Alberta's Tomorrow Project
Data Access Guidelines and Procedures

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Alberta's Tomorrow Project
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Alberta Cancer Foundation
Alberta Health Services
Alberta Innovates Health Solutions
Canadian Partnership Against Cancer / Partenariat canadien contre le cancer

Alberta's Tomorrow Project Data Access Guidelines and Procedures

1. Table of Contents

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 number 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 (CDHQ-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 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 the collection of a harmonized protocol that included questionnaires, physical measurements, and the collection of biospecimens (blood, urine and saliva). ATP invited existing Tomorrow Project participants and recruited additional Alberta residents aged 35 to 69 years to take part in CPTP. As of February 15, 2016, a total of 50,149 participants had been recruited to ATP and 39,348 of those had also consented to CPTP. Of the 39,348 CPTP participants, approximately 30,000 had completed a battery of physical measures and provided biospecimens.

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 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 data held by ATP. It is authorized under Alberta Health Services (AHS) Research Information Management Policy (Document #1146, effective January 10, 2012). 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 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 to approved users. ATP data include responses to self- and interviewer-administered questionnaires, physical measures, data derived from questionnaires and physical measures and other meta-data.

These guidelines relate only to requests for access to data. For information about how to request access to biospecimens, please consult the ATP Biospecimen and Data Access Guidelines and Procedures.

Release of data to approved users will occur following review and approval of the research proposal (see Appendix 3 for Research Application Form), and successful execution of the Alberta Health Services (AHS) Research Agreement. Upon the completion of any approved research project, all results and/or data generated must be returned to ATP to encourage ongoing use of the ATP resource by the research community.

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

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

4. Glossary of Terms

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: myatp.ca.

Alberta's Tomorrow Project Data Access Guidelines and Procedures: a document that outlines ATP's general principles and guidelines on access to its Coded Data. It is an integral part of the Research Agreement.

Ancillary Study: an investigation that involves the collection and analysis of additional Data obtained from Research Participants beyond the scope of regular ATP follow up with Research Participants.

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 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 that may be requested by Applicants.

Canadian Partnership Against Cancer (CPAC): an independent organization funded by the federal government of Canada to accelerate action on cancer control for all Canadians.

Canadian Partnership for Tomorrow Project (CPTP): a large, high quality, "population laboratory" that will facilitate research in cancer and other chronic disease etiology. CPTP is made up of five regional cohorts – Alberta's Tomorrow Project, Atlantic PATH, BC Generations Project, Ontario Health Study and Quebec's CARTaGENE.

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 derived 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.

Derived Data: data generated based on questionnaire responses 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.

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 Research Agreement.

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.

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 Agreement: an agreement developed by AHS which contractually binds Approved Users, AHS (ATP) and any other parties to ensure compliance 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 to the Approved User.

Research Lead: the ATP staff member responsible for the day to day coordination of all aspects of research involving the ATP Resource.

Research Participants: the individuals who have contributed Data to ATP.

Research Proposal: an application, still subject to approval, for the use of ATP's Coded Data 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 had their physical measurements taken.

5. The ATP Resource – Summary of Data Collected

For the complete number of each type of questionnaire collected, please refer to Table 1. A complete list of all questions and variables can be found in the data dictionaries available from ATP upon request. See Figure 1 for a visual representation of survey completion over time by Research Participants.

5.1. ATP Baseline Questionnaires (2001-2008)

5.1.1. Health and Lifestyle Questionnaire (HLQ)

This questionnaire contained sections about personal and family health history, cancer screening tests, reproductive health, smoking, sun exposure, spirituality, social support and stress, body measurements and demographic characteristics.

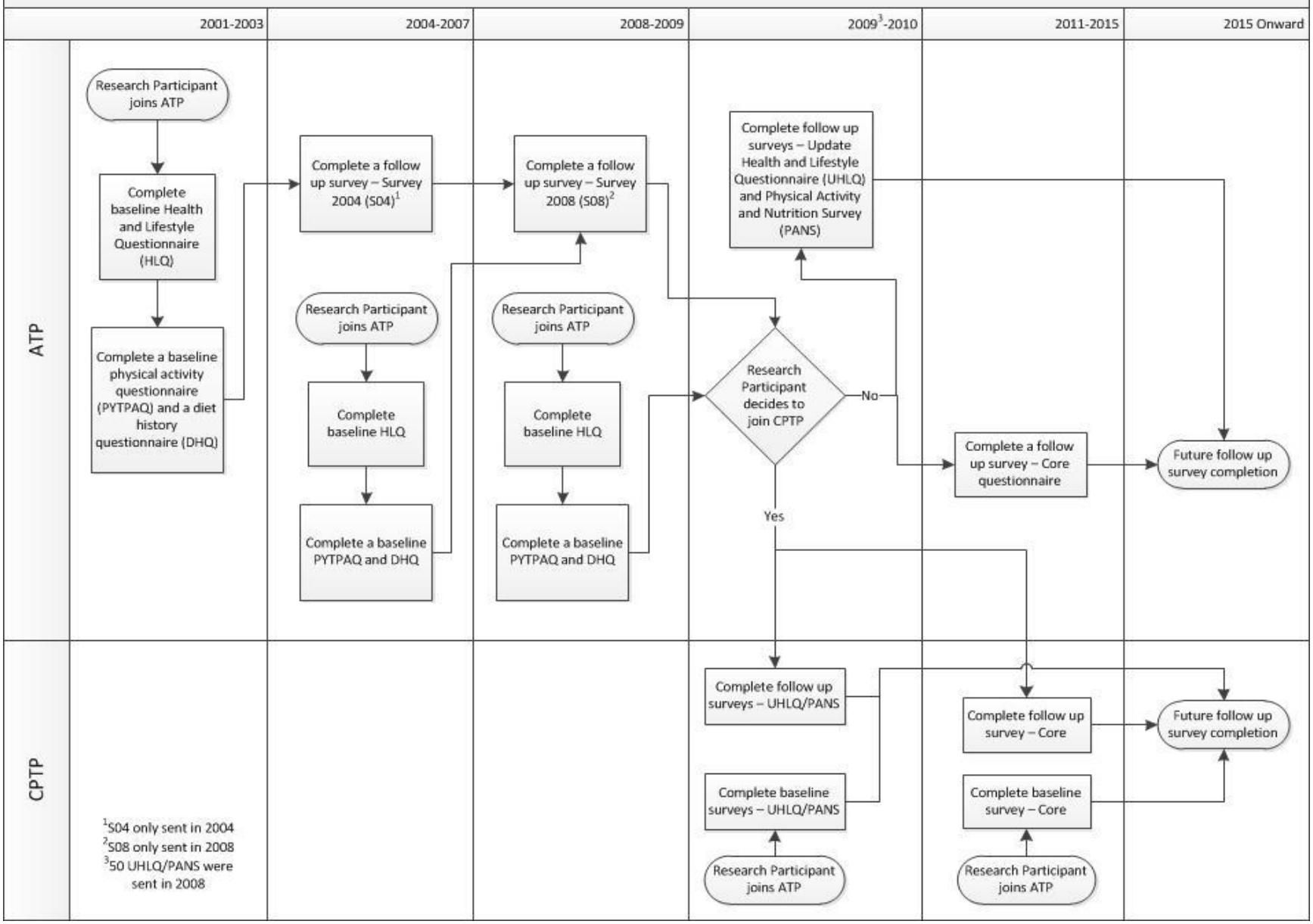
5.1.2. Diet History Questionnaire (DHQ)

This food frequency questionnaire was intended to assess food and nutrient intakes by Research Participants in the year prior to questionnaire completion (Csizmadi et al., 2007).

5.1.3. Past Year Total Physical Activity Questionnaire (PYTPAQ)

The PYTPAQ was designed to obtain information about the types and amounts of physical activities undertaken by Research Participants in the year prior to questionnaire completion. It asked Research Participants to consider the types of activities that they did in each domain of physical activity (occupation, household, leisure time and transportation) (Friedenreich et al., 2006).

Figure 1. Research Participant Survey Completion from ATP Inception to Present



5.2. ATP Follow Up Questionnaires

5.2.1. Survey 2004 (S04)

Survey 2004 was distributed in 2004 to Research Participants who joined ATP between 2000 and 2003. It contained questions on personal health history, cancer screening tests, sun exposure, smoking, body measurements, lifetime weight pattern, alcohol, sleep and shift work, health risk perception, quality of life, demographic characteristics and, for women, hormone replacement therapy use.

5.2.2. Survey 2008 (S08)

Survey 2008 was distributed in 2008 to Research Participants who joined ATP between 2000 and 2007. This questionnaire included information on lifetime residential history, personal and family health history, cancer screening tests, smoking, quality of life, fruit and vegetable intake, physical activity (IPAQ, Craig et al., 2003), sleep and shift work, built environment (Cerin et al., 2006), work history, body measurements and demographic characteristics.

5.3. CPTP Questionnaires (2008 – July 2015)

Research Participants involved in the CPTP protocol completed either an UHLQ and PANS or a Core questionnaire.

