VERSION 4.0

BIOBANK FOR THE MOLECULAR CLASSIFICATION OF KIDNEY DISEASE

RESEARCH PROJECT APPLICATION PROCESS

PRECISION MEDICINE IN NEPHROLOY PROGRAM
UNIVERSITY OF CALGARY, CANADA

BIOBANK FOR THE MOLECULAR CLASSIFICATION OF KIDNEY DISEASE

RESEARCH APPLICATION PROCESS

PROCESS FLOW CHART

PROCESS OVERVIEW

Action	Contact	Responsibilities
Initial contact with Directors or Research Program Manager	Drs. Dan Muruve, Hallgrimur Benediktsson, Michelle Nelson	Researcher/PI responsible for expression of interest
Research application package provided to researcher	Michelle Nelson	Program Manager responsible for providing fillable PDF application and other applicable documents or information with outlined timeline OR researcher may download the application off of the Program's webpage independently (www.TARGET-KD.com)
Research application package: Submission	Researcher/PI	All application documents are to be submitted within the agreed upon timeline
Research application package: Inspection	Michelle Nelson	Program Manager responsible for assessing application package to ensure completion
Research application package: Formal review	Biobank Management Committee	All appropriate BMCKD personnel are required to review the application in full in order to determine whether the proposed research study is feasible and aligned with BMCKD mission, vision, and targets
Ethics submission and approval	Researcher/PI	It is the researcher/PI's responsibility to contact the BMCKD to request a letter of support for Ethics application if desired. Once Ethics approval has been granted and study is ready to proceed. A copy of the ethics submission and approval certification is required
Research application package: Final decision	Michelle Nelson	Projects granted both BMCKD and appropriate Ethics approval must sign relevant agreements and contracts which outline final project details and responsibilities between the BMCKD and researcher
Study initiation meeting	BMCKD and PI/Research team	A meeting will be held between appropriate BMCKD personnel and the approved research team to review the study protocol and discuss logistics

RESEARCH APPLICATION DOCUMENTS

Document	Details	Purpose
Research project application	Full application package which provides space for researchers to provide the following information: protocol summary, biospecimens or data required for access or storage, research study personnel, and budget	All research projects affiliated with the BMCKD must align with the biobank mission, vision, and use targets. The research project must also be feasible to carry out
Consent form (if applicable)	Consent form must include specific details regarding the collection and/or use of biospecimens within the scope of the BMCKD	Biobank privacy and ownership management is of the utmost importance. Consent forms must clearly state the degree to which personal information will be collected and utilized ***Please see consent form instructions below***
Case report form(s) (if applicable)	Case report forms must outline biospecimens being collected and/or utilized and types of testing they are used for (ie. 6ml urine; dip stick via ChemStrip 10)	Research projects must clearly provide descriptions of how many samples will be collected/used for inventory and logistical purposes
Research Agreement	Formal agreement between the PI and BMCKD to undertake the proposed research project	Binding agreement which outlines the nature of the research project as a joint venture between the PI and the BMCKD, specifically pertaining to publication rights, proprietary data, and liabilities.
Confidentiality Non-disclosure Agreement (if applicable)	The PI is obligated to agree to full non-disclosure of any sensitive, personal information associated with BMCKD samples and records that may be related to proprietary or commercial objectives	The PI, on behalf of themselves and any other project-specific personnel, must agree to non-disclosure of any confidential information they may be exposed to during the duration of the research project, specifically in the event that the research and any related information, data, or conclusions may be used for proprietary or commercial objectives once the research project is complete
Material Transfer Agreement (if applicable)	Formal agreement between the PI and BMCKD which describes the transfer and collection and/or use of human biospecimens material for research purposes	Binding agreement which outlines the nature of the research projects as a joint venture between the PI and the BMCKD, pertaining to the transfer/use of archived human biospecimens

RESEARCH APPLICATION: CONSENT FORMS

CONSENT FORM INSTRUCTIONS

Studies that require the collection of written, informed consent pertaining to the collection and/or use of human biospecimens or medical records must clearly outline this information in the Informed Consent Form (ICF).

For studies **actively collecting samples** from participants, which will then be stored within the BMCKD for the proposed research project and future studies, the ICF must include statements similar to the following, where applicable:

- This study involves obtaining your permission to collect, store, and access biospecimens (urine, blood, biopsy, or other)
- We are requesting your permission to review, access, and use these samples for the purpose of this study
- We are requesting your permission to store and access biospecimens for similar research studies in the future
- Should you agree that your samples are utilized in future research projects, you agree that the Biobank for the Molecular Classification of Kidney Disease will maintain full guardianship over the use of these samples
- All information collected will remain confidential and will be available only to physicians and staff involved in the research projects for which your samples are being used. These individuals will have obtained Ethics Board Approval in order to conduct any research within the Biobank.
- You understand that you maintain full ownership of any and all samples and information that may be stored within the biobank, and that at any time you may request that all samples and information be destroyed and no longer utilized for research purposes
- Regardless of your decision to participate in this research project and submit samples to the biobank, you will continue to receive the same standard of care as before