review board must also be submitted with the Progress Report.

19.1.4. If the annual Progress Report is not submitted within 30 days following the due date, the Access Agreement may be terminated. Approved Research Projects that are completed in under one year are only required to complete a Final Report (see Section 21.1).

19.2. Project term and extensions

19.2.1. An Approved Research Project may remain active for a length of five years from the date of Access Agreement execution.

19.2.2. An Approved Research Project may be extended beyond five years on a case by case basis, at the discretion of ATP. Requests for extensions can be made via the annual Progress Report, or by emailing ATP as soon as the need for an extension is identified.

19.2.3. An Approved Research Project extended beyond five years will be subject to a data renewal fee per annum. This fee will be 20% of the current fees for datasets the Approved User has received from ATP. This renewal fee may be waived on a case by case basis, at the discretion of ATP.

19.2.4. Any agreements in place will be valid for the total duration of the project, including extensions, if approved by ATP.

19.3. New Principal Investigator

19.3.1. If a new Principal Investigator is named in replacement of the Approved User, the new Applicant must sign a Replacement Approved User Agreement stipulating the new Principal Investigator's agreement to, and assumption of, all responsibilities to abide by all the terms and conditions specified in the original Access Agreement for the Approved Research Project. The new Applicant's CV must be submitted to ATP along with all documentation approving the change from the relevant ethics review board. The new Applicant's Institution may also be required to sign the Replacement Approved User Agreement on a case by case basis. Approval of Replacement Approved Users will be reviewed by ATP also on a case by case basis.

19.4. Change in Institution or contact information

19.4.1. Changes to an Approved User's Institution or contact information must be reported to ATP by updating the Study Team section of their project on the ATP Researcher Portal.

19.4.2. Should there be a change of Institution, an updated Access Agreement may be required. Additionally, if an Approved User wishes to add or remove team members (other than the Principal Investigator) from an Approved Research Project, the Approved User must also update the Study Team section of their project on the ATP Researcher Portal.

19.5. Significant changes

19.5.1. The Data or Biosamples may not be used for any other purpose other than for the Approved Research Project as described in the Access Agreement.

19.5.2. If an Approved User wishes to use the ATP Biosamples and/or Coded Data already provided to them for a purpose other than the original purpose, such as an objective that was not previously stated in their proposal, they must submit a Significant Change Report form on the ATP Researcher Portal. The form will be

evaluated by the ATP Scientific Director, or designate. If the request is deemed to be minor, the change will be noted by ATP and no further follow up will be initiated. If the change is deemed to be significant or fundamental the following my be required:

i) an ethics amendment
ii) revised agreement(s)
iii) a new Access Application to ATP with the associated application fee (see Figure 3 for visual representation of process)

19.6. Additional Data or Biosample requests

19.6.1. Additional Data - If during the course of an Approved Research Project, additional Data variables are required, the Approved User should submit an Additional Variable Request form on the ATP Researcher Portal. Additional Variable Requests will be reviewed by the ATP Scientific Director, or designate. If the request is deemed to be minor, the Data will be provided to the Approved User under the same terms and conditions outlined in the original Access Agreement(s). If the request is deemed to significantly alter the original Research Proposal the following will be required:

i) a Significant Change Report form
ii) an Additional Variable Request form (see Figure 3 for visual representation of process)

19.6.1.1. An updated Access Agreement needs to be signed every time additional Data elements are released.

19.6.1.2. An ethics amendment may also be required depending on the new Data being requested.

19.6.1.3. Access Fees may be charged for generating the dataset for an Additional Variable Request. See Section 12 for more information on Access Fees.

19.6.2. Additional Biosamples - If during the course of an Approved Research Project, additional Biosamples are required, the Approved User should submit a Significant Change Report form on the ATP Researcher Portal. The form will be evaluated by the ATP Scientific Director, or designate, and potentially external reviewer(s) as well. If the request is deemed to be minor, the Biosamples will be provided to the Approved User under the same terms and conditions outlined in the original Access Agreement(s). If the change is deemed to be significant or fundamental, the following may be required:

i) revised agreement(s)

ii) a new Access Application submitted to ATP with the associated application cost (see Figure 3)
iii) proof of amended Ethics

19.6.3. Fees may be charged for preparing the additional Biosamples. See Section 12 for more information on Access Fees.

19.6.4. If other changes to the Approved Research Project are needed, the Approved User should contact ATP and they will be considered on a case by case basis.

