

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

Project Name: Data and Biospecimen Utilization Committee (DBUC)

Sponsor Name: MCC Director Douglas Yee, MD

Sponsoring Organization: Cancer Research Translational Initiative (CRTI)

Purpose

The Masonic Cancer Center (MCC) data and Cancer Specimen Banks are a supported research resource that is composed of human biospecimen collections from multiple cancer/tumor or non-malignant, rare-disease settings with associated clinical and demographic data. The Data and Biospecimen Utilization Committee (DBUC) has been established to provide consistent organizational oversight for request, release and destruction of Masonic Cancer Center biobank samples or data. The DBUC committee establishes requirements to ensure that all specimens held by MCC-supported banks and all data in MCC-supported patient registries have been acquired and managed responsibly in accordance with all applicable state, federal and university regulations and policies. The DBUC provides regulatory oversight for the distribution, return and destruction of materials. The cancer specimen banks and disease registries covered by DBUC are detailed in Appendix I.

DBUC Committee Members

The DBUC committee will consist of the following members*

1. DBUC Chair
2. CRTI Scientific Director
3. Cancer Specimen Bank PIs
4. Disease Registry/Data PIs

*Members based on current faculty roles [as of July 01, 2020]. Some individuals fill more than one role, names subject to change based on faculty turnover.

DBUC Chair

Heather Nelson, PhD, MPH

Professor, Division of Epidemiology and Community Health

CRTI Scientific Director

Deepa Kolaseri, PhD, CCRP

- The CRTI Scientific Director ensures that release of samples and/or data is in compliance with all applicable state, federal and university regulations and policies.

DBUC Administrator

Amutha Muthusamy, MSc

CRTI Process Manager

- The DBUC Administrator 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 (Translational Therapy Lab-TTL, Clinical Trials Office-CTO, Cancer Informatics Shared Systems-CISS, etc).
- The DBUC Administrator will report concerns about data requests, researchers, or committee members directly to the MCC Sponsor (Dr. Doug Yee, MD., Director Masonic Cancer Center).

Other MCC Clinical Research Groups Supporting the DBUC Process

1. Masonic Cancer Center-Clinical Informatics Support System (MCC-CISS): MCC-CISS develops and maintains disease registries. CISS provides integrated data queries (biospecimens and/or clinical data). CISS will maintain a tool to allow the DBUC Administrator to run queries to rapidly find appropriate sources of biospecimens or data for translational studies from the annotated inventory of available banked specimens and registries. CISS will develop an online tool to facilitate requests, protocol submission and review, sample/data release tracking, and long term ROI.
2. Translational Therapy Laboratory (TTL): TTL collects, processes and stores biospecimens. TTL will release biospecimens after approval by the review panel. In addition, TTL will accommodate return of unused specimen, and specimen destruction.
3. Cancer Research Translational Initiative (CRTI): CRTI will maintain DBUC and MCC Cancer Specimen Bank infrastructure and provide resources as needed.

Biospecimen Access Process

Phase I:

1. Research investigator submits request to the DBUC Administrator to determine availability of the biospecimens. Requests for associated data will follow the CISS/MCC Data Request Submission, Processing and Delivery Policy (3).
2. DBUC Administrator checks the online inventory and or registry and responds to the query within three business days.

Phase II:

1. If samples are available, the research investigator submits a project proposal. A well-defined and compelling hypothesis and testing protocol with statistical plan should be described by the applicant along with a description of the type and number of specimens and or data required for the project.
2. Depending on the type of biospecimen or data requested, DBUC Administrator assigns a disease specific ad hoc review panel from the DBUC committee.
3. The review panel reviews the project proposal for scientific merit and submits the decision within 5 business days. All projects submitted by Wednesday evening will receive a response by following Wednesday.
4. If the request includes identifiable sample/data, the DBUC Administrator will assist the investigator with a separate IRB application.
5. The DBUC Administrator informs the research investigator of the review panel's response.

- (a) Decision A: Approval. After confirmation by the DBUC administrator of IRB approval (if needed), TTL (or other Bank) releases biospecimens to the requesting investigator for the approved project and/or CISS releases data.
 - (b) Decision B: Request revision. Investigator is asked to revise the proposal and follow steps 3 to 5.
 - (c) Decision C: Deny. Response will be sent to the investigator.
6. For requests that receive approval, disbursement of samples will occur within one week of approval by the committee. The timing of the data release depends on the complexity of the request (per the CISS/MCC Data Request Submission, Processing and Delivery Policy).
7. DBUC Administrator contacts the research investigator to follow-up on
 - (a) Short-term: Sample QC
 - (b) Long-term: A request will be sent semi-annually to report return on investment (i.e., abstracts, publications, grant applications, etc.)
 - (c) Return of unused materials and destruction of data
8. DBUC Administrator maintains administrative data.

Requirements for Access

All samples and data in the MCC Cancer Specimen Banks or MCC Disease Registries 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 Cancer Specimens and/or Data will ONLY be released to a MCC member or a UMN faculty and will NOT be directly 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. Request 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 Cancer Specimen Bank or Registry.

Data Requests:

Requests that include data will be handled in accordance with the current version of the CISS/MCC Data Request Submission, Processing and Delivery Policy (3).

Biospecimen Requests:

If the research investigator requests de-identified biospecimen samples (link maintained by MCC) without any data sets, the DBUC Administrator will determine whether additional IRB approval is required prior to release. And if a request includes biospecimen and/or data with identifiable information, the DBUC Administrator will ensure an IRB approval is in place for the study prior to sample/data release.

Biospecimen Prioritization:

Investigators requesting access to MCC Cancer Specimens should refer to the process flow and be aware of the time-frame for sample release. Sample requests may be submitted by any UMN investigator 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.

Specimens acquired as part of IRB-approved clinical trials with embedded biospecimen collection for correlative studies will be tracked by the DBUC Administrator and will be made available to investigators named in the trial protocol upon approval by the study's principal investigator through administrative review.

Biospecimen/Data Storage and Retention:

Biospecimens will be stored indefinitely as long as they are viable for use and will be destroyed upon principal investigator's request as detailed in the Translational Therapy Lab (TTL) SOP, "Process To Destroy A Sample". All individual-level data will reside in the Academic Health Center-Information Exchange (AHC-IE) and will be released by MCC Clinical Informatics Shared Services (MCC-CISS) according to the MCC-CISS Data Request Submission, Processing and Delivery Policy. MCC-CISS informatics resources are part of the CTSI Best Practices Integrated Information Core (CTSI BPIC).

Quality Assurance Plan for Specimen/Data:

The quality of specimens are maintained by equipment monitoring as detailed in TTL SOP "Equipment Monitoring and Maintenance". 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.

DBUC Ad Hoc Review Panels:

Release of biospecimens or data will be reviewed by disease/cohort specific review panels. The DBUC Administrator will create ad hoc review panels of at least 3 DBUC committee members with appropriate expertise. These may include:

1. Cancer Specimen Cohort or Registry PI
2. Data or Sample Owners/Funders (when applicable)
3. Relevant Translational Working Group (TWG) lead
4. Other domain experts and stakeholders as appropriate

The application will include appropriate information to evaluate the scientific merit and feasibility for each request. A minimum of three members must review and unanimously approve each request. Each participating Registry or Cancer Specimen Bank may require certain individuals to review/approve requests, or may delegate this function to other members of the DBUC committee.

The review panel will review, provide feedback, approve request and establish requirements to return of data to the bank or registry. The expected turn-around time for review and approval is not to exceed 5 working days (often less for routine requests).

Any disagreements will be reviewed by the DBUC Chair. The committee and the DBUC Administrator will document the results of the review.

Publication Acknowledgement

Masonic Cancer Center shared resources receive grant support from the National Cancer Institute and their use should be acknowledged in any publications. The following statement is suggested: "This work was supported in

part by NIH P30 CA77598 utilizing the following Masonic Cancer Center, University of Minnesota shared resource(s)".

References:

1. TTL SOP-Process to Destroy A Sample 200917
2. Ramesh, Vidhya and AbuSalah, Ahmad. *MCC CISS Data Request Submission, Process and Delivery Policy*. Oct 2017.
3. BPIC Data Request Procedure weblink,
https://www.ctsi.umn.edu/sites/ctsi.umn.edu/files/bpic_data_request_procedures_1.pdf
4. TTL SOP-Equipment Monitoring and Maintenance 200917

Project Sponsor Sign-Off:

I have reviewed and endorse the charter and hereby establish the MCC Data and Biospecimen Use Committee.

Name: Douglas Yee, MD

Signature:

Date

Appendix I:

Cancer Specimen Banks

1. *Blood and Marrow Transplant Specimen Registries:
(MT2002-01S, MT2009-22R and future BMT Specimen Banks)*
TBT Program Leads:
Daniel Weisdorf, MD
John Wagner, MD
Protocol PIs:
Jeffrey Miller, MD
Shernan Holtan, MD
2. *Heme Malignancy Tissue Bank:*
Protocol PI and Co-Is
Veronika Bachanova, MD
Jeffrey Miller, MD
Peter Gordon, MD
3. *Thoracic Translational Working Group Lung Cancer and Pulmonary Nodule Biorepository:*
Protocol PI and Co-Is
Naomi Fujioka, MD
4. *Solid Tumor Immune Monitoring Bank:*
PI and Co-Is
Heather Nelson, PhD
Others to be named
5. *Rare Disease Monitoring Bank:*
PI and Co-Is
Troy Lund, MD, PhD
Paul Orchard, MD
6. *Future Cancer Specimen Banks TBD:*
PI and Co-Is

Disease Registry and Data PI(s)

1. *Blood and Marrow Transplant Outcome Registry*
TBT Program Leads
Daniel Weisdorf, MD
John Wagner, MD
Adult BMT Program Director: Claudio Brunstein, MD
Pediatric BMT Program Director: John Wagner, MD
2. *Urologic Cancers*
Bhadri Konety, MD

3. *Solid Tumor Registry (coming soon)*
Heather Nelson, PhD

4. *Future Registries TBD*
PIs and Co-Is