Access Committee Membership Package

Version 1.0

Alberta Health Services

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Background

The Alberta Cancer Research Biobank (ACRB) currently exists as a business unit within Alberta Health Services (AHS) – CancerControl Alberta offering pre-analytical translational support services to investigators with research projects addressing issues across the entire continuum of cancer prevention, care and survivorship. Over the past decade, the ACRB has leveraged more than $67M of funding through its major partners (Cancer Biobank, Cancer Epidemiology & Prevention Research and Alberta's Tomorrow Project) to build a biobank infrastructure and a rich inventory of human biological materials (HBMs) and associated information. The ACRB inventory consists of Restricted-Access HBMs, which remain in the custody of independent investigators, and Open-Access HBMs and associated information, which are accessible to all academic and clinical investigators who obtain the appropriate ethical and administrative approvals.

One of the key services offered by the ACRB includes the distribution of Open-Access HBMs and/or information to investigators who participate in a structured application and review process. The review of investigator application requests for Open-Access HBMs and/or information are adjudicated via a peer review process administered by the ACRB Access Committee.

Access Committee - Terms of Reference

Purpose

The ACRB Access Committee is responsible for adjudicating the distribution of human biological materials (HBMs) and/or information belonging to the ACRB Biobanking Unit according to the mandate of the ACRB business plan and local/institutional Research Ethics Board (REB) approvals.

The purpose of the Access Committee is that of a peer review, where each investigator Application Package is assessed based on availability of HBMs, appropriate use of HBMs, study sample size, scientific merit, impact of research, and promise of completing a proposed study within a reasonable time frame to ensure a fair and just means of allotting specimens.

Meetings

The Access Committee shall communicate and vote by email; if the need arises, the Access Committee chair will call for a meeting by teleconference.

Membership

The Access Committee is chaired by a Scientific Director or designate of the ACRB. Prospective Access Committee reviewers are approached by the Access Committee chair for a one year minimum membership commitment. Access Committee membership is reviewed annually by the ACRB executive committee who recommend revisions to revise membership.

The Access Committee reviewers include physicians and scientists engaged in cancer care and/or research. Other members of the ACRB may participate in a non-voting capacity as resources. Each application will be reviewed by five of the access committee members.

Criteria for Allocation

1. HBMs and/or information will only be distributed to researchers who have provided:
    - An Ethics Protocol/Application and an approval letter from a REB
    - A concise scientific summary of the proposed investigations
    - An abbreviated *curriculum vitae* (CV) with relevant publications
    - Description of funding and expertise to carry out the proposed investigations or have proposed a pilot to generate data for grant submissions to secure operating funds
    - Approval from the Access Committee
2. Access Committee reviewers will be informed of current inventory parameters (current amount, rarity, demand, etc.) related to the application so committee decision is properly informed

3. HBMs will be allocated on the basis of availability and justification for use of the materials. In some cases, the Access Committee may obtain an external expert opinion to help assess an application. Depending on the availability of HBMs in the bank, investigators may receive only partial fulfillment of requests.

ACRB Access Committee Chair Responsibilities:

The ACRB Access Committee Chair will ensure:

1. The review of investigator requests for HBMs by the ACRB Access Committee follows a multi-step process (see **Figure 1**).

2. If the Access Committee approves an application for HBMs, a separate decision will be made concerning allocation of the desired HBMs when competing requests exist for limited/rare samples.

3. Appropriate HBMs will be assigned to the approved requests and will be managed by a designated ACRB staff member in consultation with the Chair of the Access Committee.

4. HBMs found to be of unsatisfactory quality and unusable by investigator-requested analysis will be replaced at no charge. No monetary refunds will be given.

5. HBMs and/or information requests will only be permitted if an investigator is in good standing with the ACRB (e.g., demonstrated appropriate use of previously released HBMs and/or information and acknowledgment of the ACRB in all publications derived from ACRB materials and/or information).

6. If HBMs and/or information have been previously received from the ACRB, applicant researchers are expected to report usage of these materials and any relevant scientific productivity.

7. Researchers who publish their findings in scientific journals must acknowledge the source of the specimens (Alberta Cancer Research Biobank, Alberta Health Services, Alberta, Canada) in the Materials and Methods section. A copy of the published articles should be included with a subsequent request.

