

**Texas Cancer Cell Repository**  
**Standard Operating Procedure 011**

**Constitution of the TXCCR Steering Committee  
and  
Procedures for Access to Cell Lines and Xenografts by Investigators Who Are Not  
TTUHSC TXCCR Co-Investigators**

*Current Versions of this SOP and all updates are available at:*

*[www.TXCCR.org](http://www.TXCCR.org)*

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## **1.0 Purpose of the TXCCR Steering Committee**

The TXCCR Steering Committee shall review (as needed) requests for access to cell lines and xenografts within the TXCCR. It will also serve to coordinate with the Texas Cancer Research Biobank ([www.TXCRB.org](http://www.TXCRB.org)) and/or the South Plains Oncology Consortium ([www.SPONC.org](http://www.SPONC.org)) biobank for access to original patient tissue for comparative studies related to the cell lines and xenografts.

As cell lines and xenografts are a renewable resource, the access to those will not be as stringently controlled as access to original tissue in biobanks (which are non-renewable). However, all access must be by qualified investigators, who have the resources, training, and experience to utilize the cell lines and xenografts for research. In addition, although in the vast majority of cases the research being on samples for which the investigator cannot establish a link to the patient would be considered “exempt” for human subjects protection purposes, the IRB governing the requesting investigator must have reviewed and either approved the research or certified the samples are considered as exempt from the need of a formal IRB review.

### **1.1. Constitution of the TXCCR Steering Committee**

*The TXCCR Steering Committee shall consist of:*

1. The TXCCR Principal Investigator, who shall chair the committee
2. The Chair of the SPOC TR001 Biobanking Protocol
3. Co-PI's of the TXCCR
4. One TXCCR Co-Investigator who is not a Co-PI
5. The TXCCR Biobanking Core laboratory manager
6. The TXCCR Administration Coordinator (Lead CRA)

### **1.3 Meetings**

The Steering Committee will meet as required to consider requests for lines and to establish procedures for the TXCCR. To the extent possible, all communications will be carried out by email, and most reviews of requests can be done by email. When discussions beyond email are required, the Administration Coordinator will work with the members to establish a time for a meeting; members located outside of Lubbock will attend those meetings by video or teleconference.

### **1.4 Governance**

Whenever possible, decisions on policies or on requests for lines will reflect the consensus of the committee. In those rare instances where a clear consensus cannot be reached, a formal vote will be tallied, with a simple majority carrying the decision. If a request for lines comes from an investigator in which there would be a conflict of interest with a member of the Steering Committee, that member will recuse him/herself from the decision and/or voting, but may participate in the discussion. If discussion is needed without the conflicted person being involved, that will be arranged. If the conflicted

individual is the Committee Chair, than a Co-PI or Co-Investigator will chair the committee for that portion of the committee's business.

## 2.0 Procedures for Accessing TXCCR Cell Lines and Xenografts

Requests may be made via the TXCCR website (when request systems are enabled) or by emailing any member of the Steering Committee. The Administration Coordinator and the TXCCR Laboratory Manager will coordinate and insure follow-up on all requests. Email addresses for requests will be posted on the TXCCR website ([www.TXCCR.org](http://www.TXCCR.org)).

Cells and tissues for nucleic acid extraction and other analyses that are part of the initial characterization of TXCCR cell lines and xenografts will be provided to the following investigators who are CPRIT-funded and actively engaged in the TXCCR without the requirement for Steering Committee Approval:

All investigators on the TXCCR CPRIT MIRA grant  
All investigators on the TCRB CPRIT MIRA grant

While ready access to the cell lines and xenografts without specific review is provided to TXCCR and TCRB investigators, that access is limited to the use of the materials for characterization of the lines. TXCCR and TCRB investigators who seek to use the lines for research that is not related to the initial characterization of the cell lines should obtain the cell lines via one of the request processes listed below. While cells or tissue for nucleic acid extraction and characterization can be provided as derivatives of the tumor and normal cells collected on patients via the SPOC or related collection protocols to TCRB laboratories at any time (as is required to carry out the aims of the TXCCR and TCRB grants) provision of cell lines or xenografts capable of sustained growth outside of TTUHSC requires execution of an appropriate MTA.

### 2.1 Requests for Cell Lines Not on the Open Distribution List (ODL)

As these requests will be reviewed by the Steering Committee, there is no limit on the number of lines or nature of the lines that can be requested. The Steering Committee can approve a portion or all of any requests, thus insuring only reasonable requests are approved.

The requests must be made on the fillable PDF form provided at [www.TXCCR.org](http://www.TXCCR.org), or if implemented on the website, directly online. The requests must state the cell lines and or xenografts requested, the reason for the request, and succinctly but clearly outline what research will be done with the requested lines, the anticipated time to carry out the research, and the plans for publication of the research. In general, requests for non-ODL cell lines or xenografts will be by investigators who will be aiding or carrying out the major characterization of the lines. Requests for non-ODL cell lines or xenografts may be made by investigators for research not directly related to characterizing the lines if they are very well justified and of a reasonable scope. Such requests are approvable in situations where the TXCCR has a unique resource that can aid the requesting investigator in ways not easily met by other resources for cell lines and xenografts.

The request for non-ODL lines will be circulated by email for review to the Steering Committee and comments/votes sent to the TXCCR Administration Coordinator, who will inform the Steering Committee chair if a consensus has been reached or if further discussion or a formal vote is necessary. Via the Administration Coordinator, the Chair will notify the requesting investigator of the Committee decision. In the case of favorable decisions, the requesting investigator will be required to then execute a TXCCR Non-ODL MTA and also provide certification of IRB approval from the IRB governing the investigator. Once those documents have been provided and the investigator has provided a Fed Ex account number or other mechanism for the TXCCR to ship the requested samples to the investigator at no cost to the TXCCR, then the TXCCR Laboratory Manager will insure the requested cell lines and xenografts are shipped to the requesting investigator.

## **2.2 Requests for Cell Lines Not on the Open Distribution**

Once cell lines or xenografts have been published in the peer-reviewed literature, or when sufficient characterization has been carried out and made publically available (and has been scientifically validated, most often by peer-reviewed publication) than the cell lines or xenografts will be included in the TXCCR Open Distribution List (ODL).

The Open Distribution List (ODL) will be defined by the TXCCR Steering Committee. While there is no requirement for any TXCCR lines to be on the ODL, withholding lines from the ODL once they have been published in the peer-reviewed literature will require a formal consensus or vote of the TXCCR Steering Committee.

Cell lines and xenografts on the ODL will be made freely available to qualified investigators under the following conditions:

1. Reasonable limitations apply to the requests. Up to 3 lines can be requested and automatically approved by lab staff if all other conditions (see below) are met. Up to 10 lines can be approved in the same fashion by the TXCCR Principal Investigator, if suitably justified in a request that clarifies the need for 10 cell lines in a document 1 page or less. More than 10 cell lines (or > 5 xenografts) requires a 2 page or less justification that is reviewed and approved by the Steering Committee. Procedures for review will be as outlined above for non-ODL requests
2. The investigator must provide a transport account number so that shipping is at no cost to the TXCCR.
3. The provision of lines at no cost from TXCCR is contingent upon continual funding for doing so by CPRIT or other external sources.
4. The investigator must provide a copy of IRB approval or exemption for use of the cell lines in his/her institution
5. An MTA must be executed to obtain the cell lines

## **2.3 MTA for Non-ODL lines**

The Uniform Biological Materials Transfer Agreement (UMBTA), developed by the Association of University Technology Managers ([www.AUTM.net](http://www.AUTM.net)) will be used for Non-ODL requests. Most universities and medical schools are signatories to the UMBTA

process. All ODL material has no direct linkage to patient identifiers and the only data available for ODL material will be that made publically available via publications and [www.TXCCR.org](http://www.TXCCR.org). The MTA will consist of the letter describing the material (as per the UMBTA) and that letter will activate the already signed UMBTA. TXCCR will provide copies of executed UMBTA on at least a quarterly basis to the TTUHSC Office of Sponsored Program.

## **2.4 Requests from Commercial (Non-Academic) Institutions**

All requests from non-academic institutions (i.e. commercial entities) will be handled on a case by case basis, regardless of whether the request is for ODL or non-ODL lines. The Non-ODL MTA will serve as a template for such requests, but the final version of the MTA and the terms of the MTA, including potential compensation to TXCCR for obtaining the lines will be determined by the Steering Committee and TTUHSC leadership. If lines are deposited in the TXCCR for which distribution to commercial entities would involve an institution other than TTUHSC, than TTUHSC Office of Sponsored Programs will coordinate working with the other institutions(s) to arrive at a mechanism for distribution of the lines.