Masonic Cancer Center Data and Biospecimens Utilization Committee (DBUC) Charter

Project Name: Data and Biospecimens Utilization Committee (DBUC)

Sponsor Name: Douglas Yee, MD Masonic Cancer Center (MCC) Director

Sponsoring Organization: Cancer Research Translational Initiative (CRTI)

Revision History

Revision #	Version Date	Summary of Changes
1	9/22/2023	Original submitted to IRB
2	11/25/2024	Added Revision History, updated DBUC Chair and Appendix I, and other minor revisions, temporarily removed signatures due to expected upcoming biobank addition

Purpose

The Masonic Cancer Center (MCC) Biobanks are a supported research resource that is composed of human biospecimens collections from multiple cancer/tumor or non-malignant, rare-disease settings with associated clinical and demographic data. The Data and Biospecimens Utilization Committee (DBUC) ensures that all specimens held by MCC-supported banks have been acquired and managed responsibly in accordance with all applicable state, federal and university regulations and policies. DBUC provides regulatory oversight for the distribution, return and destruction of materials. Appendix I contains the list of MCC biobanks currently covered by DBUC.

DBUC Committee

The DBUC Committee will have the final authority over the release of samples and/or data in MCC biobanks and maintain the link between samples and identifiable data.

The DBUC Committee will consist of the following:

1. DBUC Chair
2. DBUC Co-Chair
3. DBUC Administrator

DBUC Chair
Naomi Fujioka, MD
Associate Professor of Medicine, Division of Hematology, Oncology, and Transplantation

DBUC Co-Chair (Scientific Director of Translation)
Deepa Kolaseri, PhD, CCRP

- The Scientific Director of Translation oversees DBUC operations and ensures compliance across all regulations and policies.
- Act as an impartial member when the DBUC Review Panel considers applications.

DBUC Administrator

Katherine Novak, BA

Cancer Biospecimens Management Specialist

- The DBUC Administrator (DBUC Admin) ensures that the release of samples and/or data complies with all applicable state, federal and university regulations and policies. The role reports to the CRTI Scientific Director and serves as the Data Steward, protecting patient privacy. This includes management of all sample and data requests, and serving as a liaison between the requestor and other MCC resources.
- The DBUC Admin will report concerns about data requests, researchers, or committee members to the CRTI Scientific Director and/or Sponsor.

Other MCC Clinical Research Groups Supporting the DBUC Process

1. Clinical Informatics Shared Services (CISS): CISS develops and maintains disease registries. CISS provides integrated datasets (biospecimens and/or clinical data). DBUC Admin will collaborate with CISS to run queries rapidly to find appropriate sources of biospecimens and/or data for translational studies from the annotated inventory of available banked specimens. MCC-CISS informatics resources are part of the CTSI Best Practices Integrated Information Core (CTSI BPIC).

2. Translational Therapy Laboratory (TTL): TTL collects, processes, and stores biospecimens. TTL will release biospecimens after approval by the DBUC Committee. In addition, TTL will accommodate return of unused specimen, and specimen destruction.

3. Cancer Research Translational Initiative (CRTI): CRTI will maintain DBUC and MCC Biobank infrastructure and provide resources as needed.

DBUC Review Panel

The DBUC Chair and DBUC Co-Chair will act as impartial members of each application DBUC Review Panel. Additional ad hoc members of a DBUC Review Panel will be dependent on the DBUC application. A DBUC Review Panel will include a PI from the biobank under consideration who has the best expertise on those samples. Each participating biobank may require additional individuals to serve as ad hoc members to review/approve requests. The DBUC Review Panel must have a minimum of three members and can consist of the following:

1. DBUC Chair
2. DBUC Co-Chair
3. Biobank PI
    - Cohort PI (For any Solid Tumor Biobank requests)
    - Original PI (For any Legacy Sample Biobank requests)
4. Any other MCC member that the Biobank PI appoints
5. Ad hoc panel members

Biobank PI Responsibility

Each biobank PI will serve on the DBUC Review Panels that evaluate requests directly relevant to the application under consideration. They will have access to samples and data within their biobank, however, in order to use the samples and/or data for a research project; the PIs will need to utilize the DBUC process detailed below. The respective biobank PI is exempt from the DBUC Review Panel gathered to review their own DBUC application due to conflict of interest. This will also apply to the DBUC chair if they submit a DBUC application. The biobank PI must notify the DBUC Committee of any major changes to their biobank (i.e. study closing to accrual, closing at the IRB, external collaborations, etc).

