# Alberta's Tomorrow Project
# Access Guidelines and Procedures

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In Partnership With
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Partenariat canadien contre le cancer

# Alberta's Tomorrow Project Access Guidelines and Procedures

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## 2. **Aim and Purpose of Alberta's Tomorrow Project (ATP)**

Alberta's Tomorrow Project 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, Alberta's Tomorrow Project 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 who chose at the time of CanPath consent not to attend a study centre and thus did not contribute blood or urine. ATP invited existing ATP participants and recruited additional Alberta residents aged 35 to 69 years to take part in CanPath. Once recruitment was completed in 2015, a total of 54,932 participants had been recruited to ATP and 39,959 of those had also consented to 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. An additional 9,691 saliva samples, donated by CanPath participants, were used for the extraction of DNA. In 2018, the Manitoba Tomorrow Project (TMTP) also joined CanPath as the sixth cohort, and in 2020 the Saskatchewan Partnership for Tomorrow's Health (Saskatchewan PATH) joined as the seventh cohort of CanPath.

The aim of Alberta's Tomorrow Project 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.

## 3. **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 Alberta Health Services (AHS) Research Information Management Policy (Document #1146, effective October 16, 2019). It should be noted that all 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, biosamples, data associated with those biosamples, 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 Alberta Health Services (AHS) Disclosure Notice or Material Transfer Agreement (for release of biosamples). 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.

For a high level overview of the access process, please see Figures 1-2.

## 4. **Glossary of Terms**

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 of a Research Proposal involving Biosamples and to make decisions regarding approval of each such Research Application.

Alberta Health Services (AHS): a regional health authority, established under the Regional Health Authorities Act.

Alberta's Tomorrow Project (ATP): a longitudinal research platform promoting research into the etiology of cancer and other chronic diseases. ATP is considered to be a resource of AHS and is subject to AHS 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. It is an integral part of the Disclosure Notice.

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, Research 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 21).

Applicant: a Canadian or international researcher 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 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 Disclosure Notice.

Approved Research Project: a Research Proposal 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 Disclosure Notice and Material Transfer Agreement. Also includes such future samples as may be collected by Ancillary Studies.

Canadian Partnership for Tomorrow's Health (CanPath): a large, high quality, "population laboratory" that will facilitate 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, The Manitoba Tomorrow Project, and Saskatchewan PATH.

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 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.

Disclosure Notice: a document developed by AHS which informs Approved Users, AHS (ATP) and any other groups of their responsibility to comply with legislation, AHS (ATP) policies and procedures and any conditions imposed by AHS (ATP) specifically to the Approved Research Project. It must be signed prior to the transfer of ATP's Coded Data and/or Biosamples to the Approved User.

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.

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 an AHS employee, an individual working in association with an AHS employee, an individual using AHS resources (which includes ATP), or a partnership of one or more individuals or organizations.

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

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 linking Coded Data to a Research Participant.

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

Research Proposal: an application, still subject to approval, 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.

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.

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

## 5. Letters of Support

**5.1.1.** ATP is willing to 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.

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

**5.1.3.** Potential Applicants who require a letter of support to complete funding or ethics applications are required to 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. Instructions for how to register are found on https://myatpresearch.ca/Account/Register. 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 fee estimate will be produced, and the Feasibility Inquiry Form will be approved.

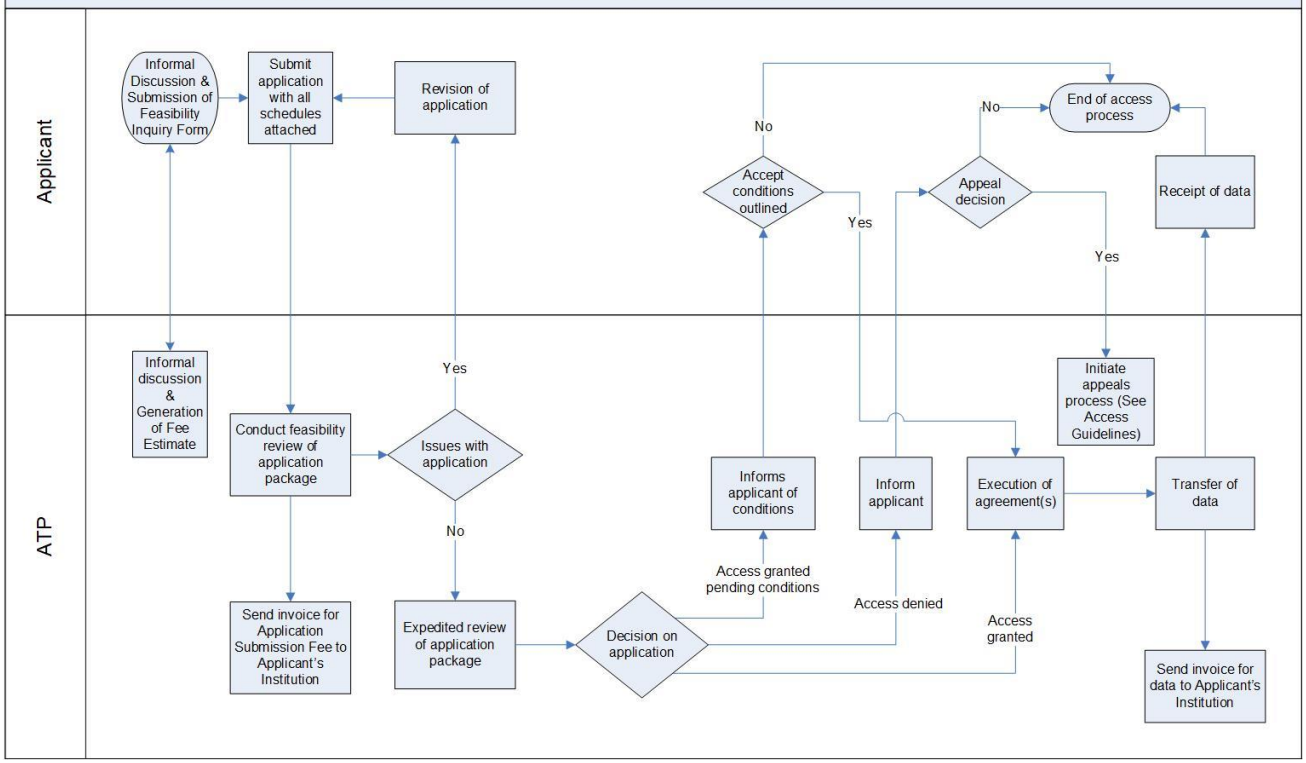
**5.1.4.** Evidence of ethical approval for a Research Proposal is not required to receive a letter of support for funding applications.

**5.1.5.** 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 Biosamples for any potential Applicant.

## 6. Data Access Process – 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 AHS Disclosure Notice. The access process is visually represented in Figure 1.

Figure 1. Visual Representation of the ATP Access Process for Data Only Requests




## 6.1. Informal Discussion

**6.1.1.** 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/Account/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.

**6.1.2.** ATP's Data Access team will inform a potential Applicant if their proposed project may be similar to another Approved Project already ongoing (see Section 16).

**6.1.3.** Please allow 5 business days for any preliminary analyses to be run.

**6.1.4.** It is highly encouraged that a potential Applicant contact ATP at least 1 month prior to submitting their application, to allow for a Fee Estimate (see section 17) and to ensure the project is feasible.

**6.1.5.** When the project is deemed feasible, the Feasibility Inquiry Form will be approved in the system and the Applicant will receive an email.

### 6.2. Submission of Application Form

**6.2.1.** 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.

**6.2.2.** Applications may be submitted at any time and they will be reviewed on an ad hoc basis.

**6.2.3.** Applicants are required to submit a completed application form, a Research Proposal that is specific to ATP, ethics review board application and approval, evidence of funding, and CV to begin the process of gaining access to the ATP Resource. ATP will acknowledge receipt of the application form within 5 business days of submission. In exceptional circumstances, ATP may accept Research Proposals without ethics review board approval if an application to the ethics review board has been submitted. However, the Research Proposal 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.

### 6.3. Feasibility Review

**6.3.1.** Shortly after an Application Form 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 protocol that relates directly to the submitted application form
v) Inclusion of evidence of funding
vi) Status of the ethical approval for the specific research protocol being submitted
vii) Consistency between the ethical application and approval, the research protocol, 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

**6.3.2.** 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 Research Proposal will be advanced to the Expedited Review.

### 6.4. Expedited Review by ATP

**6.4.1.** The ATP Expedited Review process will be undertaken by ATP's Research Lead, Data Access Research Associate and Data Manager or designates. The following areas will be examined: the Applicant, the detail and scientific robustness of the research proposal and application form and the 'fit' with ATP's purpose. A decision regarding access will be communicated to the Applicant within 1 week after the successful completion of the Expedited Review.

