NATIONAL CANCER INSTITUTE RAID MATERIAL TRANSFER AGREEMENT

The National Cancer Institute (NCI) Rapid Access to Intervention Development program (RAID) has been designed to assist academic investigators with the development steps necessary for them to initiate clinical trials with their own discoveries. The program makes available to the academic research community, on a competitive basis, NCI resources for the pre-clinical development of drugs and biologics. A specific description of the RAID program is available at http://dtp.nci.nih.gov/docs/raid/raid_index.html

Provider: _____

Recipient: _____

1. Provider agrees to transfer to Recipient's Investigator the following Research Material:

_____

2. The Research Material will only be used for research purposes by Recipient's investigator in his/her laboratory for the research project described below, under suitable containment conditions. When NCI is the Recipient, the Research Material may also be used in the laboratory of Recipient's contractor or subcontractor as provided in Article 8. This Research Material will not be used for commercial purposes for screening, production or sale, for which a commercialization license may be required. Recipient agrees to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material.

2(a).Are Research Materials of human origin?

_____ Yes
_____ No

2(b).If yes in 2(a), were Research Materials collected according to 45 CFR Part 46, "Protection of Human Subjects"?

_____ Yes (Please provide Assurance Number: _____)
_____ No
_____ Not Applicable (Materials not collected from humans)

3. This Research Material will be used by Recipient's investigator solely in connection with the following research project ("Research Project") described with specificity as follows (use an attachment page if necessary):

_____
_____

4. In all oral presentations or written publications concerning the Research Project, Recipient will acknowledge Provider's contribution of this Research Material unless requested otherwise. 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 Provider's written information about this Research Material that is stamped "CONFIDENTIAL," except for information that was previously known to Recipient or that is or becomes publicly available or which is disclosed to Recipient without a confidentiality obligation. Any oral disclosures from Provider to Recipient shall be identified as being CONFIDENTIAL by written notice delivered to Recipient within thirty (30) days after the date of the oral disclosure. Recipient may publish or otherwise publicly disclose the results of the Research Project, but if Provider has given CONFIDENTIAL information to Recipient such public disclosure may be made only after Provider has had thirty (30) days to review the proposed disclosure to determine if it includes any CONFIDENTIAL information, except when a shortened time period under court order or the Freedom of Information Act pertains.

5. This Research Material represents a significant investment on the part of Provider. Recipient's investigator therefore agrees to retain control over this Research Material and further agrees not to transfer the Research Material to other people not under her or his direct supervision without advance notification of Provider except as provided under Article 8. When the Research Project is completed, the Research Material will be disposed of, if directed by Provider.

6. This Research Material is provided as a service to the research community. IT IS BEING SUPPLIED TO RECIPIENT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Provider makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties. No indemnification for any loss, claim, damage, or liability is intended or provided by either Party under this Agreement. Each Party shall be liable for any loss, claim, damage, or liability that said Party incurs as a result of said Party's activities under this Agreement, except that NCI, as an agency of the United States, assumes liability only to the extent as provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171 Sections 2671-2680).

7. When Recipient is NCI: Normally, NCI will not acquire intellectual property rights to inventions made by its employees with Research Materials under RAID, unless Provider and NCI mutually agree that to do so would be in the best interest of the Provider. NCI will inform Provider of any such inventions, and after consultation with Provider, NCI will decide whether or not to file a patent application on any such invention. If NCI does file a patent application, Provider will be given an opportunity to negotiate for a license in accordance with the procedures set forth in 37 CFR Part 404.

8. When Recipient is NCI: In conducting a portion of the RAID research, it may be necessary for NCI to utilize the services of one of the NCI's contractors or subcontractors under a funding agreement as defined by 35 U.S.C. § 201(b):

8(a). Normally the contractor may elect and retain title to subject inventions developed under the funding agreement under the provisions of the Bayh-Dole Act (35 U.S.C. § 200, et. seq.). Such NCI contractors have, as a term and condition of their funding agreement, agreed to offer a first option to negotiate a license to subject inventions made using the Research Materials to the Provider.

8(b). Certain other NCI contractors or subcontractors may be subject to a Determination of Exceptional Circumstances (35 U.S.C. § 202(a)(ii)), through which their rights in subject inventions made using the Research Materials may be assigned to the Provider.

9. When Provider is NCI: Recipient shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project. Recipient agrees not to claim, infer, or imply endorsement by the Government of the United States of America (hereinafter referred to as "Government") of the Research Project, the institution or personnel conducting the Research Project or any resulting product(s).

10. When Provider is NCI: Because the NCI is responsible for the data and Research Material which it develops, NCI must ensure that these data are used, communicated and reproduced appropriately and completely. In order to ensure that the Food and Drug Administration (FDA) receives a complete data set for its review, all relevant data generated by the NCI will be supplied to FDA in a Master File. The Recipient will be provided a letter of cross reference to the Master File along with a copy of the data. Recipient shall use data and the Research Material in accordance with all Federal laws and regulations that govern the use of investigational agents in clinical trials.

- Recipient agrees that the Research Material supplied is for investigational use only under Recipient's Investigational New Drug Application (IND) and may not be transferred to a third party without written notification to the NCI.

- Recipient agrees that the data supplied by NCI will be used only in preparing the Recipient's IND and may not be transferred to or shared with a third party without written notification to NCI.

- Recipient agrees that the Research Material supplied will be used in a clinical study only after an approved IND is on file with the FDA and the Office for Human Research Protections (OHRP) assurance has been obtained as well as all other appropriate approvals, which may include Office of Biotechnology Activities, Institutional Biosafety Committee, and Institutional Review Board (IRB). Recipient further agrees that the Research Material will be used only in accordance with FDA approved clinical protocols and in accordance with FDA IND regulations. In addition Recipient will submit all amendments to clinical protocols to the IRB and the FDA (and other groups as required).

- Recipient or any third party to whom Recipient transfers the data and/or the Research Material shall provide NCI with the data in the format that it is intended to be used by the Recipient or third party, at least 30 days prior to its use. Furthermore, the Recipient agrees to provide such data and/or the Research Material only to third parties who agree to this provision.

11. The undersigned Provider and Recipient expressly certify and affirm that the contents of any statements made herein are truthful and accurate.

12. This MTA shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.

Signatures Begin on the Next Page

Date Recipient's Investigator and Title

Date Authorized Signature for Recipient and Title

Recipient's Official and Mailing Address:

Date Provider's Investigator and Title

Date Authorized Signature for Provider and Title

Provider's Official and Mailing Address:

Please address all correspondence for the NCI related to this agreement to both:

Coordinator RAID Program
Developmental Therapeutics Program
Executive Plaza North, Room 8022
6130 Executive Blvd.
Rockville MD 20852

Clinical Science Unit Coordinator
Technology Transfer Branch, NCI
6120 Executive Blvd., Suite 450
Rockville, MD 20852

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§ 3801-3812 (civil liability) and 18 U.S.C. § 1001 (criminal liability including fine(s) and/or imprisonment).