UNIVERSITY OF MIAMI
MILLER SCHOOL of MEDICINE

CReATe Biorepository:
Material Transfer Agreement

CReATe Therapies for ALS & Related Disorders

CReATe CONSORTIUM at UNIVERSITY OF MIAMI
MATERIAL TRANSFER AGREEMENT

RECIPIENT	Recipient Scientist:	
	Recipient Scientist's Email:	
	Recipient Organization:	
	Organization Phone:	
	Organization Email:	
	Organization Address:	

PROVIDER	Providing Scientist:	Michael Benatar, MD, PhD
	Scientist's Email:	MBenatar@med.miami.edu
	Providing Organization:	CReATe Consortium at University of Miami
	Organization Phone:	(305) 243-5689
	Organization Email:	um.ott.mta@miami.edu
	Organization Address:	UM, Office of Technology Transfer 1951 NW 7th Avenue, Suite 300 Miami, FL 33136

"Agreement" shall mean this CReATe Material Transfer Agreement, as managed by the University of Miami.

"Party" or "Parties" shall mean the party and/or parties to this Agreement.

"Effective Date" shall mean the last dated signature that Agreement is fully executed by all Parties.

"Provider" shall mean the University of Miami on behalf of the CReATe Consortium, a rare diseases clinical research consortium, created and maintained by prime awardee under NIH Award U54NS092091, whose function is to focus on ALS and related degenerative disorders that include PLS, HSP, PMA, and FTD. CReATe, in addition to other roles, acts as a repository to store Original Material and distribute Original Material to Recipients in order to facilitate research as dictated or approved by CReATe.

"Recipient" shall mean the organization receiving the Original Material from Provider.

"Recipient Scientist" shall mean the individual responsible for the use of the Material at Recipient.

"Requested Material" shall mean <carefully describe the specific material being requested>.

"Material" shall mean Original Material, Progeny, and Unmodified Derivatives pertaining to the Requested Material.

"Original Material" shall mean biological samples including blood, tissue, urine, serum, plasma, peripheral blood mononuclear cells, buffy coat, cerebrospinal fluid, RNA and extracted DNA.

"Progeny" shall mean the unmodified descendant from Material, such as virus from virus, cell from cell, or organism from organism.

"Unmodified Derivative" shall mean any substance created or identified by Recipient which constitutes an unmodified functional subunit or product expressed by the Original Material. Examples include, but are not

limited to, subclones of unmodified cell lines, purified or fractionated subsets of the Original Material, proteins expressed by DNA/RNA supplied by Provider, or monoclonal antibodies secreted by a hybridoma cell line.

"Modification" shall mean any substance created by Recipient which contains/incorporates Material or Unmodified Derivative.

"Associated Data" shall mean any anonymized, pseudonymized and/or de-identified data that is provided with Original Material and ties directly to that sample.

"Research Results" shall mean any data or results created by Recipient using Original Material, Progeny, Unmodified Derivatives or Modifications.

"Commercial Purpose" shall mean the sale, lease, license, or other transfer of Material or Modifications to a for-profit organization. Commercial Purpose shall also include the use of Material or Modifications by any organization, including Recipient, to perform contract research including, but not limited to, screening of compound libraries, production or manufacture of Material or Modification for general sale, or the conduct of research activities that result in any sale, lease, license, or transfer of the Material or Modifications to a for-profit organization. However, industry-sponsored academic research or internal non-commercial research shall not be considered a Commercial Purpose unless any of the above conditions of this definition are met. For the sake of clarity, and by way of an example, the Parties understand and agree that the identification and characterization of a new biomarker does not constitute Commercial Purpose because this use does not rely on the continued use, sale, or incorporation of Material or Modification in products sold.

In response to Recipient's request for the Material, Provider requests that Recipient and Recipient Organization agree to the following before receipt of Material:

1. Provider retains ownership of Material and Associated Data, including Material contained or incorporated in any Modification.

2. Recipient retains ownership of (a) Modifications, with the exception that Provider retains ownership rights to any Material included in the Modification, and (b) Substances created through the use of Material or Modifications, but which are not Progeny, Unmodified Derivatives, or Modifications (i.e., do not contain any Original Material, Progeny, or Unmodified Derivative). If either of the preceding results from a collaborative effort of the Provider and Recipient, joint ownership may be negotiated.