8. The Access Committee chair is ultimately responsible for maintaining the breadth and depth of the ACRB Biobanking Unit inventory to meet the overall goals of the ACRB business plan.

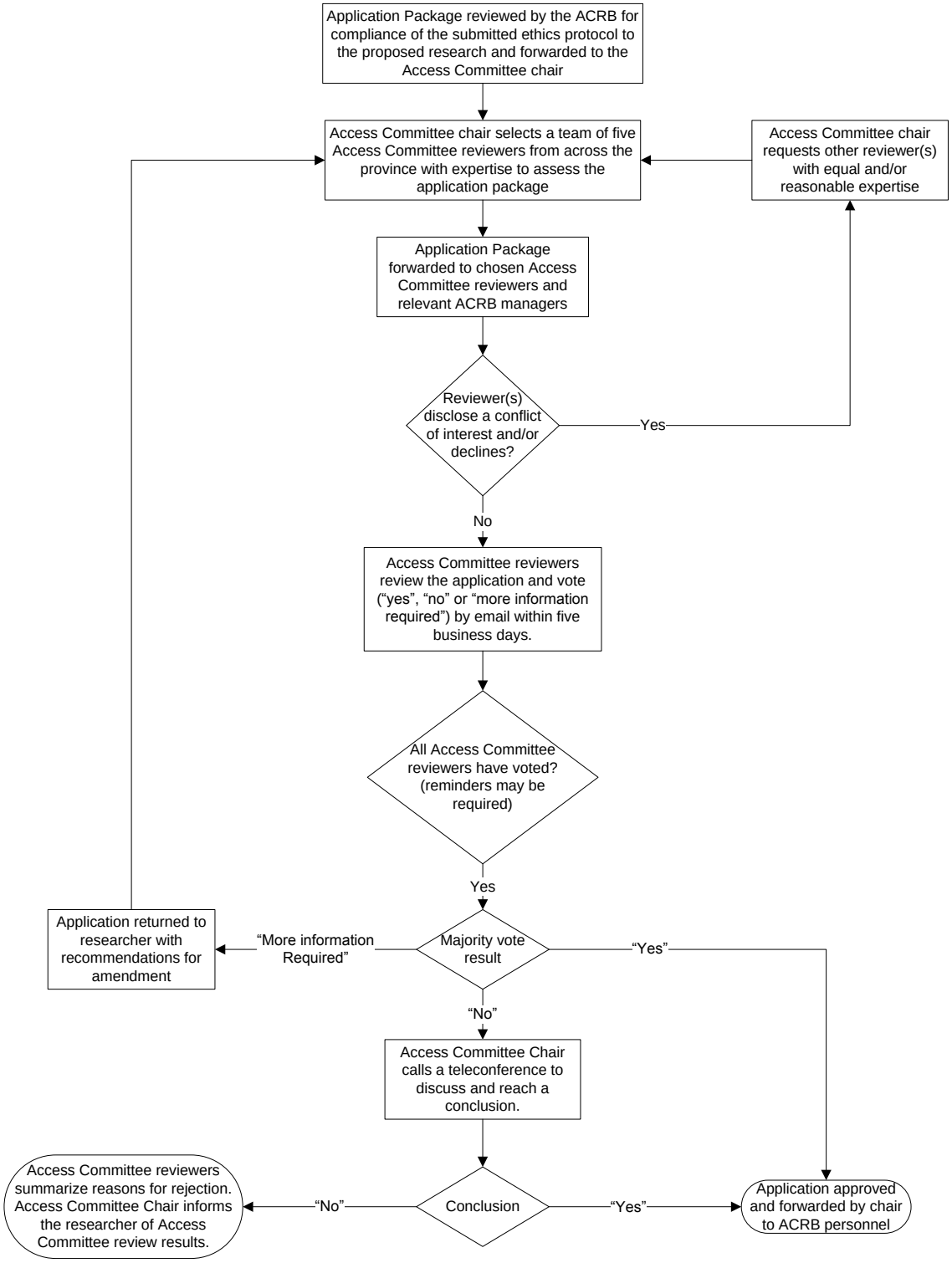


Figure 1: Alberta Cancer Research Biobank (ACRB) Access Committee Review Process

Application, Review and Release procedures for access to Human Biological Materials and/or Data

1.0 PURPOSE:

To ensure the process of application is simple and streamlined, without undue delays in providing access of human biological materials (HBMs) and/or data to researchers, while abiding by AHS and the Alberta Cancer Research Biobank (ACRB) policy to ensure compliance with the Alberta Health Information Act and appropriate local/institutional Research Ethics Boards (REBs).