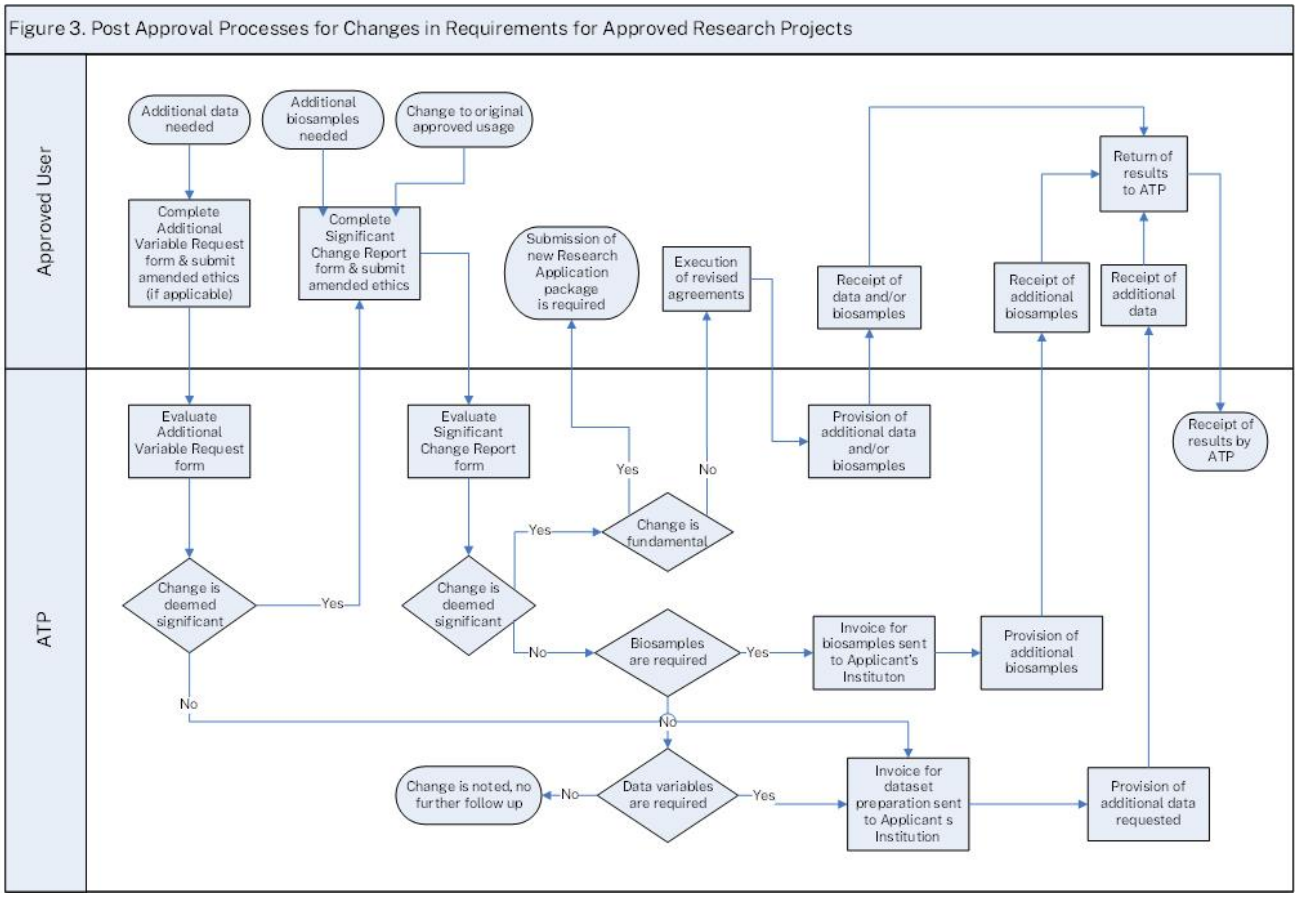


Figure 3. Post-approval processes for changes in requirements for Approved Research Projects

19.7. Additional Funding

19.7.1. If additional sources of funding are obtained during the course of an Approved Research Project, or if the original source of funding has changed in some way, the Approved User must inform ATP by submitting an Additional Funding Report form on the ATP Researcher Portal.

19.8. Ethics Renewals

19.8.1. For the duration of an Approved Research Project, active ethical approvals must be maintained (including, but not limited to, while conducting Data analyses) and any annual renewals must be submitted to ATP with a Progress Report.

20. **Publications and Other Outputs**

Approved Users of ATP's Resource are encouraged to publish their research Results so as to benefit both the scientific community and the general population.

20.1. Publications

20.1.1. Approved Users are encouraged to use their best endeavors to publish the findings of any Approved Research Project in an academic journal or on an open source publication site within 6 months of the date of closure of the research protocol with the relevant ethics review board.

20.1.2. Approved Users must submit final drafts of manuscripts intended for peer review to ATP *prior* to submission to a journal. Manuscripts must be uploaded with a completed ATP Publication Checklist on the ATP Researcher Portal. ATP will not undertake a formal peer review, but will review draft manuscripts to determine if:

i) any confidential and/or proprietary information has been disclosed
ii) the methods related to ATP (e.g., participant recruitment, Data collection, etc.) are appropriately described
iii) the Publication may bring ATP/AHS into disrepute
iv) the conditions laid out in the ATP Access Guidelines and Procedures and the Access Agreement have been followed
v) the scope of the reported analysis is compliant with the Approved Research Project

20.1.3. In most cases, ATP will advise the authors of the Results of the review within 10 business days of receipt of the draft manuscript. The authors are not duty bound to follow the advice provided unless confidentiality, IP rights, ATP/CCA/AHS reputation and/or adherence to the Access Agreement appear to have been compromised.

