

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

The National 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>

Provider: _____

Recipient: _____

1. Provider agrees to transfer to Recipient's Investigator, named below, the following Research Material(s):

2. The Research Material(s) 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 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. 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 the answer to 2(a) is "Yes", 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. Research Material(s) 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 the Research Material(s) 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. The Research Material(s) represent(s) a significant investment on the part of Provider. Recipient's investigator therefore agrees to retain control over the Research Material(s) and further agrees not to transfer the Research Material(s) to other people not under her or his direct supervision without advance written approval of Provider except as provided under Article 7 of this Agreement. When the Research Project is completed, the Research Material(s) will be disposed of, if directed by Provider.

6. The Research Material(s) is/are 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(s) will not infringe any patent or proprietary rights of third parties.

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).

7(a) 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. As a term and condition of their funding agreements, certain NCI and NIDDK contractors involved with the RAID programs have agreed to offer Provider a first option to negotiate a license to subject inventions made using the Research Material(s).

7(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 Material(s) may be assigned to the Provider.

8. In exchange for the assistance provided by the T1D-RAID program, the Provider agrees that in the event Provider's commitment to development toward IND clinical trials ceases for a progressing project, Provider will grant to the NIDDK 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, Provider agrees that at the request of the NIH, Provider will license responsible applicants 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 commitment of resources to achieve the milestones set out in the initially-provided, or subsequently-amended and NIDDK-approved, Statement of Commitment provided as part of the application to use the T1D-RAID resources will serve to indicate that Provider's commitment to development toward IND clinical trials has ceased.

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 FOLLOWING PAGE

FOR PROVIDER:

Provider's Investigator and Title Date: _____

Authorized Signature for Provider and Title Date: _____

Provider's Official Mailing Address:

FOR RECIPIENT:

Recipient's Investigator and Title Date: _____

Authorized Signature for Recipient and Title Date: _____

Recipient's Official Mailing Address:

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

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Senior Advisor, Diabetes Translational Research
Division of Diabetes, Endocrinology and
Metabolic Diseases, NIDDK, NIH
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e-mail: T1D-RAID@nidk.nih.gov

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

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).