CLINICAL TRIAL AGREEMENT

This clinical trial agreement (“**Agreement”**) is entered into as of the date of the last signature of the parties on this Agreement (“**Effective Date**”) by and between [*SPONSOR NAME*] with offices located at [*ADDRESS*] (“**Sponsor**”) and the University of Florida Board of Trustees, a public body corporate of the state of Florida with offices at the UF Division of Sponsored Programs, 207 Grinter Hall, Gainesville, FL 32611-5500 (“**Institution**”). The parties to this Agreement are referred to individually as a “**Party**” or collectively as the “**Parties**”.

**WHEREAS**, the research contemplated by this Agreement is aimed to produce results of mutual interest to Institution and Sponsor;

**WHEREAS**, Sponsor is the regulatory sponsor of a {multicenter} clinical trial described in the protocol entitled, “{PROTOCOL TITLE}” (“**Protocol**”), which is incorporated herein by reference as Exhibit A (“**Study**”);

**WHEREAS,** [NAME OF PRIME FUNDING AGENCY or N/A] is providing funding to Sponsor in support of the Study, and all terms and conditions that flow-down to the Institution from that agreement are included in Exhibit C to this Agreement; (“**Prime Agreement**”)

**WHEREAS**, by separate agreement, Sponsor has engaged {**CRO, Inc.**}, a contract research organization, and its affiliates, acting as an independent contractor, to act on behalf of Sponsor for the purposes of transferring certain obligations in connection with Sponsor’s Study (“**CRO**”). Said obligations include, but are not limited to negotiation and execution of this Agreement and payment administration for the conduct of the Study described hereunder;.

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. **Scope of Agreement**

The Study will be conducted by the Institution under the direction of {PRINCIPAL INVESTIGATOR NAME}, an employee and agent of the Institution, who will act as the principal investigator for the Study (“**Principal Investigator**”). Institution may act by or through its Principal Investigator in performing its obligations under this Agreement. The Principal Investigator is not a party to this Agreement, but will be bound by the terms and conditions. All of Institution’s employees participating in the conduct of the Study, including the Principal Investigator (“**Study Personnel**”) will be appropriately trained and qualified to assist in the conduct of the Study. Institution will conduct the Study in accordance with this Agreement, the Protocol, Applicable Laws, and any reasonable written instructions provided by or on behalf of Sponsor. Institution will use its reasonable efforts to recruit Study Subjects in accordance with the Protocol. In the event of any conflict between the terms and conditions of this Agreement and the Protocol, the Protocol will control with respect to matters of the clinical conduct of the Study and the terms of this Agreement will control with respect to all other matters.

1. **Study Drug and Materials**

Sponsor will provide to Institution on a timely basis, without charge, the required quantities of properly-labeled Sponsor drug(s) or biologic(s) known as XXXXXX (“**Study Drug**”) and/or device(s) known as XXXXXX (“**Study Device**”) and other materials (e.g., Investigator’s Brochure, handling and storage instructions, and, if applicable, placebo) (collectively “**Study Materials**”) necessary for Institution to conduct the Study in accordance with this Agreement, the Protocol, Sponsor’s instructions, and Applicable Laws. Unless stated otherwise in writing by Sponsor, all Study Materials are and will remain the sole property of Sponsor until administered or dispensed to Study Subjects during the course of the Study. Receipt, storage, and handling of the Study Materials will be in compliance with all Applicable Laws, the Protocol, and Sponsor instructions. Institution may receive, store, disperse, dispose of, and maintain records regarding the Study materials by and through its investigational pharmacy.

1. **Applicable Laws**

Sponsor and Institution will comply with and conduct all aspects of the Study in compliance with all applicable federal, state, and local laws and regulations including without limitation generally accepted standards of good clinical practice (“**GCP**”) as developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (“**ICH**”) and adopted by current U.S. Food & Drug Administration (“**FDA**”) regulations and statutes; United States export control laws and regulations; the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (“**HIPAA**”) with respect to the collection, use, storage, and disclosure of Protected Health Information (“**PHI**”) as defined in HIPAA; the Medicare, Medicaid, and SCHIP Extension Act of 2007 ("**MMSEA**"); and any other regulations of the U.S. government relating to clinical trials, exportation of technical data, computer software, laboratory prototypes, and other commodities as applicable to academic institutions (“**Applicable Laws**”). Sponsor will notify Institution before providing Institution with any export controlled information or materials.

