CLINICAL SERVICE AGREEMENT

#### BY AND BETWEEN

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

##### AND

**THE UNIVERSITY OF UTAH ON BEHALF OF ITS**

**HEALTH SCIENCES CENTER**

This Clinical Service Agreement (“Agreement”) is entered into and effective as of \_\_\_\_\_\_\_\_\_, 201\_ (the “Effective Date”) by and between \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ having its principal place of business at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, (“Sponsor”) and the University of Utah, a body politic and corporate of the State of Utah, on behalf of its Health Sciences Center, with offices located at 75 South 2000 East, RAB Rm. 211 Salt Lake City, UT 84112 (“Institution”).

**RECITALS**

WHEREAS, Sponsor wishes to have certain clinical services conducted in accordance with the scope of work outlined in this Agreement; and

WHEREAS, the performance of such services is consistent, compatible and beneficial to the academic role and mission of Institution as an institution of higher education; and

WHEREAS, Institution engages only in clinical studies that are compatible and consistent with and contribute importantly to its educational and health care mission; clinical service to be undertaken pursuant to this contract satisfies the foregoing standards; and the Principal Investigator(s) and staff approved to conduct the study contemplated by this Agreement are qualified to conduct such clinical service.

##### AGREEMENT

NOW, THEREFORE, for and in consideration of the mutual covenants, conditions and undertakings herein set forth, the parties agree as follows:

1. Scope of Work. Subject to receipt of Compensation as provided for in Section 4 below, Institution agrees to perform for Sponsor certain clinical services in accordance with the terms of this Agreement (“Study”) for the project with protocol number \_\_\_\_\_\_\_ entitled, “\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,” as described in the protocol, attached hereto as Appendix A and incorporated herein by this reference, as it is amended time to time and as approved by Institution’s IRB (“Protocol”). The Study shall be performed under the direction and supervision of Institution’s employee, who is not a party to this Agreement, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, \_\_\_\_, (“Principal Investigator”).
2. Period of Performance. This Agreement is intended to commence on the Effective Date set forth above and continue until the work is completed or until this Agreement is terminated by either party in accordance with Section 16 of this Agreement.
3. Supply. Sponsor shall promptly provide Institution with \_\_\_\_\_\_, the investigational drug/device, (*and any comparator drugs or placebo*) free of charge following execution of this Agreement and approval of the Study by Institution’s Institutional Review Board (“IRB”), and throughout the course of the Study, in amounts sufficient to perform the Study
4. Compensation and Payment.
   1. Compensation. Sponsor shall pay to Institution for performance of the Study under this Agreement in accordance with the Study budget, attached hereto as Appendix B and incorporated herein by this reference.

Invoices shall be delivered to Sponsor at the following address:

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Compensation checks shall be payable to “The University of Utah,” Tax ID #87-6000525, shall reference the Principal Investigator and Study, and shall be delivered to:

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* 1. Payment upon Termination. If the Study is terminated prior to completion, Sponsor shall provide payment to Institution for work already performed in accordance with Appendix B, and non-cancelable expenses incurred, including but not limited to IRB fees related to the Study. Sponsor shall pay Institution within thirty (30) days receipt of invoice or bill from Institution, regardless of whether the Study was initiated or approved by the IRB. Sponsor shall also pay Institution for any services performed after the date of termination that are necessary to safeguard subject safety or to comply with applicable laws, rules, regulations or Sponsor requirements.

1. Reporting Requirements. During and for a period of at least two years after the completion of the Study, Sponsor shall promptly (within 30 days of becoming aware of relevant information) report to the Principal Investigator and/or Institution any information that could directly affect the health or safety of past or current Study subjects or influence the conduct of the Study, including but not limited to the Study results and information in site monitoring reports and data safety monitoring committee reports as required by the Protocol. In each case, the Principal Investigator and Institution shall be free to communicate these findings to each Study subject and the IRB.
2. Equipment. All equipment, instruments and materials purchased or used by Institution in connection with performance of the Study shall at all times remain under the sole control and ownership of Institution.
3. Biological Samples. Human specimens and samples that are collected from Study subjects and transferred by Institution to Sponsor or Sponsor’s authorized designee pursuant to the Protocol (“Samples”) shall be owned by Institution. Sponsor’s rights regarding access to and use of such Samples shall not conflict in any way with this Agreement, any relevant patient consent forms, as approved by Institution’s IRB, or any applicable federal, state, or local laws. Further, nothing in this Agreement may be construed as limiting the Institution’s right to use these Samples for any lawful purpose.
4. Publication, Trial Registration, Confidentiality.
   1. Publication. In furtherance of Institution’s role as a public institution of higher education, it is necessary that significant results of research testing and service activities be reasonably available for publication by the Institution, and Sponsor acknowledges that Institution may publish the data and results of research and services conducted in connection with this Agreement.