Mechanisms for release/use of HBMs and/or data to researchers from the Open-Access collection are designed to promote the goals of the repository to advance cancer research and safeguard the interests of participants.

2.0 SCOPE:

All personnel responsible for the process of handling HBMs and/or data requests from researchers and the completion of appropriate contractual agreements between the repository and researchers.

This document applies to the ethical, legal and practical considerations that arise in the process of informing and/or assisting researchers in preparing an application requesting HBMs and/or data from the ACRB Open-Access collection, application review by the ACRB Access Committee and the release of HBMs and/or data to researchers. For details on the ACRB Access Committee membership and review process, refer to the ACRB **Access Committee - Terms of Reference**

3.0 ROLES AND RESPONSIBILITIES:

It is the responsibility of the ACRB Director to approve/update procedures, ensure all personnel are appropriately trained and to delegate responsibility for the day to day operations of the program.

4.0 MATERIALS, EQUIPMENT AND FORMS:

Materials and Equipment	
Documentation/Forms:	Application Form and Instructions ACRB Access & Release for Research Flow Diagram Access Committee - Terms of Reference AHS Material Transfer Agreement

5.0 PROCEDURES:

A consistent standard of scientific and ethical review for tissue requests will ensure that all Open-Access materials and information requests meet ethical standards and a high level of scientific merit. This procedure is also designed to ensure efficient handling of requests and adequate completion of contractual agreements.

5.1 APPLICATION

5.1.1 Request

5.1.1.1 The Principal Investigator (PI) of a research project is encouraged to email a general request for Human Biological Materials (HBMs) and/or data to biobank@albertahealthservices.ca.

5.1.1.2 One designated ACRB staff member (ACRB delegate) is assigned to the request by the ACRB Access Committee Chair.

5.1.1.2.1 The ACRB delegate is responsible for documenting all components of the application process, including: request and, application forms, review decisions, contractual agreements and applicant notifications.

5.1.2 Screening

5.1.2.1 The ACRB delegate assesses the inventory of the bank and determines if the requested HBMs and/or data are available. If required, the ACRB delegate will contact the applicant to clarify any requests.

5.1.2.2 The request is further evaluated by the ACRB delegate for requested individually identifying information and/or the risk of the applicant to perform re-identification of information via data matching.

5.1.2.2.1 The release of individually identifying information is not permitted for Open-Access materials. Applications requiring this information will not be accepted.

5.1.2.3 When the availability of samples has been clarified and the risk of data matching minimized, the PI is instructed by the ACRB delegate to complete a full application form.

5.1.2.4 The application form and instructions are located on the ACRB website.

5.1.3 Submission

5.1.3.1 PI's complete an application form and submit it via email to the ACRB delegate.

5.1.3.2 The ACRB delegate reviews the application form and checks for completion.

5.1.3.2.1 Application forms are considered complete if the applicant(s) have met all of the following criteria:

1. Local/institutional Research Ethics Board (REB) approval with an active REB Number or official REB exemption to undertake the research.
2. Provided a research ethics protocol including all relevant amendments.
3. Provided a concise scientific abstract/summary of the proposed investigations.
4. Provided a short resume/*curriculum vitae* including relevant publications.
5. Indicate availability of funding or have proposed a pilot study.
6. If the applicant has previously obtained samples from the ACRB, research progress made with those samples must be provided.

5.1.3.2.2 The ACRB delegate does not exercise judgment or assess the application on any criteria other than completeness

5.1.3.2.3 Applicants with application forms deemed incomplete are notified within five (5) regular business days of the application submission date by the ACRB delegate. Once notified, applicants are offered the chance to resubmit an amended application.

5.1.3.2.4 If necessary, application forms deemed complete by the ACRB delegate are evaluated based on the availability of HBMs and/or information in the ACRB inventory. If required, the ACRB delegate will contact the applicant to clarify any requests.