20.1.4. If it appears that the Access Agreement or ATP/CCA/AHS reputation have been compromised, ATP will seek advice from CCA legal counsel, and will proceed as directed. Additional consequences may apply as outlined in the Compliance with ATP Guidelines and Procedures section of this document (see Section 25).

20.1.5. Under all circumstances, ATP reserves the right to submit letters or papers for publication in response to any Publication that utilized the ATP Resource to explain study procedures or to express a coherent scientific argument.

20.1.6. Approved Users must send ATP copies of the final published paper in electronic format.

20.1.7. ATP has adopted authorship and acknowledgement guidelines for Publications (see Appendix 1) to assist Approved Users in preparing Publications or presentations based on the ATP Resource. If the guidelines are not appropriately followed, ATP reserves the right to take this into account in judging future access requests from the responsible parties. ATP does not require an ATP staff member to be a co-author on Publications arising from use of the ATP Resource.

20.1.8. ATP reserves the right to work with the Approved User to develop a communications strategy that may be deployed when a manuscript is published. ATP strongly encourages Approved Users to inform ATP if a manuscript is further publicized. This approach is not intended to introduce a significant delay in publication but rather to ensure that ATP and CCA/AHS are in a position to respond effectively to any queries they may receive from Research Participants, the media or any other bodies or persons.

20.1.9. In addition, ATP can help further promote the Publication through social media and other communication outlets.

20.1.10. Approved Users must submit a final version of any other outputs, including meeting abstracts, conference presentations, online reports/blogs, or others, to ATP along with a completed ATP Presentation Report form or ATP Alternative Research Output form on the ATP Researcher Portal.

20.1.11. ATP requests submission of an electronic copy of any theses that use any portion of ATP's Resource as soon as possible after a degree is awarded. Theses may be uploaded on the File Exchange page of the ATP Researcher Portal.

20.2. Acknowledgement Statements

20.2.1. ATP would like to have all work linked to ATP to be easily identified, including in electronic searches. ATP encourages Approved Users to include 'Alberta's Tomorrow Project' as a keyword and in the abstract.

20.2.2. All Publications based on the ATP Resource should clearly acknowledge ATP's funders, Research Participants and staff. The following acknowledgement must be included as is (or in a modified form to fit the journal requirements) in all Publications and presentations using the ATP Resource:

"Alberta's Tomorrow Project is only possible because of the commitment of its research participants, its staff and its funders: Government of Alberta, Alberta Cancer Foundation, Canadian Partnership Against Cancer and Health Canada, and substantial in kind funding from Cancer Care Alberta. The views expressed herein represent the views of the author(s) and not of Alberta's Tomorrow Project or any of its funders."

20.2.3. If the Approved User utilized **Alberta Cancer Registry** Data, the following acknowledgment must be included:

"Alberta's Tomorrow Project is only possible because of the commitment of its research participants, its staff and its funders: Government of Alberta, Alberta Cancer Foundation, Canadian Partnership Against Cancer and Health Canada, and substantial in kind funding from Cancer Care Alberta. Cancer registry Data was obtained through linkage with Surveillance & Reporting, Data and Analytics, Health Shared Services. The views expressed herein represent the views of the author(s) and not of Alberta's Tomorrow Project or any of its funders."

20.2.4. If the Approved User utilized **CANUE Data**, the following acknowledgement must be included after the ATP, or ATP and ACR, acknowledgement:

"Environmental exposure data was obtained through linkage with Canadian Urban Environment Health Research. The views expressed herein represent the views of the author(s) and not of Alberta's Tomorrow Project or any of its funders."

20.2.5. If the Approved User utilized **Linked Evict Radon National Study (ERNS) data**, the following acknowledgement must be included after the ATP, or ATP and ACR, acknowledgement:

"The outcomes of this study were made possible, in part, using data collected by the researchers of the Evict Radon National Study, headquartered at the University of Calgary, with approvals conferred by the Health Research Ethics Board of Alberta-Cancer Committee. The outcomes expressed herein represent the views of the [Approved User] and do not necessarily represent the views of the Evict Radon National Study or the University of Calgary. For more information on the national study, please visit www.evictradon.org."

20.2.6. If the Approved User utilized **administrative Data obtained through Alberta SPOR Support Unit**, the following acknowledgement must be included as a separate paragraph after the ATP or ATP and ACR acknowledgement:

"This study was supported by Provincial Research Data Services (PRDS) which is funded by the Alberta SPOR SUPPORT Unit (AbSPORU), the Alberta VITAL project and Health Shared Services. AbSPORU is funded by CIHR, Alberta Innovates,

University Hospital Foundation, University of Alberta and University of Calgary. VITAL is funded by Innovation, Science and Economic Development (ISED) Canada.

Data were extracted from the Health Shared Services Enterprise Data Warehouse. This study is based in part on Data provided by Preventative and Primary Health Services and Health Shared Services. The interpretation and conclusions contained herein are those of the researchers and neither the Government of Alberta nor any provincial health agencies/corporations expressed any opinion in relation to this study."