In the event Institution wishes to publish research, Institution shall first provide to Sponsor written notice of Institution’s intent to publish and a draft of such publication. Sponsor shall have ten (10) days after receipt of the draft for an abstract or presentation and thirty (30) days after receipt of the draft for a publication or manuscript (each a “Review Period”, as applicable) to request in writing the removal of portions deemed by Sponsor to contain confidential or patentable material owned by Sponsor, or to request an additional delay of up to thirty (30) days in submission of the draft for publication pending Sponsor’s application for patent protection. In either event, Institution shall have no obligation to delay publication of the draft for longer than forty (40) days following delivery of Institution’s notice to Sponsor of intent to publish an abstract or to present, or sixty (60) days in the case of publications and manuscripts. If Institution does not receive Sponsor’s written response to the notice of intent to publish within the Review Period, then Institution shall be free to publish without further obligation to Sponsor. Information supplied to Institution by Sponsor and identified by Sponsor as proprietary information shall not be included in any material published by Institution without prior written consent of Sponsor.

* 1. Clinical Trial Registration. Prior to the initiation of Study enrollment, Sponsor shall be responsible for posting the Study on a clinical trial registry which meets the criteria and contains the information required by the International Committee of Medical Journal Editors (“ICMJE”) for publication and meets the requirements of the Food and Drug Administration (“FDA”) and any other state or federal law pertaining to registration of the Study. Sponsor shall be responsible for updating such registration as required to comply with updates to any such ICMJE, FDA, and/or legal requirements.
  2. Confidentiality. During the term of this Agreement, including any extension thereof, and for five (5) years thereafter, Institution shall exercise reasonable care to prevent the unauthorized disclosure of Confidential Information (no less care than the degree of care employed by Institution to safeguard its own Confidential Information), shall not provide it to any third party, and shall not use it for any purpose other than as provided for under this Agreement without the Sponsor’s prior written approval. As used herein, the term “Confidential Information” refers to all confidential and proprietary information of Sponsor regarding the Study disclosed to Institution by Sponsor or its authorized designee, which are identified in writing as confidential at the time of disclosure or in the case of an oral transfer of information, within 30 days of such transfer; except any portion thereof which:

1. is known to Institution before receipt thereof under this Agreement; or
2. is independently developed by or for Institution without benefit of disclosing party’s Confidential Information; or
3. is disclosed to Institution by a third party having a legal right to make such disclosure and under no restriction; or
4. is or becomes part of the public domain through no fault of Institution.

Nothing in this Agreement shall be construed to restrict Institution from disclosing the Confidential Information as required by law, regulation or court order or other governmental order or request, provided in each case Institution shall promptly inform Sponsor of such requirement and provide reasonable assistance to Sponsor should Sponsor seek to limit such disclosure by appropriate legal means.

* 1. Records Statutes. Institution is subject to the Utah Government Records Access and Management Act, Section 63G-2-101, et. seq., Utah Code Ann. ("GRAMA"), as amended; Under GRAMA, certain records in connection with this Agreement may be subject to public disclosure; Sponsor acknowledges Institution’s confidentiality obligations under this Agreement shall be subject in all respects to compliance with GRAMA.  Pursuant to Section 63G-2-309 of GRAMA, any confidential information provided to Institution that Sponsor believes should be protected from disclosure must be accompanied by a written claim of confidentiality and a concise statement of reasons supporting such claim.  The Institution’s Business Confidentiality Claim Form is available at the following website: <http://osp.utah.edu/resources/agreement/index.php>

1. Indemnification. Sponsor shall indemnify, defend and hold harmless Institution, its directors, officers, agents and employees against any actions, suits, proceedings, liabilities and damages that may result from the conduct of the Study pursuant to the Protocol.
2. Subject Injury. Sponsor agrees that it shall pay for any illness or injury which the Principal Investigator determines, in his/her independent medical judgment, is caused by: 1) the investigational drug/device, 2) implementation of the Protocol, or 3) following Sponsor’s instructions.
3. Patents and Inventions.