5.1.3.3 To facilitate the review process, the ACRB delegate and/or ACRB Managers fill out an Additional Information Form that informs the Access Committee reviewers of:

5.1.3.3.1 The total number of HBMs in the inventory of the type(s) requested

5.1.3.3.2 The estimated number of HBMs suitable for the request, as well as the percentage of inventory remaining

5.1.3.3.3 Any discrepancies between the materials requested and the materials reflected in the ethics protocol provided

5.1.3.3.4 Any additional conditions that pertain to the application

5.2 REVIEW

5.2.1 Review of applications by the Access Committee is governed by the **Access Committee - Terms of Reference**.

5.2.2 Application forms deemed complete by the ACRB delegate are forwarded via email to the chair of the ACRB Access Committee for review.

5.2.3 Applications for 10 or fewer samples may be evaluated and approved or rejected by the Chair of the Access Committee.

5.2.3.1 Signing of the application form by the Access Committee Chair acts as a waiver for the Access Committee process. All steps below subsequent to the review process remain.

5.2.4 If the application is appropriate for review, the Access Committee Chair selects five reviewers from a panel of available Access Committee reviewers from both Edmonton and Calgary with expertise to assess the application.

5.2.4.1 The Access Committee Chair or delegate forwards completed application package via email to the five chosen Access Committee reviewers, the ACRB delegate and ACRB managers

5.2.5 It is the responsibility of selected Access Committee reviewers to declare any conflict of interests regarding reviewed applications. If a conflict of interest is declared, the Access Committee chair will request other Access Committee reviewer(s) with equal or reasonable expertise to review the application.

5.2.6 Each of the five selected Access Committee members reviewing an application must vote via email ‘yes’, ‘no’, or ‘more information required’ within 5 regular business days to the Access Committee Chair and all

Access Committee reviewers. Moreover, selected Access Committee members are expected to explain the reasoning for their vote by providing a brief written summary of the research project. The Access Committee Chair does not vote on applications.

5.2.7 Failure to vote on an application is not considered a decision for 'yes', 'no' or 'more information required'. If an Access Committee reviewer fails to provide their vote in a timely manner, the Access Committee chair or delegate will send an email reminding the reviewer of the pending review. If the reviewer continues to be non-responsive, the Access Committee chair will request other Access Committee reviewer(s) with equal or reasonable expertise to review the application.

5.2.8 Applications will only be approved if there is a majority vote (3/5) of 'yes' between the five selected Access Committee reviewers.

5.2.9 If a majority vote (3/5) amongst Access Committee reviewers is 'no', the Access Committee Chair may call for a teleconference with all reviewers to discuss and reach a conclusion. If, after all deliberations, the vote remains 'no', Access Committee reviewers will provide a brief summary to the applicant PI explaining the reasons for rejecting their request for HBMs.

5.2.10 The Access Committee chair and/or ACRB delegate informs the applicant PI of the outcome of the Access Committee review and forwards the decision to the ACRB Repository Owner(s) or delegate(s)

5.3 RELEASE

5.3.1 Preparation

5.3.1.1 Once the ACRB Access Committee application is approved, the ACRB Delegate informs relevant Biostorage personnel and may provide them with:

5.3.1.1.1 A copy of the Application which contains shipping information

5.3.1.1.2 A list of sample IDs and storage unit positional information generated from the inventory management system

5.3.1.2 The sample pull is initiated; once the pull is complete the samples are held in reserve pending the successful completion of the below mentioned MTA

5.3.1.2.1 If a quality issue is identified and samples are unavailable and/or deemed unusable, Biostorage personnel inform the ACRB Delegate and, if possible, a replacement is identified

5.3.1.2.2 Except in the case of prospectively collected HBMs for fresh, immediate release, the MTA cannot be executed until the availability of all samples are confirmed

5.3.2 Material Transfer Agreement (MTA)

5.3.2.1 When the availability of HBMs are confirmed (or a mutually agreed upon prospective collection), the ACRB Delegate prepares the AHS MTA and forwards it to the PI applicant for completion.

5.3.2.1.1 When the applicant does not agree to the terms of the AHS MTA, the applicant will inform the ACRB Delegate. AHS legal may be consulted and altered

terms may be agreed upon. If an agreement cannot be reached the application will be rejected and the applicant notified within thirty (30) days.