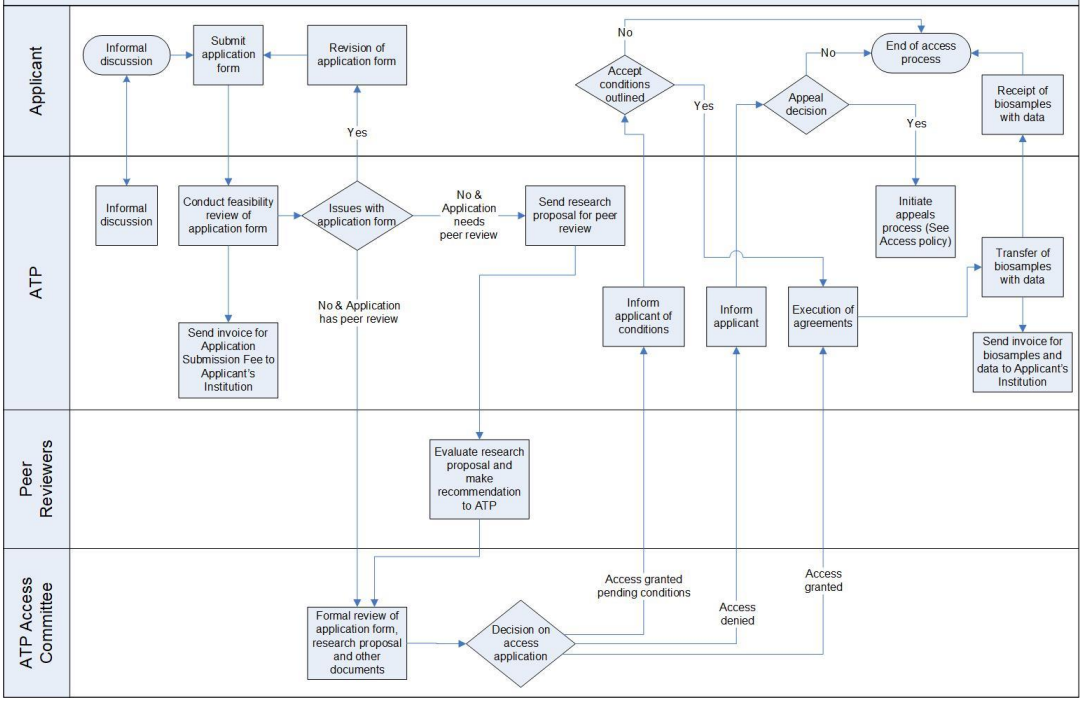
**6.4.2.** ATP will send a letter to the Applicant outlining the decision regarding access (approval, approval pending conditions or rejection) and, if appropriate, the conditions which would permit approval of the Research Proposal.

**6.4.3.** The Applicant will have 3 weeks to agree to the conditions proposed by ATP and if agreeable, access will be granted. However, if agreement cannot be reached, access will not be permitted and a new application form for a new Research Proposal must be submitted with the application submission fee and evidence of ethical approval.

## 7. Access Process (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 AHS Material Transfer Agreement. The access process is visually represented in Figure 2.

Figure 2. Visual Representation of the ATP Access Process for Biosamples with Data



## 7.1. Informal Discussion

**7.1.1.** 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/Account/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.

**7.1.2.** ATP's Data Access team will inform a potential Applicant if their proposed project may be similar to another Approved Project already ongoing (see section 16).

**7.1.3.** Please allow 5 business days for any preliminary analyses to be run.

**7.1.4.** It is highly encouraged that a potential Applicant contact ATP at least 1 month prior to submitting their application, to allow for a Fee Estimate (see section 17) and to ensure the project is feasible.

**7.1.5.** When the project is deemed feasible, the Feasibility Inquiry Form will be approved in the system and the Applicant can begin the online application form.

## 7.2. Submission of Application Form

**7.2.1.** Applications must be completed on the ATP Researcher Portal. Once the Feasibility Inquiry Form has been approved, the Applicant may begin the formal application form.

**7.2.2.** Applications may be submitted at any time and they will be reviewed on an ad hoc basis.

**7.2.3.** Applicants are required to submit a completed application form, a Research Proposal specific to ATP, ethics review board application and approval, evidence of funding, and CV to begin the process of gaining access to the ATP Resource. ATP will acknowledge receipt of the application form within 5 business days of submission. In exceptional circumstances, ATP may accept Research Applications without ethics review board approval if an application to the ethical review board has been submitted. However, the Research 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.

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

**7.2.5.** 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.

## 7.3. Feasibility Review

**7.3.1.** Shortly after an Application Form 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 volume needed and justification for each type of Biosample (if multiple types required)
iv) Availability of the Coded Data and Biosamples for release, and the applicability to the research question
v) Inclusion of the research protocol that relates directly to the submitted application form
vi) Inclusion of evidence of funding
vii) Status of the ethical approval for the specific research protocol being submitted
viii) Consistency between the ethics review board application and approval, the research protocol 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

**7.3.2.** 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 Research Proposal will be advanced to the next step in the access process.

## 7.4. External Peer Review

### 7.4.1. Research Proposal ***with*** peer review prior to submission to ATP

**7.4.1.1.** If a Research Proposal underwent peer review prior to submission to ATP, ATP may not require additional peer review prior to the formal review by the ATP Access Committee.

**7.4.1.2.** All relevant documentation and evidence of the prior peer review must be submitted to ATP along with the application form.

**7.4.1.3.** It should be noted that ATP reserves the right to send any Research Proposal for peer review even if one has been completed prior to submission to ATP.

### 7.4.2. Research Proposal ***without*** peer review prior to submission to ATP

**7.4.2.1.** If a Research Proposal has not undergone peer review prior to submission to ATP, ATP may require peer review by external experts. If ATP requires peer review, ATP will seek input from three independent experts as to the scientific quality of the Research Proposal. Each peer review will address four main themes: the Applicant, the originality of the research proposal, the research approach and the potential impact of the research. Peer reviews are completed and returned to ATP within two weeks of receipt by the reviewer. The reviews will be presented to the ATP Access Committee and will assist in forming a decision on granting or denying access.

**7.4.2.2.** If a Research Proposal has not undergone formal peer review but has been successful in a recognized grant competition (e.g. Canadian Institutes of Health Research, Canadian Cancer Society, etc.), ATP may not require additional peer review prior to the formal review by the ATP Access Committee. The Applicant must provide the reviewer comments from the grant competition to ATP with their completed Research Application.

## 7.5. Formal Review by ATP Access Committee

**7.5.1.** 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 a Research Proposal. A minimum of 3 members will evaluate Research Proposals according to the terms of reference included in Appendix 8. In summary, the following aspects will be evaluated:

i) Relevance of the Research Proposal to the vision and aim of ATP
ii) Experience and qualifications of the Applicant
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) 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 biological material 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)

The Access Committee membership and structure is described in Appendix 8.

**7.5.2.** The application form, relevant supporting documentation and ATP's Biosample with Data Review Form for Access Committee will be sent to the voting members of the Access Committee by ATP three weeks prior to the Access Committee meeting date. Voting members will complete the Biosample with Data Review Form for Access Committee within three weeks. The Committee members will indicate if the Research Proposal is either approved, rejected or approved pending conditions.

**7.5.3.** In the case of unanimous approval, ATP will notify all Access Committee members and ensure that all voting members and the Chair agree that there is no need to meet for further discussion. ATP will then send a letter of approval to the Applicant.

**7.5.4.** In the case of unanimous conditional approval, it may not be necessary to have a meeting and email communication may be used to formulate feedback for the Applicant. ATP will notify all Access Committee members and ensure that all voting members and the Chair agree that there is no need to meet for further discussion. ATP will send a letter to the Applicant outlining the Access Committee's decision (e.g., approval pending conditions) and the conditions which would permit approval of the Research Proposal.

**7.5.5.** 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 Research Proposal.

**7.5.6.** The Applicant will have 3 weeks to agree to the conditions proposed by the Access Committee and if agreeable, access will be granted. However, if agreement cannot be reached, access will not be permitted and a new application form for a new Research Proposal must be submitted with the application fee and evidence of ethical approval.

## 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 (Section 6) with the only difference being the review process. A condensed review process and will be conducted by the ATP Data Manager and the ATP Data Access Team only.

**8.1.2.** Staff members seeking access to biosamples and data will undergo the same process as external researchers (section 7).

**8.1.3.** ATP staff members who are the principal investigators of a Research Proposal are exempt from fees but remain bound by all other policies including the conflict of interest considerations as outlined in Appendix 3.