20.2.7. If the Approved User utilized **COVID-19 Questionnaire or COVID-19 Antibody Testing Data**, the following acknowledgement must be included as a separate paragraph after the ATP or ATP and ACR acknowledgement:

In addition, this study is based in part on COVID-19 data which was supported by a Canadian Institutes of Health Research subgrant from the Ontario for Cancer Research (OICR) to Alberta's Tomorrow Project and subgrant funding from the Government of Canada, through the COVID-19 Immunity Task Force and Public Health Agency of Canada.

20.3. Data Availability Statements

If the journal requires information about the availability of and access to the Data used by the Approved User, please use the following statements.

20.3.1. ATP Data only

"Access to individual-level data is available in accordance with the Health Information Act of Alberta and the Alberta's Tomorrow Project (ATP) Access Guidelines and Procedures.To inquire about accessing ATP data contact ATP.Research@cancercarealberta.ca or visit https://myatpresearch.ca"

20.3.2. Alberta administrative health Data

"*Administrative data for this study was extracted from the Health Shared Services Enterprise Data Warehouse with support from the Alberta SPOR Support Unit. The dataset from this study is held securely in coded form within Health Shared Services Provincial Research Data Services. While legal data sharing agreements between investigators and data custodians (including Government of Alberta, Alberta Health Services, and Cancer Care Alberta) prohibit Alberta SPOR Support Unity from making the dataset publicly available, access may be granted to those who meet pre-specified criteria for confidential access. Requests can be submitted through www.absporu.ca*"

21. **Project Completion**

21.1. Final Report

At the conclusion of an Approved Research Project, the Approved User must complete a Final Report on the ATP Researcher Portal. Lay and scientific summaries of the Project's findings are required for the Final Report, as well as a description of all outputs and the returned Derived Data.

21.2. Return of Data

As a condition of access, any new Data (e.g., derived from ATP Data, produced from Biosample analysis, etc.) generated during an Approved Research Project must be returned to ATP to encourage ongoing use of the ATP Resource by the research community.

21.2.1. Upon Approved Research Project Completion, the Approved User is required to provide ATP with a copy of *all* Data generated for inclusion in the ATP Resource in such detail and format as ATP reasonably requires. This includes, but is not limited to:

- Any raw or Derived Data and related syntax
- Materials
- Remaining Biosamples
- Statistical programs and/or laboratory methodologies
- Supporting documentation, including data dictionaries in the standard ATP data dictionary format

21.2.2. All Approved Users will be granted an embargo of 6 months after the return of Results, Data and/or Biosamples prior to any re-release by ATP, unless a different embargo period is negotiated.

21.3. Data Destruction

Approved Users are required to delete all individual level raw Data that they were provided in order to complete the Approved Research Project.

21.3.1. If the Approved User's Institution requires that individual level raw Data be retained past the Approved Research Project Completion, this will not supercede ATP's Access Guidelines and Procedures. Instead, ATP will retain the individual level raw Data in its original form on behalf of the Approved User should there be a need to verify or replicate the work.

21.3.2. ATP will give reasonable consideration to written requests (containing an appropriate explanation) for an extension of time limits described in these guidelines.

22. **Intellectual Property (IP)**

ATP and CCA adhere to the AHS IP Policy (Document #1137, effective November 8, 2012) and the AHS IP Procedure Manual. The definition of IP is included in the glossary of this document. One of the main objectives of AHS's IP policy is to provide guidance on the rights and obligations of AHS/ATP and IP Creators in the disclosure, ownership, transfer, Commercialization and revenue sharing of IP that may arise as a result of analyses on the ATP Resource released by ATP to an Approved User. IP Creators should note that each innovation is different and factors to consider will therefore vary between Approved Research Projects.

Full details of CCA/AHS IP policy and procedures may be obtained by emailing ATP at ATP.Research@cancercarealberta.ca.

22.1. IP Ownership Considerations

22.1.1. ATP is the owner of the property in the databases and the Biosamples (including any such future collections as may occur) and retains all the intrinsic IP rights to the ATP Resource. Approved Users are granted limited licenses (but not any ownership rights) to use the Data and/or Biosamples to conduct an Approved Research Project for a particular period of time. These rights are not assignable or transferable, and nor is there any ability to sub-license.

22.1.2. If an Approved User creates separate datasets as a result of their use of the ATP Resource, then IP rights in the Approved User generated datasets will be owned by the Approved User and/or their Institution, subject to the requirement to return such datasets to ATP and grant ATP a non-exclusive license for its use on an irrevocable, perpetual, worldwide, fully paid-up, royalty free, fully sub-licensable basis. These datasets will, therefore, be available for use by other Approved Users who are granted access use the Resource (after such embargo periods as may apply). However, ATP would not expect naturally occurring genetic sequences, biomarkers, proteins or biochemical processes to be made the exclusive preserve of one party.

