**Data Use Agreement - Human Tissue Procurement Facility (HTPF)**

This Data Use Agreement (“Agreement”), effective \_\_\_\_\_\_\_\_\_\_\_\_\_\_, 20\_\_\_ (the “Effective Date”) is entered into between \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“Recipient”) and University Hospitals Case Medical Center (“Covered Entity”) (collectively the “Parties”).

The parties have a Master Services Agreement (the “Research Agreement”) and accompanying Protocol (the “Protocol”, together with the Research Agreement, the “Underlying Agreement”), pursuant to which Covered Entity discloses certain personal health information in the form of a limited data set to Recipient. The Underlying Agreement, attached hereto, is incorporated herein by this reference.

Both Parties shall comply with the Standards for Privacy of Individually Identifiable Health Information (the “Privacy Rule”) issued under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the American Recovery and Reinvestment Act of 2009 and associated Health Information Technology for Economic and Clinical Health Act (“HITECH”). Statutory and regulatory references herein are to the aforementioned laws as currently in effect or as subsequently updated, amended or revised.

1. Permitted Uses and Disclosures.

1.1 Recipient represents and warrants that the information requested on case report forms or in other data formats from Covered Entity meets the criteria of a “limited data set” as that term is defined under 45 C.F.R. § 164.514(e)(2) and does not include patient or subject initials (referred to herein as a “Limited Data Set” or “Limited Data Sets”.)

1.2 Recipient may only use and disclose the Limited Data Set as necessary to perform its obligations under the Underlying Agreement.

1.3 Recipient represents and warrants that only the individuals or groups identified in the Underlying Agreement will use or disclose the Limited Data Set pursuant to this Agreement.

2. Recipient Responsibilities. Recipient agrees to:

2.1 Use or disclose the Limited Data Set only as permitted by this Agreement or as required by law;

2.2 Use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as permitted by this Agreement;

2.3 Report in writing to Covered Entity any use, disclosure or breach of the Limited Data Set not permitted by this Agreement of which it is aware or should have been aware;

2.4 Require any of its subcontractors or agents that receive or have access to the Limited Data Set to agree to the same restrictions and conditions on the use and/or disclosure of the Limited Data Set that apply to Recipient under this Agreement; and

2.5 Not use the information in the Limited Data Set, alone or in combination, to identify or contact the individuals who are data subjects.

3. Term and Termination.

3.1 This Agreement will commence on the Effective Date and terminate upon the termination or expiration of the Underlying Agreement, unless sooner terminated as set forth in this Agreement. Upon termination, Recipient will promptly return all copies of the Limited Data Set to Covered Entity or destroy such copies and certify to their destruction; provided however, if Recipient determines and Covered Entity agrees that neither return nor destruction is feasible, the parties agree to continue to extend the protections of this Agreement to the Limited Data Set(s).

3.2 Covered Entity shall provide written notice to Recipient of any determination that Recipient has breached a material term of this Agreement and Covered Entity shall provide Recipient with an opportunity to cure the breach or end the violation. If Recipient fails to cure the breach or end the violation within thirty (30) days after receipt of notice, Covered Entity may immediately terminate this Agreement and may report the breach to the Secretary of the Department of Health and Human Services.

3.3 The obligations contained herein shall survive any termination or expiration of this Agreement.

4. Miscellaneous.

4.1 Change in Law. The parties shall amend this Agreement to comply with changes to HIPAA or other federal and state laws that affect either Parties’ obligations under this Agreement. If the Parties are unable to agree to mutually acceptable amendments, either party may terminate this Agreement at any time.

4.2 Choice of Law. The laws of the State of Ohio govern all matters arising out of this agreement. The Parties shall file any action relating to this Agreement in the state or federal courts located in Cuyahoga County, Ohio.

4.2 Interpretation. The Parties intend for any ambiguity in this Agreement to comply with HIPAA and all regulations thereunder.

4.3 Indemnification. Recipient shall defend, indemnify and hold harmless the Covered Entity, including Covered Entity’s directors, officers, staff, employees, agents and affiliates, from and against any and all liability, damages, expenses, fees (including reasonable attorney’s fees), costs and fines arising from Recipient’s breach or violation of this Agreement.

4.4 Third Party Beneficiaries. This Agreement shall not confer upon any party other than the Parties hereunder, any rights, remedies, obligations or liabilities.

4.4 Modification. No amendment of this Agreement will be effective unless it is in writing and signed by the Parties.

4.5 Ownership Rights. The Parties agree that Covered Entity retains all ownership rights to the information contained in the Limited Data Set and that Recipient does not obtain any right to any of the data provided by Covered Entity.

4.6 Publicity. The Parties shall not use each other’s name, trademark, logo or other image in advertising or publicity without the prior written consent of the other party.

4.7 Notices; Reporting. Any notices or reporting to be given to a Party under this Agreement shall be made via U.S. Mail or express courier to such Party’s address given below and/or (other than for the delivery of fees) via facsimile to the facsimile numbers listed below.

If to Covered Entity: If to Recipient:

Center for Clinical Research and Technology

University Hospitals Case Medical Center

11100 Euclid Avenue

Cleveland, OH 44106

Attn: Vice President of Research and Technology

Tel: (216) 844-5576

Fax: (216) 844-1547

With a copy to:

University Hospitals Health System, Inc.

Attn: Chief Legal Officer

3605 Warrensville Center Road

Shaker Heights, OH 44122

And to:

University Hospitals Health System, Inc.

Attn: Chief Compliance Officer

3605 Warrensville Center Road

Shaker Heights, Ohio 44122

The parties are executing this Agreement as of the Effective Date above.

**COVERED ENTITY RECIPIENT**

By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Print Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title: