**National Cancer Institute (NCI) -- Patient-Derived Models Repository (PDMR) Program**

**INTERNAL MATERIAL TRANSFER AGREEMENT**

## For Distribution Within the NIH

## Summary Page (“Coversheet”)

Name of NIH IC: Click or tap here to enter text.

Name of NIH Investigator: Click or tap here to enter text.

Mailing Address: Click or tap here to enter text.

 Click or tap here to enter text.

Telephone: Click or tap here to enter text.

Fax: Click or tap here to enter text.

Email: Click or tap here to enter text.

**Term of Agreement**: This Agreement will continue in perpetuity until cancelled in writing by Recipient for any reason or by Provider for breach of this Agreement.

The Annual Report (identified in Article 6) containing all data generated using these materials is to be returned to the NCI Patient-Derived Models Repository. An Annual Report is due on the first and each subsequent anniversary of the Effective Date for the first five (5) years following the Effective Date, as defined below. If the Agreement is terminated for any reason, a final Annual Report will be due within 90 days of termination.

For your convenience, an Excel template for data entry may be requested from the Repository at NCI\_PDM\_Repository@mail.nih.gov.

The report may be submitted by email to: NCI\_PDM\_Repository@mail.nih.gov, Attn: Yvonne A. Evrard, Ph.D. Whole exome and genome files and RNASeq files should be submitted as zipped FASTQ files or an FTP of Globus drop can be established; please contact the NCI-PDMR for details.

Send MTA paperwork to: NCI\_PDM\_Repository@mail.nih.gov

## Signature Page

The RECIPIENT and/or the NIH INVESTIGATOR and PROVIDER have entered into this Agreement effective as of the Recipient’s signature date below (“Effective Date”):

**RECIPIENT INFORMATION**

|  |  |
| --- | --- |
| Signature of Authorized Official or NIH Investigator: |  |
| Date |  |

Address for Notices Regarding the Materials:

Cindy R. Timme, Ph.D.

Frederick National Laboratory for Cancer

1050 Boyles St. Bldg. 1066, Rm. 126

Frederick, MD 21702

Phone: 301-846-1327

Address for Legal Notices:

Technology Transfer Center.

National Cancer Institute

9609 Medical Center Drive, Rm 1E-530

Bethesda, MD 20892-9702

Phone: 240-276-5530

**MATERIAL TRANSFER AGREEMENT**

**National Cancer Institute (NCI)**

**Patient-Derived Models Repository (PDMR) Program**

This internal Material Transfer Agreement ("iMTA" or “Agreement”) has been adopted for use by the National Cancer Institute Patient Derived Models Repository ("NCI-PDMR") for transfers of materials to investigators within the NIH (“NIH Investigators”) for research purposes. The Repository is comprised of patient-derived xenografts (PDXs) and in vitro patient-derived cell cultures, to serve as a resource for public-private partnerships and for academic drug discovery efforts. Contributing Institutions have provided previously generated patient-derived materials for distribution by the PDMR (the “Contributing Institutions”).

1. Recipient agrees to use the Research Material, described with specificity in Appendix 1 (patient-derived xenograft requests) and Appendix 2 (in vitro culture requests), attached hereto, in accordance with this Agreement.

2. THIS RESEARCH MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS. The Research Material will only be used for research purposes by the NIH Investigator in his/her laboratory under suitable containment conditions. This Research Material will not be used for commercial purposes or with other materials obtained from a third party under a CRADA. Recipient agrees to comply with all Federal rules and regulations applicable to the handling of the Research Material. These samples are being provided in a manner that does not allow for direct identifiable patient information to the NIH Investigator, and therefore do not constitute Human Subject Research as defined in 45 CFR Part 46, “Protection of Human Subjects”. The NCI-PDMR represents that the collection of Research Material and its sharing with Recipient for research purposes was approved or exempted by the relevant Institutional Review Board and authorized by donors under informed consent in accordance with federal, state and local laws and regulations which address protection of human subjects in research, including 45 CFR part 46.

3. This Agreement will terminate as specified on the Coversheet. Within thirty (30) days of termination of the Agreement, the Research Material will be destroyed unless otherwise directed by NCI-PDMR. Articles 4-7 will survive termination or expiration of this Agreement.

4. In all oral presentations or written publications concerning the Research Material, Recipient will acknowledge the NCI-PDMR's contribution and that of the Contributing Institution(s), if any, of this Research Material unless requested otherwise in writing.