1. **IRB Submission and Informed Consent**

Institution will obtain the approval of the applicable Institutional Review Board (“**IRB**”) for the Study and will provide Sponsor proof thereof. Institution will not begin initiation of the Protocol or begin its conduct of the Study until IRB approval is obtained. Institution will obtain from each patient participating as a subject in the Study (“**Study Subject**”), a signed informed consent form (“**ICF**”) and other necessary authorization to disclose health information to Sponsor, including a HIPAA authorization form (“**HIPAA Authorization**”), or a waiver of consent as directed by the IRB, prior to the Study Subject's participation in the Study. The ICF will be in a form approved in writing by the IRB and Sponsor and consistent with Institution's policies.

1. **HIPAA and HIPAA Privacy**

Sponsor will collect, use, store, access, and disclose PHI and Subject Material only as permitted by Applicable Laws, the ICF and HIPAA Authorization. Pursuant to Section 111 of the MMSEA, Sponsor has an obligation to submit certain reports to the Centers for Medicare and Medicaid Services with respect to Medicare beneficiaries who participate in the Study and experience a research injury for which diagnosis or treatment costs are incurred. Institution and Sponsor are subject to laws and regulations protecting the confidentiality of PHI, accordingly: (1) upon prior written request, Institution will provide to Sponsor, or a third-party vendor as designated by Sponsor, certain identifiable patient information required by MMSEA for Study Subjects who are Medicare beneficiaries and incur medical costs in association with a research injury and whose costs are reimbursed by Sponsor pursuant to this Agreement; and (2) Institution will otherwise cooperate with Sponsor, or a third-party vendor as designated by Sponsor, to the extent necessary for Sponsor to meet its MMSEA reporting obligations. Sponsor will not attempt to identify or contact any Study Subject unless permitted by the ICF and/or HIPAA Authorization.

1. **Monitoring and Auditing**

Institution will provide Sponsor and Sponsor’s representatives access to Institution’s facilities where Institution is conducting the Study, and all records and materials directly related to the Study, wherever stored, including the Source Documents (as defined by ICH GCP), Study Data, documents and data related to adverse events, specimens, Subject Material, and Study Materials, all for the purpose of enabling Sponsor to review, validate, monitor, audit, and inspect the Study documents as required by the Protocol, Applicable Laws, and this Agreement.

* 1. Sponsor Access/ Coordination of Sponsor Visits and Reasonable Safeguards. All site visits and access by Sponsor and/or its authorized designee (e.g., Study monitor), (including during agency audits referenced below) will be scheduled in advance for times mutually acceptable to the Parties during normal business hours. Sponsor’s and/or authorized designee’s access will be subject to reasonable safeguards to ensure confidentiality of Institution’s medical records and systems.
  2. Regulatory Audit. Upon becoming aware of an audit or investigation related to the Study by a regulatory agency with jurisdiction over the Study, to the extent permitted by Applicable Laws and the regulatory agency, the Party with knowledge of the audit/investigation will provide the other Party with prompt notice thereof, or, if there is no prior notice, that an inspection has commenced. If not prohibited by the regulatory agency and otherwise permissible under Applicable Law and allowable in accordance with the Institution’s policy, Sponsor may request to be present at Institution’s site during such audit of the Institution with approval from the auditor. Sponsor will not alter or interfere with any documentation or practice of Institution. Institution will be free to respond to any regulatory agency inquiries and will provide Sponsor with a copy of any formal response to the regulatory agency or documentation regarding the audit, unless prohibited by Applicable Law or the regulatory agency. Sponsor’s ability to review the Study Subjects’ Study-related information contained in the Study Subject’s medical record will be subject to reasonable safeguards for the protection of Study Subject confidentiality in accordance with the Study Subjects’ ICF and HIPAA Authorization.
  3. Adverse Event Reporting. Institution will report each adverse event to the Sponsor as required by the Protocol and Applicable Law. When required by Applicable Law and/or the IRB, Institution will also report such adverse events to the IRB. Institution will submit to Sponsor all associated documentation for each adverse event upon Sponsor’s request.
  4. Sponsor Reporting Requirements. During and for a period of two (2) years after completion of the Study, Sponsor will promptly report to the 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 Data and information in monitoring reports and data safety monitoring committee reports as required by the Protocol. In each case, the Institution will be free to communicate these findings to each Study Subject and the IRB.