* 1. Prior Intellectual Property. Intellectual property that either party owned prior to execution of this Agreement or develops independently of the Study is that party’s separate property. It is not affected by this Agreement. Neither party has any claims to or rights in such intellectual property of the other party.
  2. Sponsor Inventions. Institution agrees that any patentable inventions, discoveries or improvements directed to the formulation or dosage of the Study drug provided by Sponsor during and through the direct performance of the Study (collectively “Sponsor Inventions”) shall be owned by Sponsor and shall be promptly disclosed by Institution to Sponsor in confidence.
  3. Institution Inventions. All patentable inventions, discoveries or improvements other than those owned by Sponsor pursuant to Section 11.2 developed under this Agreement solely by Institution shall be owned by Institution (“Institution Inventions”).

1. Data. Institution shall own all source documents, subject medical records and the data contained therein (“Site Data”). Sponsor shall own all study case report forms and reports which are completed by Institution or Principal Investigator and required by the protocol (“Sponsor Data”). Sponsor may use Sponsor Data only as required for regulatory purposes subject to signed consent authorization and IRB approval. Institution shall retain the right to use Sponsor Data for its teaching, research and patient care purposes.
2. Compliance With Laws. In performance of the Study, Institution and Sponsor shall comply with all applicable federal, state and local laws, codes, regulations, rules and orders.
3. HIPAA. The parties acknowledge that in the performance of this Agreement, each may have access to patient medical records and other protected health information, the confidentiality of which is protected by law. Neither party, its employees, nor its contractors shall use or disclose to any third party any patient information, medical record information, or other protected health information, except where permitted by the patient in a signed IRB approved informed consent or written authorization or as required by law. Both parties shall comply with all federal and state laws, regulations, and policies regarding the confidentiality of such patient information. Each party represents that it shall at all times be in compliance with the requirements of the Health Insurance Portability and Accountability Act ("HIPAA"), and all applicable regulations, including without limitation the "Final Privacy Rule" as found under 45 CFR, parts 160 and 164. The provisions of this section regarding the confidentiality of patient medical records and protected health information shall survive for as long as the Privacy Rule remains applicable to the protected health information referenced therein.
4. Relationship of Parties. In assuming and performing the obligations of this Agreement, Institution and Sponsor are each acting as independent contractors and neither shall be considered nor represent itself as a joint venturer, partner, agent or employee of the other. Neither party shall include the name or any trademark of the other party in any advertising, sales promotion or other publicity matter without the prior written approval of the other party.
5. Termination. This Agreement may be terminated by either party at any time, by giving written notice thereof to the other party pursuant to section 18.4 of this Agreement. Such termination shall be effective thirty (30) days after receipt of such notice. Termination shall not relieve either party of any obligation or liability accrued hereunder prior to such termination, or rescind or give rise to any right to rescind any payments made prior to the time of such termination. This Agreement may be terminated immediately by either party if necessary to protect the safety and welfare of Study subject(s). Institution may terminate immediately if Institution’s IRB or the FDA withdraws approval of the Study. Upon termination, Institution will cease Study subject enrollment and stop or complete Study activities as requested by Sponsor; provided, however, that if, at the time of termination pursuant to this section, any subjects are enrolled in the Study, Sponsor shall be responsible for all costs for safe withdrawal of the subjects from the Study.
6. Uncontrollable Forces. Neither Sponsor nor Institution shall be considered to be in default of this Agreement if delays in or failure of performance shall be due to uncontrollable forces the effect of which, by the exercise of reasonable diligence, the nonperforming party could not avoid. The term “uncontrollable forces” shall mean any event which results in the prevention or delay of performance by a party of its obligations under this Agreement and which is beyond the control of the nonperforming party. It includes, but is not limited to, fire, flood, earthquakes, storms, lightning, epidemic, war, riot, civil disturbance, sabotage, inability to procure permits, licenses, or authorizations from any state, local, or federal agency or person for any of the supplies, materials, accesses, or services required to be provided by either Sponsor or Institution under this Agreement, strikes, work slowdowns or other labor disturbances, and judicial restraint.
7. Miscellaneous.
   1. Assignment. Neither party shall assign any rights or obligations under this Agreement without the prior written consent of the other party.
   2. Entire Agreement. This Agreement, with its attachments, constitutes the entire agreement between the parties regarding the subject matter hereof and supersedes any other written or oral understanding of the parties. This Agreement may not be modified except by written instrument executed by both parties. The invalidity or unenforceability of any provision in this Agreement shall not affect the validity or enforceability of any other provision of this Agreement.
   3. Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties, their successors and permitted assigns.
   4. Notices. Except as provided in Section 4 regarding payment of invoices, any notice or other communication required or permitted to be given to either party under this Agreement shall be in writing and shall be deemed to have been properly given and effective: (a) on the date of delivery if delivered in person during recipient’s normal business hours; or (b) on the date of delivery if delivered by courier, express mail service or first-class mail, registered or certified, return receipt requested; or (c) on the date of delivery by fax, with transmission confirmed by the sending machine. Such notice shall be addressed to the appropriate party at the address given below, or to such other address as is subsequently specified in writing in accordance with this Section.