5.3.1. Update Health and Lifestyle Questionnaire (UHLQ) or Health and Lifestyle Questionnaire II (HLQ-II)

This questionnaire was based on ATP's original Health and Lifestyle Questionnaire completed by all participants who joined ATP between 2000 and 2008. Questions covered topics such as personal and family health history, health check-ups, reproductive health, past year medication use, alcohol, smoking, sun exposure, sleep, work and demographic characteristics.

5.3.2. Physical Activity and Nutrition Survey (PANS)

This survey asked about physical activity and dietary habits. The physical activity section was the long form of the International Physical Activity Questionnaire (IPAQ, Craig et al., 2003), while the nutrition sections asked about consumption of servings of several food groups similar to those used in Canada's Food Guide (Bush et al., 2007).

5.3.3. Core Questionnaire (Core)

This questionnaire was a refined version of the UHLQ combined with the PANS. Small changes were made based on feedback from Research Participants to make the questionnaire easier to complete. It included sections on demographic characteristics, cancer screening tests, reproductive health, personal medical history, current medication use, family health history, sleep, sun exposure, food consumed, alcohol, smoking, physical activity, work and body measurements. The

cohorts in CPTP used the same questions to ensure that the same information was collected across all cohorts.

5.3.4. Physical Measurements

Research Participants who attended a Study Centre had several measurements taken during their visit. These included blood pressure, sitting height, standing height, waist and hip circumferences, grip strength, weight and bioimpedance. Measurements were recorded in one of two potential formats: electronically (Onyx, OBiBA open source software) or in a combination of the Study Centre Questionnaire (SCQ) and Physical Measures Recording Booklet (PMRB).

Table 1. Summary of the ATP Resource - Data

Survey[1]		**Number of Research Participants**	**Collection Start Date (M/D/Y)**	**Collection End Date (M/D/Y)**
HLQ		31,212	02/27/2001	08/05/2010
DHQ		26,973	03/29/2001	08/31/2010
PYTPAQ		26,900	03/29/2001	08/31/2010
S04		9,693	04/28/2004	07/04/2006
S08		20,801	05/01/2008	12/06/2011
S08 Residential History		20,781	05/01/2008	09/12/2011
UHLQ[2]		12,685	12/16/2008	01/06/2015
PANS[2]		12,663	12/16/2008	01/06/2015
Core[2]		26,764	02/06/2011	10/01/2015
Physical Measurements[2]	Onyx	29,384	07/13/2009	07/27/2015
	SCQ	1,215	12/19/2008	03/02/2010
	PMRB	1,210	12/19/2008	01/11/2012
HLQ and CPTP (either UHLQ/PANS or Core)		15,696	N/A	N/A

[1]Full names of surveys are as follows: HLQ (Health and Lifestyle Questionnaire), DHQ (Diet History Questionnaire), PYTPAQ (Past Year Total Physical Activity Questionnaire), S04 (Survey 2004), S08 (Survey 2008), S08 Residential History (Survey 2008 Residential History section of survey only), UHLQ (Update Health and Lifestyle Questionnaire), PANS (Physical Activity and Nutrition Survey), Core (unabbreviated), Onyx (unabbreviated), SCQ (Study Centre Questionnaire), PMRB (Physical Measures Recording Booklet). Data dictionaries are available upon request by email to ATP.Research@albertahealthservices.ca.
[2]Questionnaires collected as part of CPTP

6. Data Access Process

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 Data Access Guidelines and Procedures, AHS Research Information Management Policy (Document #1146, effective January 10, 2012) and the AHS Research Agreement. The access process is visually represented in Figure 2.

6.1. Informal Discussion

6.1.1. All potential Applicants are strongly encouraged to contact ATP prior to submitting an application form to determine the feasibility of any potential access request and to determine if comparable research is already underway. ATP will not consider the issue of potential overlap between Research Proposals and/or Approved Research Projects, unless asked specifically by a prospective Applicant during the informal discussion portion of the access process.

6.2. Notification of Intent

6.2.1. Potential Applicants who require a letter of feasibility to complete funding applications are first required to submit a completed Notification of Intent form to ATP. 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 feasibility will be produced.

6.2.2. Evidence of ethical approval for a Research Proposal is not required to receive a letter of feasibility.

6.3. Letter of Feasibility

6.3.1. ATP is willing to provide a letter of feasibility to potential Applicants to support funding applications. Potential Applicants who receive a letter of feasibility from ATP are still required to complete the application form and follow the remainder of the access process once funding is in place. If funding has already been secured, a letter of feasibility is not required to submit an application.

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

6.4. Submission of Application Form

6.4.1. Applicants are required to submit a completed application form, with evidence of funding, CV, ethical approval, and the requisite application fee (see section 10) to begin the process of gaining access to the ATP Resource. A sample application form

can be found in Appendix 3. ATP will acknowledge receipt of the application form within 5 business days of receipt and shortly thereafter will commence the administrative review process.

6.5. Administrative Review

6.5.1. Within 5 business days of receipt of an application form, ATP will conduct an administrative review. This review will check the following:

i) Completeness of the application form
ii) Availability of the Coded Data for release
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 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

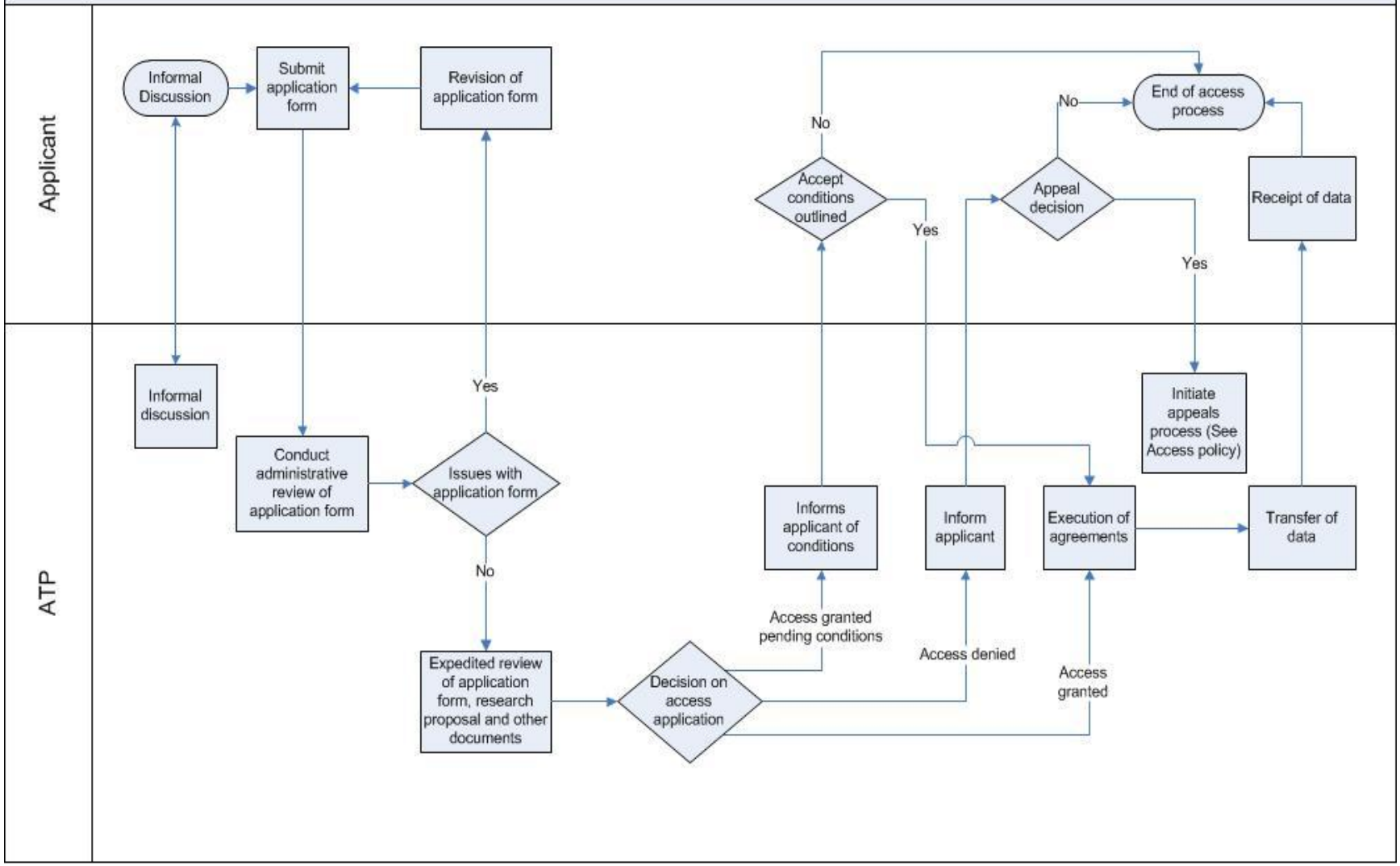
6.5.2. Should any issues be identified during the administrative review, ATP will advise the Applicant. The Applicant will be required to address any issues identified, to the satisfaction of ATP, before the Research Proposal will be advanced to the expedited review process.

