**DATA USE AGREEMENT**

THIS DATA USE AGREEMENT ("Agreement"), is made and entered into with an effective date of \_\_\_\_\_\_\_\_\_\_ \_\_\_, 20\_\_ (the "Effective Date") by and between **Lakeland Regional Medical Center, Inc.**, a Florida not for profit corporation ("LRMC") and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ("Data Recipient"). The purpose of this Agreement is to provide Data Recipient with access to medical records for use in clinical research.

1. **Definitions**. Unless otherwise specified in this Agreement, all capitalized terms used in this Agreement not otherwise defined have the meaning established for purposes of the "HIPAA Regulations" codified at Title 45 parts 160 through 164 of the United States Code of Federal Regulations, as amended from time to time.

2. **Preparation of the Medical Records**. Data Provider shall prepare and furnish to

Data Recipient relevant medical records in accordance with the clinical research protocol, as submitted and approved by the Institutional Review Board (IRB), and any applicable HIPAA or Family Educational Rights and Privacy Act (FERPA) Regulations.

3. **Data Fields in the Medical Records**. No direct identifiers such as names may be

included in the medical records. In preparing the medical records, Data Provider shall include only the information necessary for the Data Recipient to complete the clinical research.

4. **Responsibilities of Data Recipient**. Data Recipient agrees to:

(i) Use or disclose the medical records only as permitted by this Agreement or as required by law;

(ii) Use appropriate safeguards to prevent use or disclosure of the medical records other than as permitted by this Agreement and the LRH Data Management Policy, or as required by law;

(iii) Report to Data Provider any use or disclosure of the medical records of which it becomes aware that is not permitted by this Agreement, the LRH Data Management Policy, or as required by law;

(iv) Contractually require any of its subcontractors or agents that receive or have access to the medical records to agree to the same restrictions and conditions of use and/or disclosure of the medical records that apply to Data Recipient under this Agreement;

(v) Not use the information in the medical records to identify or contact the individuals who are data subjects;

(vi) Protect medical records that are transmitted in an electronic format with appropriate technology safeguards, such as the use of TLS version 1.2 with a key length of at least 2048 bits; and

(vii) Protect medical records that are stored electronically, by using electronic encryption safeguards of no less than 256 AES encryption standards.

5. **Permitted Uses and Disclosures of the Medical Records**. Data Recipient may use and/or disclose the information contained within the medical records for clinical research only, as set forth in the clinical research protocol, and as approved by the Institutional Review Board (IRB).

6. **Term and Termination**.

1. Term. This Agreement shall be effective for one (1) year commencing on

\_\_\_\_\_\_\_\_\_\_\_\_\_, 20\_\_ and expiring on \_\_\_\_\_\_\_\_\_\_\_ \_\_\_, 20\_\_, (the “Initial Term”) unless this Agreement is terminated earlier as provided in paragraphs 6.B., or 6.C. of this Agreement. This Agreement shall automatically renew on the expiration date and each year thereafter for additional and successive renewals of one (1) year (each a “Renewal Term”), upon the same terms and conditions as the preceding year, unless either party provides written notice to the other party of its intent not to renew at least sixty (60) days’ prior to the end of the applicable term, or unless this Agreement is earlier terminated or amended in accordance with the provisions set forth in this Agreement.

1. Termination by Data Recipient. Data Recipient may terminate this agreement at any time, with or without cause, by providing thirty (30) days’ written notice to Data Provider and returning or destroying the medical records, as instructed by Data Provider.
2. Termination by Data Provider. Data Provider may terminate this

agreement at any time, with or without cause, by providing written notice to Data Recipient.

1. Effect of Termination. Sections 1., 4., 5.and 7. of this Agreement shall survive any termination of this Agreement. Termination of this Agreement as provided above shall not release Data Recipient from any liability or obligation to Data Provider arising from or related to a breach of any provision of this Agreement occurring prior to the termination hereof.

7. **Miscellaneous**.

A. Change in Law. The parties agree to amend this Agreement to comport

with changes in federal law that materially alter either or both parties' obligations under this Agreement. Provided however, that if the parties are unable to agree to mutually acceptable amendment(s) by the compliance date of the change in applicable law or regulations, either Party may terminate this Agreement as provided in Section 6. Any modification of the Agreement shall in writing and signed by the parties.

B. Construction of Terms. The terms of this Agreement shall be construed to

give effect to applicable federal interpretative guidance regarding the HIPAA Regulations.

C. No Third Party Beneficiaries. Nothing in this Agreement shall confer upon

any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.

D. Counterparts. This Agreement may be executed in one or more

counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

E. Headings. The headings and other captions in this Agreement are for

convenience and reference only and shall not be used in interpreting, construing or enforcing any of the provisions of this Agreement.

F. Jurisdiction. This Agreement shall be governed by the laws of the State of

Florida, County of Polk and any applicable federal provisions.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf.

**LAKELAND REGIONAL DATA RECIPIENT**

**MEDICAL CENTER, INC.**

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

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

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