## 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., the Alberta Cancer Registry dataset which CanPath does not hold or data collected prior to the formation of CanPath in 2008) by submitting an application to ATP. 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. A Data Disclosure Notice or AHS Data Disclosure Agreement is required for the data obtained directly through ATP. ATP will also honour CanPath's annual progress reports.

## 10. Execution of Agreements

**10.1.1.** Upon approval of the Research Proposal, the Approved User, ATP and AHS will enter into a Disclosure Notice, AHS Data Disclosure Agreement and/or Material Transfer Agreement (MTA) as needed. All parties will be required to sign the agreement(s) and representatives of each implicated Institution may also need to sign.

**10.1.2.** 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 22.2 for more information about CANUE data).

**10.1.3.** Any required agreements will be signed by the ATP Scientific or Strategic Director on behalf of ATP. In the event they are unable to sign the required agreements, the AHS Executive Director of Cancer Research & Analytics will fulfill the role. If an institutional signature is also required from AHS, the AHS Director of Health System Access, Health Evidence & Innovation will sign any required agreements on behalf of Alberta Health Services.

### 10.2. Transfer of Data and Biosamples

Coded Data and Biosamples will only be released to Approved Users once all required agreements have been successfully executed (see section 15 on confidentiality).

### 10.2.1. Transfer of Data

**10.2.1.1.** 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.

### 10.2.2. Transfer of Biosamples

**10.2.2.1.** Once all the required agreements are successfully executed, the Approved User will be responsible for securing any required permits, licenses or other documentation for shipping the Biosamples. This must be completed ***prior*** to ATP removing the biosamples from the ATP biorepository.

**10.2.2.2.** Once all the permits, licenses or other documentation are secured by the Approved User and received by ATP, the requested Biosamples will be removed from the ATP biorepository and will be packaged on dry ice and sent to the location specified by the Approved User on their ATP Research Application form. 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. A trial shipment 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.

**10.2.2.3.** 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 with option to request review by member(s) of the Access Committee 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.

**10.2.2.4.** 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.

## 11. Post 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@albertahealthservices.ca.

### 11.1. Progress Report

**11.1.1.** If an Approved Research Project is scheduled to extend beyond one year, an annual Progress Report form will be required from Approved Users. 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. The due date for the Progress Report will be 1 year after the date the data and/or biosamples was received by the Approved User. Proof of a current annual renewal from the relevant ethics review board must also be submitted with the Progress Report form. If the annual Progress Report form is not submitted within 30 days following the due date, the Disclosure Notice/Material Transfer Agreement may be terminated.

### 11.2. Renewals or Extensions

**11.2.1.** Approved Users will be permitted to extend an Approved Research Project a maximum of two renewals or for a total Approved Research Project length of three years from the date of the Data Disclosure Notice/Material Transfer Agreement execution, whichever is least amount of time. An Approved Research Project may be extended for additional time on a case by case basis, at the discretion of ATP. Any agreements in place will be valid for the total duration of the project, including extensions, if approved by 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.

### 11.3. New Principal Investigator

**11.3.1.** If a new Principal Investigator is named in replacement of the Approved User, the new Applicant must sign a Replacement Approved User Agreement (see Appendix 2) 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 Disclosure Notice and/or Material Transfer Agreement for the Approved Research

Project. The new principal investigator's CV must be submitted to ATP along with all documentation approving the change from the relevant ethics review board. The new Principal Investigator'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.

### 11.4. Institution or contact information change

**11.4.1.** 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.

**11.4.2.** Should there be a change of institution, an updated Disclosure Notice and/or Material Transfer 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.

### 11.5. Significant Changes

**11.5.1.** If an Approved User wishes to use ATP Biosamples and/or Coded Data already supplied for a purpose other than the original purpose outlined in the agreement(s), 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 Scientific Director of ATP, or designate, and 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, an ethical amendment may be required, revised agreement(s) may need to be signed or a new research application form may need to be submitted to ATP with the associated application cost (see Figure 3 for visual representation of process).

### 11.6. Additional Variable or Biosample Requests

**11.6.1.** 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 for evaluation. Additional variable requests will be approved upon ATP consideration. If the request is deemed to be minor by the ATP Scientific Director, or designate, the data will be provided to the Approved User under the same terms and conditions outlined in the original agreements. If the request is deemed to significantly alter the original research proposal, a Significant Change Report form will be required in addition to an Additional Variable Request form (see Figure 3 for visual representation of process).

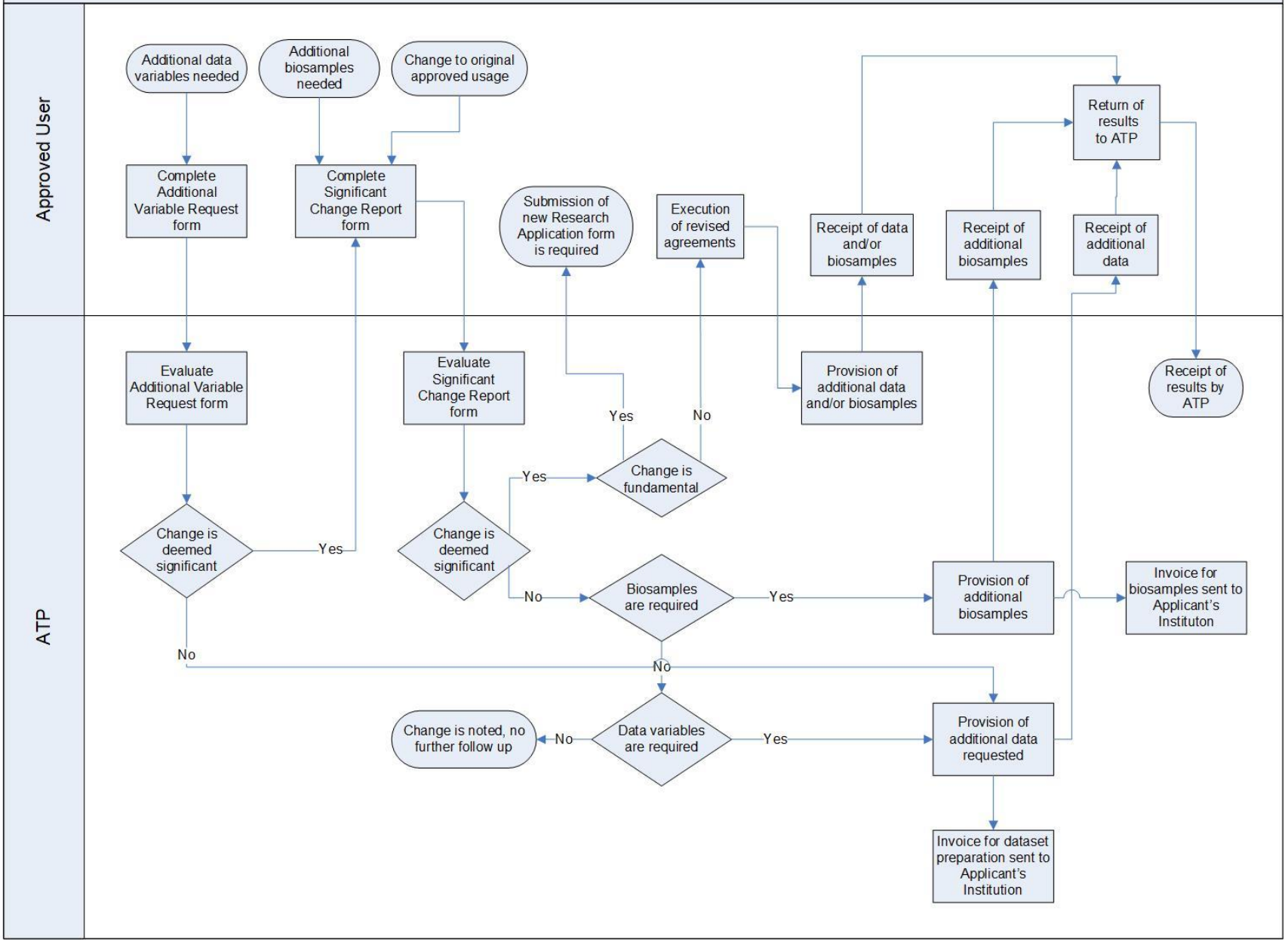
**11.6.1.1.** An updated Disclosure Notice needs to be signed every time additional data elements are released.

**11.6.1.2.** Fees may be charged for generating the dataset for an Additional Variable Request. See Section 17 for more information on Fees.

**11.6.2.** 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 Scientific Director of ATP, or designate, and 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 agreements. If the change is deemed to be significant or fundamental, revised agreement(s) may need to be signed or a new research application form may need to be submitted to ATP with the associated application cost (see Figure 3).

**11.6.2.1.** Fees may be charged for preparing the additional biosamples. See Section 17 for more information on Fees.

Figure 3. Visual Representation of Post Approval Processes for Changes in Requirements for Approved Research Projects



**11.7.** If further changes to the Approved Research Project are needed, they will be considered only on a case by case basis.

**11.8. Additional Funding**

**11.8.1.** If additional sources of funding are obtained during the course of an Approved Research Project, or if the original source of funding has been modified, the Approved User must inform ATP by submitting an Additional Funding Report form on the ATP Researcher Portal.

**11.9. Ethics Renewals**

**11.9.1.** For the duration of an Approved Research Project, active and current 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 form.

**11.10. Final Report Form**

**11.10.1.** At the conclusion of an Approved Research Project, the Approved User must complete a Final Report Form for ATP on the ATP Researcher Portal. A lay and scientific summary of the Project's findings are reported on the Final Report Form, as well as a description of all outputs and the returned derived data.

**11.11. Return of Results, Data and/or Biosamples to ATP**

**11.11.1.** It is a condition of access that any data or variables generated during an Approved Research Project must be returned to ATP to encourage ongoing use of the ATP Resource by the research community. 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 along with supporting documentation, including data dictionaries in the standard ATP data dictionary format.

**11.11.2.** Upon Approved Research Project Completion, ATP will request submission of a Final Report form on the ATP Researcher Portal and Approved Users will be required to delete all individual level raw data that they were provided in order to complete the Approved Research Project.

**11.11.3.** 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.

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

## 12. **Denial of Access**

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

**12.1.1.** The ability of the Applicant to execute the Research Proposal is in doubt or the Research Proposal is considered inadequate 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.

**12.1.2.** 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.

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

**12.1.4.** Without compromising the future scientific value of the ATP Biosample collection, the requested Biosample volume is deemed to be too large in the context of the specific Research Proposal, or the available volume held by ATP is insufficient to fill the request.

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

**12.1.6.** 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 3 for the ATP Conflict of Interest Guidelines).

### 12.2. Appeals

**12.2.1.** 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.

**12.2.2.** The process for appealing a decision concerning a Research Proposal is as follows:

**12.2.2.1.** 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;

**12.2.2.2.** Within 4-6 weeks of receipt of such a request, ATP's Access Committee will review it along with the original Research Proposal (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;

**12.2.2.3.** 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.

**12.2.3.** If, following reconsideration under the appeals process, the recommendation is to deny access, the Applicant will not be able to submit the same Research Proposal 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 agreements 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 application form for a new Research Proposal will have to be submitted.

## 13.**Audits**

**13.1.1.** On reasonable notice to the Approved User, and in order to confirm or investigate compliance with the Disclosure Notice and/or Material Transfer Agreement, ATP may itself or via appropriate third parties:

**13.1.1.1.** Choose to 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.

**13.1.2.** 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.

**13.1.3.** 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 Disclosure Notice and/or Material Transfer Agreement, and expects that the recommendations will be implemented by the Approved User and their Institution within 15 business days.

## 14. **Access Limitations**

**14.1.** 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 Alberta Health Services Legal and Privacy portfolios and in accordance with Alberta's Health Information Act and the Freedom of Information and Protection of Privacy Act.

**14.2.** The Data or Biosamples may not be used for any other purpose other than for the Approved Research Project as described in the Disclosure Notice. The Approved User must inform ATP of ***any*** changes in purpose of the Approved Research Project for continued approval via a Significant Change Report form. The Significant Change Report form will be reviewed by the ATP Scientific Director or delegate. If the change is deemed to be fundamental, the Approved User may be required to submit a new application (with the associated application submission fee) and supporting documentation (including ethics approval) to ATP, and to go through the request review process as described in sections 6-7).

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

**14.4.** Applications for access to Biosamples will be subject to a minimum 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.

**14.5.** Applications will not be accepted from Applicants who wish to access Biosamples to test methodologies, test laboratory/analytical equipment, to perform pilot studies, or for other activities that are not consistent with the goals of ATP. However, discovery research may be permitted if the justification for using ATP Biosamples is sufficiently robust.

**14.6.** 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.

## 15. Confidentiality

### 15.1. Research Participants

Protecting the confidentiality of Research Participants is a primary concern for ATP. As such, the least amount of information principle and the following conditions are in place:

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

**15.1.2.** 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 also 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 AHS may be initiated with the Approved User and their Institution.

**15.1.3.** The 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.

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

**15.1.5.** 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.

**15.1.6.** 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. This includes that researchers cannot present (e.g. in presentations, publications, etc.) aggregate information on groups <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).

**15.1.7.** 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.

### 15.2. Research Proposals

**15.2.1.** All information on Research Proposals submitted to ATP will be kept confidential. 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

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

**15.2.3.** It should be noted that 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. Competing Research

### 16.1. Research Proposals for Coded Data only

**16.1.1.** Prior to submitting a Research Proposal to access the ATP Resource, prospective Applicants are strongly encouraged to contact ATP at ATP.Research@albertahealthservices.ca in order to determine if comparable research is already underway.

**16.1.2.** ATP's Data Access team will inform a prospective Applicant if there is comparable research already underway once the prospective Applicant has completed the Inquiry Form.

**16.1.3.** For Data only applications, ATP will not consider the issue of potential overlap between Research Proposals and/or Approved Research Projects during the Application Review Process.

**16.1.4.** For Data only applications, if similar Research Proposals are received concurrently by ATP for review under the access process, as outlined in section 6, each Research Proposal will be considered separately and evaluated according to the criteria listed in section 6.4.1.

**16.1.5.** There will be no exclusivity of access for data only Research Proposals or Approved Research Projects.

### 16.2. Research Proposals for Coded Data and Biosamples

**16.2.1.** Prior to submitting a Research Proposal to access the ATP Resource, prospective Applicants are strongly encouraged to contact ATP at ATP.Research@albertahealthservices.ca in order to determine if comparable research is already underway.

**16.2.2.** ATP's Data Access team will inform a prospective Applicant if there is comparable research already underway once the prospective Applicant has completed the Inquiry Form.

**16.2.3.** As the amount of Biosamples is limited, ATP may suggest collaboration between Applicants submitting similar Research Proposals concurrently. By encouraging collaboration between Applicants, the Biosamples can be used more efficiently. If the Applicants are not willing to collaborate, each Research Proposal will be considered separately and evaluated according to the criteria listed in section 7.5.1.

**16.2.4.** If a Research Proposal is received that closely resembles an Approved Research Project already begun, a collaboration between the Applicant and the Approved User may be suggested. However, if collaboration is not possible, the Applicant submitting the Research Proposal will be required to provide additional robust justification to warrant access to the Biosamples, and the proposals may be compared against each other.

## 17. **Fees**

### 17.1. Research Proposal Submission Fee

**17.1.1.** There is a fixed application review fee for each Research Proposal of $500.00 CDN to help defray ATP's initial costs for the administration of the review process for the

Research Proposal. This charge will be invoiced for upon submission of the application form.

### 17.2. Dataset Preparation Fees

**17.2.1.** Please contact ATP to determine dataset preparation fees prior to the submission of the completed application form. This charge will be invoiced for on receipt of the completed dataset.

**17.2.2.** Generally, Applicants based in non-profit and/or academic institutions will be charged a subsidized dataset preparation fee.

**17.2.3.** Applicants based in commercial and/or for-profit institutions will be charged a non-subsidized dataset preparation fee.

### 17.3. Biosample Preparation Fees

**17.3.1.** Please contact ATP to determine biosample preparation fees prior to the submission of the completed application form. This charge is payable on receipt of the biosamples and dataset (if applicable).

**17.3.2.** Generally, Applicants based in non-profit and/or academic institutions will be charged a subsidized biosample preparation fee.

**17.3.3.** Applicants based in commercial and/or for-profit institutions will be charged a non-subsidized biosample preparation fee.

**17.3.4.** Approved Users will be responsible for covering any costs related to packing and shipping the Biosamples to meet the conditions outlined in the Disclosure Notice and Material Transfer Agreement (if applicable).

**17.3.5.** 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.

### 17.4. Future Amendments to Fees

**17.4.1.** ATP will keep these fee guidelines under review and it should be noted that the fees may change. Potential Applicants should contact ATP to ensure that they have up to date information concerning fees.

## 18. 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.

**18.1.** Approved Users are encouraged to use their best endeavors to publish the findings of any Approved Research Project deriving from the ATP Resource 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.