3. Recipient and Recipient Scientist agree that the Material and Associated Data:

   (a) Is to be used solely for internal research purposes as outlined in the CReATe Biorepository Sample Request Form, and Materials will not be included in any products for sale and will not be utilized in any for-profit services;

   (b) Will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of Provider and any relevant IRB or other regulatory approvals;

   (c) Is to be used only at the Recipient Organization and only under the direction or direct supervision of the Recipient Scientist; and

(d) Material and Associated Data shall not be transferred to a third-party without the prior written consent of Provider. Notwithstanding the foregoing, Recipient may transfer materials to contract research organizations (CROs) for use on Recipient's behalf in connection with this Agreement PROVIDED that: (1) CRO agrees in writing to be bound by the terms of this Agreement (other than the payment provisions) as if it were the Recipient; and (2) in the event of a breach of this Agreement by CRO, both Recipient and CRO will be liable to Provider.

4. Material may be distributed to Recipient after the Recipient has submitted a signed Investigator Assurance Form and CReATe Biorepository Sample Request Form to Provider and Provider has reviewed and approved the Recipient's proposal.

5. Recipient and Recipient Scientist agree to refer any request for the Material and Associated Data from anyone other than those persons working under the Recipient Scientist's direct supervision to Provider.

6. Neither the Recipient nor the Recipient Scientist shall provide or distribute any substances created by the Recipient through the use of the Original Material, including but not limited to those substances which are Progeny, Unmodified Derivatives, or Modifications without the written consent of Provider. If Providing Organization consents to distribution of substances to a specific third-party, the Recipient Organization must have an agreement with such third-party recipient that contains obligations consistent and no less restrictive than the terms and conditions of this Agreement. Additionally, without written consent from Provider, Recipient and/or Recipient Scientist shall not provide Modifications for any Commercial Purpose. It is recognized by Recipient that Commercial Purpose may require a commercial license from Provider and that Provider has no obligation to grant a commercial license to its ownership interest in the Material or Modifications.

7. Recipient acknowledges that Material is or may be the subject of a patent application. Except as provided in this Agreement, no express or implied licenses or other rights are provided to Recipient under any patents, patent applications, trade secrets, or other proprietary rights of Provider, including any altered form of the Material made by Provider. In particular, no express or implied licenses or other rights are provided to use the Material, Modifications, or any related patents of Provider for Commercial Purposes.

8. If the Recipient desires to use or license Material or Modifications for Commercial Purpose, Recipient agrees, in advance of such use, to negotiate in good faith with Provider to establish the terms of a commercial license. Recipient understands and agrees that Provider shall have no obligation to grant such a license to Recipient, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the Material to any third-party, subject to any pre-existing rights held by others and obligations to the Federal Government.

9. Any Material delivered by Provider pursuant to these terms is understood to be experimental in nature and may have hazardous properties. PROVIDER MAKES NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

10. Except to the extent prohibited by law, Recipient assumes all liability for damages which may arise from its use, storage or disposal of the Material. Provider shall not be liable to Recipient for any loss, claim or demand made by Recipient, or made against Recipient by any other party, due to or arising from the use of the Material by Recipient, except to the extent permitted by law when caused by the gross negligence or

willful misconduct of Provider.

11. Nothing herein shall be interpreted to prevent or delay publication of Research Results resulting from the use of the Material or Modifications. Recipient Scientist agrees to provide appropriate acknowledgement of Provider in all publications, and authorship credit for all Providers as appropriate based on widely accepted guidelines and the CReATe Publication and Authorship Policy (www.rdcrn.org/create).

12. Recipient agrees to use the Material in compliance with all applicable statutes and regulations, including Public Health Service and National Institutes of Health regulations and guidelines such as, for example, those relating to research involving the use of animals or recombinant DNA.

13. The Recipient and Recipient Scientist acknowledge that the conditions for use of the Material are in accordance with the Department of Health and Human Services regulations as described in 45 CFR Part 46, including Institutional Review Board (IRB) approval, as applicable.

14. The Recipient and Recipient Scientist agrees to abide by the terms and conditions set forth by the Health Insurance Portability and Accountability Act (HIPAA) of 1996, and the Standards for Privacy of Individually Identifiable Health Information as set forth in 45 CFR Part 160 and 164.

15. Either party may terminate this Agreement upon thirty (30) day's written notice. Upon termination, Recipient and Recipient Scientist agree to return or destroy the Material and Modifications, at the sole discretion of Provider, and notify the Provider as appropriate.

16. Sections 1, 2, 8, 9, and 10 shall survive termination.

17. Provider shall collect fees for cost recovery purposes including processing, preparation, and distribution of the Material.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their respective duly authorized representatives as of the day and year written following their respective signatures.

RECIPIENT		PROVIDER	
Signature	Date	Signature	Date
Printed Name		Printed Name	
Printed Title		Printed Title	

Reviewed and approved by CReATe Resource Access Committee: _____ (date)

Name:

Title:

Signature: