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

Project Name: Establishing Data and Biospecimen Utilization Committee (DBUC)

Sponsor Name: MCC Director Douglas Yee, MD

Sponsoring Organization(s): Cancer Research Translational Initiative (CRTI)

Purpose

The Masonic Cancer Center strategic plan has identified the need for cancer registries and biobanks to support the research mission. The MCC 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. Existing specimen banks include the BMT Immune Reconstitution Bank and the Hematologic Malignancies Bank. Cancer registries include the BMT Outcome Database and the Urologic Cancers Database. The Data and Biospecimen Utilization Committee (DBUC) has been established to provide consistent organizational oversight for request, release and use of any Masonic Cancer Center biobank samples or data. The DBUC committee establishes requirements to ensure that all cancer specimens held by all MCC-supported banks and all data in MCC-supported patient registries have been acquired and managed responsibly in the same manner and in accordance with all applicable state, federal and university regulations and policies. Specimens and data gathered as part of therapeutic clinical trials will continue to be managed according to existing procedures. The DBUC oversight will simplify the operational and regulatory burden and benefit MCC cancer research investigators who choose to participate.

DBUC Committee Members

The DBUC committee will consist of the following members* (additional may be added as needed);

1. DBUC Chair
2. Cancer Specimen Bank PIs or Co-Is
3. Disease Registry PIs/Data Owners
4. Faculty Clinical Research Officers (FCROs)
5. Translational Working Group (TWG) leads
6. MCC Clinical Research Faculty Leaders

*Members based on current faculty roles [as of Dec 15, 2017]. Some individuals fill more than one role, names subject to change based on faculty turnover

DBUC Chair
Sarah Cooley, MD, MS
Associate Professor of Medicine
Director Investigator Initiated Research
Director Cancer Experimental Therapeutics Initiative
DBUC Administrator
Marina Pillai, CRTI Process Manager

- The DBUC Administrator (in collaboration with CISS) has responsibility to ensure that release of samples or data is in compliance with all applicable state, federal and university regulations and policies. The DBUC Administrator serves as the Data Steward, protecting patient privacy. Users of DBUC-managed data and samples must register the topics they would like to query with the data steward in their initial application. The Data Steward manually reviews all sample query requests to make sure they are in compliance. CISS reviews data query requests. Actual query histories are logged and audited on a regular basis to ensure that there have been no violations of the Terms and Conditions.
- The DBUC Administrator in the role of Data Steward will report concerns about data requests, researchers, or committee members directly to the Vice Dean for Research of the UMN Medical School.

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:
   - Sarah Cooley, MD, MS
   - 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 PI(s) and Data Owner(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

**Faculty Clinical Research Officers (FCROs)**
1. Brunstein Claudio, MD
2. Melissa Geller, MD
3. Naomi Fujioka, MD
4. Robert Madoff, MD
5. Shilpa Gupta, MD
6. Veronika Bachanova, MD

**Translational Working Group (TWG) Leads**
1. Brain Tumor: Christopher Moertel, MD
2. Breast Cancer: Jane Hui, PhD
3. Cutaneous Oncology: Heather Nelson, PhD
4. Prostate Cancer: Scott Dehm, PhD
5. Gynecologic Cancers: Melissa Geller, MD
6. Heme Malignancy: Veronika Bachanova, MD
7. Sarcoma: Brenda Weigel, MD
8. Head and Neck: Frank Ondrey, MD
9. Gastrointestinal: Robert Madoff, MD and Emil Lou, MD, PhD

**MCC Clinical Research Faculty Leaders**
1. CISS: Jinhua Wang, PhD
2. TTL: Martin Felices, PhD
3. CTO: Brenda Weigel, MD
4. Associate Director Clinical Research: Bhadri Konety, MD
5. Associate Director Translational Research: Jill Sigfried
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 develop and 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 the request, protocol submission and review, IRB submission and sample/data release tracking and long term ROI.

2. Translational Therapy Laboratory (TTL): TTL will collect, process and store cancer biospecimens. TTL will release biospecimens after approval by the review panel. (Note: samples collected and stored by other groups may be included in this process by sharing the database access.)

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

Requirements for Access
All samples and data available via 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 the MCC/UMN researchers and their collaborators.

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.

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.

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 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. Collaborators receiving UMN samples 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.

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 researchers and 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.

DBUC Ad Hoc Review Panels:
Release of biospecimens or data will be reviewed by disease/cohort specific review panels unless specific IRB-approved a priori use and release guidelines are in place. The DBUC Administrator will create ad hoc review panels of at least DBUC committee 4 members with appropriate expertise. These may include:

1. Cancer Specimen Cohort or Registry PI
2. Data or Sample Owners/Funders (when applicable)
3. Relevant FCRO
4. Relevant TWG lead
5. 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.

**Biospecimen Access Process**

The application and approval process for samples is outlined in the process flow diagram and includes the following steps:

**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.
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 which will include supplemental questions required by the IRB, if necessary. 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 application 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 NECESSARY, in parallel the DBUC Administrator will assist the investigator with the IRB application (the IRB required questions will have been completed in the proposal, and CRTI will work to automate this process).

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 (identified or de-identified).
   (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.)

8. DBUC Administrator maintains administrative data.
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)"

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: [Signature]
Date: Feb 1, 2018

Version 02/04/18