Ad Hoc Panel Members

The DBUC Admin may request any of the following to serve as an ad hoc panel member:

1. Relevant Translational Working Group (TWG) lead
2. Other domain experts and stakeholders as appropriate

<u>Biospecimens Access Process</u>

Feasibility:

1. Research investigator submits request to the DBUC Admin to determine availability of the biospecimens either via email or REDCap DBUC application (1).
2. DBUC Admin checks the online inventory or submits a CISS request (2) depending on the complexity of the request. The DBUC Admin will respond to the query within three business days.

Requesting Samples:

1. If samples are available, the research investigator submits a request using the REDCap DBUC application (1) if not previously done during feasibility. The application should include appropriate information to evaluate the scientific merit and feasibility for each request. A well-defined testing plan should be submitted by the applicant along with a description of the type and number of specimens and/or data required for the project.
2. DBUC Admin will submit a CISS request (2) to verify patient consent and help with sample selection once the application has been approved.

Review Panel:

1. Depending on the source and type of biospecimens or data requested, DBUC Admin sends the application to the respective biobank DBUC Review Panel. The Review Panel will consider the application for scientific merit, provide feedback, approve request and establish requirements to return of data to the bank. The expected turn-around time for review and approval is not to exceed 5 working days (often less for routine requests). A minimum of three members must review and unanimously approve each request. All applications submitted by Wednesday evening will receive a response by the following Wednesday. The DBUC Committee will review any disagreements and the results of the review will be documented.
2. The DBUC Admin informs the research investigator of the Review Panel's response.
    a. Decision A: Approval.
    b. Decision B: Request revision. Investigator is asked to revise the proposal and re-submit.
    c. Decision C: Deny. Response will be sent to the investigator.
3. Depending on the request, the DBUC Admin will assist the investigator with next steps as indicated in the flow chart (3).

Sample/Data Release:

1. Sample/data release will only occur after approval of the Review Panel. For requests that receive approval, TTL (or other storage lab) will release biospecimens to requesting investigator and/or CISS releases data to requesting investigator. Most sample requests will be released within two week. Larger, more complex requests may take longer. The timing of the data release depends on the complexity of the request (2, 4, 5).
2. DBUC Admin contacts the research investigator to follow-up on annual return on investment (i.e. abstracts, publications, grant applications, etc.) and return of unused materials and destruction of data if deemed necessary by the DBUC Review Panel.

Requirements for Access

All samples and data in the MCC Biobanks have been collected with the informed consent of the patient in compliance with state, federal and University policies and regulations. Patients have agreed to share their samples and data for research with MCC/UMN researchers and their collaborators.

Research Investigator Definition:

A research investigator is either a MCC member, a faculty at UMN performing cancer related or non-cancer related research, or a research collaborator with MCC/UMN faculty who may or may not be located at the University of Minnesota. The MCC biospecimens and/or data will only be released to a MCC member or a UMN faculty and will not be released to students, laboratory staff, collaborators or external (non-UMN) researchers. Investigators receiving UMN samples and/or data as part of a collaboration with a MCC/UMN faculty member should utilize their institutional IRB for regulatory compliance, if applicable. Each research investigator is responsible for all activities involving specimens and/or data under his or her jurisdiction. Requests from UMN faculty performing non-cancer related research will be considered on a case-by-case basis by the DBUC Review Panel in accordance with the usage rules for the specific biobank.

Data Requests:

Requests that include data will be handled in accordance with the current version of the CISS Policy (4, 5). DBUC Admin will direct the investigator to fill out a CISS request (2) to acquire desired data.

Biospecimens Requests:

If the research investigator requests de-identified biospecimens without any data sets, the DBUC Admin will determine whether additional IRB approval is required prior to release. If a request includes biospecimens and/or data with identifiable information, the DBUC Admin will ensure an IRB approval is in place for the study prior to sample/data release (3).