5.3.2.1.2 When the applicant agrees to the terms of the AHS MTA, the applicant completes and signs the document and returns it to the ACRB Delegate

5.3.2.2 The ACRB Delegate forwards the AHS MTA to the AHS VP research, innovation and analytics or delegate for review.

5.3.2.2.1 If the AHS research, innovation and analytics or delegate does not approve of the submitted AHS MTA, the document is not signed. The AHS research, innovation and analytics or delegate returns the AHS MTA to the ACRB to file and link to the original application. The ACRB delegate will notify the applicant of the AHS MTA non-approval by the AHS research, innovation and analytics or delegate within thirty (30) days.

5.3.2.2.2 If the AHS VP research, innovation and analytics or delegate approves the AHS MTA, the document is signed and returned to the ACRB to file and link to the original application. The applicant is notified of the approval. The ACRB delegate forwards the application's Access Committee approval letter and signed AHS MTA.

5.3.3 Distribution

5.3.3.1 When the MTA is fully executed, the ACRB delegate informs relevant Biostorage personnel

5.3.3.2 ACRB Biostorage personnel package and ship samples following all relevant SOPs for local, national and international shipments.

5.3.3.3 The ACRB delegate generates an invoice

5.3.3.4 The University of Calgary issues the invoice; the ACRB revenue account is automatically credited.

5.3.3.5 The ACRB delegate and/or managers monitors the account to confirm payment

5.3.3.6 If payment has not been received within 3 months of the invoice date, a reminder is issued

5.3.3.7 If payment has not been received within 6 months of the invoice date, the Operational Managers are notified.

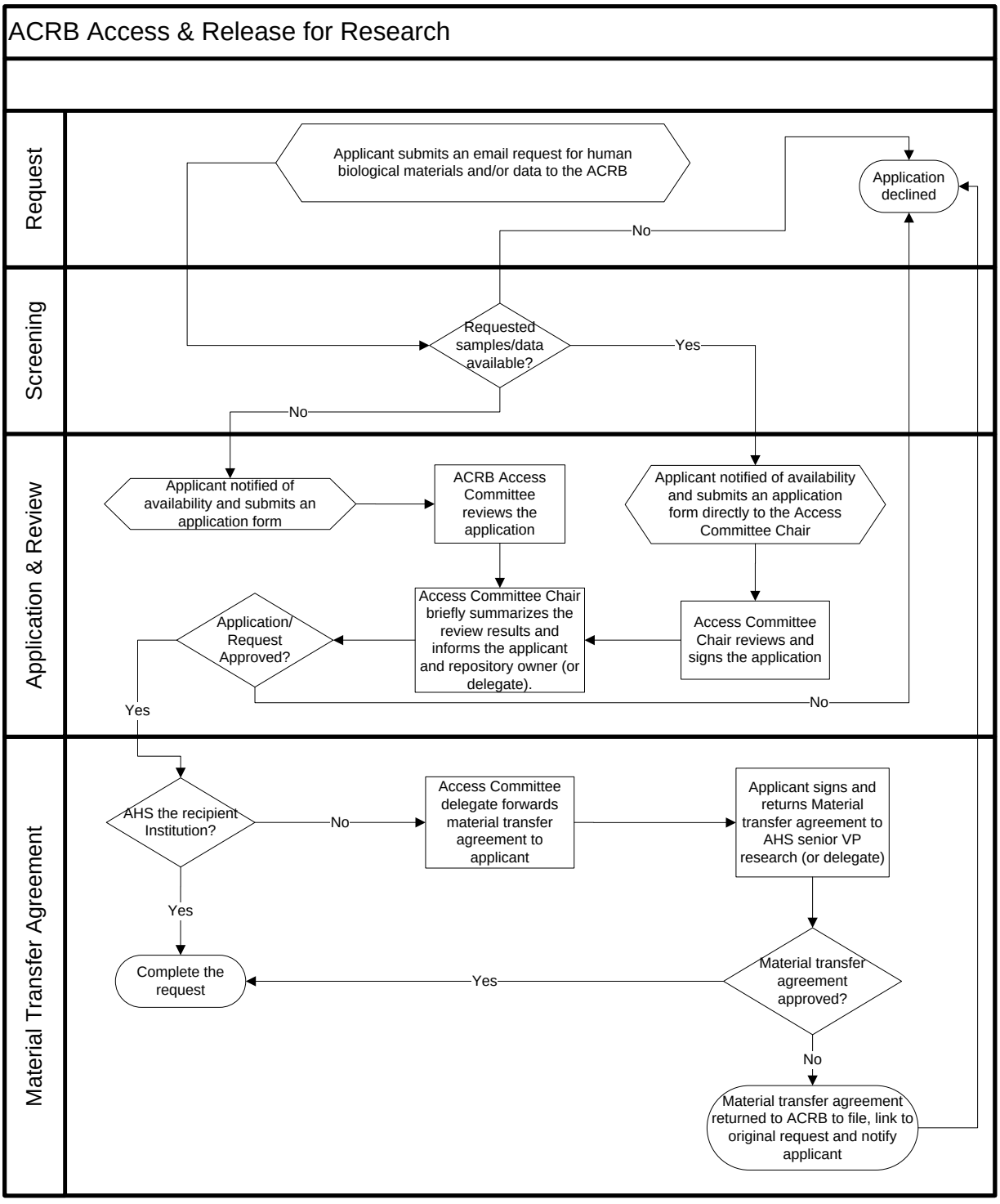


Figure 2: Flow-Diagram for the Alberta Cancer Research Biorepository Access and Release for Research Procedure

Appendix 1 – General Definitions

Access Committee: The ACRB Access Committee is responsible for the authorizing the release of samples and or data through the ACRB application and review process.

Access Committee Chair: The Chair of the Access Committee coordinates the Access Committee review process of external (non-AHS recipient) applications for HBMs and/or data. Moreover, the Access Committee chair is responsible for reviewing internal (AHS recipient) requests and waiving the full Access Committee review application requirement.

Alberta Health Information Act (HIA): Government legislation that sets out rules respecting the use and disclosure of health information in Alberta.