Institution will promptly inform Sponsor of any urgent safety measures as instructed in the Protocol or deviations from the Protocol of which Institution becomes aware. If Institution or Principal Investigator reasonably determines that adverse reactions or other Study Subject safety concerns related to the Study Materials or conduct of the Study pursuant to the Protocol have arisen, and a deviation from the Protocol is medically reasonable in the sole judgment of Institution or Principal Investigator to remediate or prevent such reaction or safety concern, such deviation will not be considered “material” and will not be considered a breach under the terms of this Agreement.

1. **Payments**
   1. Sponsor will pay Institution in accordance with the budget attached as Exhibit B (“**Budget**”), according to the actual work completed and any non-cancelable obligated expenses, for Study Subjects who are enrolled into the Study. According to its policy, Institution will apply its standard applicable facilities and administration rate on total direct costs, including pass-through costs, to all costs as provided under the Budget and this Agreement.

\*\*\*INSERT APPLICABLE PAYMENT LANGUAGE\*\*\* option 1 sponsor fund pay all etc.

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*OPTION 1: Sponsor will pay for all Protocol-required services. The Institution will not submit any claims to Study Subjects or third-party payers or insurance for medical services associated with the Study.*

*OPTION 2a: Sponsor will pay for the Protocol-required services as described in the final detailed Budget included in this Agreement. The Institution will not submit claims to Study Subjects or third-party payers or insurance for any services for which Sponsor has agreed to pay.*

*OPTION 2b: Sponsor funds will only be used to pay for the Protocol-required services that are not routine, standard of care. Routine, standard-of-care services will be billed to Study Subjects or third-party payers or insurance.*

*OPTION 3: Sponsor funds will only be used to pay for Protocol-required nonmedical activities, such as chart review, data collection, questionnaires, and follow-up phone calls.*

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* 1. Institution will not submit claims for payment to any patient, Study Subject, third-party payor, or any other person or entity for any item, procedure or service that Sponsor is obligated to pay for or provide free of charge under this Agreement.
  2. The compensation provided under this Agreement represents the fair market value for the research services to be provided by Institution, negotiated in an arm’s-length transaction, and has not been determined in a manner which takes into account the volume or value of referrals or business, if any, that may otherwise be generated between Sponsor, on the one hand, and the Institution, on the other. Nothing contained in this Agreement, including any transfer of value hereunder, is intended to be, nor will it be construed as (a) an obligation or inducement, either express or implied, for Institution or Study Personnel to purchase, prescribe, provide favorable formulary status, promote or otherwise support specific Sponsor products; (b) a reward for any such purchase, prescription, promotion or other support by Institution or Study Personnel; or (c) a requirement that Institution or Study Personnel refer any patients or other business to Sponsor, or enroll any Study Subjects in the Study. The Parties acknowledge and confirm that no such expectations exist.
  3. In addition to other necessary routing information detailed in the Budget, each payment will clearly reference the Study Protocol Number and the Principal Investigator’s name and Institution’s OCR number.
  4. If Sponsor defaults in any payment obligations when due and fails to cure the default within thirty (30) days, time being of the essence, the amount due will bear interest from such time until paid at the highest rate allowable under the State of Florida. Sponsor will pay all court-awarded costs, including a reasonable attorney's fee, if counsel will be employed by Institution to collect any sums due hereunder.

