DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Institute of
Neurological Disorders
and Stroke

Memorandum

Date Month Date, Year

Subject MTA

RECIPIENT INFORMATION and AUTHORIZED SIGNATURE

Project Title:

Recipient Scientist:

Recipient Organization:

Address:

Name of Authorized Official:

Title of Authorized Official:

Signature of Authorized Official Date

Certification of Recipient Scientist: I understand that all transfer of material and data for work on the project designated above will utilize the standard Material Transfer Agreements (MTA) attached.

Signature of Recipient Scientist Date

NATIONAL INSTITUTES OF HEALTH RAID PROGRAM
INCOMING MATERIAL TRANSFER AGREEMENT

The National Institutes of Health (NIH) Rapid Access to Intervention Development program (NIH-RAID) has been designed to assist investigators with the development steps necessary to initiate clinical trials with their discoveries. The program makes available to the research community, on a competitive basis, NIH resources for the pre-clinical development of therapeutics. A specific description of the NIH-RAID program is available at http://nihroadmap.nih.gov/raid/.

Provider: _____

Provider's Investigator: _____

Recipient: National Institutes of Health

1. Provider agrees to transfer to Recipient or Recipient's contractor or subcontractor (collectively referred to as "Recipient") the following Research Material:

_____
_____
_____

2. The Research Material will only be used for research purposes under suitable containment conditions by Recipient for the NIH-RAID research project No. XXXXXXX. ("Research Project"). The Recipient will not use the Research Material for commercial purposes. Recipient agrees to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material.

3. If the Research Material is of human origin, was the Research Material collected according to 45 CFR Part 46, "Protection of Human Subjects"?

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

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 of CONFIDENTIAL information 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 therefore agrees to retain control over this Research Material and further agrees not to transfer the Research Material to other persons 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 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 NIH, 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. NIH will inform Provider of any inventions made with the Research Material in accordance with its use under article 2 of this agreement by NIH employees or others under an obligation to assign to the NIH. After consultation with Provider, NIH will decide whether or not to file a patent application on any such invention. If NIH files a patent application, Provider will be given an opportunity to apply for a license in accordance with the procedures set forth in 37 CFR Part 404.

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

8(a). Normally such contractors and subcontractors 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.). In order to encourage applicants to participate in the RAID program, such contractors and subcontractors have agreed to include as a term and condition of their funding agreements, an agreement to offer to Provider a first option to negotiate a license to subject inventions made using the NIH-RAID Provider's Research Material.

8(b). Certain other 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 Material may be assigned to the Government. Provider may then apply to NIH for a license to NIH's rights in such subject inventions.

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

Signatures Begin on the Next Page

ACCEPTED AND AGREED

FOR PROVIDER:

_____

Date Authorized Signature for Provider and Title

Certification of Provider's Investigator: I have read the terms in this Agreement and understand my obligations under them.

_____

Date Provider's Investigator and Title

Provider's Official Mailing Address:

FOR RECIPIENT:

_____

Date Dr. Thomas Miller, Program Director,
Extramural Research, Technology Development Program, NINDS, NIH
On behalf of the NIH RAID Program

Recipient's Official and Mailing Address:

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).

NATIONAL INSTITUTES OF HEALTH RAID PROGRAM
OUTGOING MATERIAL TRANSFER AGREEMENT

The National Institutes of Health (NIH) Rapid Access to Intervention Development program (NIH-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, NIH resources for the pre-clinical development of drugs. A specific description of the NIH-RAID program is available at http://nihroadmap.nih.gov/raid/.

Provider: National Institutes of Health

Recipient: _____

Recipient's Investigator: _____

1. Provider agrees to transfer to Recipient the following Clinical Material, Research Material or Research Data: _____
_____

If Recipient designates a third party to receive Clinical Material, Research Material or Research Data, then the Recipient will ensure that its designee complies with the terms of this Agreement.

2. The Clinical Material, Research Material or Research Data will only be used for research purposes, under suitable containment conditions, by Recipient. Recipient agrees to comply with all Federal rules and regulations applicable to the handling of the Research Material.

3. In all oral presentations or written publications concerning the Clinical Material, Research Material or Research Data, Recipient will acknowledge Provider's contribution as follows unless requested otherwise.

"This research was supported by the NIH RAID Program under the NIH Roadmap initiative."

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 Clinical Material, Research Material or Research Data 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 of CONFIDENTIAL information 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 Recipient's research results concerning the Clinical Material, Research Material or Research Data, but 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, other applicable law or the Freedom of Information Act pertains.

4. THIS CLINICAL MATERIAL, RESEARCH MATERIAL OR RESEARCH DATA IS BEING SUPPLIED TO RECIPIENT BY THE PROVIDER 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 Clinical Material, Research Material or Research Data will not infringe any patent or proprietary rights of third parties. Unless prohibited by law from doing so, Recipient agrees to hold the Government of the United States of America (hereinafter referred to as "Government") harmless and to indemnify the Government for all liabilities, demands, damages, expenses and losses arising out of Recipient's use for any purpose of the Clinical Material, Research Material or Research Data.

