BLOOD SPECIMEN RESEARCH RESOURCE DATA AND BIOREPOSITORY ACCESS COMMITTEE (DBAC) AND STANDARD OPERATING PROCESS

Existing data and biospecimens from the Blood Specimen Research Resource (BSRR) are 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 and biospecimens collected under the BSRR source protocol (LAB03-0320) requires approval from the BSRR DBAC.

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

Resolution of any conflicts that may arise regarding access and use of BSRR specimens 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 BSRR protocol, Dr. Stanley Hamilton, will provide long-term stewardship for BSRR data and biospecimens. To minimize any potential conflicts of interest, they will serve as non-voting members of the DBAC. A scientific administrator will lead in evaluation of protocol compliance. Five rotating committee members with diverse expertise in research involving biospecimens will serve for 3-year terms, with two members rotating off annually.

The DBAC Committee is comprised of the following members:

Non-voting standing members:

- Chair, Department of Epidemiology - DBAC Chair
- Stanley R. Hamilton, MD - PI of the BSRR protocol
- Sonia Cunningham, PhD – Epidemiology

Voting rotating members:

- Jian Gu, PhD, Epidemiology
- Manal M. Hassan, MD, PhD, Epidemiology
- Christopher J. Logothetis, MD, Genitourinary Medical Oncology
- Maria Alma Rodriguez, MD, VP Medical Affairs
- Wong-Ho Chow, PhD, Epidemiology
PROCESS TO REQUEST BSRR BIOSPECIMENS FOR RESEARCH USE

Investigators planning research studies that would require the use of existing BSRR biospecimens must submit a completed BSRR Biospecimen Feasibility Assessment Form. The assessment will consider the availability of biospecimens required to conduct the study.

PROCESS AND CRITERIA FOR EVALUATING REQUESTS

Requests for BSRR biospecimen 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; 4) portfolio balance; and 5) potential to deplete the BSRR.

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 1 to 5 scale (with 1 as the highest impact score) for each of the five evaluation criteria outlined above. Committee members will discuss and vote on the application. Access to biospecimens will require approval vote from 3 of the 5 voting members.

To minimize conflicts of interest, requests submitted by stewards of the BSRR or members of the DBAC will be discussed and voted on at the end of the meeting and in the absence of the requesting committee member. When the requestor is a voting member, to maintain the 3/5 approval vote, a former DBAC member will be invited by an impartial committee member to review and vote on the request via email.

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 biospecimen use in approximately 4 weeks, assuming no additional information is required or contingencies are identified that will need to be addressed by the investigator.

Following BSRR approval, the requesting investigator must submit evidence of an active IRB approved use protocol to the DBAC before any biospecimens/data may be released. The DBAC scientific administrative lead will review the use protocol for: 1) IRB approval and activation, 2) reference to the BSRR source protocol (LAB03-0320), and 3) project goals to ensure data and specimen use is within the scope of the BSRR source protocol. The DBAC Chair and protocol PI will review and sign off on the compliance review before any sample is released.

OTHER CONSIDERATIONS

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

All publications must appropriately acknowledge the Duncan Family Institute and its various funding sources as appropriate. An MTA is required if samples are leaving MD Anderson.

DBAC APPROVAL

Revision Date: March 14, 2019