5. This Research Material represents a significant investment on the part of NCI-PDMR. The NIH Investigator therefore agrees to retain control over this Research Material and further agrees not to transfer the Research Material to other people not under Recipient Investigator’s direct supervision or to anyone outside the NIH without advance written approval of NCI-PDMR. NCI-PDMR reserves the right to distribute the Research Material to others and to use it for its own purposes.

6. The NIH Investigator agrees to provide NCI-PDMR on a confidential basis a written report containing all data related to the NIH Investigator’s direct use of the Research Material (the “Annual Report”). Data include, but are not limited to, short tandem repeat profiles (assessment of model stability), NextGen sequence files, model drug resistance or sensitivity, array data, metabolomics profiles, and pharmacodynamic profiles (“Data”). The Annual Report will be provided as described on the Coversheet. General templates for deposits of data will be provided on the NCI-PDMR public web site or upon request.

7. It is the intent of NCI-PDMR to make the Data disclosed in said Annual Report available to the scientific community by various means of publications (including digital distribution and oral presentation). The NIH Investigator hereby agrees that NCI-PDMR may make Data from the Annual Reports concerning molecular targets, available to the scientific community after one (1) year from date of receipt of the Annual Report by NCI-PDMR. The NCI-PDMR understands that the NIH Investigator may need additional time to obtain proper protection of Intellectual Property which may arise during the course of research, Therefore, the time for release of the Data to the scientific community from said Annual Reports by NCI-PDMR may be extended up to one additional year upon notice by the IC Technology Development Coordinator (“TDC”) to the NCI-PDMR.

8. The NIH Investigator acknowledges the following with respect to the Research Material:

    For Cryopreserved PDX fragments, the NIH Investigator is required to implant the Research Material into NOD-SCID gamma IL2 receptor null (NSG) mice and establish a stock of cryopreserved vials to re-supply the NIH Investigator for future studies and the NIH Investigator should generate a short tandem-repeat profile of their stock for comparison to the provided distribution lot;

    Pathology and sequence data provided on the NCI-PDMR website are representative of the model that they request but there may be vial-to-vial variations due to inherent heterogeneity of the early-passage preclinical models provided by NCI-PDMR; and

    Specific PDX fragments from specific lineages within a model cannot be provided.  A single vial will be randomly selected from the distribution lot to supply requests received for a model.

    For Cryopreserved in vitro models including patient-derived tumor cultures (PDCs), cancer-associated fibroblasts (CAFs), and organoids (PDOrg), the Recipient is required to initially expand and establish a stock of cryopreserved vials to re-supply Recipient for future studies using the PDMR-provided SOPs and recommended media for the specific culture received. Recipient should generate a short tandem-repeat profile of their stock for comparison to the provided distribution lot.

    Models developed by Contributing Institutions and provided to the NCI-PDMR for distribution may vary (e.g., variations in molecular characterization, histopathology, etc) between institutions because they have distinct passage histories. Variations in methodology (e.g., fragment implant vs dissociated tumor implant), implant site (heterotopic vs orthotopic), tumor heterogeneity (different regions of a donor tumor may grow distinct subsets of the originating tumor) and mouse strain (e.g., NSG vs NOG vs SCID.bg) may result in expansion of distinct subsets of the tumor after a single passage which can be magnified with further passage. Therefore, direct comparisons of a specific tumor model from two independent sources should be approached cautiously. These same influences occur when Recipients expand the models at their own facilities and make comparisons to the representative data provided by the NCI-PDMR on the public web site (as well as other users of the same model).

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**Appendix 1: PDX Materials**

**Patient-Derived Xenograft Materials (format: 123456-123-X). Cannot request specific fragments. Distribution lots can be found listed in the PDMR Database at the following link:** <https://pdmdb.cancer.gov/pls/apex/f?p=101:41>

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| # | Distribution Lot Name | Cryovial for PDX Generation | PDX DNA Vial | PDX RNA Vial | PDX Flash-Frozen Vial |
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**Appendix 2: In Vitro Materials**

**Patient-Derived Tumor Culture (PDC), Cancer-Associated Fibroblast (CAF), and Organoid (PDOrg) Material (format: 123456-123-X-PDC, 123456-123-X-CAF, 123456-123-X-organoid). Distribution lots can be found listed in the PDMR Database on the in vitro culture tab at the following link:** <https://pdmdb.cancer.gov/pls/apex/f?p=101:43>

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