## In the case of Institution with a copy to the Principal Investigator:

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| University of Utah |  | PI Name |
| Office of Sponsored Projects |  | Address |
| Attn: Director |  | Address |
| 75 South 2000 East, RAB RM 211 |  | City/State/Zip |
| Salt Lake City, UT 84112-8930 |  |  |
| Telephone: (801) 581-8949 |  | Telephone: |
| Fax: (801) 585-5749 |  | Fax: |
| e-mail: ospawards@osp.utah.edu |  | e-mail: |

In the case of Sponsor:

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* 1. Governing Law and Disputes. The laws of the State of Utah govern this Agreement. The Courts of the State of Utah have legal jurisdiction over this Agreement without regard to conflict-of-laws provisions.
  2. Survival. The terms contained herein which by their nature are intended to survive the termination of this Agreement shall survive the termination hereof.
  3. Nonwaiver. A waiver by either party of any breach of this Agreement shall not be binding upon the waiving party unless such waiver is in writing. In the event of a written waiver, such a waiver shall not affect the waiving party’s rights with respect to any other or further breach.
  4. Use of Name. Sponsor may not use the name of Institution in any news release or advertising or any publications directed to the general public without written approval of Institution.
  5. Order of Precedence. In the event of any conflict, inconsistency or discrepancy between this Agreement, the Protocol, and Study documents or any attachments hereto, and any other documents, the terms of this Agreement shall control. In the event a purchase order or other payment document is issued under this Agreement and such purchase order or other payment document contains standardized terms and conditions, the terms and conditions of this Agreement shall supersede and replace all such purchase order and payment document standardized terms and conditions.
  6. Export Control. In the event that a party under this Agreement intends to provide information, equipment or materials restricted under applicable export control law or regulations (including but not limited to Export Administration Regulations and International Traffic in Arms Regulations, to the other party during the course of any activity under this Agreement, the disclosing party must first notify receiving party of its intention to provide this data at least 30 days in advance of actually providing this information, equipment or materials, and indicate to whom at receiving party the information, equipment or materials is being provided, along with specific reference to the applicable regulatory sections. Receiving party will then determine whether it will accept such information, equipment or materials or decline. In addition, each party’s performance of any activity under this Agreement is subject to compliance with all U.S. export control and Office of Foreign Assets Controls (OFAC) regulations.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives effective as of the day and year first written above.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **UNIVERSITY OF UTAH**

“Sponsor” “Institution”

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| --- | --- | --- | --- | --- |
| By: |  |  | By: |  |
|  | Signature |  |  | Signature |

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| --- | --- | --- | --- | --- |
| Name: |  |  | Name: | Brent K. Brown, Esq. |
|  | (Please print) |  |  |  |
| Title: |  |  | Title: | Director, |
|  |  |  |  | Office of Sponsored Projects |
|  |  |  |  |  |
| Date: |  |  | Date: |  |

**APPENDIX A**

**[Insert Protocol referenced in Article 1.]**

APPENDIX B

**CLINICAL SERVICE AGREEMENT BUDGET**

**[Insert Budget referenced in Article 4.1]**