

**NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
T1D-RAID MATERIAL TRANSFER AGREEMENT**

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Type-1 Diabetes Rapid Access to Intervention Development program (T1D-RAID) is designed to assist translation to the clinic of novel therapeutic interventions for Type 1 diabetes and its complications. The program makes available NIH resources on a competitive basis for the pre-clinical development of drugs and biologics. A specific description of the T1D-RAID program is available at <http://www.nidDK.nih.gov/fund/diabetesspecialfunds/T1D-RAID/index.htm>

Parties: *Full name of T1D-RAID Requester Entity (shorthand name to be later used in place of 'Requester')*; National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH; and National Cancer Institute (NCI), NIH.

REQUESTER Investigator: *PI of Requester*

1. **REQUESTER** agrees to transfer to NCI and NIDDK the following Research Material(s):

{Describe here the information and/or material(s) to be transferred by Requester, including also a brief description of the purpose or intent of the transfer. For example, one might include as information transferred, a brief description of the information necessary to evaluate manufacturing processes known to Requester, or information necessary to evaluate the regulatory status, safety, and toxicology of the product transferred by Requester.}

2. Research Material(s) transferred by **REQUESTER** according to Article 1 will only be used for research purposes in the laboratory(ies) of NCI and NIDDK for the research project described below, under suitable containment conditions. When either the National Cancer Institute (NCI) or NIDDK is the recipient, the Research Material(s) may also be used in the laboratory of an NIH contractor or subcontractor as provided in Article 7. Research Material(s) received by NCI or NIDDK will not be used for commercial purposes for screening, production, or sale, for which a commercialization license may be required. All recipients agree to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material(s).

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

_____ Yes _____ No

2(b). If the answer to 2(a) is "Yes", were Research Materials of **REQUESTER** collected according to 45 CFR Part 46, "Protection of Human Subjects"?

_____ Yes (Please provide Assurance Number: _____)
_____ No

3. NCI and NIDDK agree to transfer to **REQUESTER**'s Investigator the following Research Material(s):

{Describe here the information and/or material(s) to be transferred out of NIH to Requester, e.g., preclinical-grade drug material; or, information relating to pre-clinical drug development such as regulatory status, safety, toxicology, stability, formulation, and manufacturing.}

4. Research Material(s) exchanged by the Parties will be used solely in connection with the following research project ("Research Project"):

{Describe here the nature of the studies to be carried out both by Requester and by NIDDK and NCI and contractors and subcontractors of the latter. Such studies may include studies of dose ranging, pharmacokinetics, and toxicology; animal studies of efficacy; and manufacture of GMP grade material. Please note that the following non-highlighted sentence is vital to maintain the managerial direction of the studies by NIDDK.}

All milestones and all specific amounts of materials to be produced will be identified subsequently by NIDDK in consultation with **REQUESTER**..

5. In all oral presentations or written publications concerning the Research Project, a Party which receives Research Material will acknowledge the providing Party's contribution of their Research Material(s) unless requested otherwise. To the extent permitted by law, all Parties agree to treat in confidence, for a period of three (3) years from the date of its

disclosure, any written information about Research Material(s) received from another Party that is stamped "CONFIDENTIAL", except for information received by a receiving party that was known by receiving party before its receipt or that is or becomes publicly available or which is disclosed to receiving party without a confidentiality obligation. Any oral disclosures from a disclosing party to a receiving party shall be identified as being CONFIDENTIAL by written notice delivered to receiving party within thirty (30) days after the date of the oral disclosure. The Parties agree to work together to make the results of their research publicly available, however, before a Party submits a paper or abstract for publication, each other Party shall have thirty (30) days to review the proposed publication to ensure that its Confidential Information is protected except when a shortened time period under court order or the Freedom of Information Act pertains.

6. Research Material(s) represent(s) a significant investment on the part of the providing party. Receiving parties therefore agree to retain control over providing party's Research Material(s) and further agree not to transfer providing party's Research Material(s) to other people not under receiving party's direct supervision without advance written approval of providing party except as provided under Article 7 of this Agreement. When the Research Project is completed, Research Material(s) will be disposed of, if directed by the providing party.

7. In conducting a portion of the T1D-RAID research, it may be necessary for NIDDK or NCI to use the services of one of the NIDDK's or NCI's contractors or subcontractors under a funding agreement as defined by 35 U.S.C. §201(b).

REQUESTER acknowledges that:

Under the Bayh-Dole Act (35 U.S.C. §200 et. seq.), a contractor may elect and retain title to subject inventions developed under a funding agreement. Certain NCI and NIDDK contractors involved with the T1D-RAID programs may agree in a separate transaction independent of this Agreement to offer **REQUESTER** a first option to negotiate a license to subject inventions made using **REQUESTER's** Research Material(s). Certain other NCI contractors or subcontractors involved with the T1D-RAID program 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 **REQUESTER's** Research Material(s) may be assigned to **REQUESTER**.

8. In exchange for the assistance provided by the T1D-RAID program, **REQUESTER** agrees that in the event **REQUESTER's** commitment to development toward IND clinical trials ceases for a progressing project, **REQUESTER** will grant to the NIDDK or NCI a royalty-free, irrevocable, nonexclusive license under any patent on such compound or product or process for use of such, to manufacture and/or use the invention for purposes related to or connected with therapy or diagnosis of type 1 diabetes and its complications. Further, in such event, **REQUESTER** agrees that at the request of the NIH, **REQUESTER** will license to responsible applicants the rights to manufacture and/or use the invention for purposes related to or connected with therapy or diagnosis of type 1 diabetes and its complications, including for commercial purposes, under terms that are reasonable under the circumstances. Evidence of a lack of continued interest and required resources to work with NIDDK or NCI to progress in the development of the Research Material toward the conduct of an IND clinical trial will serve to indicate cessation of **REQUESTER's** commitment to development.

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

10. **REQUESTER** shall retain title to any patent or other intellectual property rights in inventions made by its own employees in the course of the Research Project. **REQUESTER** 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).

11. Research Material(s) is/are provided by the Parties as a service to the research community. IT IS BEING SUPPLIED WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Each Party makes no representations that the use of its Research Material(s) 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 any Party under this Agreement. Each Party shall be liable for any loss, claim, damage, or liability that said Party incurs as a result of its activities under this Agreement, except that the 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. Sec. 2671 et seq..

12. Each of the undersigned expressly certify and affirm that the contents of any statements made herein are truthful and accurate.

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

SIGNATURES BEGIN ON FOLLOWING PAGE

FOR *REQUESTER*:

REQUESTER's Investigator and Title: _____ Date:

Authorized Signature for *REQUESTER* and Title: _____ Date:

REQUESTER's Official Mailing Address:
Requester Name
Address

FOR NIDDK and NCI:

NIDDK's Investigator and Title: _____ Date:
Myrlene Staten, M.D., Senior Advisor, Diabetes Research Translation

Authorized Signature for NIDDK and Title: _____ Date:
Rochelle S. Blaustein, J.D., Director, Technology Transfer and Development

Authorized Signature for NCI: _____ Date:
Kathleen Carroll, Ph.D., Technology Transfer Branch, NCI

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

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Office of Technology Transfer and Development
National Institute of Diabetes and Digestive and Kidney Diseases
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12 South Drive, Room 3011
Bethesda, MD 20892-5632

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

Coordinator RAID Program
Developmental Therapeutics Program, NCI
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).