

1 For **Biological** Samples from the **National Children's Study**

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3 MATERIAL TRANSFER AGREEMENT  
4 FOR THE TRANSFER OF HUMAN MATERIALS  
5 FOR NON-PROFIT RESEARCH PURPOSES  
6

7 This Human Material Transfer Agreement ("MTA") is between the *Eunice Kennedy Shriver* National  
8 Institute of Child Health and Human development ("PROVIDER"), part of the National Institutes of  
9 Health, a component of the United States Department of Health and Human Services and ("RECIPIENT"),  
10 located at \_\_\_\_\_,  
11 for the transfer of human material, with or without accompanying data, for research purposes as further  
12 defined below. PROVIDER and RECIPIENT may each be referred to as Party or collectively as Parties.  
13

14 This MTA will become effective on the date of the last signature below.  
15

16 PROVIDER Investigator:

17 Steven Hirschfeld, MD, PhD  
18 \_\_\_\_\_

19 RECIPIENT Investigator:  
20 \_\_\_\_\_  
21

22 The RECIPIENT and the PROVIDER agree as follows:

- 23 1. The PROVIDER will transfer to the RECIPIENT the following: \_\_\_\_\_  
24 \_\_\_\_\_ with the following data  
25 \_\_\_\_\_ (collectively "Human Material").  
26 2. Descriptive title of RECIPIENT's research with Human Material is: \_\_\_\_\_  
27 \_\_\_\_\_ ("Research Project").  
28 3. RECIPIENT agrees to use the Human Material for teaching and non-profit research purposes only  
29 and will not use the Human Material for any commercial purposes, including selling, commercial  
30 screening, or transferring Human Material to a third party for commercial purposes.  
31 4. PROVIDER will provide RECIPIENT with personally identifiable information or the code to  
32 personally identifiable information with the Human Material:  
33 \_\_\_\_\_ Yes  
34 \_\_\_\_\_ No  
35

36 If Box "Yes" is checked above, then RECIPIENT's use of the Human Material is subject to:

- 37 a. The Privacy Act of 1974, as amended, at 5 U.S.C. §552a ("Privacy Act") requirements; and  
38 b. Applicable human subjects regulations and guidance, which may include 45 C.F.R. Part

39 46, 21 C.F.R. Parts 50 and 56, and FDA Good Clinical Practice Guidelines (ICH E6 Good  
40 Clinical Practice: Consolidated Guidance, 62 FR 25692 (1997)); and

41 c. RECIPIENT's agreement to:

42 (i) maintain any transferred personally identifiable information in a secure manner that restricts  
43 access to any individual not involved in the Research Project (e.g., for paper records – locked file  
44 cabinets or continual physical presence in a room that locks, or for electronic records – encryption  
45 and password protection); and

46 (ii) remove or destroy the information that identifies the individual who is the subject at the  
47 earliest time at which removal or destruction can be accomplished consistent with the purpose of  
48 the Research Project; and

49 (iii) make no further use or disclosure of the information unless approved by the PROVIDER,  
50 except as required by law.

51 5. RECIPIENT will only use the Human Material for the Research Project.

52 6. RECIPIENT represents that it has obtained Institutional Review Board approval, as  
53 appropriate, to use Human Material.

54 7. THE RECIPIENT AGREES THAT THIS HUMAN MATERIAL MAY NOT BE USED IN  
55 HUMANS OR FOR ANY DIAGNOSTIC, PROGNOSTIC, OR TREATMENT PURPOSES.

56 8. RECIPIENT will allow the use of Human Materials only by RECIPIENT's Investigator and  
57 RECIPIENT's Investigator's research team that are under the direct supervision of RECIPIENT  
58 Investigator and only after they have been informed of and agreed to the provisions and restrictions  
59 stated herein. Any transfer of Human Material to other than RECIPIENT's Investigator's research  
60 team requires the advanced written approval of the PROVIDER.

61 9. All Confidential Information that is transferred between PROVIDER and RECIPIENT is subject to  
62 the following:

63 All information to be deemed confidential under this MTA shall be clearly marked  
64 "CONFIDENTIAL" by the PROVIDER and maintained in confidence by the RECIPIENT for a  
65 period of three (3) years from the RECIPIENT's receipt of the Confidential Information. Any  
66 Confidential Information that is orally disclosed must be reduced to writing and marked  
67 "CONFIDENTIAL" by the PROVIDER and such notice must be provided to the RECIPIENT within  
68 thirty (30) days of the oral disclosure.