5. Recipient shall retain title to any patent or other intellectual property rights in inventions made by its employees. Inventorship and ownership of any patent or intellectual property rights shall be governed by United States patent law or other applicable laws.

6. Recipient agrees not to claim, infer, or imply endorsement by the Government of the Recipient, Recipient's personnel or any product(s).

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

8. Results of the Recipient's research using Clinical Material, Research Material or Research Data shall be provided to the Provider including, all publications thirty (30) days prior to public disclosure or within thirty (30) days as requested by the NIH, which ever occurs earlier.

9. If Provider is providing Clinical Material, Research Material or Research Data for use in support of research on humans, Recipient agrees to the terms of the Clinical Addendum attached hereto.

Signatures begin on the next page

ACCEPTED AND AGREED

FOR RECIPIENT:

_____	_____
Date	Signature of Recipient Investigator Name, Title and Address of Recipient
_____	_____
Date	Authorized Signature for Recipient Institution Name, Title and Address

Recipient's Official and Mailing Address:

_____

_____

_____

FOR PROVIDER:

NATIONAL INSTITUTES OF HEALTH

_____	_____
Date	Dr. Thomas Miller, Program Director, Extramural Research, Technology Development Program, NINDS, NIH On behalf of the NIH RAID Program

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).

NIH RAID PROGRAM OUTGOING MTA
CLINICAL ADDENDUM

10. Research Data may include "Preclinical Data" which means data identified by the National Institutes of Health (NIH) or its contractor or sub-contractor as Preclinical Data or as required for submission with an Investigational New Drug Application (IND).

11. Because the NIH is responsible for the Clinical Material and Preclinical Data that it develops, the NIH must be assured that the Clinical Material and Preclinical Data are used, communicated and reproduced appropriately and completely. The named Recipient agrees to retain control over this Clinical Material and Preclinical Data and further agrees not to transfer the Clinical Material or Preclinical Data to another person not under Recipient's direct supervision, other than investigators participating in clinical trials under an active IND supporting the use of the Clinical Material, without prior written approval of Provider.

a. *Use of Clinical Material.* The NIH is providing this Clinical Material for use in human subjects only under an active IND on file with the Food and Drug Administration (FDA) or under an active foreign equivalent application on file with the appropriate foreign health authority. Upon completion of all studies using the Clinical Material in human subjects, Recipient may use any remaining Clinical Material for non-clinical research purposes only.

b. *Use of Preclinical Data in support of an IND.* In order to ensure that the FDA or equivalent foreign health authority receives a complete data set for its review, Recipient agrees to ensure that all Preclinical Data are included in a submitted IND or foreign health equivalent prior to the use of this Clinical Material. Recipient agrees to ensure that any third party to which Recipient transfers Preclinical Data provides written assurance that all such Preclinical Data will be included in an IND and submitted to the FDA or foreign health equivalent. Recipient will provide the NIH with a copy of such written assurance before Recipient shares or transfers the Preclinical Data. Recipient agrees that the Clinical Material supplied will be used in a clinical study only after FDA review and clearance of the IND containing all available Preclinical Data.

c. *Appropriate Approvals for Use of Clinical Material.* Recipient agrees to ensure that all appropriate approvals are obtained, including from the FDA, from the Office for Human Research Protection (OHRP), and from an appropriate Institutional Review Board (IRB). Recipient will provide the NIH with copies of the FDA Acknowledgement letter that the IND has been filed and of the signed IRB approval letter before the Clinical Material is shipped.

d. *Use of Clinical Material and Preclinical Data in Accordance with Applicable Regulations and Recipient Policies.* Recipient agrees that the clinical use of the Clinical Material and Preclinical Data will be in accordance with clinical protocols cleared by the FDA or corresponding foreign health authority and in accordance with the respective governing authorities. Recipient agrees to comply with all applicable Recipient policies

regarding conflict of interest. Recipient agrees to submit all amendments to clinical protocols to the IRB and the FDA or corresponding foreign health authority.

e. *Use in accordance with Federal law.* Recipient agrees to ensure that this Clinical Material and Preclinical Data are used in accordance with all Federal statutes and regulations, or other national law of the respective study site, that govern the use of investigational agents in clinical trials.

12. Recipient agrees to provide all results of research using the supplied Clinical Material and Preclinical Data to NIH, including all publications as described in Article 8. Recipient agrees to provide to NIH copies of Annual Reports concurrently with Recipient's submission to the FDA or corresponding foreign health authority.

13. The Clinical Material will be used in accordance with this Agreement or disposed of in accordance with Recipient's policies, unless otherwise directed by Provider.