22.1.3. ATP/CCA/AHS will have no claim over inventions, downstream discoveries and associated IP rights that are developed by Approved Users as a result of using the ATP Resource, unless specified differently in the Access Agreement between Approved Users and ATP/CCA/AHS. However, in the event of Commercialization of IP rights owned by an IP Creator, ATP/CCA/AHS will expect 33% of any Net Revenues to be returned to ATP/CCA/AHS.

22.1.4. All IP considerations will be specified in each Access Agreement between Approved Users and ATP/CCA/AHS for each Approved Research Project and any considerations outlined in the Access Agreement will supersede any listed in the ATP Access Guidelines and Procedures.

22.1.5. Should any IP rights be owned by ATP/CCA/AHS, the procedures described in the AHS IP Policy (Document #1137, effective November 8, 2012) and AHS IP Procedure Manual and outlined below in Sections 22.2 to 22.4 will apply.

22.2. IP Assessment of CCA/AHS Owned IP

22.2.1. IP assessment is a necessary step in the due diligence conducted by ATP/CCA/AHS to maximize return on investment while minimizing risks and upcoming issues associated with CCA/AHS owned IP. CCA/AHS aims to assess IP at the outset during its developmental phase with the IP Creator so as to determine whether there is an IP position and evaluate the need to protect the IP, which will be important considerations in shaping the level of involvement and resources required on the part of CCA/AHS . CCA/AHS may request an external agency oversee all or part of the assessment or accept assessments previously completed by an external agency.

22.2.2. The procedure to assess IP begins with a submission of a report of invention (ROI) by an Approved User to ATP. ATP will forward the ROI for examination by the appropriate CCA/AHS officer or executive. Assessment of IP will be done on a variety of factors and the advice of external experts may be sought. If the assessment shows there is opportunity for Commercialization, this is presented to the IP Creator with written recommendations as to next steps, and CCA/AHS proceeds with any required patent protection. The CCA/AHS officer or executive may require that a business plan be developed.

22.2.3. Records of IP development must be kept by the IP Creator in accordance with sound scientific practice where protectable IP may arise in the course of work on any Approved Research Project. Records of IP development shall be made available to the appropriate AHS officer or executive if requested.

22.3. Commercialization and Revenue Sharing of CCA/AHS Owned IP

22.3.1. The CCA/AHS officer or executive may convene a working group for each IP Commercialization project upon an assessment of the IP. The working group will include an *ex officio* member of ATP staff. The final Commercialization strategy of the IP will be determined by the CCA/AHS officer or executive after consultation with the IP Creator and the working group as appropriate. The IP Creator will be periodically consulted on the IP Commercialization and such revenues as may arise. The IP Creator will not be responsible for paying any costs relating to the Commercialization of ATP/CCA/AHS owned IP.

22.3.2. If the CCA/AHS officer or executive determines that CCA/AHS no longer wishes to continue to commercialize the IP, CCA/AHS may discontinue such efforts provided that there are no outstanding contractual commitments, and the IP Creator has been offered a transfer of any existing right relating to the IP in accordance with the Transfer of Ownership to the Intellectual Property Creator procedure.

22.3.3. CCA/AHS shall maintain a perpetual, royalty free, non-exclusive, and irrevocable license to make, use and modify any IP transferred back to the IP Creator solely for use by CCA/AHS for not-for-profit activities or for the provision of health care services. CCA/AHS shall not sell or sub-license IP that has been assigned back to the IP Creator.

22.3.4. The CCA/AHS officer or executive consults with the working group to make decisions regarding revenue sharing and in exceptional circumstances may enter into alternate arrangements other than those described in the AHS IP policy.

22.3.5. Before CCA/AHS commercializes the IP, ATP/CCA/AHS and the IP Creator enter into an agreement which, at minimum, specifies how Net Revenues are distributed when the relationship between ATP/CCA/AHS and the IP Creator ceases to exist and describes the rules for collecting, reporting and paying Net Revenues to each party. All revenues are paid directly to ATP/CCA/AHS and distributed by the appropriate CCA/AHS officer or executive.

22.3.6. In some circumstances, CCA/AHS may determine that it is appropriate to obtain stock, stock options, warrants or similar financial options in lieu of or in addition to cash in exchange for the transfer or license of an invention owned by CCA/AHS .

22.3.7. In the event of multiple IP Creators, the IP Creators determine the division of Net Revenue among them, which is proportionate to their relative contributions to the IP.

23. **Audits**

23.1.1. On reasonable notice to the Approved User, and in order to confirm or investigate compliance with the Access Agreement, ATP may itself or via appropriate third parties inspect the premises and other relevant facilities of the Approved User, in order to review the security, storage or other arrangements for the Coded Data and/or Biosamples.

23.1.2. ATP will bear the costs of such audits unless a material default within the procedures and processes of the Approved User is discovered, in which case the Approved User will be obliged to reimburse the reasonable costs of ATP and any relevant third parties.

23.1.3. If ATP deems it appropriate, ATP will make recommendations to the Approved User and the Approved User's Institution to improve their compliance with the Access Agreement, and expects that the recommendations will be implemented by the Approved User and their Institution within 15 business days.

