PATIENT HISTORY DATABASE ACCESS COMMITTEE (DBAC), STANDARD OPERATING PROCESS, EVALUATION AND PRIORITIZATION CRITERIA

PATIENT HISTORY DATABASE ACCESS COMMITTEE (DBAC) AND STANDARD OPERATING PROCESS

Existing data from the Patient History Database (PHDB) is available for investigator use in conducting research related to cancer and other chronic diseases and to further MD Anderson’s mission. The use of data collected under the PHDB source protocols (LAB03-0320) requires approval from the PHDB DBAC.

The DBAC is charged with reviewing and providing access to the PHDB data to advance cancer-related research by facilitating access to this resource. The DBAC is charged with the responsibility for: 1) establishing and maintaining a process for PHDB data access; 2) establishing and maintaining criteria for evaluation, prioritization and approval of requests for PHDB data; 3) reviewing, evaluating, prioritizing and approving requests for PHDB data; and 4) ensuring that the data are distributed according to MD Anderson’s policies and IRB guidelines.

Resolution of conflicts that may arise regarding access and use of PHDB data will be referred to the Chair, Department of Epidemiology and he/she will work with the Institutional Biospecimen Utilization Committee to resolve the issue in a timely manner.

The Chair of the Department of Epidemiology and the PI of the protocol, Dr. Stanley Hamilton, will provide long-term stewardship for PHDB data. Five additional rotating committee members with diverse expertise in research involving human subjects will serve for 3-year terms, with two members rotating off annually.

The DBAC is comprised of the following members:

Non-voting standing members:

- Chair, Department of Epidemiology - DBAC Chair
- Stanley R. Hamilton, MD - PI of protocol LAB03-0320 under which historical PHDB data was collected

Voting rotating members:

- Carrie Daniel, PhD, MPH, Epidemiology
- Chad Huff, PhD, Epidemiology
- Sharon Giordano, MD, MPH, Health Services Research
- J Jack Lee, PhD, Quantitative Sciences - Biostatistics
- Yuanqing Ye, PhD, Epidemiology

PROCESS TO REQUEST PATIENT HISTORY DATABASE RESOURCES FOR RESEARCH USE
Investigators planning research studies that would require the use of existing PHDB resources must submit a completed PHDB Feasibility Assessment Form. The assessment will consider the availability of data required to conduct the study.

**PROCESS AND CRITERIA FOR EVALUATING REQUESTS**

Requests for PHDB data use will be evaluated for: 1) scientific merit based on the scientific significance/relevance of the project, rationale, potential for further research, and methodology; 2) funding source in the following priority sequence: a) peer-reviewed sponsored projects, b) non peer-reviewed sponsored projects, c) unsponsored projects intending to create preliminary data for sponsored applications, with priority to junior investigators, d) unsponsored projects to be completed independent of funding sources; 3) the project timeline; and 4) portfolio balance.

Reviews will be conducted by each voting member of the committee and require telephone conference call or in-person attendance of all 5 voting members and both standing members. Each voting member will score the application on a 1 to 5 scale (with 1 as the highest impact score). Committee members will discuss and vote on the application. Access to biospecimens will require approval vote from 3 of the 5 voting members.

The possible decisions include: (1) approve, (2) approve with contingency, (3) defer with request for additional information, and (4) disapprove with clearly stated reasons and suggestions for possible resubmission.

Investigators can expect a response to their request for data use in approximately 4 weeks post DBAC review, assuming no additional information is required or contingencies are identified that will need to be addressed by the investigator.

Following PHDB approval, IRB approval of an appropriate use protocol must be obtained by the requesting investigator before any data may be released. The two standing members will be responsible for ensuring that requesting investigators have the approved IRB protocol and the data use is within the scope of the PHDB source protocol. Furthermore, the IRB-approved protocol will be reviewed to ensure that the PHDB source protocol are referenced (protocol LAB03-0320).

**OTHER CONSIDERATIONS**

Fees for data will be assessed in accordance with the rates set by the DBAC and will follow approved institutional policies and guidelines.

An MTA is required if samples are leaving MD Anderson.

**DBAC APPROVAL**

Revision Date: May 21, 2018