Biospecimens Prioritization:

Investigators requesting access to MCC biospecimens should refer to the process flow (3). It may take at least 4 weeks for simple requests and 8 weeks for more complex requests before receiving samples and/or data so plan accordingly. Any UMN investigator may submit sample requests but priority will be given to MCC members. All concepts are reviewed for feasibility, scientific merit, and alignment with MCC scientific priorities for growth. Concepts designed to investigate associations between laboratory and clinical outcomes are encouraged.

Biospecimens/Data Storage and Retention:
Biospecimens will be stored indefinitely as long as they are available and will be destroyed upon PI's request or patient's request as detailed in the Translational Therapy Lab (TTL) SOP, "Process To Destroy A Sample"(6). All individual-level data will reside in the Academic Health Center-Information Exchange (AHC-IE) and will be released by CISS according to CISS policy (4, 5).

Quality Assurance Plan for Specimen/Data:
The quality of specimens are maintained by equipment monitoring as detailed in TTL SOP "Equipment Monitoring and Maintenance"(7). All samples processed in TTL are maintained in Laboratory Information Management System (LIMS). MCC-CISS receives sign off from the TTL Coordinator prior to LIMS data integration or extraction. If samples are stored outside of TTL, DBUC will follow DBUC SOP "Requirements for DBUC Samples Housed Outside of TTL" (8). DBUC and CISS act as honest brokers to maintain linkage of identifiable data and samples.

Publication Acknowledgement

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References:

1. DBUC REDCap Application: https://redcap.link/DBUC
2. BPIC Data Request Procedure weblink, https://ctsi.umn.edu/sites/ctsi.umn.edu/files/2021-03/BPIC-Data-Request-Procedures.pdf
3. DBUC Specimen Request Process Flowchart
4. Aliferis, Constantin. *Extraction of Identifiable Data from the AHC Information Exchange.* June 2020.
5. Aliferis, Constantin. *Extraction of De-Identified Data from the AHC Information Exchange.* July 2020.
6. TTL SOP-Process to Destroy A Sample 200917
7. TTL SOP-Equipment Monitoring and Maintenance 200917
8. DBUC SOP-Biobank Samples housed outside of TTL

Appendix I:

MCC Biobanks

1. *Immune Reconstitution Biobank (IMR):*
   Protocol PI:
   Jeffrey Miller, MD

2. *Immune Monitoring Biobank (IMR2):*
   Protocol PI:
   Shernan Holtan, MD

3. *Heme Malignancy Tissue Bank (HMTB):*
   Protocol PI and Co-Is:
   Veronika Bachanova, MD, PhD
   Jeffrey Miller, MD
   Peter Gordon, MD, PhD

4. *Thoracic Translational Working Group Lung Cancer and Pulmonary Nodule Biorepository (LUNG):*
   Protocol PI and Co-Is:
   Naomi Fujioka, MD
   Manish Patel, DO
   Robert Kratzke, MD

5. *Solid Tumor Immune Monitoring Bank (STU):*
   Protocol PI:
   Naomi Fujioka, MD
   Cohorts (as of 11/25/2024):
   1. Lung Cohort – Naomi Fujioka, MD
   2. Breast (DEEP) Cohort – Deepali Sachdev, PhD and Heather Beckwith, MD
   3. Prostate (GU) Cohort – Nicholas Zorko, MD PhD and Emmanual Antonarakis, MD
   4. Ovarian (OV) Cohort – Melissa Geller, MD and Heather Nelson, PhD, MPH
   5. Mesothelioma (MESO) Cohort – Manish Patel, DO
   6. Microbiome (MCBM) Cohort – Amit Kulkarni, MBBS and Manish Patel, DO
   7. Head and Neck (HN) Cohort – Naomi Fujioka, MD
   8. Small Celled Lung Cancer (SCLC) Cohort – Naomi Fujioka, MD
   9. Never Smoker (LCNS) Cohort– Naomi Fujioka, MD

6. *Legacy Sample Biobank:*
   Protocol PI:
   Jeffrey Miller, MD

7. *The Minnesota CAR-T Biorepository (CART):*
   Protocol PI

Veronika Bachanova, MD

8. *Immune Reconstitution for HCT and Novel Therapies (IMR3):*
   Protocol PI
   Jeffrey Miller, MD

9. Biorepository and Laboratory Services (BLS) Repository:
   Protocol PI
   Emmanual Antonarakis, MD

10. *Future MCC Biobanks TBD:*