

Biological Material/Data Request – Process for the Alberta Prostate Registry and Biorepository

Process

Step 1: After receiving a request, the Alberta Prostate Cancer Research Initiative (APCaRI) director or a delegate will clarify the request/inquiry with the researcher, and will ensure that biological materials and/or data are available. The researcher may wait until availability is confirmed before submitting an application package.

Step 2: When an application package requesting biological materials and/or data is received by APCaRI, the Science and Data Quality Committee (SDQC) Review Process is started.

- See below description of the "SDQC - Review Process".

Step 3: Following SDQC approval of the request, the APCaRI Director or delegate prepares a Material Transfer Agreement (MTA) that will describe the type and quantity of human biological materials (HBMs) and/or data to be transferred to the researcher. The MTA will need to be signed by the Chair/Co-Chair of APCaRI, as the custodian of the biological materials and /or data, and by the institution of the Researcher that will receive the biological material and/or data. Researcher and Researcher's Institution will have to sign and return a PDF copy of the MTA before HBMs and/or can be shipped.

Step 4: Approval document from SDQC and application information is forwarded to the Alberta Cancer Research Biorepository (ACRB) for shipping the biological materials or to the database administrator for data transfer.

Step 5: An invoice is generated by the APCaRI Director or delegate and/or by the grant administrator, and is sent to the researcher for payment, preferably with the transfer of biological materials and /or data.

Step 6: Grant administrator will inform the APCaRI Executive Committee at bi-annual intervals if payments have been received.

Science and Data Quality Committee (SDQC) for APCaRI – Review Process

SDQC Chair:

Dr. John Lewis, Frank and Carla Sojonyk Chair in Prostate Cancer Research, Associate Professor, Dept. Oncology, University of Alberta

General Role

The role of SDQC is to ensure a fair and just means to allot the specimens and/or data based on scientific merit, impact of research and promise of completing the study within a reasonable time frame.

Review Process

Step 1: Requests for materials will be screened by the APCaRI Director or delegate, who will clarify the request with the researcher and will ensure that biological materials and/or data are available in the registry and biorepository. ACRB staff will ensure all materials required in the application package are submitted (REB approval for the stated study, proof of availability of funds, technical expertise, whether the proposed study and funding is peer reviewed).

Step 2: The APCaRI Director or delegate forwards the application to the Chair of the SDQC. The Chair will select a team of 3 reviewers from a panel of available SDQC reviewers (from both Edmonton and Calgary) with expertise to assess the application.

Step 3: The application package will be forwarded to these 5 SDQC reviewers, who should declare if there is a conflict of interest. In such case, the Chair will request other SDQC reviewer(s) with equal or reasonable expertise to assess the application.

Step 4: The 5 SDQC reviewers will be required to provide a written summary/comments on the research project in a brief/concise manner. All five SDQC reviewers will vote (Yes, No or request for additional information to help assess the application) by email to the Chair. The vote should be sent to the Chair within 5 working days. Silence is not a vote. The email replies should be started using the button “Reply to All” of the email program.

Step 5: A simple majority of YES (at least 2/3 votes) will mean approval of the request. Chair will not vote. If the majority is a NO (2/3 votes), then the application is sent to 3 additional SDQC members for further discussions. Chair may call for a teleconference to discuss and reach a conclusion. If, after all the deliberations, the vote is a NO, SDQC reviewers will provide a brief summary or comments to the researcher to explain the reasons for rejection of the request for biological materials.

Step 6: The researcher is informed of the outcome of the SDQC review by the SDQC Chair.

Science and Data Quality Committee (SDQC) APCaRI - Terms of Reference

Purpose Check other functions in terms of reference

Science and Data Quality Committee (SDQC) is responsible, among other things, for distribution of biorepository specimens and/or data.

Meetings

For sample distribution purposes, the SDQC shall communicate and vote by email; if the need arises the Chair will call for a meeting by teleconference.

Membership

The SDQC is chaired by Dr. John Lewis. The SDQC includes physicians and scientists engaged in cancer care and/or research. Other members of APCaRI may be present in a non-voting capacity as resources.

Criteria for Allocation

1. Specimens and/or data will only be distributed to APCaRI internal researchers and external researchers who:
 - Have received Research Ethics Board (REB) approval or official REB exemption to undertake the research
 - Have provided a concise scientific summary of the proposed investigations
 - Have provided short resume with relevant publications
 - Have provided proof 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
 - Have a SDQC-approved request.
2. Initially specimens will only be allocated to APCaRI internal investigators. Samples will be distributed to APCaRI members that meet the criteria explained above at no charge. Only direct charges associated with sample pull from the Alberta Cancer Research Biorepository (our storage solution) will be invoiced to the requesting investigator. Access to external investigators will be discussed in the future when cohorts have been established.
3. Specimens will be allocated on the basis of availability and justification for use of the samples. In some cases, the SDQC may obtain an external expert opinion to help assess an application. Investigators may receive only partial fulfillment of requests.

Review of requests

- See the document for “SDQC - Review Process”.
1. If the request is deemed acceptable, a separate decision will be made concerning allocation of the desired specimens if there are competing requests for limited/rare samples.
 2. Appropriate specimens will be assigned to the accepted requests by APCaRI staff, in consultation with the Chair of the SDQC.
 3. Specimens will be held for an approved request for up to six months, following which time they will be returned to the Alberta Cancer Research Biorepository for reallocation if they have not been collected by the applicant.
 4. Specimens found to be unusable by investigator-requested analysis will be replaced, as will specimens found to be mislabeled or shipped erroneously. No monetary refunds will be given.
 5. Specimen/data requests will only be permitted if an investigator is in good standing with the APCaRI, e.g., through satisfactory completion of yearly outcome reports, and acknowledgment of the APCaRI in all publications derived from APCaRI materials and/or data.
 6. Researchers requesting samples/data in a different year than a previously accepted request are encouraged to include proof of usage of the specimens/data and of scientific productivity.
 7. Researchers who publish their findings in scientific journals must acknowledge the source of the specimens/data (APCaRI Alberta Prostate Cancer Registry and Biorepository, www.APCaRI.com) in the Materials and Methods section. A copy of the published articles should be included with a subsequent request.