69 For the purposes of this MTA, Confidential Information includes any scientific or business data  
70 relating to the Human Material that a Party asserts are confidential and proprietary, except for data  
71 that:

72 a. have been published or otherwise publicly available at the time of disclosure to the RECIPIENT;  
73 or

74 b. were in the possession of or were readily available to the RECIPIENT without being subject to a  
75 confidentiality obligation from another source prior to the disclosure; or

- 76 c. have become publicly known, by publication or otherwise, not due to any unauthorized act of the  
77 RECIPIENT; or
- 78 d. the RECIPIENT can demonstrate it developed independently, or acquired without reference to, or  
79 reliance upon, such Confidential Information; or
- 80 e. are required to be disclosed by law, regulation, or court order.
- 81 10. The RECIPIENT will not contact or make any effort to identify individuals who are or may be the  
82 sources of the Human Material, without specific written approval from the PROVIDER.
- 83 11. The RECIPIENT will comply with all laws, rules and regulations applicable to the handling and use  
84 of the Human Material.
- 85 12. Either Party may terminate this Agreement with sixty (60) days written notice to the other Party.
- 86 13. When the Research Project is completed or this Agreement is terminated or three (3) years from the  
87 date of sample receipt, whichever comes first, any unused Human Material will either be destroyed in  
88 compliance with all applicable statutes and regulations or will be returned to the PROVIDER as  
89 requested by the PROVIDER.
- 90 14. In all oral presentations or written publications concerning the use of Human Materials, the  
91 RECIPIENT will acknowledge the PROVIDER's contribution of the Human Material unless  
92 requested otherwise by PROVIDER.
- 93 15. Any Human Material delivered pursuant to this Agreement is understood to be experimental in nature  
94 and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND  
95 EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE  
96 ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR  
97 A PARTICULAR PURPOSE, OR THAT THE USE OF THE HUMAN MATERIAL WILL NOT  
98 INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.
- 99 16. No indemnification for any loss, claim, damage, or liability is intended or provided by either Party  
100 under this MTA. Each Party shall be liable for any loss, claim, damage, or liability that said Party  
101 incurs as a result of said Party's activities under this MTA, except that the PROVIDER, as an agency  
102 of the United States, may be liable only to the extent as provided under the Federal Tort Claims Act  
103 (28 U.S.C. Chapter 171). No indemnification for third party claims is intended or implied by either  
104 Party.
- 105 17. This MTA shall be construed in accordance with United States Federal law as applied by the Federal  
106 courts in the District of Columbia.

107 The Parties have executed this MTA by their respective duly authorized officers on the day and year  
108 hereinafter written. Any communication or notice to be given shall be forwarded in writing to the respective  
109 addresses listed below.

110 **FOR THE PROVIDER:**

111

112 \_\_\_\_\_ Date

113 (Signature of Authorized Official)  
114 Jack Moye, Jr., MD  
115 Director, Laboratories and Repository

116 \_\_\_\_\_ Date

117 (Signature of NIH Technology Development Coordinator)  
118 Charlotte McGuinness  
119 NICHD Technology Development Coordinator

120 Mailing Address for Notices:

<p>Jack Moye, Jr., MD Director, Laboratories and Repository National Children’s Study Telephone 301-594-8624 Fax 301-480-1222 Email: <a href="mailto:moyej@exchange.nih.gov">moyej@exchange.nih.gov</a></p> <p>(U.S.P.S. delivery address) <i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development Bldg. 6100, Rm. 5C01D, MSC 7510 9000 Rockville Pike Bethesda, MD 20892-7510</p> <p>(Hand or commercial courier delivery address) 6100 Executive Boulevard Room 5C01D Rockville, MD 20852</p>	<p>Charlotte McGuinness NICHD Technology Development Coordinator Telephone 301-435-3130 Fax 301-402-2117 Email: <a href="mailto:mcguinnc@mail.nih.gov">mcguinnc@mail.nih.gov</a></p> <p>(U.S.P.S. delivery address) National Cancer Institute Technology Transfer Center Competitive Service Center for NICHD Executive Plaza South, Suite 450 6120 Executive Boulevard (MSC 7182) Bethesda MD 20892-7182</p> <p>(Hand or commercial courier delivery address) National Cancer Institute Technology Transfer Center Competitive Service Center for NICHD 6120 Executive Boulevard Suite 450 Rockville MD 20852</p>
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122 **FOR THE RECIPIENT:**

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124 \_\_\_\_\_ Date

125 (Signature of Authorized Official)

126 (Printed Name and Title)

127 Mailing Address for Notices:

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133 RECIPIENT INVESTIGATOR:

134

135 I have read and understood the terms and conditions of this MTA and I agree to abide by them in the receipt  
136 and use of the Human Material.

137 \_\_\_\_\_

138 (Signature) Date