

## MATERIAL TRANSFER AGREEMENT

The National Cancer Institute (NCI) Development of Clinical Imaging Drugs and Enhancers Program (DCIDE) has been designed to assist academic and business investigators to acquire the data necessary for them to file an Investigational New Drug (IND) application with the Food and Drug Administration (FDA). The program makes available to the academic and business research community, on a competitive basis, NCI resources for the pre-clinical development of imaging agents and molecular probes. A detailed description of the DCIDE program is available at <http://www3.cancer.gov/bip/dcide.htm>

Provider: Cancer Imaging Program (CIP), DCTD, NCI

Recipient:

1. Provider agrees to transfer to Recipient's Investigator the following Research Material/Research Data (and any additional reports included at a later time as a supplement):

2. The Research Material/Research Data will only be used for research purposes by Recipient's investigator for the Research Project described below. This Research Material/Research Data will not be used 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/Research Data.

3. This Research Material/Research Data will be used by Recipient's investigator solely in connection with the following research project ("Research Project") described with specificity as:

NCI DCIDE Application entitled "XXX."

4. In all oral presentations or written publications concerning the Research Project, Recipient will acknowledge Provider's contribution of this Research Material/Research Data 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/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 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/Research Data represents a significant investment on the part of Provider. Recipient's investigator therefore agrees to retain control over this Research Material/Research Data and further agrees not to transfer the Research Material/Research Data to other people not under her or his direct supervision without prior written approval of Provider.

6. This Research Material/Research Data 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/Research Data 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. 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).

8. Because the NCI is responsible for the Research Data/Research Material that it develops, NCI must ensure that these Research Data/Research Material are used, communicated and reproduced appropriately and completely. In order to ensure that the FDA receives a complete data set for its review, Recipient's Investigational New Drug Application (IND) shall include all the Research Data generated by NCI (and any supplements that may follow) in its entirety. Recipient shall use the Research Data/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 Data/Research Material supplied by NCI is for investigational use only under Recipient's Investigational New Drug Application (IND) and may not be transferred to a third party without the prior written approval of NCI. In the event that the Research Material/Research Data supplied by NCI is transferred to or shared with a third party following written approval of NCI, the third party must also provide written assurance that all Research Data (and any supplements which may follow) will be included in any IND submitted to the FDA in its entirety.
- Recipient agrees that the Research Material/Research Data 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. Recipient further agrees that the Research Material/Research Data 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).
- The Research Data may be supplemented by other clearly marked, Recipient Investigator-derived data.

- In the event the Recipient does not file an IND using the Research Data in accordance with the Research Project within one year of the receipt of the Research Data, NCI will have the option to file an IND as the primary sponsor using the Research Data and any supplements supplied by NCI to the Recipient.
- NCI shall have the right to cross-file on any IND filed by Recipient that incorporates the Research Data with or without supplements from any source unless such IND cross-filing would interfere with commercialization of the product.
- NCI shall have the nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any invention which Recipient may have or obtain on the Research Material, its manufacture, or on the process for use of the Research Material, throughout the world, for use in NCI-sponsored clinical trials. In exercising this license, NCI shall have the right to have the Research Material manufactured for use in such NCI-sponsored clinical trials.

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 the Federal courts in the District of Columbia.

**Signatures begin on the next page.**

\_\_\_\_\_  
Date

\_\_\_\_\_  
Recipient Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Authorized Signature for Recipient and Title

Recipient Mailing Addresses:

\_\_\_\_\_  
Date

\_\_\_\_\_  
John M. Hoffman, M.D.  
Chief, Molecular Imaging Branch, CIP, NCI

\_\_\_\_\_  
Date

\_\_\_\_\_  
Kathleen Carroll, Ph.D., MBA  
Technology Transfer Specialist, Technology Transfer Branch, NCI

Please send all correspondence for the NCI related to this agreement to both via express mail:

Dr. Barbara Croft  
Coordinator, DCIDE Program  
National Cancer Institute  
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Rockville, MD 20852-7181

Clinical Science Unit Coordinator  
Technology Transfer Branch  
National Cancer Institute  
6120 Executive Blvd., Suite 450  
Rockville, MD 20852-7181

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).