

Public Health Service

MATERIAL TRANSFER AGREEMENT

This Material Transfer Agreement (MTA) has been adopted for use by the National Institutes of Health, the Food and Drug Administration and the Centers for Disease Control and Prevention collectively referred to herein as the Public Health Service ("PHS") in all transfers of research material ("Research Material") whether PHS is identified below as its Provider or Recipient.

Provider: PHS

Recipients: Washington University, St. Louis and Georgetown University

1. Provider agrees to transfer to Recipient's Investigator named below the following Research Material: Data regarding cGMP inspections of pharmaceutical manufacturers.

2. THIS RESEARCH MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS.

This 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. This Research Material will not be used for commercial purposes such as serving, 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 ___X___no

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

Please provide Assurance Number: _____

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): Data will be used to undertake a risk-based assessment of the likelihood of the FDA initiating a cGMP inspection of manufacturing facilities. Then, conditional on the likelihood of inspection, we will estimate the likelihood of various inspection outcomes based on product, plant, manufacturer, and FDA related variables.

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 all of the data obtained from the Provider.

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, except when 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, and is considered proprietary to 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 written approval of Provider. Provider reserves the right to distribute the Research Material to others and to use it for its own purposes. When the Research Project is completed, or three (3) years have elapsed, whichever occurs first, the Research Material will be destroyed by Recipient or otherwise disposed of as mutually agreed by Provider and Recipient.

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.

7. **When Provider is the PHS:** 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 Governmental endorsement of the Research Project, the institution or personnel conducting the Research Project or any resulting commercial product (s). Unless prohibited by law from doing so, Recipient agrees to hold the United States 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 Research Material.

8. **When Recipient is the PHS:** The PHS shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project. The PHS is not authorized to promise rights in advance for inventions developed under this Agreement. Provider acquires no intellectual property rights under this MTA, but may apply for license rights to any patentable invention that might result from this Research Project. It is the intention of PHS that Provider not be liable to PHS for any claims or damages arising from PHS's use of the Research Material; however, no indemnification is provided or intended.

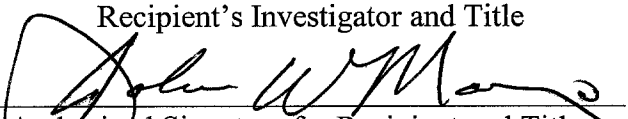
9. The undersigned Provider and Recipient expressly certify and affirm that the contents of any statements made herein are truthful and accurate.

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

11. Any additional terms: The terms of this MTA may be modified retroactively by a CRADA entered into between Washington University, St. Louis and Georgetown University and the FDA should the Research Material qualify under the CRADA.

Date: 08/08/2003 Jeffrey T. Macher, Assistant Professor
Recipient's Investigator and Title

Date: 08/08/2003

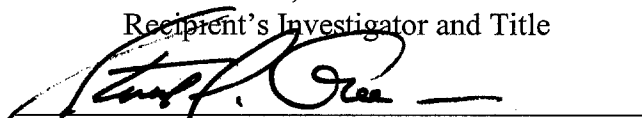

Authorized Signature for Recipient and Title

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SCHOOL OF BUSINESS

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Date: 08/08/2003 Jackson A. Nickerson, Associate Professor
Recipient's Investigator and Title

Date: 08/08/2003


Authorized Signature for Recipient and Title

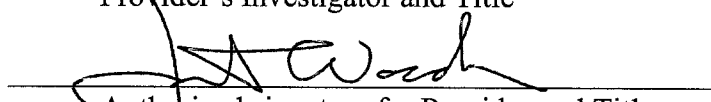
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Date: 8/18/03

Janet Woodcock, M.D.
Director, CDER
Provider's Investigator and Title

Date: 8/18/03


Authorized signature for Provider and Title

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