6.6. Expedited Review by ATP

6.6.1. The ATP expedited review process will be undertaken by ATP's Scientific Director, Research Lead and Data Manager or designates. Research Proposals will be evaluated according to the Expedited Review Checklist (see Appendix 5 for template). The following areas will be examined: the Applicant, the ethical approval and the 'fit' with ATP's purpose. A decision regarding access will be reached within 3 weeks after the successful completion of the administrative review.

6.6.2. The ATP Research Lead, or designate 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.

Figure 2. Visual Representation of the ATP Access Process for Data Only Requests



6.6.3. 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 fee and evidence of ethical approval.

6.7. Execution of Agreements

6.7.1. Upon approval of the Research Proposal, the Approved User, ATP and AHS will enter into a Research Agreement. All parties will be required to sign the agreement and representatives of each implicated Institution may also need to sign.

6.7.2. If the Scientific Director of ATP is involved in an Approved Research Project, the Strategic Director of ATP or the AHS Executive Director of C-MORE will sign any required agreements on behalf of ATP.

6.8. Transfer of Data

6.8.1. Only Coded Data will be released to Approved Users once all required agreements have been successfully executed (see section 8 on confidentiality).

6.8.2. Once all required agreements are successfully executed, the ATP Data Manager, or designate, will send the Approved User by email a username and password for a secure file transfer protocol (SFTP) website. The Data Manager, or designate, will then provide a password over the phone for a self decrypting archive. The Approved User then will have access to the website for a maximum of 2 weeks during which the Coded Data files should be downloaded. The files will be provided, when possible, in the format selected by the Approved User on their Research Application form.

6.9. Post Approval

6.9.1. If an Approved Research Project is scheduled to extend beyond one year, an annual Progress Report (see Appendix 7) 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. Proof of a current annual renewal from the relevant ethical review board must also be submitted with the Progress Report form. If ATP does not receive the annual Progress Report form within 30 days following the due date, the Research Agreement may be terminated.

6.9.2. Moreover, if a new principal investigator is named either in addition to, or in replacement of, the Approved User, the new Applicant must sign a Replacement Approved User Agreement (see Appendix 13) 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 Research Agreement and/or BMTA for the Approved Research Project. 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 additional or replacement Approved Users will be reviewed by ATP on a case by case basis.

6.9.3. If an Approved User wishes to use ATP Coded Data already supplied for a purpose other than the original purpose outlined in the Research Agreement, they must submit a Significant Change Report form to ATP. 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, 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).

6.9.4. If during the course of an Approved Research Project, additional data variables are required, the Approved User should submit an Additional Variable Request form to ATP for evaluation. 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 Research Agreement. 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).

6.10. Return of Results and Data to ATP

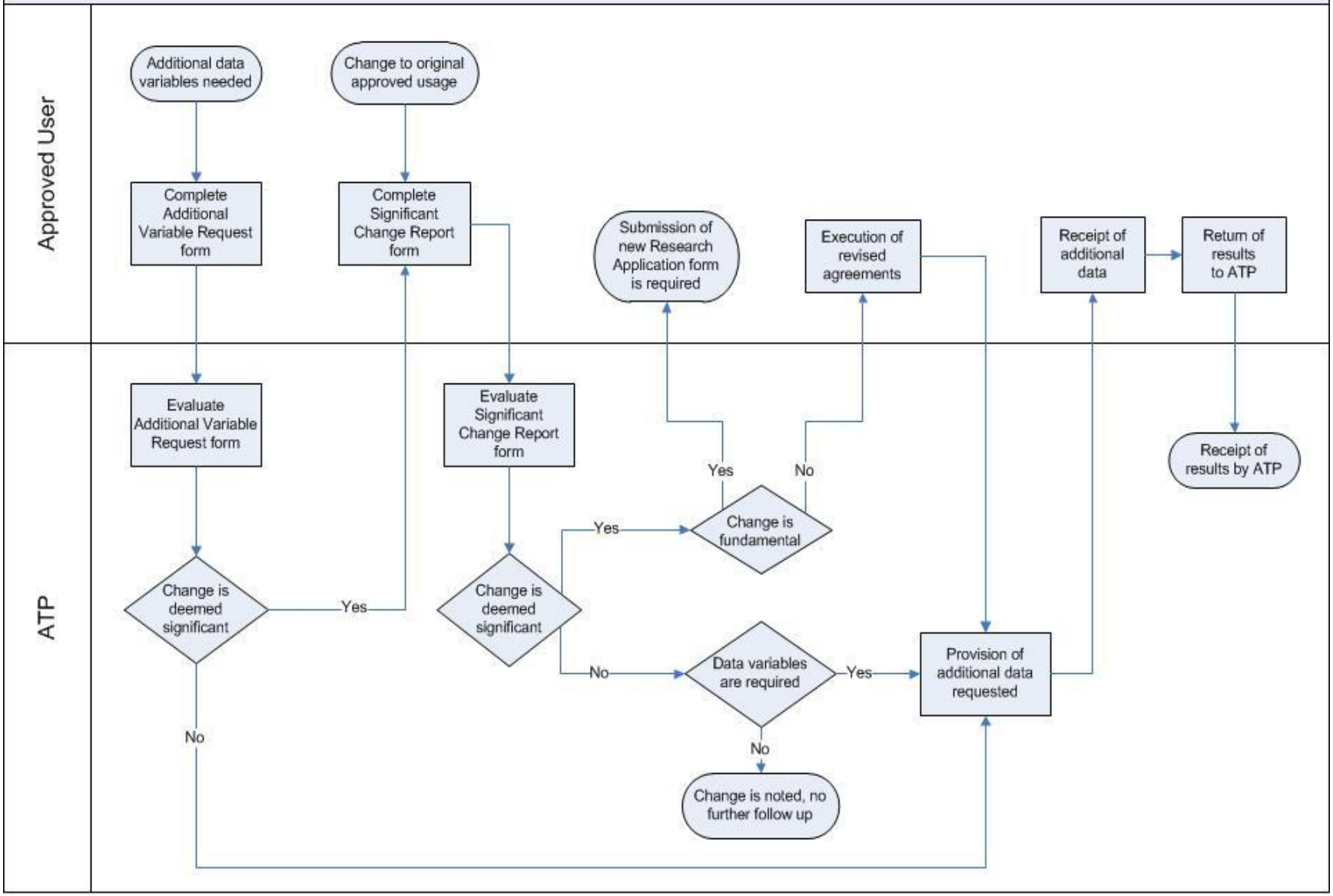
6.10.1. It is a condition of access that any new data or variables generated during an Approved Research Project must be returned to ATP to encourage ongoing use of the ATP Resource by the research community. Upon Approved Research Project Completion, the Approved User is required to provide ATP with a copy of *all* data generated for inclusion in the ATP Resource in such detail and format as ATP reasonably requires. This may include any raw or derived data and/or statistical programs along with supporting documentation, including data dictionaries.

6.10.2. Upon Approved Research Project Completion, ATP will request submission of a Final Report form (see Appendix 11).

6.10.3. All approved Users will be granted an embargo of 6 months after the return of results and Data prior to any re-release by ATP.

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

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



6.11. Denial of Access

Access to ATP Data may be denied for several reasons, for example:

6.11.1. The ability of the Applicant to execute the Research Proposal is in doubt or the Research Proposal is considered inadequate during the expedited review conducted by ATP. The Applicant will have to show evidence of expertise, resources, financing and the ability to execute the Research Proposal to its successful completion.

6.11.2. 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 data 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.

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

6.11.4. There is a conflict of interest in relation to the Research Proposal (see Appendix 2 for the ATP Conflict of Interest Considerations).

6.12. Appeals

6.12.1. Any Applicant who wishes to appeal the decision of the expedited review can apply to ATP for appeal consideration by ATP's Scientific Advisory Committee (or subset thereof). 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.

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

6.12.2.1. 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;

6.12.2.2. Within 4-6 weeks of receipt of such a request, ATP's Scientific Advisory Committee (or subset thereof) 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 Scientific Advisory Committee's recommendation;

6.12.2.3. If considered necessary, ATP's Scientific Advisory Committee (or subset thereof) 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.

6.12.3. 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 the Research Agreement and any subsequent steps. The Scientific Advisory 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.

6.13. Audits

6.13.1. On reasonable notice to the Approved User, and in order to confirm or investigate compliance with the Research Agreement, ATP may itself or via appropriate third parties:

6.13.1.1. 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.

6.13.2. 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.

6.13.3. 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 Research Agreement and/or BMTA, and expects that the recommendations will be implemented by the Approved User and their Institution within 15 business days.

6.14. Access process for ATP staff members

6.14.1. The access process for members of the ATP staff is the same as for any other Applicant. However, staff members are exempt from the application fee but remain bound by all other policies including the conflict of interest considerations as outlined in Appendix 2.

7. Access Limitations

7.1. 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.

7.2. Disclosure to Law Enforcement

7.2.1. Information may be disclosed if it relates to the commission of an offence, when there is immediate harm to the subject individual or others; or when law enforcement presents a subpoena for the information. When there is a situation of immediate harm the amount of information disclosed shall be considered in consultation with the AHS Legal and Privacy Portfolios, and shall be the minimum amount to prevent harm. When law enforcement presents a subpoena, ATP shall redirect law enforcement to the Information Privacy Office and contact the Office to inform them of the pending request.