1. **Confidentiality/Confidential Information**
   1. The Party receiving information will be referred to as the “Receiving Party,” and the Party disclosing information will be referred to as the “Disclosing Party.”
   2. “Confidential Information” is proprietary information related to the Study that is marked as “confidential” or that a reasonable person familiar with the Study would understand to be confidential due to the context, scope, content, or nature of its disclosure.
   3. The Receiving Party will use the Confidential Information of the Disclosing Party only for the conduct of the Study and will limit disclosure to its officers, employees, servants, and agents who require access for the Study and who have a legal obligation of confidentiality and non-use (“Representatives”). Receiving Party will be responsible for the Receiving Party’s Representatives actions under the terms of this Agreement. A Receiving Party and its Representatives will protect Confidential Information with at least the same level of care that it protects its own confidential information of a comparable nature, which must be no less than reasonable care, to prevent any unauthorized disclosure or use for a period of seven (7) years after expiration or termination of this Agreement. Each Party reserves the right to not receive or accept the other Party’s trade secrets, unless such secrets are required for the conduct of the Study.
   4. The Receiving Party will not use any Confidential Information for any commercial purpose or development of any products or technology and will not use or attempt to practice any invention arising from, or disclosed in, the Confidential Information or any part thereof, without first entering into an agreement with the Disclosing Party permitting such use or practice.
   5. Prior to any disclosure of the Confidential Information for any reason to persons outside of the Receiving Party, the Receiving Party must obtain the Disclosing Party’s written approval. The Receiving Party will notify the Disclosing Party as soon as reasonably practical upon discovery of any unauthorized disclosure or use of Confidential Information or any other breach of the Agreement by the Receiving Party or its Representatives. The Receiving Party will cooperate with the Disclosing Party in every reasonable way to help the Disclosing Party regain possession of its Confidential Information, prevent further unauthorized disclosure or use, and mitigate any loss.
   6. This Agreement imposes no confidentiality and use obligations on information that:
      1. the Receiving Party can show by written record that it possessed without an obligation of confidentiality to the Disclosing Party prior to its receipt from the Disclosing Party;
      2. was already available to the public or became so through no fault of the Receiving Party;
      3. is subsequently disclosed to the Receiving Party by a third party that has the right to disclose it to the Receiving Party free of any obligations of confidentiality to the Disclosing Party;
      4. the Receiving Party can show by written record that the same information was independently developed by or for the Receiving Party without use of or reliance on the Disclosing Party’s Confidential Information;
      5. is required to be disclosed by law. To the extent that a Receiving Party is required to disclose Confidential Information by law, the Receiving Party must provide written notice to the Disclosing Party of such required disclosure as soon as practical to allow the Disclosing Party to seek a protective order or take other action to protect its Confidential Information.
   7. Notwithstanding any “confidential” watermark or footer or any other terms in this Agreement, the Parties acknowledge that under Section 1004.22, Florida Statutes, upon receipt of a public records request, Institution must release the title and short description of the Study, the name of the researcher, and the amount and source of funding for the Study without prior consent of the Sponsor.
   8. All Confidential Information will remain the property of the Disclosing Party and the Receiving Party will return or destroy all Confidential Information within thirty (30) days after a request by Disclosing Party, except that Receiving Party may retain one (1) copy for its legal and archival purposes.

1. **Data Use/Ownership**
   1. “**Study Data**” means all data and information generated by Institution as a result of conducting the Study that is required to be delivered to Sponsor in accordance with the Protocol. Sponsor will own and have the right to use the Study Data in accordance with the signed ICF and HIPAA Authorization, Applicable Laws, and this Agreement.
   2. “**Source Documents**” means all original documents, data, and records (e.g., hospital records; clinical and office charts; research notebooks; laboratory notes; memoranda; Study Subjects’ diaries or evaluation checklists; pharmacy dispensing records; recorded data from automated instruments; copies or transcriptions certified after verification as being accurate copies; microfiches; photographic negatives; microfilm; magnetic, electronic, or digital media; x-rays; Study Subject files; and records kept at the pharmacy, laboratories other departments involved in the Study), and all other primary data sources and raw data obtained by Institution in conducting the Study. Source Documents remain the sole and exclusive property of the Institution or its medical provider.
   3. Notwithstanding any licenses or other rights granted to either Party herein, Institution will retain the right to use the Study Data and results of the Study for its publication, IRB, regulatory, legal, and internal non-commercial clinical, educational, research and patient-care purposes, including the right to publish such data and results, without violating the terms of this Agreement.
2. **Subject Material**

Subject Material means any biologic material of human origin including, without limitation, tissues, blood, plasma, urine, spinal fluid, or other fluids derived from the Study Subjects in accordance with and pursuant to the Protocol.

Institution will make the Subject Material available to the Sponsor in accordance with the Protocol for the purposes of the Study. The Subject Material may be used by the Sponsor, central lab, or other contracted party only as allowed by the Study Subject’s ICF, HIPAA Authorization, Applicable Laws and direction from the pertinent IRB. Any use of Subject Materials, other than as allowed by the Study Subject’s ICF or HIPAA Authorization, will require additional IRB review and approval.

