Thomas Jefferson University

Request for Sidney Kimmel Comprehensive Cancer Center
Translational Research Group & Biorepository Services

Request for Specimens and/or Clinical Data

A translational research program is an indispensable resource for researchers to address clinically relevant questions using high-quality, clinically-annotated human biospecimens. While accessibility and biospecimen utilization are very important, the Sidney Kimmel Comprehensive Cancer Center Translational Research Group (TRG) needs to manage biospecimen usage to ensure that these valuable resources will be properly utilized to address important scientific questions for current and future researchers. Therefore, it is the responsibility of the researchers and the translational research staff to work together in the following manner to meet the goals of the researchers while keeping in mind the need for future research as well.

Upon determining the need and available funding for research involving biospecimen use, the researcher should submit the attached "Request for Sidney Kimmel Comprehensive Cancer Center Translational Research Group & Biorepository Services" along with a signed "Agreement for Use of Sidney Kimmel Comprehensive Cancer Center TRG & Biorepository Services" to **stefany.hinojosa@jefferson.edu.**

Researchers should submit the request to the Sidney Kimmel Comprehensive Cancer Center Translational Research Group before submitting for IRB approval. This allows the Sidney Kimmel Comprehensive Cancer Center Translational Research Group to provide the researcher with guidance in obtaining the proper regulatory permissions and allows the group time to evaluate feasibility of the researcher's request. After the request is received, the Biospecimen Use Committee will review the request and notify the researcher regarding their decision. The purpose of the Biospecimen Use Committee is to support access to biospecimens for research through the assessment of criteria such as scientific rationale, validity of the scientific project, potential conflicts of interest, and fair biospecimen/data allocation practices. If the Biospecimen Use Committee approves the request, the researcher must then acquire the appropriate regulatory permissions and contracts for biospecimen use according to their institution.

Required Permissions for Researchers to Use the TRG & Biorepository Services

In accordance with national, state, and local laws, along with TJU policies, all researchers are required to obtain proper regulatory forms for use of human subject materials. This includes use of the tissue and/or any associated patient data. While the Sidney Kimmel Comprehensive Cancer Center Translational Research Group has IRB-approved protocols in place for the collection and storage of various biospecimens and accompanying clinical data, the protocols do not include research of the biospecimens or analysis of clinical data. Therefore, it is the responsibility of all researchers wishing to use Sidney Kimmel Comprehensive Cancer Center Translational Research Group resources to obtain the appropriate

regulatory permissions for their laboratory to conduct the research and analysis. Below is a breakdown of the minimum required permissions for researchers. It is the responsibility of the researchers, with the help of the Sidney Kimmel Comprehensive Cancer Center Translational Research Group, to determine what regulatory requirements they need to meet for their specific research.

- For TJU researchers: The researcher must determine whether a non-exempt IRB protocol is necessary or if an OHR-19 (Research Involving Coded or Anonymous Private Information and Biological Specimens), or an equivalent, is sufficient.
    - After the IRB approves the appropriate forms, the researcher may then submit the IRB-approved form or protocol to the Sidney Kimmel Comprehensive Cancer Center Translational Research Group.
    - Documentation of annual review of non-exempt protocols must be forwarded to the Sidney Kimmel Comprehensive Cancer Center Translational Research Group to maintain eligibility to receive tissue.
- For researchers outside of the TJU network, a Material Transfer Agreement (MTA) and/or contract must be established.
    - Once the appropriate regulatory approvals and contracts are in place, the researcher must send approved copies to the Sidney Kimmel Comprehensive Cancer Center Translational Research Group.

For questions or concerns, or to submit a request for services, please email **stefany.hinojosa@jefferson.edu**

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Please complete the information below regarding the proposed research for the translational research specimens/data. After the information is complete, please read the Agreement for Use and sign and date the bottom. Email the completed form to **stefany.hinojosa@jefferson.edu.**The Biospecimen Use Committee will then review the information and contact you when the review is complete.

1. The study title

2. A short summary of the proposed research for the resources

3. Funding source (please include current charge code)

By providing the above charge code, you are authorizing the Sidney Kimmel Comprehensive Cancer Center Translational Research Group and Biorepository to use this code for costs associated with this research request.

Thomas Jefferson University

4. Desired biospecimens
    a. Diagnosis type:

    b. Patient population/specific demographics required:

    c. Number of patients:

    d. Type of biospecimen

5. Desired timeline for specimen access

6. Desired clinical data

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Agreement for Use of Sidney Kimmel Comprehensive Cancer Center TRG & Biorepository Services

1. The researcher agrees that biospecimens provided by the Sidney Kimmel Comprehensive Cancer Center Translational Research Group will be used only by the laboratory of the recipient principal investigator for the research specified in the submitted request and shall be used for no other purpose.
2. The researcher agrees that biospecimens distributed to their lab will not be shared with other researchers/labs without prior written permission from the Sidney Kimmel Comprehensive Cancer Center Translational Research Group.
3. The researcher agrees not to attempt to identify donors that have provided biospecimens to the Sidney Kimmel Comprehensive Cancer Center Translational Research Group.
4. The researcher agrees to submit a semi-annual report of the research project resulting from biospecimen use back to the Sidney Kimmel Comprehensive Cancer Center Translational Research Group. The report must include a summary of the results of the research project and information regarding specimen utilization. Upon completion of the research, the researcher agrees to submit a final report of the research results.
5. The researcher agrees that other researchers may contact them regarding their research results. This promotes collaboration between researchers.
6. The researcher agrees to cite the Sidney Kimmel Comprehensive Cancer Center Translational Research Group in all publications resulting from the use of the translational research resources. Recommended wording for the methods or acknowledgement section is “Biospecimens were provided by the Thomas Jefferson University-Sidney Kimmel Cancer Center Translational Research Group, a College of American Pathologists (CAP)-accredited biorepository (CAP# 8427654), with support from the Cancer Center Grant 5P30CA056036-17”. Formal analysis of scientific impact can provide evidence of the inherent and extrinsic scientific value and contribution of the resource.
7. If the Sidney Kimmel Comprehensive Cancer Center Translational Research Group and researcher agree upon the return of resources, the date of return will be defined before the specimens are distributed to the researcher. The researcher agrees to return the specimens by the agreed upon date unless the Sidney Kimmel Comprehensive Cancer Center Translational Research Group is notified and approves of the need for an extension.
8. If a study is not progressing as planned, the TRG reserves the right to reassess the study and adjust the budget, schedule, accrual goals, or specimens, in conjunction with the PI, to better represent actual feasibility of the study.

Name of PI

Signature Date

Name of Sidney Kimmel Comprehensive Cancer Center Translational Research Group Recipient

Signature Date