7.3. The Data may not be used for any other purpose other than for the Approved Research Project as described in the Research Agreement. The Approved User must inform ATP of *any* changes in purpose to 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 cost) and supporting documentation (including ethics approval) to ATP, and to go through the access review process as described in Section 6.

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

8. Confidentiality

8.1. 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:

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

8.1.2. 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 (see Appendix 10) 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.

8.1.3. The Approved Users are responsible for having the necessary technical and organizational measures in place to protect the Coded Data from unauthorized access.

8.1.4. Approved Users must not link the Coded Data provided with any other dataset without the prior permission of ATP.

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

8.1.6. 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.

8.2. Research Proposals

8.2.1. 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, their academic credentials and professional experience
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

8.2.2. 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.

8.2.3. 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.

9. Competing Research

9.1. 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. ATP will not consider the issue of potential overlap between Research Proposals and/or Approved Research Projects, unless asked specifically by a prospective Applicant during the informal discussion portion of the access process.

9.2. 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 6.6.1. Research Proposals that only require access to data will not be compared against each other.

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

10. Cost Recovery

10.1. Cost of submission of a Research Proposal

10.1.1. There is a fixed application 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 is payable on submission of the application form.

10.1.2. Those exempt from the application cost are as follows:

i) Staff members of ATP
ii) Applicants, including post doctoral fellows, who have received grant funding from the same funders that support ATP (Alberta Cancer Prevention Legacy Fund, Alberta Cancer Foundation or CPAC) to conduct research using the ATP Resource
iii) Students or other trainees as approved on a case by case basis by ATP

10.1.3. Post doctoral fellows who begin an Approved Research Project with funding from ATP or one of ATP's funders but whom later obtain financial support from alternative sources will continue to be exempt from any application costs for the duration of the Approved Research Project.

10.1.4. It should be noted that Applicants with funding from AHS will not be exempt from any of the costs associated with accessing the ATP Resource.

10.2. Future Amendments to Cost Recovery

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

11. Publications

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.

11.1. 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.

11.2. Approved Users must provide 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 (manuscript guidelines in section 11.3). Such outputs must be accompanied by a list describing the authors, date of publication/presentation, presentation type, presentation venue, and citation (if published in conference proceedings).

11.3. Approved Users must send final drafts of manuscripts intended for peer-review to ATP *prior* to submission to any journal. Manuscripts for review by ATP must be accompanied by a completed ATP Publications Checklist (see Appendix 9). 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 manuscript may bring ATP/AHS into disrepute
iii) The conditions laid out in the ATP Data Access Guidelines and Procedures and the AHS Research Agreement have been followed
iv) The scope of the reported analysis is compliant with the Approved Research Project

11.3.1. 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 Research Agreement 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 Data Access Guidelines and Procedures section of this document (section 16). 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.

11.4. 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.

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

11.6. 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.

11.7. 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.

11.8. 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 due to the commitment of its research participants, its staff and its funders: Alberta Cancer Foundation, Canadian Partnership Against Cancer, Alberta Cancer Prevention Legacy Fund (administered by Alberta Innovates – Health Solutions) 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."

11.9. 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.

12.Intellectual Property (IP)

ATP adheres to the AHS IP Policy and Procedure Manual (Document #1137, effective November 8, 2012). 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.

12.1. IP Ownership Considerations

12.1.1. ATP is the owner of the property in the databases and the biospecimens (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 biospecimens 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.

12.1.2. 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.

12.1.3. 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 Research 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.

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

12.1.5. Should any IP rights be owned by ATP/AHS, the procedures described in the AHS IP Policy and Procedure Manual (Document #1137, effective November 8, 2012) and outlined below in sections 13.2 to 13.4 will apply.

12.2. IP Assessment of AHS Owned IP

12.2.1. 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.

12.2.2. 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.

12.2.3. 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.

12.3. Commercialization and Revenue Sharing of AHS Owned IP

12.3.1. 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.

12.3.2. 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 (see Appendix 3).

12.3.3. 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.

12.3.4. 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.

12.3.5. 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.

12.3.6. 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.

12.3.7. 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.

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

13.Incidental Findings

13.1. 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 CPTP Ethics, Legal and Social Issues Standing Committee and the relevant research ethics boards.

13.2. 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 Data Access Guidelines and Procedures, will not have access to any contact information for Research Participants.

14.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 collection.

14.1. Requests to collect additional Data from ATP Research Participants

14.1.1. ATP will not consider *ad hoc* requests to collect additional Data from ATP Research Participants. Prior to the development and implementation of each scheduled ATP Data collection protocol, ATP will put out a targeted call for expressions of interest to the research community. Interested Applicants will, at that time, be invited to submit a Question/Biospecimen Inclusion Proposal Form. All Question/Biospecimen Inclusion Proposal Forms will be reviewed from a competitive perspective by the ATP Scientific Steering Committee and evaluated 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

14.1.2. Applicants will be informed of the outcome of the review by ATP. Successful Applicants will work collaboratively with ATP to integrate question collection protocols into the overall ATP protocol.

14.1.3. All additional Data 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 collection and processing.

14.2. Applicants will be expected to contribute to the costs of implementation, collection and processing of any additional data done for the purpose of an Ancillary Study.

14.3. ATP reserves the right to conduct Ancillary Studies that are necessary to test the feasibility, acceptability, repeatability and/or validity of new approaches for the collection of Data. In addition, ATP reserves the right to conduct Ancillary Studies related to quality improvement or calibration required to enhance the utility of the existing ATP Resource. Such studies must involve the Scientific Director of ATP as Principal

Investigator or Co-Investigator, and they must be consistent with the ATP Strategic Plan (current version: 2013-18).

15.Linkage Data

15.1. 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.

16.Compliance with the ATP Data Access Guidelines and Procedures

16.1. The Approved User and their Institution shall comply with the ATP Data Access Guidelines and Procedures and the Research 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 Data Access Guidelines and Procedures.

16.2. If an Approved User or Approved User's Institution breach the provisions of the Research Agreement, it could lead to immediate revocation of the approval to use the ATP Resource. 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.

16.3. 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.

16.4. 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.

17.Disclaimers and Limitations of Liabilities

17.1. The 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 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 by the Approved User or the Approved User's Institution.

17.2. 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.

17.3. ATP bears no legal responsibility for the accuracy, provenance, integrity or comprehensiveness of the Data supplied.

17.4. 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 Research 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.

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

17.6. The Research 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 Research Agreement.

17.7. ATP will keep copies of all application forms, application review forms, minutes/proceedings of expedited review process 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.

18.Future Amendments to the ATP Data Access Guidelines and Procedures

18.1. This ATP Data 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 Scientific Advisory Committee with advice for additional experts as required. In the case of approved amendments, a revised version of the ATP Data Access Guidelines and Procedures will become available. Researchers are directed to contact ATP for the most recent version by emailing ATP.Research@albertahealthservices.ca.

19.References

19.1. 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.

19.2. 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.

19.3. 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.

19.4. 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.

19.5. 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.

19.6. 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.

19.7. 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.

19.8. 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.

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

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 Publication section of the ATP Data Access Guidelines and Procedures (section 11). 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 due to the commitment of its research participants, its staff and its funders: Alberta Cancer Foundation, Canadian Partnership Against Cancer, Alberta Cancer Prevention Legacy Fund (administered by Alberta Innovates – Health Solutions) 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."*

Appendix 2: ATP Conflict of Interest Considerations

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

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

Application of Considerations
These considerations apply to:

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

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

Guiding Principles
Decisions concerning applications for access to the ATP Resource should be guided by ATP's Data Access Guidelines and Procedures 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 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 a in 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 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 Lead.

Conflict Action Points

Prior to beginning the expedited review process, the Scientific Director of ATP, or designate, will request that reviewers 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 Scientific Director of ATP, or designate, 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 expedited reviewers and all support staff and any other individuals convened to review a Research Proposal, 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 expedited review 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 Lead.

Appendix 3: ATP Research Application Form Template

Alberta's Tomorrow Project (ATP)
CancerControl Alberta

Research Application Form

Request for access to data/biospecimens to support research

[Applicant, Institution]

regarding

[Title of Proposed Research]

[Date of submission of Research Application Form]

SCHEDULES

Schedule 1: Research Application Form – Request for access to data/biospecimens to support research

Schedule 2: Copy of Research Proposal

Schedule 3: Copy of Research Ethics Board(s) Forms and Approvals

Schedule 4: Evidence of Funding (ex. copy of letter of award from grant agency)

Schedule 5: Brief CV of Applicant (2 pages) and Co-Applicant (if required)

Please send application with completed Schedules 1, 2, 3 and 4, application fee (unless exempt) and any other relevant supporting materials by mail or email to:

Mailing address: Alberta's Tomorrow Project
Alberta Health Services – CancerControl Alberta
Level 3, Richmond Road Diagnostic and Treatment Centre
1820 Richmond Road SW
Calgary, Alberta, Canada
T2T 5C7

Email address: ATP.Research@albertahealthservices.ca

PLEASE NOTE THAT INCOMPLETE APPLICATIONS WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

SCHEDULE 1: **Research Application Form – Request for access to data/biospecimens to support research**

ALBERTA'S TOMORROW PROJECT (ATP)
ALBERTA HEALTH SERVICES – CANCERCONTROL ALBERTA

PROPOSAL TITLE: [Insert Title]

This proposal is a request for access to data only	**YES** ☐ **NO** ☐

1. Please provide the following information:

Applicant's Name	
Applicant's Educational Qualifications (PhD, MD etc)	
Applicant's Position(s) (Rank, Faculty, Department, Institution)	
Mailing Address	
Phone Number(s)	
Fax Number	
Email address	
If Applicant is a trainee (e.g. graduate student), please provide the name, educational qualifications, position and contact information of a supervisor (co-applicant) **Not applicable** ☐	

2. Please list all co-investigators, data managers, project staff and students who will be involved in the research using the requested data and/or biospecimens (add more rows if required):

Name and Educational Qualifications	Position (Rank, Faculty, Department, Institution)	Role in project	Access to data/samples? Yes/no

3. Project Information

Study Coordinator (name and contact information)	
Data Manager (name and contact information)	
Lay summary (maximum of 300 words – will be published on ATP's website and/or in other publicly available ATP material) ***Note: may be edited or modified to suit ATP needs***	
Scientific abstract (maximum of 300 words – will be published on ATP's website and/or in other publicly available ATP material)	

Project duration (Day/Month/Year)	**Proposed start date:** **Proposed end date:**
List all anticipated outcome(s) of project (e.g., manuscript, discovery research etc.)	
Funding source	
Funding approved or pending? If approved, please attach a copy of the letter of award.	
Are industry funds involved in support of this project? If yes, please provide details of the industry and the nature of support provided by the industry.	
Date of ethical approval* (Day/Month/Year) Please attach a copy of all relevant ethical approval documents in Schedule 3.	
Name of Research Ethics Board(s), address(es) and contact information	

*The administrative review process will not be initiated until a copy of all relevant ethical approval documents have been sent to the Research Lead of ATP.

4. Biospecimen specifications ☐ **Not applicable/No biospecimens required**
(If selected skip to next section - Data specifications)

Type(s) of biospecimen(s) requested from ATP	
Volume of biospecimens requested	
Number of biospecimens requested	
Does your study have sufficient statistical power to meet your objectives? Please provide a power calculation or other justification.	
Justification for <u>use</u> and <u>volume</u> of ATP's biospecimens - what characteristics of the biospecimens make them more suitable for use than biospecimens that could be obtained from another source?	
Date biospecimens are required (Day/Month/Year)	
Biospecimen donor - age range	
Biospecimen donor - sex	
Other inclusion/exclusion criteria (e.g., ethnicity, prescription medication use, geographic location, prior disease, fasted for at least 4 hours etc.)	
Additional parameters required	
Where will biospecimens be shipped, stored, processed and analyzed? List all locations, mailing addresses and contact information.	
Please provide a description of biospecimen storage conditions. (eg. stored at -80° C)	

What biospecimens (and resulting analytical data) will be returned to ATP?	
Describe all electronic and physical safeguards that will be in place to protect the security and integrity of biospecimens that may be released by ATP to support the research described in Schedule 2.	
Laboratory experience using the assay (length of time assay used, number of assays completed per year, recent and past % coefficients of variation and interclass correlations. If applicable, also include manufacturer's assay quality assurance information).	
List 2-5 publications which demonstrate feasibility of the assay for the proposed research (manufacturer or peer-reviewed publications acceptable)	

5. Data specifications (copies of questionnaires and data dictionaries may be obtained by emailing ATP at ATP.Research@albertahealthservices.ca)

ATP questionnaires from which data are requested	
Does your study have sufficient statistical power to meet your objectives? Please provide a power calculation or other justification.	

Variables requested (variable name and description), including brief rationale for each variable	
Date data required (Day/Month/Year)	
Research participant age range	
Research participant sex	
Other inclusion/exclusion criteria (e.g., ethnicity, prescription medication use, geographic location, prior disease, etc.)	
Additional parameters required	

Where will data be stored and analyzed? List all locations, mailing addresses and contact information.	
What data and derived variables created in the analysis process for the study in question (including metadata such as data dictionary) will be returned to ATP?	
Describe all electronic and physical safeguards that will be in place to protect the security and integrity of ATP data under the following headings: • **Designated servers with physical and electronic access control** • **Laptops with encrypted hard drives** • **Encrypted flash drives** • **Institutional password policy for password complexity and expiry** • **Data backups** • **Restricted access to those listed in Table 2 (Question 2 Page 5)**	
Data Format Requested (choose one only)	☐ SAS ☐ STATA ☐ SPSS ☐ ACCESS ☐ EXCEL ☐ CSV ☐ OTHER If other, state format and provide justification:
Select operating system in which analyses will be done (choose one only)	☐ WINDOWS ☐ OSX ☐ LINUX

6. Other sources of biospecimens and/or data

Have you applied for biospecimens and/or data for the research proposal from another source?

☐ YES ☐ NO

If yes: Where? _____

What is the status of the request?

☐ APPROVED ☐ PENDING ☐ DECLINED

7. Please provide the name and contact details of three external reviewers who could review your research proposal (<u>only</u> if requesting access to biospecimens).

_____

_____

_____

8. Application fee will be submitted: ☐ YES ☐ NOT APPLICABLE

If yes, date of submission (D/M/Y): _____

The person(s) named in the research team is/are applying to ATP - Alberta Health Services (AHS) for access to health information and/or biospecimens for the research purposes described in the Research Proposal provided in Schedule 2.

ATP - AHS may provide access to information and/or biospecimens applied for by the Applicant to the Applicant, pending approval by ATP's Access Review Panel (if accessing biospecimens), using the guidelines outlined in the ATP Terms of Reference for the Data and Biospecimens Access Review Process.

Please note that data/biospecimens will not be released until the applicant has received written approval from ATP <u>and</u> has signed the AHS Research Agreement and the Biospecimen Material Transfer Agreement if required (sample agreement templates available upon request at ATP.Research@albertahealthservices.ca).

By signing hereunder, the Applicant and Co-Applicant (if required) accept responsibility for the conduct of all members of the research team as listed in Schedule 1 and is/are responsible for ensuring the adherence of all listed individuals to the terms and conditions of all agreements required to access ATP biospecimens and/or data.

9. Signature of Applicant

I acknowledge that the details in this application are correct and are fully compliant with the terms of the ethical approval materials appended as Schedule 3.

_____ _____

Applicant Date (D/M/Y)

_____ _____

Co-Applicant (if required) 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 Lead at 1-877-919-9292 or via email at ATP.Research@albertahealthservices.ca.

SCHEDULE 2: Copy of the Research Proposal

Provide a copy of the Research Proposal relevant to this request, including the research question, hypothesis, objectives and detailed methodology.

Please ensure that each page of the research proposal has the name of the Applicant, the title and date of application included in the header. Limit proposal to a maximum of five (5) pages, on letter size paper (8.5' X 11'), with a font size no smaller than Arial 10 or Times New Roman 12.

SCHEDULE 3: Copy of the Research Ethics Board(s) Approvals

Provide a copy of all Research Ethics Board(s) Application forms and approvals, as well as all amendments associated with the Research Proposal described in Schedule 2.

Ethical approval must be obtained from an organization that certifies compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans or comparable international ethical norms.

SCHEDULE 4: Evidence of Funding

Please provide evidence of funding such as a copy of the letter of award from a grant agency or other similar documents.

SCHEDULE 5: Brief CV of Applicant and Co-Applicant (if required)

Please provide a CV for the Applicant listing (i) education, (ii) positions held and (iii) relevant publications in the five (5) years prior to completing the current application.

The CV should not exceed two (2) pages in length.