1. **Record Retention**

Institution will maintain complete, accurate and current Study records, including, without limitation, Source Documents, signed ICFs, case report forms (“**CRF**s”), laboratory data, and summaries of financial records related to the conduct of the Study (“**Study Records**”). Institution will, at Sponsor’s expense, retain in a safe and secure location at least one (1) copy of all Study Records for the period required by Applicable Laws.

IF FDA Regulated Study: “The Budget provides for record retention and storage costs for up to six (6) years after completion of the Study. In the event that a marketing application is not approved by the FDA within four (4) years after completion of the Study and/or Institution otherwise becomes obligated to store Study Records for a period that exceeds six (6) years after completion of the Study, Sponsor will pay all additional reasonable costs of record retention and storage upon receipt of an invoice from Institution, including applicable facilities and administration costs.”

Institution will give Sponsor sixty (60) days’ prior written notice of its intent to destroy any Study Records so that Sponsor may provide for alternate long-term storage or transfer the records to Sponsor or its designee, at Sponsor’s reasonable expense. If Sponsor does not respond to Institution’s notice of intent to destroy within the sixty (60) days, Institution may destroy the Study Records without penalty under this Agreement.

1. **Intellectual Property, Discoveries and Patents**

* 1. “**Intellectual Property**” means patentable discoveries, inventions, improvements, and prototypes, including, software, copyrighted and copyrightable works other than publications and reports, trademarks, and service marks, which are conceived and made during the conduct of the Study.
  2. Neither Party has any claims to or rights in any intellectual property owned or controlled by a Party prior to the Effective Date or conceived outside of the research conducted under this Agreement.
  3. “**Research Results**” means data and technical information that are obtained in performance of the Study. Research Results are expressly excluded from the definition of Intellectual Property.
  4. Ownership. Institution owns Intellectual Property that is conceived or made solely by employees of Institution (“**Institution Intellectual Property**”). Sponsor owns all Intellectual Property that is conceived or made solely by employees of Sponsor (“**Sponsor Intellectual Property**”). Institution and Sponsor jointly own Intellectual Property that is conceived or made jointly by employees of Institution and Sponsor (“**Joint Intellectual Property**”).
  5. Disclosure. Institution will provide Sponsor with written disclosure of Institution Intellectual Property promptly after it is disclosed by an Institution employee to UF Innovate, Institution’s technology licensing division (“**Tech Licensing**”). Sponsor will provide Tech Licensing with a written disclosure of any Sponsor Intellectual Property promptly after it is disclosed by a Sponsor employee to Sponsor. Each Party will retain all Intellectual Property disclosures submitted by the other Party in confidence.
  6. Patent Rights. If Sponsor directs that a patent application for Institution Intellectual Property or Joint Intellectual Property be filed, Institution will promptly prepare, file, and prosecute, at the expense of Sponsor, patent rights for that Intellectual Property, using patent counsel reasonably acceptable to Sponsor. Sponsor and Institution will cooperate to assure that patent applications cover, to the best of Sponsor’s knowledge, all items of commercial interest and importance. While Institution is responsible for making decisions regarding scope and content of the patent applications, Sponsor may review and provide input. Institution will keep Sponsor reasonably apprised as to developments with respect to the patent applications and will promptly supply to Sponsor copies of all papers received and filed in connection with the prosecution. If Sponsor decides to discontinue the financial support of the patent applications, Institution may file or continue prosecution and maintain any protection in the United States and any foreign countries at Institution’s sole expense with no further obligation to Sponsor.
  7. Cooperation. Institution and Sponsor will cooperate in the preparation, filing, prosecution, and maintenance of all patent rights for Institution Intellectual Property and Joint Intellectual Property. Cooperation includes (i) promptly executing or requiring employees to execute papers and instruments as reasonable and appropriate; and (ii) promptly informing the other Party of matters that may affect the preparation, filing, prosecution, or maintenance of those patent rights.
  8. Payment of Expenses. Within thirty (30) days after Institution invoices Sponsor, Sponsor will reimburse Institution for all reasonable patent-related expenses incurred by Institution. Sponsor may elect, upon sixty (60) days’ advance written notice to Institution, to cease payment of the expenses associated with obtaining or maintaining that patent protection for one or more patent rights in one or more countries. In that event, Sponsor loses all rights under this Agreement with respect to patent rights in those countries.
  9. Option Rights. Institution grants Sponsor a first right to negotiate a worldwide, royalty-bearing, exclusive license to Institution Intellectual Property or to Institution’s rights in Joint Intellectual Property (“**Option Right**”). Sponsor’s right commences when Institution notifies Sponsor and expires ninety (90) days later (“**Option Period**”). Sponsor may exercise the Option Right by written notice to Tech Licensing during the Option Period. If Sponsor does not exercise the Option Right during the Option Period, Institution may license its commercial rights under the relevant Intellectual Property to any third parties. If Sponsor exercises the Option Right, Tech Licensing and Sponsor will negotiate in good faith a license agreement with commercially reasonable terms. If the Parties fail to execute a license to Institution Intellectual Property or to Institution’s rights in Joint Intellectual Property within six (6) months after Sponsor’s exercise of the Option Right, Institution has no further obligation to Sponsor for that Intellectual Property.
  10. Licenses. In any license Tech Licensing grants to Sponsor for Institution Intellectual Property or for Institution’s rights in Joint Intellectual Property, among other customary license terms, the Parties will include terms to obligate Sponsor to (a) develop the Intellectual Property diligently for practical application and (b) pay all patent costs.
  11. Use of Research Results. Each Party may use Research Results for any purpose. However, in the case of Sponsor, the use may not infringe any claim of a patent application or an issued patent included in Institution Intellectual Property rights for which Sponsor has failed to obtain a license.
  12. Copyrightable Works. Institution or its employees own any copyrighted or copyrightable works (including reports and publications) that are created by Institution employees in the performance of the Study. Institution and the Principal Investigator grant Sponsor an irrevocable, royalty-free, nontransferable, non-exclusive right to copy and distribute for internal purposes only any Copyrightable Works that are furnished to Sponsor under this Agreement.
  13. Research Partially Funded by Third Parties. If any patentable invention in the Intellectual Property has been funded by the federal government, this Agreement and the grant of any rights in that invention are governed by federal law set forth in 35 U.S.C. §§ 201-211 and corresponding regulations, as amended, or any successor statutes and regulations. If any Intellectual Property has been funded by a non-profit organization or state or local agency, this Agreement and the grant of rights in that Intellectual Property are subject to the terms of the applicable agreement. If any term of this Agreement fails to conform to applicable law, regulations, or agreements, the relevant term is invalid and the Parties will modify the term.