**18.2.** Approved Users must submit a final version of any meeting abstracts, conference presentations, online reports/blogs, or any other outputs, other than manuscripts submitted for peer review, to ATP along with a completed ATP Presentation Report form or ATP Alternative Research Output form on the ATP Researcher Portal.

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

i) Any confidential and/or proprietary information has been disclosed
ii) The Publication may bring ATP/AHS into disrepute
iii) The conditions laid out in the ATP Access Guidelines and Procedures and the Disclosure Notice and/or Material Transfer Agreement(s) have been followed
iv) The scope of the reported analysis is compliant with the Approved Research Project

**18.3.1.** 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/AHS reputation and/or adherence to the Disclosure Notice, AHS Data Disclosure Agreement and/or Material Transfer Agreement(s) appear to have been compromised. If it appears that signed agreements or ATP/AHS reputation have been compromised, ATP will seek advice from AHS 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 23). 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.

**18.4.** 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 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.

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

**18.6.** 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.

**18.7.** 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.

**18.8.** 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: Alberta Health, Alberta Cancer Foundation, Canadian Partnership Against Cancer and Health Canada, and substantial in kind funding from Alberta Health Services. The views expressed herein represent the views of the author(s) and not of Alberta's Tomorrow Project or any of its funders."*

**18.9.** 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: Alberta Health, Alberta Cancer Foundation, Canadian Partnership Against Cancer and Health Canada, and substantial in kind funding from Alberta Health Services. Cancer registry data was obtained through linkage with Surveillance & Reporting, Cancer Research & Analytics, 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."*

**18.10.** 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."*

**18.11.** If the Approved User utilized AH derived variables, the following acknowledgement must be included as a separate paragraph after the ATP or ATP and ACR acknowledgement:

*"This study is based in part on data provided by Alberta Health. The interpretation and conclusions contained herein are those of the researchers and do not necessarily represent the views of the Government of Alberta. Neither the Government nor Alberta Health express any opinion in relation to this study."*

**18.12.** If the journal requires information about the availability of the data, please use the following note:
"*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. More information can be obtained via https://myatpresearch.ca."*
If more information is needed, please contact ATP at ATP.Research@albertahealthservices.ca.

**18.13.** 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.

## 19. Intellectual Property (IP)

ATP adheres 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 from Approved Research Project to Approved Research Project.

### 19.1. IP Ownership Considerations

**19.1.1.** 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.

**19.1.2.** 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.

**19.1.3.** ATP/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 Material Transfer Agreement between Approved Users and ATP/AHS. However, in the event of commercialization of IP rights owned by an IP Creator, ATP/AHS will expect 33% of any net revenues to be returned to ATP/AHS.

**19.1.4.** All IP considerations will be specified in each Material Transfer Agreement between Approved Users and ATP/AHS for each Approved Research Project and any considerations outlined in the Disclosure Notice will supersede any listed in the ATP Access Guidelines and Procedures.

**19.1.5.** Should any IP rights be owned by ATP/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 18.2 to 18.4 will apply.

### 19.2. IP Assessment of AHS Owned IP

**19.2.1.** IP assessment is a necessary step in the due diligence conducted by AHS/ATP to maximize return on investment while minimizing risks and upcoming issues associated with AHS owned IP. 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 AHS. AHS may request an external agency oversee all or part of the assessment or accept assessments previously completed by an external agency.

**19.2.2.** 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 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 AHS proceeds with any required patent protection. The AHS officer or executive may require that a business plan be developed.

**19.2.3.** 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.

### 19.3. Commercialization and Revenue Sharing of AHS Owned IP

**19.3.1.** The 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 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 AHS/ATP owned IP.

**19.3.2.** If the AHS officer or executive determines that AHS no longer wishes to continue to commercialize the IP, 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.

**19.3.3.** 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 AHS for not-for-profit activities or for the provision of health care services. AHS shall not sell or sub-license IP that has been assigned back to the IP Creator.

**19.3.4.** The 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.

**19.3.5.** Before AHS commercializes the IP, AHS/ATP and the IP Creator enter into an agreement which, at minimum, specifies how net revenues are distributed when the relationship between AHS/ATP 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 AHS/ATP and distributed by the appropriate AHS officer or executive.

**19.3.6.** In some circumstances, 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 AHS.

**19.3.7.** 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.

**19.4.** Full details of AHS IP policy and procedures may be obtained by emailing ATP at ATP.Research@albertahealthservices.ca.

## 20.**Incidental Findings**

**20.1.** 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.

**20.2.** 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.

## 21.**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.

### 21.1. Requests to collect additional Data and/or Biosamples from ATP Research Participants

**21.1.1.** 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.

**21.1.2.** Interested Applicants should contact ATP and complete an Ancillary Study Proposal Form (see Appendix 9). 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.

**21.1.3.** 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) Research Participant burden

v) Resources required
vi) Resource contribution by the Applicant
vii) Ethical and practical considerations

**21.1.4.** 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.

**21.1.5.** 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.

**21.2.** 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.

## 22. Linkage Data not held by ATP

**22.1.** 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 Linkage 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.

**22.2.** 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 Research Application form 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.

## 23. Linkage Data held by ATP

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

### 23.1. Alberta Cancer Registry (ACR) Data

**23.1.1.** Applicants may request access to a select number of variables from the Alberta Cancer Registry (ACR) that has been linked to ATP participants. If the Research Proposal is approved, the ACR data will be covered under the same ATP Disclosure

Notice, AHS Data Disclosure Agreement and/or Material Transfer Agreement as the other ATP-owned data and/or biosamples requested from ATP.

**23.1.2.** If the Applicant requires additional data from the Alberta Cancer Registry, other than the variables held by ATP, a separate application to AHS' Surveillance & Reporting department will be required. ATP can provide support with the application process. An AHS Data Disclosure Agreement may be required prior to release of data.

### 23.2. Canadian Urban Environmental Health Research Consortium (CANUE) Linkage data

**23.2.1.** 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 ATP Disclosure Notice, AHS Data Disclosure Agreement and/or Material Transfer 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 linkage dataset for the Approved User.

## 24. Compliance with the ATP Access Guidelines and Procedures

**24.1.** The Approved User and their Institution shall comply with the ATP Access Guidelines and Procedures, the Disclosure Notice, AHS Data Disclosure Agreement and/or Material Transfer 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 Alberta's Tomorrow Project Access Guidelines and Procedures.

**24.2.** If an Approved User or Approved User's Institution breach the provisions of the Disclosure Notice and/or Material Transfer 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.

**24.3.** 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.

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

## 25. Disclaimers and Limitations of Liabilities

**25.1.** The Biosamples and Data 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 Alberta Health Services 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.

**25.2.** 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.

**25.3.** The Approved User acknowledges that the Biosamples provided by ATP may contain viruses, latent viral genomes or other infectious agents. The 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.

**25.4.** The Approved User or their Institution will not use the Biosamples in any experiments involving humans and will not 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.

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

**25.6.** The Approved User will indemnify ATP and 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 Disclosure Notice and/or Material Transfer Agreement by the Approved User; or ii) any negligence or willful default of the Approved User, provided that Alberta Health Services agrees to use its reasonable endeavors to mitigate any loss.

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

**25.8.** The Disclosure Notice and Material Transfer 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 Disclosure Notice and/or Material Transfer Agreement.

**25.9.** ATP will keep copies of all application forms, application 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.

## 26. **Future Amendments to the ATP Access Guidelines and Procedures**

**26.1.** These ATP Access Guidelines and Procedures will be reviewed at least every two years by the ATP Scientific Steering Committee. Any amendments must be approved by ATP's Scientific Steering Committee with advice from additional experts as required. In the case of approved amendments, a revised version of the ATP Access Guidelines and Procedures will become available. Researchers are directed to contact ATP for the most recent version by visiting https://myatpresearch.ca or by emailing ATP.Research@albertahealthservices.ca.

## 27.**References**


**27.1.** 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.

**27.2.** 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.

**27.3.** 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.

**27.4.** 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.

**27.5.** 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.

**27.6.** 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.

**27.7.** 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.

**27.8.** 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.

**27.9.** 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 (section 17). 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 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.

