

NC PDMR In Vitro Material Request Procedures

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The following items are required to receive materials:

1. Fill out a PDMR In Vitro Model Request Form.
 - a. Currently only requests from Domestic sites, until further notice
 - b. Please note, currently only payments using a check made out to “**Leidos Biomedical Research**” can be accepted. Funds will subsequently be deposited with the National Cancer Institute.
2. Send the Material Transfer Agreement (MTA) with all requested models included in Appendix 2 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.
 - a. Intramural Investigators: Use the designated MTA for Intramural Investigators
3. On the In Vitro Model Request Form, provide a brief description of the research plan for the requested material in Section 4 of the Request Form.
4. If requesting CAF cultures, be sure the research plan includes details on expected use and potential novel contributions to the field should be included. Also ensure you state that you clearly understand these models are only guaranteed for 3 passages of growth, though additional population doublings and subcultures are possible.

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 approval:

- **Vial of Cryopreserved Patient-derived Mixed Tumor Culture (PDC) cells:** Vial contains a minimum of 7.5×10^5 cells. Cells are non-clonal, not transformed, and have been grown out to 20 passages maintained on Matrigel-coated surface in the recommended Complete 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 when maintained on Matrigel-coated surface in the recommended Complete Media + Y compound.

MTA Information

- Multiple models may be ordered using a single MTA
- Clearly identify each requested item in **Appendix 2** of the MTA.
- Newly requested material and MTA renewals 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.
- Note: For standard requests for research-use of PDMR material, the check-box in bullet #3 does not need to be checked. This is for specific use-case collaborations set-up by the NCI.

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 life time and therefore care will be taken to ensure end-users have the experience to utilize the material.

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.

All applicants should have a clear plan for banking cell culture material for their planned studies.

Limitations and Caveats (see website for a more detailed list):

- PDCs and CAFs are non-transformed cells.
- PDC and CAF cultures use specialized Complete Media and grow with a variety of growth characteristics. A model-specific Certificate of Analysis (COA) will be provided with the distributed material. This COA and the PDMR SOPs should be used to ensure culture success – these models should not be treated like traditional in vitro cultures (e.g., HeLa, MCF7).
 - Failure to grow cells in the recommended Complete Media in the provided model-specific COA and follow the PDMR SOPs posted on the public website may result in loss of the culture. Replacement material would not be provided under these circumstances.
- PDCs can be derived from primary patient material, PDXs, or PDOrgs. CAFs can be derived from primary patient material or in rare cases early passage PDXs. Derivation information is detailed in the PDMR database.
- PDCs are referred to as “mixed” tumor cultures. Cultures are maintained at early passage and no clonal selection is performed so that the maximum heterogeneity possible is maintained in the culture within the limitations of model generation.
- CAFs have a finite lifespan in vitro. CAFs are guaranteed for experimental use for up to 3 passages when maintained on Matrigel-coated surface in the recommended Complete Media + Y compound. Additional population doublings and subcultures are possible, but overall fitness of culture may deteriorate with subsequent passages
- All PDCs are tested for ability to generate a cell-line derived xenograft (CLX) in NOD.Cg-Prkdc^{scid}Il2rg^{tm1Wjl}/SzJ (NSG) mice, though as with traditional cell line models, we expect that some models will be unable to generate CLXs. CAFs are also tested for to ensure they fail to form a CLX when implanted into NSG mice.
- Recipients should perform their own model validation once cells have been expanded at their site to ensure the model matches that is distributed by the PDMR. STR profiles are provided for all models in the PDMR database at the patient record level and should be used for model authentication.

General Shipping and Handling Information

Domestic Recipients

- A Federal Express account number provided by the Recipient to which the shipment can be charged is required for all Domestic requests
- An invoice for the Distribution Costs (excluding shipping; see table below) will be e-mailed to the designated Recipient Billing Contact once materials have been shipped.

International Recipients (NOT YET AVAILABLE):

- As stated above, the PDMR currently does not distribute to International requestors. Date to be determined and announced.

Contact information:

NCI Patient-Derived Models Repository - NCI_PDM_Repository@mail.nih.gov

Distribution Costs (excluding shipping)

- Payment by **check only**, made payable to the “**Leidos Biomedical Research**” can be accepted. 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-Profits: both Domestic & International & non-MD campus NCI/NIH Investigators	Commercial Entities: both Domestic & International
Per Cryopreserved vial: Patient-derived Mixed Tumor Culture (PDC)	\$0	\$250	\$2500
Per Cryopreserved vial: Cancer Associated Fibroblast Culture (CAF)	\$0	\$200	\$1500