
PURPOSE

The major purpose of the TexGen Oversight Committee is to manage the data and biospecimens in the TexGen Biorepository. The goal is to make these governance processes transparent to the M.D. Anderson community.

POLICY STATEMENT

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

SCOPE

This policy applies to all samples collected under protocols LAB01-526 and LAB10-0434 (i.e., the TexGen protocols) with the following exception: Oversight of samples archived in the TexGen Consortium Biorepository is provided by the TexGen Consortium.

DEFINITIONS

TexGen Biorepository ("TexGen"): A research specimen biorepository developed for the purpose of collecting, processing, storing and distributing human blood and related data to MDACC investigators on behalf of protocols LAB01-526 and LAB10-0434. These operations are supported by the Department of Epidemiology.

TexGen Consortium: A multi-institutional initiative that collects and stores biological specimens and clinical data from each participating Texas Medical Center (TMC) institute. Members of the Consortium may request specimens and data from other members of the Consortium.

TexGen Consortium Biorepository: Samples collected under LAB01-526 that were assigned to the Consortium portion of the Biorepository. These operations are supported by the Department of Epidemiology. Oversight of these samples is provided by the TexGen Consortium. Samples were collected for the Consortium from April 2002 through August 2008.

Biological Samples: Any biological material collected from a patient or research participant including, without limitation, blood, serum, fluid, and tissue samples. The TexGen protocols collected blood which was processed into plasma, buffy coat, and extracted DNA.

PROCEDURE

1.0 Major Principles

- 1.1 All those seeking access to specimens in the TexGen Biorepository should first consult with Ms. Anna Garcia to determine if their needs can be met by the Biorepository.

- 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.

2.0 Characteristics of an Official Tissue Repository or Data Bank

- 2.1 All such repositories should be guided by an Oversight Committee.
- 2.2 This committee should include the individual or individuals responsible for the development and maintenance of the tissue repository or data bank and at least one member from the clinics from which patients were recruited (i.e., the Gastrointestinal and Urology Centers).
- 2.3 At least one member of the Oversight Committee should be a faculty member from outside of the program affiliated with the tissue repository or data bank.

3.0 Prioritization

- 3.1 The Oversight Committee will weigh the requests it gets from faculty for use of the research resource under its jurisdiction.
- 3.2 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.
- 3.3 Prioritization criteria would be developed by the Oversight Committee and made available to the faculty.
- 3.4 Any request should be accompanied by documentation that the IRB has approved the proposed research.

4.0 Review Process

- 4.1 The Principal Investigator (PI) of the TexGen protocols is responsible for ensuring that requests for specimens from the Biorepository are reviewed and evaluated. The PI may delegate responsibility for the operational/administrative aspects of this process to a program manager/program director (i.e., the PI's authorized manager). This delegation must be noted in the study's Delegation of Authority. The PI remains ultimately responsible for all activities overseen by his or her authorized manager.
- 4.2 If a researcher wishes to access TexGen biospecimens, s/he must first submit a protocol and specimen request for the Oversight Committee to review. The feasibility of a request (i.e., whether TexGen is able meet the request) will be verified before it is sent to the Oversight Committee.
- 4.3 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. The Oversight Committee may review requests that have not yet been approved by the IRB. However, IRB approval must be obtained before any data or biospecimens may be released.
 - All biospecimen requests will be reviewed by at least one member of the Oversight Committee or their designee. At least one reviewer must be from the clinic/center from which the requested samples were collected. 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.

5.0 Request evaluation criteria

- 5.1 Requests for TexGen biospecimens and/or data 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) TexGen portfolio balance. Evaluation criteria may be revised by the Oversight Committee as needed.
- 5.2 The evaluation will also consider the request's potential to deplete the TexGen resource.

6.0 Committee Membership

The TexGen Oversight Committee is comprised of the following members:

- Xifeng Wu, MD, PhD, Principal Investigator (PI) of the TexGen protocols
- Stanley Hamilton, MD, Co-PI of the TexGen protocols
- Michelle Hildebrandt, PhD, (representative of Epidemiology)
- Jaffer Ajani, MD (representative of the Gastrointestinal Clinic)
- Jeri Kim, M.D. (representative of the Genitourinary Clinic)
- Christopher Wood, M.D. (representative of the Urology Clinic)