**Individual Investigator Agreement**

THIS AGREEMENT (“Agreement”) is made and entered into with an effective date of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, (“Effective Date”) by and between **Lakeland Regional Health Systems, Inc.** a Florida not for profit corporation, for itself and on behalf of its wholly owned subsidiary **Lakeland Regional Medical Center, Inc.**, collectively hereinafter referred to as "LRH", and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**,** hereinafter referred to as "Investigator".

W I T N E S S E T H:

WHEREAS, LRH operates a non-profit health system consisting of the Hospital and several outpatient ambulatory clinics, all located in Polk County, Florida; and

WHEREAS, LRH also operates an Institutional Review Board (“IRB”) for overseeing the review and approval of human subjects research; and

WHEREAS, it is in the best interest of LRH, the Hospital, the Hospital's Medical Staff, the Investigator and the community to have the LRH IRB oversee the human subjects research contemplated herein; and

WHEREAS, the Individual Investigator is a duly licensed, qualified, and experienced physician or researcher who is conducting human research pursuant to the U.S. Department of Health and Human Services (“HHS”) regulatory authority of 42 U.S.C. 289 and the regulations codified at 45 CFR part 46, subparts A through D; and

WHEREAS, LRH desires to enter into an Investigator Agreement for the benefit of the parties and the community; and

WHEREAS, the Investigator desires to conduct such human research, trial or study under the oversight and review of the LRH IRB and pursuant to the terms and conditions hereinafter set forth; and

NOW THEREFORE, in consideration of the mutual covenants and agreements of the parties contained herein and for other good and valuable consideration, the parties hereby agree as follows:

1. **Responsibilities of Individual Investigator**.The Investigator agrees that he/she, at the time of entering into this Agreement has reviewed, will maintain compliance with, and agrees to be bound by the following:
	1. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Declaration of Helsinki, the Nuremberg Code, the Common Rule and the ethical principles of the practice of medicine.
	2. The HHS regulations for the protection of human subjects as promulgated at 45 CFR part 46.
	3. The Federal Wide Assurance (“FWA”) ID No. FWA 00002092 and the applicable Terms of the FWA for the assuring institution Lakeland Regional Health Systems, Inc., and the research entitled: \_\_\_\_\_\_\_\_\_\_\_\_\_ .
	4. The assuring institution, its internal and LRH IRB policies and procedures for the protection of human subjects.
	5. The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.
	6. The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.
	7. The Investigator will abide by all determinations of the LRH IRB designated under the above FWA and will accept the final authority and decisions of the LRH IRB, including but not limited to directives to terminate participation in designated research activities.
	8. The Investigator will complete any educational training required by the Institution and/or the LRH IRB prior to initiating research covered under this Agreement.
	9. The Investigator will report promptly to the LRH IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior LRH IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
	10. The Investigator will report immediately to the LRH IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.
	11. The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject’s legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the LRH IRB.
	12. The Investigator acknowledges and agrees to cooperate in the LRH IRB’s responsibility for review, continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the LRH IRB in a timely fashion.
	13. The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the LRH IRB.
	14. Emergency medical care may be delivered without LRH IRB review and approval to the extent permitted under applicable federal regulations and state law.
	15. This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.
	16. The Investigator agrees and acknowledges that he/she will be responsible for the supervision of the research team, staff and assistants and hereby certifies that each person is sufficiently trained and qualified to participate in such research.
	17. The Investigator agrees to maintain all records, consents, protocol materials, documents and data associated with said research, present for inspection the same if requested by the LRH IRB and maintain the confidentiality and security of such records.
	18. The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject’s rights and welfare must take precedence over the goals and requirements of the research.
2. **Responsibilities of the IRB.** The LRH IRB will oversee and approve all aspects of the research as contemplated herein pursuant to its rules, regulations, guidelines and governing documents.
3. **Scope of the Agreement**. This Agreement applies to the research performed by this Investigator, in collaboration with the institution providing the FWA above, and does not apply to other research in which the investigator may be involved.
4. **Independent Relationships**. None of the provisions of this Agreement are intended to create nor shall be deemed or construed to create any relationship between the LRH IRB and Investigator other than that of independent parties contracting with each other hereunder solely for the purpose of effecting the provisions of this Agreement. Neither of the parties hereto shall be construed to be the employer, agent, or representative of the other.
5. **Term of Agreement and Termination**. The term of this Agreement shall be from the Effective Date above and continue until such time as the research contemplated herein is completed, transferred to another IRB for review or terminated by either of the parties. This Agreement may be terminated with or without cause with at least thirty (30) days written notice and upon either voluntary the termination of the research or the transfer of review responsibilities to another qualified IRB.
6. **Notices**. Any notices required or authorized under this Agreement shall be in writing and shall be deemed given when sent by United States mail, certified and return receipt requested, or by hand delivery, addressed as follows:

 LRH: Lakeland Regional Health Systems, Inc.

 1324 Lakeland Hills Blvd.

 Lakeland, Florida 33805

 Attention: Lance Green,

 EVP/Chief Financial Officer

With a copy to: Lakeland Regional Health Systems, Inc.

1324 Lakeland Hills Blvd.

Lakeland, Florida 33805

 Attention: General Counsel, Chief Legal Officer

 Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Either party may subsequently change its address contained in this notice provision by giving the other party written notice of said change in accordance with the provisions of this paragraph.

1. **Draftsmanship**. The fact that one of the parties may have drafted or structured any provision of this Agreement or any document attached as an exhibit hereto shall not be considered in construing the particular provision either in favor of or against such party.
2. **Entire Agreement**. This Agreement constitutes the entire Agreement between the parties hereto and supersedes all prior oral or written agreements, representations, statements, negotiations, understandings, proposals and undertakings with respect to the subject matter hereof

IN WITNESS WHEREOF the parties hereto have executed this Agreement as of the day and year first written above.

**LAKELAND REGIONAL HEALTH INVESTIGATOR**

**SYSTEMS, INC.**

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

 Timothy Regan, MD Print Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Chief Medical Officer Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_