**4.2.** All Publications based on the ATP Resource should clearly acknowledge ATP's funders, Research Participants and staff. The following acknowledgement must be included 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: Alberta Health, Alberta Cancer Foundation, Canadian Partnership Against Cancer and Health Canada, and substantial in kind funding from Alberta Health Services. The views expressed herein represent the views of the author(s) and not of Alberta's Tomorrow Project or any of its funders."*

**4.3.** 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: Alberta Health, Alberta Cancer Foundation, Canadian Partnership Against Cancer and Health Canada, and substantial in kind funding from Alberta Health Services. Cancer registry data was obtained through linkage with Surveillance & Reporting, Cancer Research & Analytics, 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."*

**4.4.** 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."*

**4.5.** If the Approved User utilized AH derived variables, the following acknowledgement must be included as a separate paragraph after the ATP or ATP and ACR acknowledgement:

> *"This study is based in part on data provided by Alberta Health. The interpretation and conclusions contained herein are those of the researchers and do not necessarily represent the views of the Government of Alberta. Neither the Government nor Alberta Health express any opinion in relation to this study."*

**4.6.** If the journal requires information about the availability of the data, please use the following note:
"*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. More information can be obtained via https://myatpresearch.ca."*
If more information is needed, please contact ATP at ATP.Research@albertahealthservices.ca.

# Appendix 2: Replacement Approved User Agreement Template

**REPLACEMENT APPROVED USER AGREEMENT**

Title of approved research project: ***[insert title]*** ("Project")
Project Number assigned by Alberta's Tomorrow Project: ***[insert number]***

This Agreement is made effective as of ***[insert date]*** ("Effective Date") by and among:

Alberta Health Services
("AHS")

Name of original approved user [insert name]
("Former Approved User")

Name of replacement approved user [insert name]
("Replacement Approved User")

Name of original approved user and replacement approved user's institution [insert name of institution]
("Approved Institution")

AHS, Former Approved User, Replacement Approved User and Approved Institution are collectively the "Parties" and each is a "Party".

Whereas AHS, Former Approved User and Approved Institution are parties to the Disclosure Notice dated [***insert date***] attached hereto as Appendix 1 ("Disclosure Notice") [and/or Material Transfer Agreement dated [***insert date***] attached hereto as Appendix 2 ("Material Transfer Agreement")]; and

Whereas Former Approved User wishes to withdraw from the Project and the Replacement Approved User wishes to assume all of the responsibilities of the Former Approved User as of the Effective Date under the Disclosure Notice [and/or Material Transfer Agreement].

NOW THEREFORE the Parties agree as follows:

1. Effective as of the Effective Date, the Former Approved User ceased to be the Approved User under the Disclosure Notice [and/or Material Transfer Agreement] and the Replacement Approved User became the Approved User under the Disclosure Notice [and/or Material Transfer Agreement] and assumed all rights, title, interests, duties, responsibilities, and obligations as Approved User under the Disclosure Notice [and/or Material Transfer Agreement].

2. The Former Approved User agrees to continue to be bound by the terms of the Disclosure Notice [and/or Material Transfer Agreement] in respect of all matters arising prior to the Effective Date.

3. The Replacement Approved User consents to the collection by AHS of the personal information of the Replacement Approved User under the legal authority of section 33(c) of the Freedom of Information and Protection of Privacy Act and the use by AHS or disclosure by AHS of such personal information for the purpose of Alberta Tomorrow Project research administration and reporting.

4. This agreement may be signed in counterparts, and each counterpart may be delivered by facsimile or signed PDF by email. Each counterpart shall constitute an original, and when taken together, shall constitute one and the same instrument.

**Alberta Health Services**

By: _____ Date
Signature

Name:

Title:

By: _____ Date
Signature

Name:

Title:

***[Name of Approved Institution]***

By: _____ Date
Signature

Name:

Title:

By: _____ Date
Signature

Name:

Title:

***[Name of Replacement Approved User]***

Signature: _____

Date: _____

***[Name of Former Approved User]***

Signature: _____

Date: _____

Attachments: Appendix 1 [Appendix 2]

# Appendix 3: 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 Research Proposal 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 a Research Proposal, including (but without limitation) being involved in the preparation of the Research Proposal, being involved in a "competing" research activity, and/or being in a current collaboration or co-investigation with the Applicant or other investigators named on the Research Proposal.

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 a Research Proposal 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 Research Proposals 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 Research Proposal. In particular, the individual must not:

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

**Appendix 4: Expedited Review Form**

# Alberta's Tomorrow Project (ATP)
# Cancer Care Alberta - Alberta Health Services
# Data Only Application
# Expedited Review Form

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**Applicant's name and educational qualifications:**

**Title of research proposal:**

**Request number assigned by Alberta's Tomorrow Project:**

1. In your opinion, is the research proposal congruent with ATP's mandate, vision and goals?

**Yes** ☐ **No** ☐ **NA – Outside my expertise as reviewer** ☐

Please explain:

| |
|---|
| |

2. Is the applicant appropriately qualified and experienced to undertake the research proposal or has the support of an appropriately qualified co-applicant?

**Yes** ☐ **No** ☐ **NA – Outside my expertise as reviewer** ☐

Please explain:

3. Does the applicant have sufficient resources to undertake the research proposal?

**Yes** ☐ **No** ☐ **NA – Outside my expertise as reviewer** ☐

Please explain:

4. Are the objectives, methodology and variable justifications described in the research proposal and application form scientifically robust?

**Yes** ☐ **No** ☐ **NA – Outside my expertise as reviewer** ☐

Please explain:

6. Will the anticipated derived variables generated by the Applicant enrich the ATP resource?

**Yes** ☐ **No** ☐ **NA – Outside my expertise as reviewer** ☐

Please explain:

**Recommendation:**

- ☐ **Approve**
- ☐ **Reject**
- ☐ **Approval Pending Conditions**

Please provide a brief rationale for the recommendation and any conditions imposed, as well as any comments for the researcher:

**Date of Review (DD/MM/YYYY):**

**Reviewers:**

| | | |
|---|---|---|
| Name of ATP's Research Lead (or designate) | Signature | Date (DD/MM/YYYY) |
| Name of ATP's Data Access Research Associate (or designate) | Signature | Date (DD/MM/YYYY) |

| Name of ATP's Data Manager | Signature | Date (DD/MM/YYYY) |
|---|---|---|

(or designate)

*Your personal information is collected under the legal authority of section 33(c) of the Freedom of Information and Protection of Privacy Act. This information will be used by or disclosed for the purpose of ATP research administration and reporting. For questions, concerns or more information about the collection, use or disclosure of your personal information, please contact ATP's Research Operations Lead at 1-877-919-9292 or via email at ATP.Research@albertahealthservices.ca*

**Appendix 5: Data for Biosample Application Review Form**

# Alberta's Tomorrow Project (ATP)
# Cancer Care Alberta - Alberta Health Services
# Data for Biosample Application Review Form

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**Applicant's name and educational qualifications:**

**Title of research proposal:**

**Request number assigned by Alberta's Tomorrow Project:**

1. In your opinion, does the research proposal fit with ATP's mandate, vision and goals?

**Yes** ☐ **No** ☐

Please explain:

| |
|---|
| |

2. Are the variable justifications described in the research proposal and application form scientifically robust?

**Yes** ☐ **No** ☐

Please explain:

| |
|---|
| |

2. The anticipated derived variables generated by the Applicant will enrich the ATP resource.

**Yes** ☐ **No** ☐

Please explain:

| |
|---|
| |

**Recommendation:**

- ☐ **Approve**
- ☐ **Reject**
- ☐ **Approval Pending Conditions**

Please provide a brief rationale for the recommendation and any conditions imposed:

| |
|---|
| |

**Date of Review (DD/MM/YYYY):**

**Reviewer:**

| Name of ATP's Data Manager (or designate) | Signature | Date (D/M/Y) |
|---|---|---|

*Your personal information is collected under the legal authority of section 33(c) of the Freedom of Information and Protection of Privacy Act. This information will be used by or disclosed for the purpose of ATP research administration and reporting. For questions, concerns or more information about the collection, use or disclosure of your personal information, please contact ATP's Research Operations Lead at 1-877-919-9292 or via email at ATP.Research@albertahealthservices.ca*

## Appendix 6: ATP External Peer Reviewer Checklist Template


# Alberta's Tomorrow Project (ATP)
# Cancer Care Alberta - Alberta Health Services
# External Peer Reviewer Checklist

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**Applicant(s) name and educational qualifications:**

**Title of research proposal:**

**Request number assigned by**
**Alberta's Tomorrow Project:**

The aim of Alberta's Tomorrow Project (ATP) is to provide a high quality research platform that will advance knowledge into the etiology of cancer and other chronic disease. Granting access to ATP biosamples for research proposals of high scientific merit is vital to achieving that goal. The criteria to assess the scientific merit of an application submitted to ATP are described herein.

Reviews provided on this checklist should be clear, concise, and objective. Your review will help guide the ATP Access Committee in making decisions about whether or not to grant access to ATP biosample repositories.

Please remember that the ATP Access Committee comprises people from a wide variety of disciplines and backgrounds. Therefore, it is important that your review is written in a style that is comprehensible. Try to avoid using jargon or terminology that is very specific to your area of expertise.