Applicant Principal Investigator (PI) researcher: The PI researcher submitting the Tumor Bank application form to request the release of HBMs.

Application Form: The ACRB Application and Instructions to request Human Biological Materials and/or Data from the ACRB form. This document is the foundation of review by the TDC and serves the purpose of formally identifying the contact information and educational qualifications of the applicant PI and co-investigators, the project's research proposal and available funding, local REB approval(s) and HBMs and/or data requested.

Approved Researcher: An individual holding a PhD and/or MD degree (or equivalent) and affiliation with a research/medical institution of a reasonable repute amongst the scientific community. The final decision of research approval will be made by the Access Committe Chair.

Confidentiality: Prevention of disclosure, to other than authorized individuals, of a subject's identity.

Data Matching: "data matching" means the creation of individually identifying health information by combining individually identifying or non-identifying health information or other information from 2 or more electronic databases, without the consent of the individuals who are the subjects of the information (Health Information Act, R.S.A. 2000, c H-5, s. 1 (1)(g)).

Human Biological Materials (HBMs): Available human biospecimens in the Tumor Bank's collection (Flash Frozen Tissue, Paraffin Embedded Tissue, Urine, DNA from Buffy Coat, Red Blood Cells, Serum and Plasma).

Individually Identifying: "individually identifying", when used to describe health information, means that the identity of the individual who is the subject of the

information can be readily ascertained from the information (Health information Act, R.S.A. 2000, c H-5, s.1 (1)(p)).

Material Transfer Agreement: An agreement to transfer tangible materials (such as human biological materials) between Alberta Health Services and a recipient institution.

Open Access Collection: A subset of the ACRB inventory that is openly accessible to applicant principle investigators who have obtained the appropriate ethical and administrative approvals.

Research Ethics Board (REB): An independent body (a review board or a committee, institutional, regional, national or supranational) constituted of medical and scientific professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in research and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on, the research project, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the research program participants.