ATP USE ONLY – DO NOT COMPLETE

Title of Research Proposal:		Application form is complete	☐ Yes ☐ No
		Data available for release	☐ Yes ☐ No
		Biospecimens available for release	☐ Yes ☐ No ☐ NA
		Linkage data needed	☐ Yes ☐ No
Name of Applicant:		Research Protocol included with application	☐ Yes ☐ No
Applicant Institution:		Status of ethical approval of research protocol	☐ Submitted ☐ Under review ☐ Additional information/ revisions requested ☐ Approved ☐ Not approved
Request number:		Ethical approval is specific to the research protocol submitted	☐ Yes ☐ No
Name of ATP administrative reviewer:		Ethical approval is consistent with information on application form	☐ Yes ☐ No
Date of administrative review (D/M/Y):		Applicant is affiliated with institution and has prior domain relevant publications	☐ Yes ☐ No
Recommendation of reviewer:	☐ Return to applicant - application incomplete ☐ Recommend for peer review ☐ Recommend for formal review by ATP Access Review Panel ☐ Recommend for expedited review by ATP (requests for data only)		
Signature of ATP reviewer:		Date (D/M/Y)	

Appendix 4: ATP Notification of Intent Form Template

Alberta's Tomorrow Project (ATP)
CancerControl Alberta - Alberta Health Services
Notification of Intent Form

Name of applicant(s) and institution(s):

Mailing address:

Email address of applicant(s):

Phone number(s) of applicant:

Potential title of research proposal:

Name(s) of funding organization(s) from which Applicant is seeking a grant:

Type of grant sought:

Short summary of research proposal (maximum 300 words):

Type(s) and characteristics of data and/or biospecimens that may be requested from ATP:

Name of Applicant	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 Lead at 1-877-919-9292 or via email at ATP.Research@albertahealthservices.ca

Appendix 5: ATP Data Only Application Expedited Review Checklist Template

Alberta's Tomorrow Project (ATP)
CancerControl Alberta - Alberta Health Services
Data Only Application
Expedited Review Checklist

Applicant's name and educational qualifications:

Title of research proposal:

Request number assigned by Alberta's Tomorrow Project:

1. Copy of ethical approval has been provided.

Yes ☐ **No** ☐

2. Ethical approval provided matches the submitted research proposal and application form.

Yes ☐ **No** ☐

3. Research proposal fits with ATP's mandate, vision and goals.

Yes ☐ **No** ☐

4. Applicant is appropriately qualified and experienced to undertake the research proposal or has the support of an appropriately qualified co-applicant (e.g. academic supervisor).

Yes ☐ **No** ☐

5. Applicant has sufficient resources to undertake the research proposal.

Yes ☐ **No** ☐

6. Applicant has provided sufficient assurance that the security and integrity of data will be safeguarded appropriately.

Yes ☐ **No** ☐

7. Applicant is eligible to sign the Alberta Health Services Research Agreement.

Yes ☐ **No** ☐

Recommendation:

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

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

Date of Review (DD/MM/YYYY):

Reviewers:

Name of ATP's Scientific Director (or designate)	Signature	Date (D/M/Y)
Name of ATP's Research Lead (or designate)	Signature	Date (D/M/Y)
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 Lead at 1-877-919-9292 or via email at ATP.Research@albertahealthservices.ca

Appendix 6: ATP Additional Variable Request Form Template

Alberta's Tomorrow Project (ATP)
CancerControl Alberta - Alberta Health Services
Additional Variable Request Form

Name of approved user(s):

Title of approved research project:

Request number assigned by Alberta's Tomorrow Project:	

List the additional variables requested from ATP for use in the approved research project:

Questionnaire Title	Variable Name	Justification

Submit completed form to ATP.Research@albertahealthservices.ca. It should be noted that this form applies to requests for additional data elements only. If additional biospecimens are required, please complete a significant change report form.

If the approved user is informed that the provision of additional data elements is deemed to significantly alter the original research proposal, the approved user must also complete a significant change report form.

If the change is deemed to be minor, the provision of the additional variables listed above by ATP to the approved user will not constitute a significant change to the approved research project covered under the terms and conditions of the Alberta Health Services Research Agreement. The approved user agrees to use the additional variables under the conditions imposed in the original signed AHS Research Agreement.

Name of Approved User	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 Lead at 1-877-919-9292 or via email at ATP.Research@albertahealthservices.ca

ATP USE ONLY – DO NOT COMPLETE

Title of Research Proposal		Name of Applicant	
Request number		Name of ATP Scientific Director (or designate)	
Date form received (D/M/Y)		Approved ethical amendment is attached	☐ Yes ☐ No
Recommendation of Scientific Director (or designate)	☐ Change is minor and coded data can be provided to the approved user ☐ Change significantly alters the original research proposal, completion of a significant change form is required by the approved user		
Signature of ATP Scientific Director (or designate)			Date (D/M/Y)

Appendix 7: ATP Progress Report Form Template

Alberta's Tomorrow Project (ATP)
CancerControl Alberta - Alberta Health Services
Progress Report Form

Name of approved user(s):

Title of approved research project:

Request number assigned by Alberta's Tomorrow Project:

1. Describe progress made to date on the approved research project:

2. Is the approved research project on track to achieve completion by the date specified in the ATP research application form?

Yes ☐ **No** ☐

If no, provide an outline of issues and describe strategies put in place to address the issues that have resulted in the delay:

Do you need to request an extension for completion of the approved research project?

Yes ☐ **No** ☐

If yes, what is the revised completion date (D/M/Y):

Name of Approved User | 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 Lead at 1-877-919-9292 or via email at ATP.Research@albertahealthservices.ca

Appendix 8: ATP Significant Change Report Form Template

Alberta's Tomorrow Project (ATP)
CancerControl Alberta - Alberta Health Services
Significant Change Report Form

Name of approved user(s):

Title of approved research project:

Request number assigned by Alberta's Tomorrow Project:	

1. List and describe the change(s) to the approved research project, indicating clearly how the change differs from the approved research project:

2. Justify why the proposed change(s) is/are needed:

3. Was an ethical amendment needed in order to accomplish the change(s):

Yes ☐ **No** ☐

If yes, please attach the approval of the amendment from the relevant ethics review board.

If no, please explain why an amendment was not submitted to the relevant ethics review board:

Name of Approved User _____ 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 Lead at 1-877-919-9292 or via email at ATP.Research@albertahealthservices.ca

ATP USE ONLY – DO NOT COMPLETE

Title of Research Proposal		Name of Applicant	
Request number		Name of ATP Scientific Director (or designate)	
Date form received (D/M/Y)		Approved ethical amendment is attached	☐ Yes ☐ No
Recommendation of Scientific Director (or designate)	☐ Change is noted by ATP and no further follow up required ☐ Change is noted by ATP and biospecimens and/or coded data can be provided to approved user ☐ Change is significant and approved user is required to sign a revised Research Agreement and Biospecimen Material Transfer Agreement ☐ Change is fundamental and approved user must submit a new research application form for evaluation under the ATP access process		
Signature of ATP Scientific Director (or designate)			Date (D/M/Y)

Appendix 9: ATP Publication Checklist Template

Alberta's Tomorrow Project (ATP)
CancerControl Alberta – Alberta Health Services
Publication Checklist

All final drafts of manuscripts (e.g. submissions to journals) emanating from Alberta's Tomorrow Project (ATP) must be sent for approval by ATP *prior* to journal submission. ATP expects to review all manuscripts within 10 business days of receipt. All manuscripts will be reviewed to determine if any confidential and/or proprietary information has been disclosed; the publication may bring ATP/AHS into disrepute; the conditions laid out in the ATP Biospecimen and Data Access Guidelines and Procedures and the AHS Research/Biospecimen Material Transfer agreements have been followed; and the scope of the reported analysis is compliant with the approved research project.

Listed below is a checklist of the requirements for manuscripts based on the ATP Resource. A signed and completed checklist must be included with each manuscript submitted for approval at ATP.Research@albertahealthservices.ca.

CHECKLIST FOR ATP MANUSCRIPTS

Name and affiliation of approved user(s):

Title of approved research project:

Request number assigned by ATP: | |

Name of corresponding author: | |

Title of manuscript: | |

- ☐ I have included Alberta's Tomorrow Project as a keyword and in the abstract
- ☐ I have included an accurate acknowledgement section[1]
- ☐ I will send ATP a copy of the final submitted manuscript and an electronic copy of the final version accepted for publication
- ☐ I will let ATP know when the manuscript is accepted for publication
- ☐ I will liaise with ATP concerning media coverage[2]
- ☐ I will provide lay and scientific summaries of the manuscript to ATP and consent to their use in communication materials disseminated to ATP research participants, funders, other stakeholders and the general public[3]

Signature of Approved User:_____ Date (D/M/Y):_____

Notes

1. 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 using the ATP resource:

   "Alberta's Tomorrow Project is only possible due to the commitment of its research participants, its staff and its funders: Alberta Cancer Foundation, Canadian Partnership Against Cancer, Alberta Cancer Prevention Legacy Fund (administered by Alberta Innovates – Health Solutions) 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."

2. ATP reserves the right to work with the Approved User to develop a communications strategy that may be deployed when the manuscript is published. 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.

3. Once a manuscript is accepted for publication, ATP will ask the lead author to prepare lay and scientific summaries of the manuscript for use in communications material disseminated to ATP research participants, funders, other stakeholders and the general public. It should be noted that lay summaries may be edited or modified to suit the needs of ATP.

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 Lead at 1-877-919-9292 or via email at ATP.Research@albertahealthservices.ca

Appendix 10: ATP Privacy Breach Notification Template

Alberta's Tomorrow Project (ATP)
CancerControl Alberta – Alberta Health Services
Privacy Breach Notification

This form is to be completed as soon as you become aware of a privacy breach. Notify ATP immediately and submit this completed form to ATP.Research@albertahealthservices.ca with the subject *Privacy Breach Notification*. If you have questions about completing this form, please contact ATP. ATP will pass this notification to AHS Legal and Privacy for investigation.