To ensure consistency, all reviewers must adhere to common scale. It is particularly important that the full scale be used and the same conventions applied to assigned ratings. To facilitate this, the following scale and descriptors should be used:

| Descriptor | Range |
|---|---|
| Very good + | 3 – 5 |
| Acceptable | 2 |
| Unacceptable | 1 |

**Evaluate the following with respect to the applicant:**

a. Qualifications of the applicant(s), including training, experience and independence (relative to career stage)
b. Qualifications of the co-applicant (if applicant is a graduate student), including co-applicant training, experience and independence (relative to career stage)
c. Experience of applicant(s) and co-applicant (if required) in the proposed area of research and with the proposed methodology.
d. Expertise of the applicant(s) and co-applicant (if required), as demonstrated by scientific productivity over the past five years (publications, books, grants held etc). Productivity should be considered in the context of the norms for the research area, applicant experience and total research funding of the applicant.

Applicant Score: | |

Justification for score:

| |
|---|
| |

**2. Evaluate the following with respect to the originality of the research proposal:**

a. Potential for the creation of new knowledge
b. Originality of the proposed research, in terms of the hypotheses/research questions addressed

Originality Score: | |

Justification for score:

| |
|---|
| |

**3. Evaluate the following in relation to the research approach:**

a. Clarity of the research question
b. Clarity of the rationale for the research approach and methodology
c. Appropriateness of the research design and research methods (including data analysis and proposed assay) to answering the research question
d. Feasibility of the research approach (including project timeline, research environment etc)
e. Anticipation of difficulties that may be encountered in the research and plans for management

Research Approach Score: | |

Justification for score:

| |
|---|
| |

**4. Evaluate the following with respect to the potential impact of the research:**

a. Research proposal addresses a significant need or gap in health research and/or the health care system
b. Potential for a significant contribution to the improvement of people's health in Canada and the world and/or to the development of more effective health services and products
c. Appropriateness and adequacy of the anticipated outcomes for knowledge dissemination and exchange.

Research Impact Score: | |

Justification for score:

| |
|---|
| |

**5. Comments to be shared with applicant(s):**

**6. Average score over all four areas:**

Please note that applications rated with a score of less than 2 will not be granted access to ATP biosamples.

Applications rated with a score of 2 or higher may be ranked on merit in situations where 'overlapping' applications have been received.

**7. Comments for ATP only.** These comments will not be shared with the applicant, but will be shared with the Access Committee. Comments may pertain to the Application under review or to the overall review process.

**Please return completed form to ATP within 2 weeks of receipt.**

Name and qualifications of reviewer:

Affiliation of reviewer:

Position title:

Signature: Date:

*Your personal information is collected under the legal authority of section 33(c) of the Freedom of Information and Protection of Privacy Act. This information will be used by or disclosed for the purpose of ATP research administration and reporting. For questions, concerns or more information about the collection, use or disclosure of your personal information, please contact ATP's Research Operations Lead at 1-877-919-9292 or via email at ATP.Research@albertahealthservices.ca*

## Appendix 7: ATP Biosample with Data Review Form for Access Committee Template

**Alberta's Tomorrow Project (ATP)**
**Cancer Care Alberta - Alberta Health Services**
**Biosamples with Data Review Form**
**for Access Committee**

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**Applicant's name and educational qualifications:**

**Title of research proposal:**

**Request number assigned by**
**Alberta's Tomorrow Project:**

***Please note that only information provided in question 10 will be shared with the applicant. Comments provided in all other boxes will be kept confidential.***

1. In your opinion, is the research proposal congruent with the vision and goal of ATP?
   (ATP vision: To be a platform to support high quality research into the etiology and prevention of cancer and chronic disease.
   ATP goal: To support a broad range of research that translates into more effective strategies for cancer and chronic disease prevention in the future)

**Yes** ☐ **No** ☐

Please explain:

r has the support of an appropriately qualified co-applicant?

*Please consider the following:*

The qualifications of the applicant(s), including training, experience and independence (relative to career stage), and the expertise of the applicant(s) and co-applicant (if required), as demonstrated by scientific productivity over the past five years (publications, books, grants held etc.). Productivity should be considered in the context of the norms for the research area, applicant experience and total research funding of the applicant.

**Yes** ☐ **No** ☐ **Don't Know** ☐

Please explain:

| |
|---|
| |

3. Does the applicant have sufficient resources to undertake the research proposal, with respect to both funding and study team?

**Yes** ☐ **No** ☐ **Don't Know** ☐

Please explain:

| |
|---|
| |

4. Evaluation of scientific merit

A) Was the peer review conducted as per the ATP Peer Reviewer Checklist:

**Yes** ☐ **No** ☐ (skip to B)

If yes, average score from each peer reviewer:

| | | |
|---|---|---|
| | | |
| Reviewer 1 | Reviewer 2 | Reviewer 3 |

B) Is the research proposal of sufficient scientific merit to warrant release of biosamples with data from ATP?

*Please consider the following:*
Clarity of the research question, rationale for the approach and methodology; appropriateness and feasibility of the research design, research methods (including data analysis and proposed assay), and the timeline; potential difficulties and plans for managing them; originality of the proposed research, in terms of the hypotheses/research questions addressed.

**Yes** ☐ **No** ☐ **Don't Know** ☐

Please explain:

| |
|---|
| |

5. Is the enrichment potential for the ATP Resource sufficiently robust to warrant granting access?

*Please consider the following:*

Does the research proposal address a significant need or gap in health research and/or the health care system? Is there potential for the creation of new knowledge? Is there potential for a significant contribution to the improvement of people's health in Canada and the world and/or to the development of more effective health services and products? Are the anticipated outcomes appropriate and adequate for knowledge dissemination and exchange?

**Yes** ☐ **No** ☐

Please explain:

| |
|---|
| |

6. Is the potential impact on future uses of ATP biosamples sufficiently small to justify use of limited biosamples? If it is a large request in either numbers (>500 samples) or volume of samples (>500µL), is there appropriate justification for the increased requirement?

**Yes** ☐ **No** ☐

Please explain:

| |
|---|
| |

7. Has the applicant demonstrated evidence of the ability to access all other data or biological material required for the research proposal? For example, if the research proposal is for ATP 'control' samples, the applicant should indicate how they plan to access 'case' samples.

**Yes** ☐ **No** ☐

Please explain:

| |
|---|
| |

8. Please indicate your overall recommendation:

☐ **Approve**

☐ **Approval Pending Conditions** (complete box A below)

☐ **Reject** (complete box B below)

A) If 'Approval Pending Conditions' is selected, please list conditions and a rationale for each condition:

| |
|---|
| |

B) Please provide a brief rationale for your recommendation to reject:

9. Please insert any feedback to be shared with the applicant:

Name and qualifications of reviewer:

Affiliation of reviewer:

Position title:

Signature: Date:

*Your personal information is collected under the legal authority of section 33(c) of the Freedom of Information and Protection of Privacy Act. This information will be used by or disclosed for the purpose of ATP research administration and reporting. For questions, concerns or more information about the collection, use or disclosure of your personal information, please contact ATP's Research Operations Lead at 1-877-919-9292 or via email at ATP.Research@albertahealthservices.ca*

# Appendix 8: ATP Terms of Reference for Access Committee Members


## Alberta's Tomorrow Project
## Cancer Care Alberta – Alberta Health Services
## Terms of Reference for Access Committee Members
## Data and Biosample Access Review Process

**Rationale**

The Data and Biosample Access Review Process provides a mechanism to support the review of research proposals from qualified applicants who request data and biosamples from Alberta's Tomorrow Project (ATP) for use in research studies that have been approved by a recognized research ethics board/committee.

This document outlines the types of proposals that will be considered, the membership of the Access Committee and committee structure, the application and review process, and conditions governing release of data and biosamples. Please note, the 01 January 2020 version supersedes any previous versions of this document.

**Types of research proposals that will be considered**

The vision of ATP is to create an infrastructure platform that can support a broad range of research into cancer and other health conditions. The ultimate goal is to learn more about the etiology and progression of disease in order to help inform the development of future prevention and control strategies. The infrastructure platform was created by enrolling up to 50,000 adult Albertans, aged 35-69y, who have consented to provide information on health and lifestyle, as well as biosamples (blood, and/or urine) to be stored to support future research. Research participants have also consented to linkage with administrative health data to answer specific research questions. Participation in ATP is completely voluntary, and research participants are free to withdraw at any time.

ATP will consider proposals for access to data and/or biosamples that are:
(a) congruent with the vision and ultimate goal of ATP;
(b) supported by approval from a recognized research ethics board/committee;
(c) submitted by qualified applicants, either internal or external to Alberta Health Services (AHS).