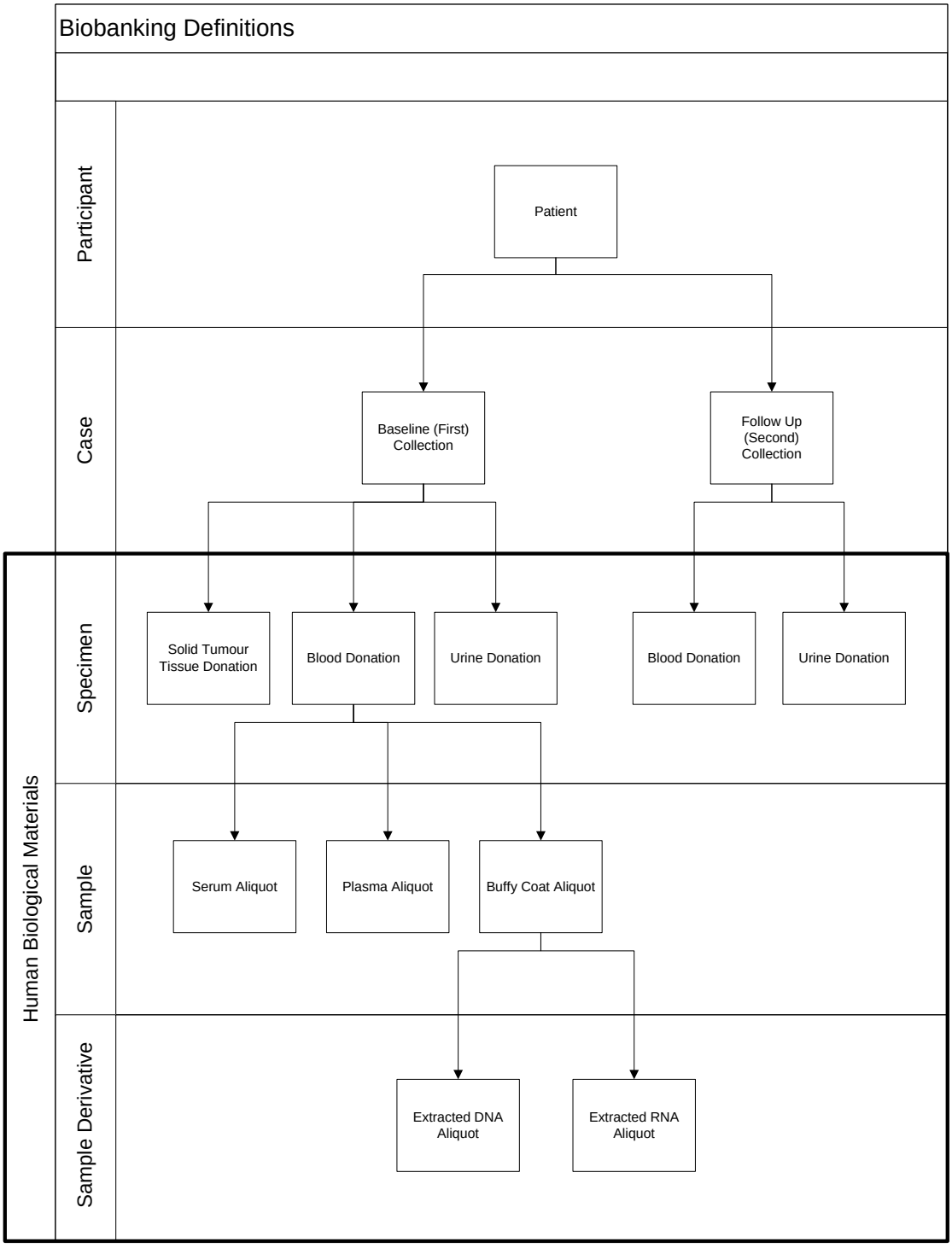
Request: A recorded communication between a PI researcher and the Tumor Bank delineating requirements for HBMs and/or data.

Repository: Regional, provincial or local repositories that coordinates the collection, processing, storage and distribution of tumor tissue and associated annotated data; normally derived from consented participants for the purpose of medical research. The term ‘bank’ and ‘repository’ are used interchangeably.

ACRB AHS Repository Owner: The information repository owner controls a specific repository and is responsible for defining the procedures and controls for accessing, storing, security, privacy, and disposition of the information in this repository. This includes ensuring that the procedures and controls meet the privacy requirements set forth by the Custodian including the preparation and submission of a Privacy Impact Assessment to the Office of the Information and Privacy Commissioner of Alberta. The Information Repository Owner is generally defined as the group or department that financed the creation and ongoing support of a repository. The Information Repository Owner can delegate the management of the repository but cannot delegate responsibility for the security and privacy of the information in a repository.

ACRB Staff Delegate: The ACRB staff member assigned to service the applicant researcher’s request for human biological materials throughout the entire application life cycle.

Appendix 2 – Biobanking Definitions



Appendix 3 – Application Forms

Please see attached documents Application and **Instructions to request Human Biological Materials and/or Data from the Alberta Cancer Research Biobank (ACRB)** and **Additional Information Regarding the Application for Materials**.