

Agreement for the Transfer of Pediatric Tumor Cell Lines and Xenografts for use in Pediatric Oncology Preclinical Protein and Tissue Array Project (POPP-TAP) Arrays

Definitions:

“*PROVIDER*” shall mean the institution and associated providing scientists who are contributing pediatric tumor cell lines or xenografts to the POPP-TAP;

“*POPP-TAP array*” shall mean any tissue/cell array or protein lysate array prepared through the collaborative National Cancer Institute and Children’s Oncology Group effort (in conjunction with various PROVIDERS who contributed pediatric tumor cell lines and xenografts) to develop such arrays based on pediatric preclinical models, and shall be understood to include gene expression profiles for the same pediatric preclinical models;

“*Material*” shall mean the pediatric tumor cell line(s), xenografts, progeny, and any unmodified derivatives thereof that the PROVIDER wishes to contribute for inclusion in POPP-TAP arrays;

“*NCI*” shall mean the National Cancer Institute;

“*COG*” shall mean the Children’s Oncology Group, a non-profit clinical research organization consisting of various academic institutions, and which is receiving a grant from the NCI to facilitate establishment of the POPP-TAP arrays;

“*Identifiable Private Information*” shall mean patient-identifying data from medical records or attached to patient specimens, to be obtained prospectively or from stored medical records or specimens, that can be linked to individual human subjects, either directly or indirectly through codes.

“*RECIPIENT*” shall mean a third party qualified investigator and his/her associated institution/company who shall have access to the POPP-TAP array through the NCI and COG.

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WHEREAS, the NCI and the COG are both working to expand the understanding of the biological functionalities leading to how different pediatric cancers develop, and

WHEREAS, the NCI and the COG are jointly working on the creation of POPP-TAP arrays, which shall be made available to third party qualified investigators from various academic and commercial entities, and

WHEREAS, the COG is desirous for the NCI to act on behalf of the COG insofar as it relates to authorizing any further third party distribution of the POPP-TAP arrays, and

WHEREAS, PROVIDER and their associated investigators wish to make available PROVIDER's MATERIAL for incorporation into the POPP-TAP arrays, that MATERIAL being defined below as:

THEREFORE, the parties to this instrument agree to the terms as follows:

1. The above MATERIAL is the property of the PROVIDER, and is being made available for inclusion in POPP-TAP arrays as a service to the research community.
2. **THIS MATERIAL WILL NOT BE MADE AVAILABLE TO RECIPIENT PARTIES FOR USE IN HUMAN SUBJECTS, INCLUDING FOR PURPOSES OF DIAGNOSTIC TESTING.**
3. Absent a separate agreement between the RECIPIENT and PROVIDER, the MATERIAL will be used by the RECIPIENT for internal research purposes only. The MATERIAL will not be used for commercial purposes such as production, sale, or screening.
4. The MATERIAL to be incorporated into the POPP-TAP arrays will not be further distributed to others. However, POPP-TAP arrays will be made available to a RECIPIENT by way of a material transfer agreement (attached as Appendix A). RECIPIENT may retain title to patent rights in inventions made by its employees in the course of the Research Project.
5. It is anticipated that RECIPIENT investigators using the MATERIAL may wish to disclose and/or publish results from their use of the MATERIAL. RECIPIENT, as a condition of receiving the MATERIAL, shall provide summary reports of data from use of the MATERIAL to the NCI and the COG within six (6) months of receipt of the MATERIAL. PROVIDER shall have advance access to summary reports of this data, which shall thereafter be made available to members of the research community by an electronic database to be established by the NCI and the COG.
6. PROVIDER asserts that no Identifiable Private Information shall be associated with the MATERIAL, and that none shall be provided.
7. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER, NCI AND THE COG MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESSED OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR

THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT OR TRADEMARK.

8. The RECIPIENT asserts that use of the MATERIAL will be in compliance with all applicable statutes and regulations, including all applicable Federal statutes and Public Health Service policies relating to the use and care of laboratory animals (see 7 U.S.C. 2131 et seq.). PROVIDER certifies that MATERIAL was obtained in compliance with the Protection of Human Subjects regulations, set out at 45 CFR Part 46. Additional information is available from the NIH Office For Human Research Protection (Telephone 301-496-7163).
9. The MATERIAL is provided for deposit in the POPP-TAP arrays at no cost (except for costs associated with preparation of materials and shipping). Subsequent transfers of POPP-TAP arrays to qualified investigators will be made on a cost recovery plus basis.
10. Should RECIPIENT discover a novel patentable discovery, or should RECIPIENT desire to obtain MATERIAL from PROVIDER for commercial use, RECIPIENT shall contact PROVIDER to make any necessary licensing arrangements.
11. If MATERIAL is of animal origin, PROVIDER will insert hereto the Institutional Animal Care and Use Committee (IACUC) approval number _____, and the institutional animal welfare assurance number _____, or equivalent.

Signatures follow on next page

SIGNATURES

The PROVIDER scientist and a PROVIDER authorized signatory show acceptance of the terms of this Agreement by signing and dating the Agreement below. The Agreement shall be made binding following the subsequent countersignature by **authorized** officials from the NCI.