Applicants who wish to submit research proposals requesting access to data and biosamples are strongly encouraged to contact ATP for an informal discussion to determine the feasibility of a proposal early in its development and to determine the suitability of ATP data and biosample repositories for the planned research.

**Application and Review Process**

If the Applicant chooses to proceed with a research proposal to access ATP's **data and biosamples**, the following process will occur:

1. The Applicant will seek and obtain ethical approval for the research proposal.

2. If funding has not been secured, the Applicant may complete a notification of intent form and submit it to ATP. At the notification of intent stage, there is no need for the Applicant to provide evidence of ethical approval. If there are no issues with the form, ATP will provide a letter of support to the Applicant in support of funding applications. It should be noted that a letter of support does not guarantee access to ATP data and/or biosamples nor does it reserve biosamples for any potential Applicant.

3. Following receipt of ethical approval and funding, the Applicant will complete ATP's Research Application Form and submit it to ATP.Research@albertahealthservices.ca with the applicable fees and ethical approval documents.

4. ATP will acknowledge receipt of the application package shortly after the application deadline and will shortly thereafter commence the review process.

5. Requests for access to biosamples with data will undergo feasibility review. Upon successful completion of the feasibility review, they may be sent for peer review (see section 7.4 of ATP Access Guidelines).

6. Following the completion of the feasibility review and peer review (if applicable) process for requests to access biosamples with data, the ATP Scientific Director (or designate) will convene the ATP Access Committee (see Membership and Committee Structure section at end of Appendix 8).

7. The Research Application Form, relevant supporting documentation and ATP Biosample with Data Review Form for Access Committee will be sent to the voting members of the Access Committee by ATP. If the members are unable to complete it in the timeframe required, they must inform ATP's Research Operations Lead (or designate).

8. Voting members will complete and return the ATP Biosample with Data Review Form for Access Committee to ATP within two weeks, indicating that the application is either approved, rejected, or approved pending conditions to address issues or concerns.

9. In the case of unanimous approval, ATP will notify all Committee members and ensure that all voting members and the Chair agree that there is no need to meet for further discussion. ATP will send a letter of approval to the Applicant and negotiations for the transfer of biosamples with data will commence.

10. In all other scenarios, a meeting (either in person, or by teleconference) will be convened with the Access Committee, where the Committee will reach a decision and formulate feedback for the Applicant. ATP will send a letter to the Applicant outlining the committee's decision and describing the nature and scope of any conditions that may be imposed.

11. The Applicant will have three weeks to agree to any conditions proposed by the Access Committee and if agreeable, negotiations for transfer of biosamples with data will commence. However, if agreement cannot be reached, access will not be permitted and a new research application form for a new Research Proposal will have to be submitted with the application fee and ethical approval.

12. Following rejection of a proposal for access to Alberta's Tomorrow Project resource, the Applicant may choose to submit a new application or initiate the appeal process.

**Decision making criteria**
All proposals for access to biosamples held by ATP will be reviewed for:

- Scientific merit of the proposed research project (considering recommendations from external peer reviewers if applicable);
- Relevance of the research proposal to the vision and aim of ATP;
- Experience and qualifications of the Applicant;
- Adequacy of resources to support the research proposal, and to protect integrity/security of data and biosamples;
- Potential impact on future uses of ATP's biosamples;
- Enrichment potential for the ATP's data and/or biosample repositories;
- Evidence of ability of Applicant to obtain access to all other data and/or biological materials required for the research proposal (e.g. if research proposal is for ATP 'control' samples, the Applicant should indicate how they plan to access 'case' samples);
- Robust justification for the use of ATP biosamples rather than other sources of biosamples.

Each voting member of the ATP Access Committee will provide a brief written appraisal of the proposal using the ATP Biosamples with Data Review Form for Access Committee.

**Conditions governing release of data and/or biosamples**
Only coded data and/or biosamples will be provided.

- For approved research projects lasting more than one (1) year, ATP will request the following on an annual basis:
    a) Confirmation of annual renewal of ethical approval;
    b) A completed progress report form
- Upon completion of the approved research project, ATP will require submission of a completed final report form.
- Researchers must sign all required agreements (the AHS Disclosure Notice and/or AHS Material Transfer Agreement) before data and/or biosamples can be released by ATP.
- If a new principal investigator is named in addition to, or in replacement of the approved user, the new applicant must sign a statement of agreement and acknowledgement 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 Disclosure Notice and/or Material Transfer Agreement.
- ATP will keep copies of all research application forms, application 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.

- ATP will also list approved research projects on its website and/or in other publicly available ATP materials. The name(s) of applicant(s), their academic credentials and institutional affiliations, the approved research project's title, scientific abstract and lay summary, scheduled start and end date and the source of funding may be listed.

- ATP may include lay summaries of approved research projects in newsletters or other publicly available ATP materials.

- Approved users are required to return results to ATP to enrich the ATP repositories but will be granted an embargo of 6 months after the return of results, data and/or biosamples prior to any re-release by ATP.

**For further information, please contact: ATP.Research@albertahealthservices.ca**

## Membership and Access Committee Structure

**Membership of the Access Committee and Committee structure**
The ATP Access Committee, chaired by the Scientific Director of Alberta's Tomorrow Project, or designate, will review and approve/approve pending conditions/reject each application for access to the ATP Resource. The Committee will be comprised of members from ATP's Scientific Steering Committee who will be chosen based on their expertise surrounding the application in progress, and may include external experts. A quorum will be reached if a total of 3 or more Committee members attend a meeting either in person or by teleconference.

*Committee Chair*
The Scientific Director of ATP, or designate, will act as the Access Committee Chair. If the Scientific Director is named on a Research Proposal as an Applicant or Co-Applicant, ATP's Research Lead, or a member of ATP's Scientific Steering Committee will act as the Access Committee Chair..

*Voting Members*
All Committee members are voting members. The Chair will not be a voting member unless in the event of a tie decision between the voting members of the Committee.

*Support Members*
Each Committee will be supported by a group of staff affiliated with ATP and other departments within AHS (for example: Legal, Health Technologies Assessment and others if deemed necessary). In addition to providing administrative support, the support members may also provide advice regarding the operational feasibility of each proposal. Included in this group are the ATP Research Lead (or designate), ATP Data Manager (or designate), ATP Data Access Lead (or designate) and Bioresource Advisor (or designate) responsible for ATP Data and Biosample management. Support members are not voting members.

## Appendix 9: Ancillary Study Proposal Form Template


# Alberta's Tomorrow Project (ATP)
# Cancer Care Alberta - Alberta Health Services
# Ancillary Study Proposal Form

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Please complete the following form in order to express interest in collaborating with Alberta's Tomorrow Project (ATP) in the collection of additional questionnaire information and/or biosamples from research participants. All forms will be reviewed according to the criteria listed in the ATP Access Guidelines and Procedures (see section 22). Please submit completed forms to ATP.Research@albertahealthservices.ca.

**Name of Applicant(s):**

**Institutional Affiliation(s):**

**Phone Number(s):**

**Email address:**

Proposed Collaborators (complete table below and add lines as needed):

| Name | Institutional Affiliation(s) | Area of Expertise |
|---|---|---|
| | | |
| | | |
| | | |

1. Rationale and objective(s) of the ancillary study:

2. Rationale for why additional data and/or biosample collection is required:

3. Methods, including specific detail about:
    a. Additional data and/or biosamples to be collected:

    b. Number of participants to be recruited:

    c. Type of participants to be recruited (sex, age etc):

    d. How are data and/or biosamples proposed to be collected:

    e. What tool(s) will be used (questionnaires, assays etc.)? Please list all tools.

    f. Number of points of data and/or biosample collection?

    g. Anticipated timeframe for data and/or biosample collection and processing (if required):

4. Please explain applicant's and/or proposed collaborators' qualifications and experience to conduct the proposed ancillary study:

Applicant's curriculum vitae attached: **YES** ☐

5. Anticipated/desired ancillary study start date:

6. Anticipated return of data date:

7. Proposed source(s) of funding to support the study:

8. Has the proposal undergone peer review? **YES** ☐ **NO** ☐
   If yes, please describe:

9. How does the proposed ancillary study fit within ATP's vision and mandate?

10. What is the benefit to ATP?

Signature: _____ Date (D/M/Y):_____

*Your personal information is collected under the legal authority of section 33(c) of the Freedom of Information and Protection of Privacy Act. This information will be used by or disclosed for the purpose of ATP research administration and reporting. For questions, concerns or more information about the collection, use or disclosure of your personal information, please contact ATP's Research Operations Lead at 1-877-919-9292 or via email at ATP.Research@albertahealthservices.ca*