Report the Breach			
Name of individual reporting the breach		Phone number(s) and email address	
Institutional affiliation	Title/Position		Role in approved research project
Title of approved research project			
Date of breach (DD/MM/YYYY)	Time of breach	ATP assigned request number	Number of individual(s) whose information is affected
Type of breach ☐ Data security/integrity ☐ Confidentiality ☐ Ethics/Research Proposal			
Briefly describe the nature of the breach, how you became aware of it, where the breach occurred and what immediate actions were taken to contain the breach.			
Follow Up			
Name of individual to contact		Phone number(s) and email address	
Role in approved research project		Title/Position	
Institutional affiliation		Institutional contact information	
ATP USE ONLY – DO NOT COMPLETE			
Received by:		Date of receipt (DD/MM/YYYY):	
Forwarded to (name and contact information):			

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 Lead at 1-877-919-9292 or via email at ATP.Research@albertahealthservices.ca

Appendix 11: ATP Final Report Form Template

Alberta's Tomorrow Project (ATP)
CancerControl Alberta - Alberta Health Services
Final Report Form

Name of approved user(s):

Title of approved research project:

Request number assigned by Alberta's Tomorrow Project:

1. Was the approved research project completed as per the project description and conditions outlined in Alberta Health Services (AHS) Research Agreement and, if biospecimens were accessed, the AHS Biospecimen Material Transfer Agreement?

   Yes ☐ **No** ☐

   If no, describe the differences between the approved research project as outlined in the agreements and the actual work performed:

2. Provide a scientific summary of the findings of the approved research project (maximum 300 words):

3. Provide a lay summary of the findings of the approved research project suitable for ATP research participants and other publicly available ATP material (maximum 300 words):
Note: May be edited or modified to suit ATP needs

4. Describe the planned outputs for the results of the approved research project (presentations, theses, manuscript publications, etc):

I hereby consent to allow ATP to use the information provided in this form in communication materials for ATP research participants, funding organizations and stakeholders and for use in any other publicly available ATP materials.

Name of Approved User	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 Lead at 1-877-919-9292 or via email at ATP.Research@albertahealthservices.ca

Appendix 12: AHS Research Agreement Template

HIA Section 54 Research Agreement

between

Alberta Health Services

and

Applicant

(Referred to as "the Researcher")

Regarding

Research Proposal

INTRODUCTION

1. Names of the parties to this agreement:

   Applicant:

   Co-Applicant (if Applicant is a trainee):

   Name:

   Name:

   Name:

2. The Researcher has applied to Alberta Health Services for the disclosure of health information for the research purposes described in the Researcher's proposal.
3. Alberta's Tomorrow Project (ATP) is a resource of AHS and complies with AHS policies and procedures.

RESPONSIBILITIES OF THE RESEARCHER

3. The Researcher agrees:

   a) To comply with the ***Health Information Act*** and all regulations made under it as well as any applicable federal legislation governing privacy, confidentiality and protection of patient information. *HIA section 54(1)(a)(i)*

   b) To comply with any conditions imposed by Alberta Health Services relating to the collection, use, protection, disclosure, return or disposal of the health information. *HIA section 54(1)(a)(ii)*

   c) To comply with any requirements of Alberta Health Services to provide safeguards against the identification, direct or indirect, of an individual who is the subject of the health information. *HIA section 54(1)(a)(iii)*

d) Not to make any attempt to contact an individual who is the subject of the health information to obtain additional identifiable health information unless the individual has provided the custodian with the consent required as part of section 55 of the *Health Information Act*. *HIA sections 54(1)(d) and 55*

e) Not to publish the health information in a form that could reasonably enable the identity of an individual who is the subject of the information to be readily ascertained. *HIA section 54(1)(c)*

f) To allow Alberta Health Services to access or inspect the Researcher's premises to confirm that the Researcher is complying with the *Health Information Act* and *Health Information Act Regulations,* any imposed conditions on use, protection, disclosure, return or disposal of the information and any requirements related to the provision of security safeguards. *HIA section 54(1)(e)*

g) To pay the costs associated with file retrieval, obtaining consents (section 55 of *Health Information Act*), data matching, and any other services provided by Alberta Health Services to the Researcher in connection with the request for disclosure of health information described herein. *HIA sections 54(1)(2)and 55*

h) To report to Alberta Health Services any breaches of confidentiality and/or security respecting the information from the records at the facility immediately upon identification of such breaches, and to take steps to both remedy the breach and prevent similar occurrences in the future.

i) To securely dispose of or return to Alberta Health Services any personally identifying information as set out in sections 9 and 10 herein.

j) To use the research information only for purposes identified in the Researcher's proposal as described in Schedule A. *HIA section 54(1)(b)*

k) Not to use or disclose the information for any subsequent or other purposes not identified in Schedule A without the prior written approval of Alberta Health Services, and, if required by the Research Ethics Board or Committee, the consent of the individual who is the subject of the information.

l) To notify all individuals on the research team that have access to the health information that they must comply with the ***Health Information Act*** and regulations and with any conditions imposed by Alberta Health Services, as set out in this Agreement.

m) To use the acknowledgement text outlined in the ATP Biospecimen and Data Access Guidelines and Procedures which acknowledges the funders of ATP including AHS.

n) To comply with the terms and conditions of this Agreement regarding the safeguarding and disposition of health information in respect of all research data and health information collected.

3.1 Researcher acknowledges that if consent to disclose health information is sought from an individual other than the individual who is the subject of the information (the participant), the researcher must ensure that the other individual is legally authorized to provide consent on the participant's behalf, in accordance with research ethics requirements and s. 104 of the HIA.

RESPONSIBILITIES OF ALBERTA HEALTH SERVICES

4. Alberta Health Services agrees to disclose the health information or data in the specific format as outlined in Schedule A and in compliance with any conditions required by the Research Ethics Board or Committee.

5. Alberta Health Services shall provide other services to facilitate the research allowed by the Research Ethics Board or Committee and as itemized in Schedule D.

6. Alberta Health Services agrees to maintain the research proposal as confidential until the research proposal is approved for access where the nature of the research proposal and names of the researchers will be disclosed in ATP materials.

DISCLAIMERS AND LIMITATIONS OF LIABILITIES

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

8. It is not the responsibility of ATP to inform the Researcher of any in progress, approval pending or approved intellectual property claims or proprietary rights of any third parties.

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

10. The Researcher or their Institution will not use the Biospecimens in any experiments involving humans and will not use the Biospecimens in contact with any cells or other materials to be infused into humans. Biospecimens will not be released for use in animal research or research with recombinant DNA.

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

12. The Researcher 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 Research Agreement and/or MTA by the Researcher; or ii) any negligence or willful default of the Researcher, provided that Alberta Health Services agrees to use its reasonable endeavors to mitigate any loss.

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

14. This 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, this Agreement.

15. ATP will keep copies of all application forms, application review forms, minutes/proceedings of Access Review Panel 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.

GENERAL PROVISIONS

16. This Agreement, meaning this HIA s54 Research Agreement and all schedules and appendices hereto, may be amended or varied in writing with the mutual agreement of the parties.

TERMINATION OR TRANSFER OF AGREEMENT

17. Termination or transfer:

    a) Termination for Convenience. This Agreement may be terminated upon the mutual written agreement of the Parties.

    b) Termination without Cause by Notice. Any Party may terminate this Agreement without cause upon the provision of 15 days' prior written notice.

    c) Automatic Termination. This Agreement shall automatically and immediately terminate if a Party becomes bankrupt or insolvent, ceases to carry on business, or is subject to an order made or a resolution passed for the winding up of its operations or if the ATP ceases to be funded or is terminated for any other reason.

    d) Termination for Breach by Notice. Any Party may terminate this Agreement: (1) if another Party fails to carry out a material duty or obligation under this Agreement and such default has not been remedied to the satisfaction of the non-defaulting Party within 10 days written notice to the defaulting Party detailing the nature of the default; or (2) in the event of a conflict between the terms of this Agreement and applicable laws.

    e) Request for Information. If the ATP has concerns about the Researcher's compliance with the terms and conditions of this Agreement, ATP shall provide the Researcher with written notice of such concerns and its reasons for them. The Researcher shall, within five days of receipt of the notice, investigate the matter and provide ATP with a report stating the cause of the deficiency, if any, and the steps taken to prevent a recurrence, if required.

    f) Suspension of Access. ATP may immediately suspend the Researcher's access to the health information if it reasonably believes that there is: (a) a breach of any material term of this Agreement; or (b) an extreme circumstance that would warrant such action including a compromise of the integrity or security of the health information.

18. In the event the agreement is breached by Researcher and/or health information is disclosed or used in contravention of the terms and conditions of the agreement or the ***Health Information Act*** or the regulations, the agreement may be immediately terminated by Alberta Health Services. *HIA section 54(4).* Alberta Health Services may withdraw the research privileges of the Researcher and will require that all individually identifying health information that has been disclosed for the research purpose be returned to Alberta Health Services.

19. Upon the expiration of the time period for which the Researcher must retain the health information to comply with relevant legislation, policies and procedures, the Researcher must return or dispose of the health information provided by Alberta Health Services and any copies made thereof by the Researcher. Should Alberta Health Services agree to the disposition rather than its return, the researcher shall provide Alberta Health Services with a letter that confirms the date and the means of disposition.