24. **Incidental Findings**

24.1.1. As a general principle, ATP will not return individual research Results from analyses conducted by Approved Users back to Research Participants. Nevertheless, given the duration of ATP and the impossibility of foreseeing the nature of Research Projects that may be conducted using the ATP Resource, Approved Users shall be aware of the possibility of a requirement that ATP may decide to return validated Results back to individual Research Participants if such information is determined to be critical for the care of the Research Participant. The decision regarding this return, whether and what to return, and how to return will be made in consultation with appropriately qualified medical advisors, the CanPath Ethics, Legal and Social Issues Standing Committee and the relevant research ethics boards.

24.1.2. In any situation in which Results of analyses are returned to ATP Research Participants, this process will be managed by ATP, and not by the Approved User who, in keeping with the ATP Access Guidelines and Procedures, will not have access to any contact information for Research Participants.

25. **Compliance with the ATP Access Guidelines and Procedures**

25.1.1. The Approved User and their Institution shall comply with the ATP Access Guidelines and Procedures, the Access Agreement as well as any renewals or revisions of same. They also agree to follow all applicable laws and regulations in regard to the subject matter of the ATP Access Guidelines and Procedures.

25.1.2. If an Approved User or Approved User's Institution breach the provisions of the Access Agreement, it could lead to immediate revocation of the approval to use the ATP Resource. Any Biosamples transferred to the Approved User may be retrieved by ATP, and costs related to packing and shipping will be borne by the Approved User. It may also lead to other actions, such as informing the Approved User's Institution, funders, as well as regulatory bodies, and prohibiting further access to the Resource by the Approved User and/or Approved User's Institution. Serious breaches of any agreement(s) will be prosecuted to the full extent of the law.

25.1.3. In addition, in the event of non-compliance, the Approved User and the Approved User's Institution will not be able to use any part of the ATP Resource or any outcome of an Approved Research Project carried out based on the ATP Resource.

25.1.4. Notification of compromised data security, integrity or confidentiality must be reported immediately to ATP, and the Approved User must submit a Privacy Breach Notification form to ATP.

26. **Disclaimers and Limitations of Liabilities**

26.1.1. The Data and Biosamples that have been collected, processed and stored by ATP are experimental in nature and provided to Approved Users without any representations or warranties, express or implied, including but not limited to any warranty of merchantability or fitness for a particular purpose. The Approved User and the Approved User's Institution agree to assume all liability for damages which arise from the Approved User's use, storage or disposal of the Biosamples and Data, and ATP and CCA/AHS shall not be liable to the Approved User or Approved User's Institution for any loss, claim or demand made, due to or arising from the use, storage or disposal of the Data and Biosamples by the Approved User or the Approved User's Institution.

26.1.2. It is not the responsibility of ATP to inform Approved Users of any in progress, approval pending or approved Intellectual Property claims or proprietary rights of any third parties.

26.1.3. ATP bears no legal responsibility for the accuracy, provenance, comprehensiveness or integrity of the Data and/or Biosamples supplied.

26.1.4. The Approved User will indemnify ATP and CCA/AHS against all losses (whether direct or indirect, reasonably foreseeable or specifically contemplated by all parties), damages, costs, expenses (including but not limited to reasonable legal costs and expenses) that it incurs directly as a result of: i) any material breach of the Access Agreement by the Approved User; or ii) any negligence or willful default of the Approved User, provided that CCA/AHS agrees to use its reasonable endeavors to mitigate any loss.

26.1.5. If the whole or any part of a provision of the Access Agreement is void, unenforceable or illegal for any reason, that provision will be severed and the remainder of the provisions of the Access Agreement will continue in full force and effect as if the Access Agreement had been executed with the invalid provision eliminated.

26.1.6. The Access Agreement will be governed by and construed in accordance with Albertan and Canadian law and the parties irrevocably agree that the Albertan and Canadian courts will have exclusive jurisdiction over any suit, action, proceedings or dispute arising out of, or in connection with, the Access Agreement.

26.1.7. ATP will keep copies of all application forms, review forms, minutes/proceedings of Access Committee meetings, and all associated correspondence or other relevant documents on file at ATP's offices in Calgary, AB, Canada (or in a secure off-site storage facility). Records will be stored securely in electronic or paper format. Records will be retained for the duration of ATP.

27. **Ancillary Studies**

Continued involvement of Research Participants in ATP is critical to the long-term goals of ATP, and as such the following guidelines are in place to minimize Research Participant burden while allowing for additional Data and/or Biosample collection.

27.1.1. ATP may consider ad hoc requests to collect additional Data and/or Biosamples from ATP Research Participants if such projects are of mutual benefit to ATP as well as the investigator requesting the collection. ATP must be consulted prior to inclusion in any ethics or funding proposals.

27.1.2. Interested Applicants should contact ATP and request an Ancillary Study Proposal Form. Preliminary evaluation of the proposals will be conducted by the ATP senior management team based on the potential enrichment value of the Ancillary Study to the ATP repositories and the operational implications.

