## Human Materials Transfer Agreement

## From:

To:

University of Florida Board of Trustees on behalf of the Network for Pancreatic Organ Donors with Diabetes ("nPOD") in the University of Florida Diabetes Center of Excellence("University")

("Recipient")

The parties are individually referred to in this Agreement as "Party" and collectively referred to as "Parties."

## **Definitions:**

Recipient Scientist:

Original Material:

Progeny: Unmodified descendant from the Original Material, such as, cell to cell.

**Unmodified Derivatives:** Substances which constitute an important unmodified functional subunit or expression product of the Original Material, e.g., subclones of unmodified cell lines, purified or fractionated sub-sets of the Original Material such as nucleic acids, proteins, or lipids or proteins expressed from the nucleic acids.

Material: Original Material, Progeny, and Unmodified Derivatives.

**Modifications:** Substances that contain or incorporate the Material.

**Research:** as stated in the Recipient Scientist's nPOD application that is approved by nPOD.

## **Terms:**

1. The University owns the Material, including Material that is incorporated into a Modification (or it has the right to share a third party's Material) and makes it available as a service to the research community. Recipient may utilize the Material and Modifications only for the Research in accordance with the term of the approved nPOD application. Recipient may not make any additional use of the Material without the prior review and consent by the University.

- 2. Recipient may not share the Material with anyone without the University's written consent. The Recipient shall refer any request for the Material to the University.
- 3. Recipient and Recipient Scientist may not attempt to determine the identity of or contact subjects from whom the Material was collected. Should a human subject from whom Material was collected object to the use of the Material, then Recipient agrees to comply promptly with University's request to return or destroy that Material.
- 4. Recipient shall use the Material in a safe manner and in compliance with all applicable local, state, and federal laws and regulations, including applicable National Institutes of Health guidelines. University represents and certifies that it has coordinated with the relevant Institutional Review Board ("IRB") to secure approval for provision of the Material and has obtained patient consents, if applicable, to permit Recipient to conduct the Research, and will provide Recipient with a copy of the IRB approval. Recipient warrants, if applicable, that it has obtained any Institutional Review Board or Ethics Committee approval that is required for this use of the Material in addition to the University IRB.
- 5. Recipient may not use the Material and Modifications in humans in any way.
- 6. Recipient affirms agreement with the nPOD data sharing and publications policy in the Recipient Scientist's <u>nPOD application</u>, which is incorporated into this Agreement.
- 7. The Material is experimental and is likely to have hazardous properties. THE MATERIAL IS PROVIDED WITHOUT ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. UNIVERSITY DOES NOT REPRESENT THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER RIGHTS OR THAT THE MATERIALS WILL NOT POSE A HEALTH OR SAFETY RISK. Recipient assumes all liability for claims and damages of third parties which arise from its use, storage, or disposal of the Material. However, Recipient is not liable for claims or damages to the extent they arise from the University's gross negligence or willful misconduct.
- 8. Any provisions of this Agreement which by their nature are required or intended to be observed or performed after termination or expiration of this Agreement survive termination or expiration of this Agreement.
- 9. This Agreement is binding upon and inures to the benefit of the Parties and their respective successors and assigns.
- 10. The parties shall send notices with respect to this Agreement by certified or registered mail return receipt requested to the following addresses. Notices are duly made on the date of actual receipt. Either party may by written notice designate a substitute address from time to time.
- 11. In order to comply with the Florida Protecting DNA Privacy Act, F.S. 760.40, Recipient and Provider represent to and agree with each other that this transfer is intended to be and

is part of "conducting research, or designing and preparing research" which is, "subject to the requirements of, and in compliance with, 45 C.F.R. part 46, 21 C.F.R. parts 50 and

56, or 45 C.F.R. parts 160 and 164; or utilizing information that is deidentified consistent with 45 C.F.R. parts 160 and 164 and that is originally collected and maintained for research subject to the requirements of, and in compliance with, 45 C.F.R. part 46, 21 C.F.R. parts 50 and 56, or 45 C.F.R. parts 160 and 164."

12. <u>Compliance</u> Recipient expressly agrees to comply with all applicable local, state, and federal procedures, rules, regulations, and laws, including Public Health Service and National Institutes of Health regulations and guidelines. Recipient expressly agrees to abide by all U.S. Export Control laws and regulations, including but not limited to the International Traffic in Arms Regulations (ITAR), 22 CFR Parts 120 through 130, and the Export Administration Regulations (EAR), 15 CFR Parts 730 through 799, and all embargoes and/or other restrictions imposed by the Treasury Department's Office of Foreign Asset Controls (OFAC). It is understood that University and Recipient are subject to United States laws and regulations controlling exports, and that Recipient's rights hereunder are contingent upon compliance by Recipient with applicable U.S. export laws and regulations. Import or export permits or other requirements for transporting the Material are the responsibility of Recipient.

TO Recipient:

TO University:

Name:	Mark Atkinson
Title:	College of Medicine
Address:	University of Florida
	1275 Center Drive, BMS Rm J586
	PO Box 100275
	Gainesville, Florida 32610

THIS AGREEMENT IS EFFECTIVE UPON SIGNATURE BY RECIPIENT'S INSTITUTIONAL OFFICIAL AND RECIPIENT SCIENTIST. RECIPIENT HEREBY AGREES THAT PROVIDER NEED NOT SIGN THIS AGREEMENT IN ORDER FOR IT TO TAKE EFFECT.

AGREED:	READ and ACKNOWLEDGED BY:	
Recipient:	<b>RECIPIENT SCIENTIST</b>	
By:, (authorized signature)	By:,, ,, ,,	
Printed Name:	Printed Name:	
Title:	Title:	