20. The Researcher agrees to obtain authorization from Alberta Health Services prior to the transfer of the agreement to another person. Authorization may be withheld at the discretion of Alberta Health Services. Successors shall be bound by the terms and conditions of this Agreement.

☐ By checking the box, the researcher agrees to comply with all of the conditions in Alberta's Tomorrow Project Biospecimen and Data Access Guidelines and Procedures including, without limitation, the provisions that require derived variables created by a researcher to be returned to ATP as a means of enriching/growing the resource and having those variables available for subsequent researchers to use, an embargo of 6 months granted to the researcher after the return of results prior to any re-release by ATP, and costs for biospecimen handling, processing, packing and shipping (if applicable) covered by the researcher.

By my signature hereunder, I AGREE to be bound by the terms and conditions herein.

Researcher (Applicant)

_____

Name

_____

Signature

_____

Date

Co-Applicant (if required)

_____

Name

_____

Signature

_____

Date

Alberta Health Services

Name (Repository Owner(s) / Service Owner(s))	Title	Date	Signature

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.

SCHEDULE A: COPY OF THE RESEARCH PROPOSAL

SCHEDULE B: COPY OF THE RESEARCH ETHICS BOARD OR COMMITTEE APPROVAL

SCHEDULE C: LIST OF REQUIRED DATA ELEMENTS

SCHEDULE D: ADDITIONAL CONDITIONS

SCHEDULE A: COPY OF THE RESEARCH PROPOSAL

A copy of the Researcher's Proposal along with any amendments and approved consent/assent forms.

See attached for the Study Protocol:

- Document title (filename)

See attached for the Informed Consent Forms:

- Document title (filename)

SCHEDULE B: COPY OF THE RESEARCH ETHICS BOARD OR COMMITTEE APPROVAL

A copy of the approval letter(s) (original and re-approvals as well as approvals for any amendments to the proposal) of the Research Ethics Board or Committee designated under the Health Information Act.

See attached for the Ethics Approval:

- Document Title (filename)

SCHEDULE C: LIST OF REQUIRED DATA ELEMENTS

List of required data elements and data sources.

See attached for the Case Report form:

- Document title (filename)
- Description if necessary of how the data is being used, compiled etc.

SCHEDULE D: ADDITIONAL CONDITIONS

1) **The Researcher has additional team members working on the study who will need access to coded ATP data?**
☐ Yes ☐ No

If yes, please specify names and affiliation:

Name	Employer				
	University (specify)	AHS employee/ physician/ Volunteer	PI with AHS as Paymaster	Independent Contractor	Manager's Name & Title

*Note – this list reflects the team members known as of the date this Research Agreement was signed. The Researcher must notify ATP (AHS) of all new team members added to the study.

Comments:

X	The Researcher understands and agrees that the above named Research Team Members may be required to take privacy and security training and sign a Confidentiality and User Agreement at the request of the AHS, and that if there are changes to the Research Team or to those who have access to the individually identifying Health Information and/or Personal Information, the Researcher will notify ATP (AHS) in writing.

2) **AHS is required to perform data matching?** ☐ Yes ☐ No

If yes, check all that apply:

☐	ATP (AHS) will provide data matching services for the Researcher.
☐	AHS will data match the information from (source) and provide the data requested by the Researcher in accordance with the Research Ethics Board approval letter.
X	Information will be provided in accordance with the following privacy principles: least amount of information, highest degree of anonymity and on a need to know basis.
X	Data will be provided in a secure manner and in a coded format

Comments:

3) **Health information being provided to the researcher/team in electronic form?** ☐ Yes ☐ No

It be provided the following method(s), check all that apply:
OPTIONS EDITED (SOME REMOVED)

☐	CD or DVD – need to encrypt identifiable health information on CD or DVD that meets ITSC approved encryption standard
☐	SFTP – identifiable health information must be transmitted using sftp that meets ITSC approved standard
☐	Email – encrypted email for identifiable health information
☐	Other – contact Information & Privacy (I&P) and ITSC

Comments:

4) **Fees are applicable for acquisition of this data?** ☐ Yes ☐ No
*Fees are charged by some AHS departments in accordance with the Health Information Act.
Comments:

5) **Maintaining confidentiality of patient data.**

X	Master Lists linking patient identifiers to study codes will be held by ATP and will not be provided to the Researcher
☐	De-identification of information has been confirmed by using the AHS standard Non-Identifying Health Information
☐	Researcher agrees to not attempt to re-engineer identity of patients (if provided with non-identifying information),
X	Researcher agrees to not contact patients for additional health information or any other purpose except in accordance with patient consent (i.e. the individual has provided the custodian with the consent required as part of section 55 of the *Health Information Act*)
X	Researcher agrees to only use the data for the purpose for which it is disclosed, unless with the prior written approval of Alberta Health Services, and, if required by the Research Ethics Board or Committee, the consent of the individual who is the subject of the information.
X	Researcher agrees to not perform data matching without first contacting AHS/ATP and the Office of the Information and Privacy Commissioner.
X	Researcher will complete an ATP Privacy Breach Notification form should any privacy breach occur.

Comments:

6) **Storage of health information provided for research**? ☐ Not applicable

If applicable, check all that apply:

☐	AHS network
☐	Non-AHS network (Researcher to provide security standards) EDITED CONTENT IN THIS LINE ONLY
☐	Stand alone computer
☐	Locked Filing Cabinet
☐	Server in a controlled access room

Comments:

7) **Secondary use of Data not described in the Research Ethics Board approved study?**

X	AHS is disclosing the information for the purpose of this research study and not for any other purpose. Where the Researcher wants to use the information for another purpose, the Researcher must notify the Research Ethics Board and get their protocol amended and contact ATP, complete a Significant Change Report form and ATP will coordinate with AHS and the Applicant to amend the AHS research agreement.

Comments:

8) **Retention and destruction of research records study?**

X	The Researcher may retain the research records for 7 years (clinical trials 25 years) after completion of the study in accordance with the AHS and University records retention policies.
X	The Researcher must return the records to AHS (Alberta's Tomorrow Project) and/or destroy the records provided by AHS (Alberta's Tomorrow Project) for the study after the retention period expires. Destruction must be done in compliance with AHS/industry standards.

Comments:

9) **Publication**

X	Researcher will not publish any details that may potentially identify an individual, bring ATP into disrepute, violate conditions of any signed agreements or that are beyond the scope of the Research Proposal.
X	Researcher will use the AHS standard Non-Identifiable Health Information (draft) to help determine if the information is potentially identifiable.

Comments:

10) **De-identified information /biological sample transfer to a third party?** ☐ Yes ☐ No

If yes, check all that apply:

☐	The following information/samples will be disclosed to (name of 3rd party) for the purpose of (purpose). • (list data elements and/or refer to Schedule C) • (list samples)
X	Attached is/are the contract(s) or agreement (s) [Material Transfer Agreement (MTA); Data Transfer Agreement (DTA)] between Researcher and the third party that binds that third party to agreeing to those conditions that AHS has put on the Researcher. ○ Will not attempt to re-engineer identity of patients ○ Will not contact patients ○ Will only use for the purpose for which it is being disclosed ○ Will not data match without connecting with AHS

Comments:

11) **Biospecimens provided?** ☐ Yes ☐ No

If yes,

X	Researcher will return any remaining biospecimens to ATP upon approved research project completion.
X	Researcher will return all detailed laboratory methodologies used and any other supporting documentation to ATP.

Comments:

12) **Return of Results and Data to ATP**

X	Researcher will return all data generated as part of an approved research project, such as any raw or derived data, materials, statistical programs and/or laboratory methodologies and any other supporting documentation, for inclusion in the ATP Resource in such detail and format as ATP reasonably requires.

Comments:

Appendix 13: Replacement Approved User Agreement

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 Research Agreement dated [***insert date***] attached hereto as Appendix 1 ("Research Agreement") [and/or Material Transfer Agreement dated [***insert date***] attached hereto as Appendix 2 ("Biospecimen Material Transfer Agreement")]; and

Whereas Former Approved User wishes to withdraw from the Project and the Approved User wishes to assume all of the responsibilities of the Former Approved User as of the Effective Date under the Research Agreement [and/or Biospecimen 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 Research Agreement [and/or Biospecimen Material Transfer Agreement] and the Replacement Approved User became the Approved User under the Research Agreement [and/or Biospecimen Material Transfer Agreement] and assumed all rights, title, interests, duties, responsibilities, and obligations as Approved User under the Research Agreement [and/or Biospecimen Material Transfer Agreement].

2. The Former Approved User agrees to continue to be bound by the terms of the Research Agreement [and/or Biospecimen 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: _____ By: _____
Signature Date Signature Date

Name: Name:

Title: Title:

[name of Approved Institution]

By: _____ By: _____
Signature Date Signature Date

Name: Name:

Title: Title:

[Name of Replacement Approved User]

Signature: _____

Date: _____

[Name of Former Approved User]

Signature: _____

Date: _____

Attachments: Appendix 1 [Appendix 2]