

---

## **PURPOSE**

The major purpose of the Blood Specimen Research Resource (BSRR) Oversight Committee is to manage the residual blood specimens in the BSRR. The goal is to make these governance processes transparent to the M.D. Anderson community.

---

## **POLICY STATEMENT**

The BSRR should have an oversight committee to govern the activities of the resource to ensure compliance with all federal, state, and institutional policies and regulations.

---

## **SCOPE**

This policy applies to residual blood samples processed and stored in the BSRR under the front door consent (protocol LAB03-0320).

---

## **DEFINITIONS**

Front door consent: The front door consent operates under protocol LAB03-0320 (PI: Stanley Hamilton). It is an institutional protocol that allows for the collection and storage of residual tissues, including blood, from MD Anderson patients and individuals seen in outreach and screening events affiliated with MD Anderson. To be enrolled in LAB03-0320, an individual must sign the front door consent.

Residual blood samples: Unused, non-diagnostic blood that remains following diagnostic testing as determined by a pathologist.

Blood specimen research resource (BSRR): An initiative started in 2010 in which residual blood samples collected under the front door consent are processed and stored for use in future research. These operations are supported by the Center for Translational and Public Health Genomics.

---

## **PROCEDURE**

### **1.0 Major Principles**

- 1.1. The BSRR Oversight Committee is charged with stewardship of BSRR specimens to advance cancer-related research, and with facilitating access to this resource. The Oversight Committee is charged with the responsibility for 1) establishing and maintaining a process for BSRR specimen access, 2) establishing and maintaining criteria for evaluation, prioritization and approval of requests for BSRR specimens, 3) reviewing, evaluating, prioritizing and approving requests for BSRR specimens, and 4) resolving any conflicts that may arise regarding access and use of BSRR specimens.

- 1.2. All specimens are the property of MD Anderson Cancer Center unless otherwise agreed to by MD Anderson institutional officials such as the President, Chief Academic Officer and Chief Legal Officer.
- 1.3. This committee should include the individual or individuals responsible for the development and maintenance of the biospecimen repository and representatives from the diverse research interests across MD Anderson.

## **2.0 Prioritization/Evaluation**

- 2.1 The Oversight Committee will weigh the requests it gets from faculty for use of the research resource under its jurisdiction.
- 2.2 The Oversight Committee will be independent of other such committees such that investigators wishing to utilize the resources of more than one repository will have to make independent requests to do so.
- 2.3 Prioritization/evaluation criteria are to be developed by the Oversight Committee and made available to the faculty. Criteria are listed in section 4.1.

## **3.0 Review Process**

- 3.1 To ensure that adequate specimens are available to accomplish the proposed research, requests should be made to the Oversight Committee before naming the BSRR as a source of biospecimens in an MD Anderson protocol. A protocol should not be submitted to the IRB before a request is made for biospecimens. This procedure helps assure: 1) the BSRR can meet the request, and 2) the protocol can be more easily modified to include any changes requested by the BSRR. The intent of this procedure is to minimize burden on institutional IRB resources.
- 3.2 The Oversight Committee will evaluate requests for biospecimens from MD Anderson researchers. The following are the responsibilities of the Oversight Committee:
  - Review the requesting researcher's protocol and request for biospecimens. Following BSRR approval, IRB approval must be obtained before any biospecimens may be released.
  - All biospecimen requests will be reviewed by at least two reviewers with at least one member of the Oversight Committee or their designee. Reviews will normally be conducted via e-mail. The reviewer will approve or disapprove the request or approve it with contingencies. No grading or scoring is required.
  - If a request is not approved, state reasons and make suggestions for resubmission to the Oversight Committee.
  - If a request is approved with contingencies, state the contingencies.

## **4.0 Request Evaluation Criteria**

- 4.1 Requests for BSRR biospecimens 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) BSRR portfolio balance. Evaluation criteria may be revised by the Oversight Committee as needed.
- 4.2 The evaluation will also consider the request's potential to deplete the BSRR.

## 5.0 Committee Membership

The BSRR Oversight Committee is comprised of the following members:

- Jian Gu, PhD
- Stanley Hamilton, MD
- Jack Roth, MD
- Elizabeth Wagar, MD
- Xifeng Wu, MD, PhD

## 6.0 Other Considerations

Investigators using BSRR biospecimens will be asked to submit all data to the Center for Translational and Public Health Genomics after they have completed their specific aims. Data will be returned to the Center for Translational and Public Health Genomics so that they may be used to facilitate institution-wide collaborations and for research into clinical outcomes. Complete confidentiality of data is guaranteed until the date of publication or award of a patent.

All publications must appropriately acknowledge the Center for Translational and Public Health Genomics and its various funding sources as appropriate. Contact staff person for assistance with acknowledgement wording.