27.1.3. Ancillary Study Proposal Forms which are deemed to be feasible by the ATP Senior Management team will be brought to the ATP Scientific Steering Committee for discussion and evaluation based on the following criteria:

i) value to the ATP Resource
ii) feasibility
iii) 'fit' with the ATP vision and mission
iv) esearch Participant burden
v) resources required
vi) resource contribution by the Applicant
vii) ethical and practical considerations

27.1.4. Applicants will be informed of the outcome of the review by ATP. Successful Applicants are expected to develop protocols in collaboration with ATP and obtain all necessary ethics approvals and funding.

27.1.5. All additional Data and/or Biosamples collected under these conditions will be added to the ATP Resource and will be made available to the research community after one year following completion of Data and/or Biosample collection and processing, unless an alternative embargo period has been agreed upon.

27.1.6. Applicants will be expected to contribute to the costs of implementation, collection and processing of any additional Data or Biosamples done for the purpose of an Ancillary Study.

References

Borugian MJ, Robson PJ, Fortier I et al. (2010) The Canadian Partnership for Tomorrow Project: Building a pan-Canadian research platform for disease prevention. *Canadian Medical Association Journal*, 182(11): 1197-1201.

Bryant HE, Robson PJ, Ullman R, Friedenreich C & Dawe U (2006) Population-based cohort development in Alberta, Canada: a feasibility study. *Chronic Diseases in Canada*, 27(2): 55-63.

Bush MA, Martineau C, Pronk JA, Brule D. (2007) Eating Well with Canada's Food Guide: "A tool for the times". *Canadian Journal of Dietetic Practice and Research* 68(2): 92-6.

Cerin E, Saelens BE, Sallis JF, Frank LD. (2006) Neighborhood Environment Walkability Scale: validity and development of a short form. *Medicine and Science in Sports and Exercise* Sep;38(9): 1682-91.

Craig CL, Marshall AL, Sjostrom M, Bauman AE, Booth ML, Ainsworth BE, et al. (2003) International physical activity questionnaire: 12-country reliability and validity. *Medicine and Science in Sports and Exercise* Aug; 35(8): 1381-95.

Csizmadi I, Kahle L, Ullman R, et al. (2007) Adaptation and evaluation of the National Cancer Institute's Diet History Questionnaire and nutrient database for Canadian populations. *Public Health Nutrition*, 10(1): 88-96.

Friedenreich CM, Courneya KS, Neilson HK et al. (2006) Reliability and validity of the past year total physical activity questionnaire. *American Journal of Epidemiology*, 163(10): 959-970.

International Committee of Medical Journal Editors. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (Updated December 2014). Available at http://www.icmje.org/, accessed on January 23, 2015.

OBiBa, Open Source Software for BioBanks, www.obiba.org

During this document's original development, access policies from the following cohorts were consulted:

- 1958 Birth Cohort (1958 National Child Development Study)
- Avon Longitudinal Study of Parents and Children
- Born in Bradford
- Canadian Health Measures Survey
- Canadian Longitudinal Study on Aging
- Canadian Partnership for Tomorrow Project
- CARTaGENE
- European Prospective Investigation into Cancer and Nutrition
- Framingham Heart Study
- Generation Scotland
- LifeGene

- Ontario Health Study
- UK Biobank

Appendix 1: ATP Authorship Guidelines for Publications

1. Introduction

1.1. These guidelines are intended to inform authorship considerations and discussions relating to any scientific manuscripts or other Publications arising from work connected directly with ATP or using the ATP Resource. All manuscripts must be approved by ATP prior to submission for publication. Further information about the submission process is outlined in the Publications and Other Outputs section of the ATP Access Guidelines and Procedures (see Section 20). Any proposed deviation from the authorship guidelines should be discussed with ATP in advance of submission for approval.

1.2. It is anticipated that the adoption of these guidelines will help prevent grievances that cannot be resolved by informal discussion.

1.3. ATP guidelines are designed in accordance with those of the International Committee of Medical Journal Editors (ICMJE, www.icmje.org).

2. Authorship

2.1. An author is generally considered to be someone who has made substantive intellectual contributions to a Publication and who consents to be named as an author. Authorship establishes accountability, responsibility and credit for scientific information reported in Publications. Authorship should be limited to those individuals who have substantially contributed to the work documented in the manuscript and who have shared responsibility for and intellectual ownership over the Results and contents of the Publication.

2.2. Authorship and style of authorship of reports and Publications should be agreed upon at the start of any work intended to lead to publication.

2.3. To receive authorship credit, all of the following criteria should be met:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work,
2. Drafting the work or revising it critically for important intellectual content,
3. Final approval of the version to be submitted for publication,
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

2.4. All individuals who meet all four criteria should be listed as authors. Any author should also be able to identify which co-authors are responsible for specific other parts of the work. However, all individuals who meet the first criterion in Section 2.3 should have

SAMPLE - NOT FOR SUBMISSION

the opportunity to participate in the review, drafting and final approval of the manuscript.

