

NCI Patient-Derived Models Repository (PDMR) Material Request Procedures - Domestic

Effective Date: 8/30/2021

Please check for revision status of the SOP at

<https://pdmr.cancer.gov/sops/>

PDMR **NCI Patient-Derived Models Repository**
An NCI Precision Oncology InitiativeSM Resource

TABLE OF CONTENTS

The following items are required to receive materials:	2
Specimen types that may be requested:	3
MTA Information.....	4
PDMR Request Review Criteria.....	4
General Shipping and Handling Information.....	5
Distribution Costs (excluding shipping)	5
Contact Information	5

The following items are required to receive materials:

1. Fill out a PDMR Model Request Form.
 - a. Provide a brief description of the research plan for the requested material(s), including a plan for different fractions (i.e., viably cryopreserved fragments for PDX generation, RNA, DNA, flash-frozen) if requesting.
 - b. All applicants should have a clear plan for banking PDX and cell culture material for their planned studies. PDMR SOPs <Link: <https://pdmr.cancer.gov/sops/default.htm>> include workflow diagrams for PDX tissue/cell line receipt and banking as a guidance if needed.
 - c. If requesting CAF cultures, be sure the research plan includes details on expected use and potential novel contributions to the field. Also ensure you state that you understand these models are only guaranteed for 3 passages of growth, though additional population doublings and subcultures are possible.
 - d. Intramural investigators (MD campuses) – leave the FedEx and Payment Information blank
2. Review the Material Transfer **Terms of Agreement** <Link: <https://pdmr.cancer.gov/request/default.htm#h03>> and then fill out the Material Transfer Agreement (MTA) with all requested models included in the appropriate Appendix and the requesting site's authorizing official signature affixed. Once the request has been approved by the review committee, NCI will route for signatures by the NCI authorizing official. Modifications to NCI's MTA Terms of Agreement will not be considered.
 - a. Intramural Investigators: Use the designated MTA for Intramural Investigators
3. If requesting cryopreserved fragments for PDX generation, provide a copy of your Animal Care and Use Committee (ACUC) protocol indicating your laboratory, or designate, uses NOD.*Cg-Prkdc^{scid}Il2rg^{tm1Wjl}/SzJ* (NSG) mice. Alternatively, you may provide a Bill of Sale showing NSG mice have been purchased. All PDMR PDXs must be initially implanted into NSG mice for propagation.
4. Requests will be processed after receipt of all required documentation; partial submissions will be returned. The requests will not be reviewed until all paperwork has been received. Please send the necessary paperwork to: NCI_PDM_Repository@mail.nih.gov

Specimen types that may be requested:

A single vial of the following material will be shipped upon arrival:

- **Vial of Cryopreserved PDX fragments:** Single vial from a PDX tumor no higher than the listed maximum passage for the distribution lot; sufficient tissue to implant into 2-5 NSG mice. Material cannot be requested from a specific PDX sample in a lineage.
- **Vial of Flash-frozen DNA:** Single vial from a PDX tumor no higher than the listed maximum passage for the distribution lot. Approximately 2-3 µg DNA in at least 10 µL prepared using Qiagen's DNA/RNA AllPrep Mini Kit (cat#: 80204)
- **Vial of Flash-frozen RNA:** Single vial from a PDX tumor no higher than the listed maximum passage for the distribution lot. Approximately 2-3 µg RNA in at least 10 µL prepared using Qiagen's DNA/RNA AllPrep Mini Kit (cat#: 80204). RNA quality is periodically assessed using an Agilent 2100 Bioanalyzer and vials are maintained if the RIN is >5. For those interested in doing RNASeq, we would recommend requesting a flash-frozen fragment and performing an independent extraction.
- **Vial of Fresh-frozen PDX fragment:** For protein extraction, single vial with a 30-60 mg fresh-frozen PDX tumor fragment no higher than the listed maximum passage for the distribution lot
- **Vial of Cryopreserved Patient/PDX-Derived Heterogenous Tumor Culture (PDC) cells:** Vial contains a minimum of 7.5×10^5 cells. Cells are non-clonal, not transformed, and have been confirmed to grow at least 20 passages beyond the distribution passage when maintained on Matrigel-coated surface in the recommended defined Media + Y compound without out-growth of fibroblasts or loss of fidelity.
- **Vial of Cryopreserved Patient-derived Cancer Associated Fibroblast Culture (CAF):** Vial contains a minimum of 7.5×10^5 cells. Cells are non-clonal, not transformed, and have been grown for a minimum of 3 passages beyond the distribution passage when maintained on Matrigel-coated surface in the recommended defined Media + Y compound.
- **Vial of Cryopreserved Patient/PDX-Derived Organoid (PDOrg) cells:** Vial contains a minimum of $1-5 \times 10^5$ cells. Cells are non-clonal, non-transformed, and have been grown out to 10 passages beyond the distribution passage when maintained in the recommended defined Media + Y compound + Basement Membrane matrix according to the PDMR SOPs.