PROVIDER INFORMATION AND AUTHORIZED SIGNATURE

Organization _____

Scientist _____

Signature of Scientist _____

Address _____

Name of Authorized Official _____

Title of Authorized Official _____

Signature of Authorized Official

Signature

Date

POPP-TAP INFORMATION AND AUTHORIZED SIGNATURE

Address for POPP-TAP National Cancer Institute, Technology Transfer
Branch
6120 Executive Blvd., Suite 450
Rockville, MD 20852-7181

Name of Authorized Official _____

Title of Authorized Official _____

Signature of Authorized Official

Signature

Date

Agreement for the Transfer of Pediatric Oncology Preclinical Protein and Tissue Array Project (POPP-TAP) Array

Definitions:

“*PROVIDERS*” shall mean the institutions and their associated providing scientists who contributed pediatric tumor cell lines and/or xenografts to the POPP-TAP;

“*POPP-TAP array*” shall mean any tissue/cell array or protein lysate array prepared through the collaborative National Cancer Institute and Children’s Oncology Group effort (in conjunction with various PROVIDERS who contributed pediatric tumor cell lines and xenografts) to develop such arrays based on pediatric preclinical models, and shall be understood to include gene expression profiles for the same pediatric preclinical models;

“*NCF*” shall mean the National Cancer Institute;

“*COG*” shall mean the Children’s Oncology Group, a non-profit clinical research organization consisting of various academic institutions, and which is receiving a grant from the NCI to facilitate establishment of the POPP-TAP arrays;

“*Identifiable Private Information*” shall mean patient-identifying data from medical records or attached to patient specimens, to be obtained prospectively or from stored medical records or specimens, that can be linked to individual human subjects, either directly or indirectly through codes.

“*RECIPIENT*” shall mean a qualified investigator and his/her associated institution/company who shall have access to one or more POPP-TAP arrays.

.....
WHEREAS, the NCI and the COG are both working to expand the understanding of the biological functionalities leading to how different pediatric cancers develop, and

WHEREAS, the NCI and the COG are jointly working on the creation of POPP-TAP arrays, which shall be made available to qualified investigators from various academic and commercial entities, and

WHEREAS, the COG is desirous for the NCI to act on behalf of the COG insofar as it relates to authorizing any further third party distribution of POPP-TAP arrays, and

WHEREAS, RECIPIENT and their associated investigators wish to have access to one or more POPP-TAP arrays for their own non-commercial Research Project described as follows:

[Insert Research Project]

THEREFORE, the parties to this Agreement agree to the terms as follows:

1. The POPP-TAP arrays are the property of the NCI and the COG, and are being made available as a service to the research community. Individual pediatric tumor cell lines and/or xenografts embodied within the POPP-TAP arrays are proprietary to the various PROVIDERS who contributed to the POPP-TAP arrays.
2. **POPP-TAP ARRAYS WILL NOT BE MADE AVAILABLE TO RECIPIENT PARTIES FOR USE IN HUMAN SUBJECTS, INCLUDING FOR PURPOSES OF DIAGNOSTIC TESTING.**

3. POPP-TAP arrays will be used by the RECIPIENT for the Research Project without a separate agreement with the PROVIDERS. POPP-TAP arrays will not be used for commercial purposes such as production, sale, or screening.
4. The POPP-TAP arrays shall only be used by the RECIPIENT, and shall not be further distributed to others. The RECIPIENT shall refer any third party request for the POPP-TAP arrays to the NCI and/or COG. RECIPIENT may retain title to patent rights in inventions made by its employees in the course of the Research Project.
5. It is anticipated that RECIPIENT investigators using POPP-TAP arrays may wish to disclose and/or publish results from their use of the POPP-TAP arrays. RECIPIENT, as a condition of receipt, shall provide summary reports of data from use of the POPP-TAP arrays to the NCI and the COG within six (6) months of receipt of the Material. PROVIDERS shall likewise have advance access to summary reports of this data, which shall thereafter be made available to members of the research community by an electronic database to be established by the NCI and the COG. The RECIPIENT shall acknowledge the NCI, the COG and, as applicable, individual PROVIDERS of the POPP-TAP array cell lines and xenografts in any publications reporting use of POPP-TAP arrays, including authorship where appropriate.
6. NCI and the COG, on behalf of the PROVIDERS, assert that no Identifiable Private Information shall be associated with the POPP-TAP array, and that none shall be provided.
7. The POPP-TAP arrays delivered pursuant to this Agreement are understood to be experimental in nature and may have hazardous properties. THE PROVIDERS, NCI AND THE COG MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESSED OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE POPP-TAP ARRAY WILL NOT INFRINGE ANY PATENT, COPYRIGHT OR TRADEMARK. Unless prohibited by law, RECIPIENT will assume all liability for claims for damages against it by third parties which may arise from RECIPIENT's use, storage or disposal of the POPP-TAP arrays. RECIPIENT understands that remedies for any liability attributable to the NCI, as an agency of the United States, are limited by the Federal Tort Claims Act (28 U.S.C. Ch. 171).
8. The RECIPIENT asserts that use of the POPP-TAP arrays will be in compliance with all applicable statutes and regulations, including all applicable Federal statutes and Public Health Service policies relating to the use and care of laboratory animals (see 7 U.S.C. 2131 et seq.). Additional information is available from the NIH Office For Human Research Protection (Telephone 301-496-7163).
9. The POPP-TAP arrays are being provided to qualified investigators on a cost recovery plus basis, that fee being specified as \$_____.
10. The individual pediatric cell lines and xenografts embodied within the POPP-TAP arrays may be subject to patent protection by the various PROVIDERS who contributed such pediatric cell lines and/or xenografts to the POPP-TAP array. Should RECIPIENT discover a novel patentable discovery, or should RECIPIENT desire to obtain individual pediatric cell lines and/or xenografts included in the POPP-TAP arrays for commercial use, RECIPIENT shall contact PROVIDER to make any necessary licensing arrangements.