

**National Cancer Institute
Program for Natural Products Discovery
Fractionated Natural Products Library
Material Transfer Agreement**

The National Cancer Institute (“NCI”), Developmental Therapeutics Program (“DTP”), Natural Products Branch (“NPB”) maintains a repository of natural product materials that represent a unique international resource for qualified researchers. These materials include natural product materials from various sources including plant, marine, and microbial sources, as well as the associated extracts.

The NCI Program for Natural Product Discovery (“NPNPD”) is a national program aimed to advance natural product technologies and facilitate the discovery of structurally defined, validated lead molecules ready for translation. NPNPD has created a pre-fractionated library of natural product extracts for high throughput screening and has made the initial release of 150,000 pre-fractionated samples available as a service to the research community. The library will eventually number ~1,000,000 total pre-fractionated samples which will all be made available.

This Agreement is made by and between NCI, an agency of the United States Government and _____ (“Recipient”). Collectively or individually, the NCI and Recipient shall be referred to as “Parties” or “Party”.

This Agreement serves as a master agreement between the Parties allowing for multiple investigators from Recipient (“Recipient Investigator”) to receive NPNPD materials under the terms herein.

The terms and conditions of this Agreement are as follows:

1. NCI agrees to transfer to Recipient the following materials (“Materials”) specifically as indicated in Appendix A:
 - i. _____ Plated sets of NPNPD pre-fractionated extracts
 - ii. _____ Bulk supply of NPNPD extracts
2. The Materials will be used by an individual Recipient Investigator solely in connection with a research project described in Appendix A (“Research Project”). Recipient shall submit a new Appendix A for each Recipient Investigator to NCI. Each Recipient Investigator will sign the Appendix A describing their Research Project to acknowledge the proposed project and the obligations herein in particular the Source Country obligations in Articles 5-8.
3. THE MATERIALS MAY NOT BE USED IN HUMAN SUBJECTS OR FOR THE TREATMENT OR DIAGNOSIS OF HUMAN SUBJECTS. Recipient will use the Materials in compliance with all applicable law, statutes and regulations.

4. The Materials constitute an important investment by the NCI. Recipient agrees to maintain control of the Materials and agrees not to transfer the Materials to others without NCI's written consent.
5. As an agency of the United States Government, NCI complies with the United States Government's policy to follow the principles articulated in the United Nations Convention on Biological Diversity ("U.N. CBD"). The U.N. CBD calls for "sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Source Country providing such resources" (U.N. CBD Article 15.7). The "Source Country" will refer to the country which has provided the raw natural product from which the specific chemical substance under investigation or a derivative thereof was derived. A "Source Country Organization" will refer to an organization which has provided, on behalf of a Source Country, the raw natural product from which the specific chemical substance under investigation or a derivative thereof was derived.
6. In order to abide by these principles and address the interests of the Source Country, Recipient agrees that, should the Materials eventually be developed and the resulting product marketed by the Recipient, or licensed by Recipient to a company or other institution for development and commercialization (whether the product is a direct isolate from the Materials, structurally based upon an isolate from the Materials, a synthetic material for which the Materials provided a key development lead, or a method of synthesis or use of any aforementioned isolate, product, or material), the Recipient or Recipient's licensee(s) will negotiate and enter into an agreement with the appropriate Source Country or Source Country Organization. This agreement between the Recipient or Recipient's licensee(s) and Source Country or Source Country Organization must commence prior to the start of clinical development studies that are conducted, directed, or sponsored by either Recipient or Recipient's licensee(s). Negotiations must be completed and an agreement executed prior to commercial sale of product resulting from the Research Project. This agreement relating to the product must be binding upon the Source Country, or their designee and Recipient, and any licensee(s) or assignees of Recipient, with respect to any intellectual property rights relating to the product.
7. Recipient will seek to utilize the Source Country as its first source of supply either for commercial sale of Materials or for cultivation of raw (natural product) materials required for the manufacture of a product (regardless of whether the product is an isolated natural product or is structurally based thereon) if such material can be made available in a timely manner in quantities and quality sufficient for use by the Recipient at a mutually agreeable fair price. If such material must be cultivated, Recipient agrees to seek to utilize the Source Country as its first source of such cultivation efforts.
8. In all oral presentations or written publications concerning the Research Project, Recipient will acknowledge the contribution of NCI NPB, as well as the Source Country or Source Country Organization, and any other appropriate organizations or individuals as identified by NCI, unless requested otherwise. Specifically, Recipient will cite the

following reference in all presentations or publications concerning the Research Project: Thornburg et al. ACS Chem. Biol. 2018: 13(9); 2484-2497.

9. To the extent permitted by law, Recipient agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any of NCI's written information about the Materials, including information relating to the origin and source of the Materials and biological activity data, that is stamped "CONFIDENTIAL" ("Confidential Information"), except for information that was previously known to the Recipient, or that is or becomes publicly available, or which is disclosed to Recipient without a confidentiality obligation, or is required to be disclosed by law.
10. For each Research Project submitted to NCI for a Recipient Scientist, Recipient agrees to email biannual reports to NPB concerning the intent, progress, assay results, compounds isolated, and resulting publications to NCINatProdRep@mail.nih.gov. In addition, Recipient agrees to provide NCI with a "hit-list" of screening hits. Recipient agrees that NCI may disclose limited information related to the general presence of activity within extracts and fractions and assay type (cell-based or cell-free) from these reports to other researchers. NCI will treat specific details of the assays and reports in confidence for a period of three (3) years from the date of its disclosure, after which the information will be made publicly available in a NCI database.
11. Upon mutual agreement by the Parties, NPB may perform chemical assays to determine the chemical scaffolds of Material sub-fractions found to be biologically relevant by Recipient. NPB agrees to return the chemical scaffold and structural results to the Recipient. The Parties agree that the terms and any funds transferred for such chemical assays will be under a separate collaborative agreement between the Parties.
12. Each Party shall retain title to any intellectual property rights in inventions and works of authorship made by its employees in the course of using the Materials. The Parties will have joint title to any intellectual property rights in inventions invented jointly by the NCI and Recipient's employees as determined in accordance with United States patent law. The Parties understand that nothing herein shall be deemed to constitute, by implication or otherwise, the grant to either Party by the other of any license or other rights under any patent, patent application, or other intellectual property right or interest.
13. Any Materials delivered pursuant to this Agreement are understood to be experimental in nature and may have hazardous properties. NCI makes no representations and extends no warranties of any kind, either expressed or implied. There are no express or implied warranties of merchantability or fitness for a particular purpose, or that the use of the Materials will not infringe any patent, copyright, trademark, or other proprietary rights. Unless prohibited by law, Recipient assumes all liability for claims for damages against it by third parties which may arise from the use, storage or disposal of the Materials except that, to the extent permitted by law, NCI shall be liable to the Recipient when the damage is caused by the gross negligence or willful misconduct of NCI.

14. The Materials are provided at no cost, or with shipping fee solely to be paid by the Recipient.
15. This Agreement will expire three (3) years from the date of execution unless mutually terminated earlier by the Parties. This Agreement can be extended by amendment, which will include the authorized signatures of representatives of the Parties.
16. Upon expiration or termination of this Agreement, Recipient agrees to destroy any unused Materials and provide NCI with written certification of their destruction, unless otherwise directed by NCI.
17. Paragraphs 6, 7, 8, 9, 10, 12,13, 16, and 17 will survive expiration or termination of this Agreement. For clarity, obligations to the Source Country in Articles 5-8 survive in perpetuity.
18. Neither Party may assign or transfer any of its rights or obligations under this Agreement without the prior written consent of the other Party, such consent will not be unreasonably withheld.
19. The construction, validity, performance and effect of this Agreement will be governed by U.S. Federal law, as applied by the Federal courts in the District of Columbia.

(Signatures Begin on the Following Page)

ACCEPTED AND AGREED

FOR THE NATIONAL CANCER INSTITUTE

Dr. Barry O’Keefe
Chief, Natural Products Branch
8490 Progress Drive, Suite 400
Frederick, MD 21701

Date

Authorized Signatory for NCI
Printed Name:
Title:

Date

NCI Technology Transfer Center
8490 Progress Drive, Suite 400
Frederick, MD 21701

FOR THE RECIPIENT

Authorized Signatory for Recipient
Printed Name
Title
Address

Date

Each Recipient Scientist will sign their respective Appendix A below.

Appendix A**Research Project**

Recipient:
Recipient Scientist:
Address:
Phone:
Email:

Materials:

- i. ___ Plated sets of NPNDP pre-fractionated extracts
- ii. ___ Bulk supply of NPNDP extracts

Research Project Description (include brief reasoning behind screen and proposed project):

Please complete the following table:

<u>Assay Type</u>	
<u>Assay Endpoint</u>	
<u>Molecular or Cellular Target</u>	
<u>Definition of “Active Sample”</u>	

(Recipient Scientist Signature is on the Following Page)

By signing below the Recipient Scientist has read and understood the obligations of the master Agreement including the obligations to the Source Country in Articles 5-8.

Recipient Scientist signature

Date