2.5. If an ATP staff member meets all four authorship criteria, authorship credit should be offered.

2.6. The ordering of authors within the list of those authors who fulfill all four criteria in Section 2.3 should be guided by three principles:

1. The person who has taken the lead in writing is entitled to be the first author.
2. The person who has chief academic responsibility for the piece of research is entitled to be the last named author.
3. Those who have made a major contribution to analysis or writing (i.e. more than commenting in detail on successive drafts) are entitled to follow the first author immediately; where there is a clear difference in the size of these contributions, this should be reflected in the order of these authors.

2.7. When a large multi-author group has conducted the work, the group ideally should decide who will be an author before submitting the manuscript to ATP for approval.

2.8. It should be noted that acquisition of funding, general supervision of a research group, creation or modification of an assessment instrument (e.g., questionnaire) used to obtain information, technical or language editing and proofreading alone do not constitute grounds for authorship. In addition, it will not be the responsibility of ATP to determine who qualifies for authorship nor to arbitrate authorship conflicts with Approved Users.

3. Corresponding Author

3.1. The corresponding author is the one individual who is responsible for all contact with ATP and ensuring all publication requirements are met. When a trainee (e.g. a graduate student or post-doctoral fellow) is the first author on a manuscript, their supervisor (or Co-Applicant) will be the corresponding author in most cases.

4. Acknowledgements

4.1. All those who make a substantial contribution to a paper without meeting the authorship criteria listed in Section 2.3 should be acknowledged (with their consent), usually in an acknowledgement section specifying their contributions.

SAMPLE - NOT FOR SUBMISSION

Appendix 2: ATP Conflict of Interest Considerations

Introduction
These considerations aim to ensure that ATP's decision making processes for access to the ATP Resource are conducted in accordance with the highest standards of integrity. The key principle guiding access is the promotion of high quality research into the etiology of cancer and other chronic diseases.

These considerations align with the AHS Conflict of Interest Bylaw however, in case of a discrepancy, the AHS Conflict of Interest Bylaw will take precedence.

Application of Considerations
These considerations apply to:

- Any individual involved in the access review process
- ATP's Scientific Director and all ATP staff

Each individual covered by these considerations has an ongoing responsibility to comply with their terms. In complying with these terms, an interpretation should be taken which ensures adherence to both the spirit and the letter of these considerations.

Guiding Principles
Decisions concerning applications for access to the ATP Resource should be guided by ATP's Access Guidelines and Procedures and Terms of Reference and should be made free from external influences (such as related academic interests or positions of responsibility held outside of ATP).

Individuals must be alert to the risk of a conflict of interest arising, and appreciate that this is an ongoing responsibility. They must not make any academic or financial gain as a result of involvement in ATP's decision making processes.

A conflict of interest in this context specifically includes academic, financial, or other conflicts which (directly or indirectly) might interfere with, limit or compromise the ability of the individual to review Research Proposals to use the ATP Resource in an objective manner.

Managing Conflicts
If an individual identifies an actual, potential or perceived conflict of interest with any Access Application under review, they should disclose the nature and extent of this conflict to ATP's Research Operations Lead immediately.

Individuals should declare all direct and indirect academic interests in relation to an Access Application, including (but without limitation) being: involved in the preparation of the Access Application, involved in a "competing" research activity, and/or in a current collaboration or co-investigation with the Applicant or other investigators named on the Access Application.

SAMPLE - NOT FOR SUBMISSION

If an individual has a commercial interest in the Applicant Institution and/or funding organization for the Applicant Institution, this should be disclosed to ATP's Research Operations Lead.

Disclosures of conflict of interest may either be specific to a particular application or may be general with respect to an Applicant, Applicant Institution and/or funding organization. A general disclosure will exempt an individual from making repeat disclosures in respect to future applications involving that individual, Institution and/or funding organization.

Any Applicant or other person who considers that a conflict of interest exists should disclose their concern to ATP's Research Operations Lead.

Conflict Action Points

Prior to sending out an Access Applciation for peer review and at the beginning of each meeting of the Access Committee, the Chair will request that reviewers and Committee members declare any actual, potential or perceived conflicts of interest related to the Access Applciations that are under consideration.

In the event that a disclosure is made by any individual involved in the access review process, it will be for the Chair to determine whether it is a material conflict of interest.

In the event of a material conflict of interest, the individual must not take part in any decisions relating to that Access Applciation. In particular, the individual must not:

- be involved in the review of the Access Applciation nor any appeals or conditions which may be imposed, and
- be involved in the decisions about the Access Applciation, and
- receive any further papers or information concerning the Access Applciation, and
- attend those parts of any meetings in which the Access Applciation is discussed.

Conduct

All peer reviewers, members of the Access Committee, all support staff and any other individuals convened to review a Research Proposal and/or attend a meeting, must agree to uphold the confidentiality of:

- information and documents distributed prior to the meeting, brought to the attention of members during the meeting or relating to participation at the meeting, and
- deliberations and the minutes pertaining to the Access Committee meeting.

These considerations will be subject to periodic review. Individuals should be familiar with the most recent version of the considerations.

If individuals have any queries or concerns regarding the application of these considerations, they should consult with ATP's Research Operations Lead

SAMPLE - NOT FOR SUBMISSION