MTA Information

- Multiple models and cell fractions may be ordered using a single MTA
- Clearly identify each requested item in Appendix 1 (PDX material) and/or Appendix 2 (in vitro material) of the MTA.
- Newly requested material will require completion of a new MTA
- Requests by the same investigator for previously received material should indicate the active MTA number in the request email along with reason for duplicate request.
- NIH/NCI main Maryland campus investigators, use intramural MTA for request.

PDMR Request Review Criteria

A committee of National Cancer Institute and Frederick National Laboratory for Cancer Research scientists will review all requests prior to approval of distribution.

NCI's goal is to maintain all patient-derived models at the earliest possible passage for distribution; because of this these materials will have a limited distribution lifetime and therefore care will be taken to ensure end-users have the experience to utilize the material.

For example, sites that do not have an ACUC protocol for NOD.*Cg-Prkdc^{scid}Il2rg^{tm1Wjl}/SzJ* (NSG) mice would not be approved for distribution of cryopreserved PDX fragments as the PDMR require initial implantation into NSG mice for PDX generation. Sites requesting cryopreserved PDX fragments also need to clearly state their plan to freeze down their own stock of PDX fragments for their planned studies.

Due to the expected limited in vitro lifespan for CAF cultures, the review committee will be more stringent when reviewing requests for this material as once all generated material has been distributed it will not be able to be generated again for the same patient model.

General Shipping and Handling Information

Domestic Recipients

- A Federal Express (FedEx) account number provided by the Recipient to which the shipment can be charged is required for all Domestic requests. Alternatively, a prepaid FedEx label provided by the Recipient at time of shipment is acceptable; the PDMR will email the Requestor with the details needed to generate the label when needed.
- Orders of >15-20 vials of viably cryopreserved material will be shipped in multiple shipments and the Requestor will incur additional shipping costs. This is to minimize the loss of viability that can occur when shipments are delayed during transport or if any other shipping issues occur. This is based on real-world experience the PDMR has had with other Recipients.

Distribution Costs (excluding shipping)

- Payment can be made by (i) electronic ACH payment (contact us for details) or (ii) mailed paper check made payable to the “**Leidos Biomedical Research.**” These monies will then be transferred to the National Cancer Institute.
- An invoice for the Distribution Costs will be e-mailed to the designated Recipient Billing Contact once materials have been shipped.
- Remittance should be received within 30-days of invoice.

Specimen Type	NCI/NIH Investigators: at MD campuses only	Academia/Non-Profit: Domestic & non-MD campus NCI/NIH Investigators	Commercial Entities: Domestic
Per Cryopreserved vial: PDX fragment	\$0	\$250	\$2500
Per flash-frozen vial: DNA, RNA, or PDX fragment	\$0	\$200	\$1500
Per Cryopreserved vial: PDOrg	\$0	\$250	\$2500
Per Cryopreserved vial: PDC	\$0	\$250	\$2500
Per Cryopreserved vial: CAF	\$0	\$200	\$1500

Contact Information

For questions or comments, please e-mail the NCI Patient-Derived Models Repository at:
NCI_PDM_Repository@mail.nih.gov