* 1. The provisions of this Agreement are intended to be interpreted and implemented so as to comply with all applicable federal laws, rules, and regulations, including without limitation the requirements of Rev. Proc. 2007-47; provided, however, if it is determined by the Internal Revenue Service or any other federal agency or instrumentality (“**Government**") that the provisions of this Agreement are not in such compliance, then the Parties will modify the provisions and the implementation of this Agreement so as to be in compliance with all applicable federal laws, rules, and regulations as determined by the Government.
  2. Institution retains a royalty-free, irrevocable license to use for its own publication, IRB, regulatory, legal, clinical, educational, and internal research purposes, all inventions licensed or assigned to Sponsor hereunder.
  3. Nothing contained in this Agreement will be deemed to grant either directly by implication, estoppel, or otherwise any license under any patents, patent applications, or other proprietary interest to any other inventions, discovery or improvement of the other Party.

1. **Publication**
   1. Institution and Principal Investigator will retain the right to publish, present or otherwise publicly present Research Results of the Study, including Study Data, for educational or scientific purposes (each a “**Publication**”), provided that Institution will submit a draft of any proposed Publications, including without limitation manuscripts, abstracts, posters, oral presentation materials, and visual works based on the Study or any Research Results to the Sponsor for review no less than thirty (30) days prior to the proposed submission of such drafts for publication or presentation (“**Review Period**”). Sponsor will respond to Institution prior to the end of the Review Period with any request to (a) remove Sponsor Confidential Information other than a basic description of the Protocol, Study Data, and results of the Study at Institution; and (b) delay the proposed Publication for an additional sixty (60) days to permit Sponsor to seek patent protection. If Sponsor fails to respond to Institution within the Review Period, Institution will be free to publish the Publication. Institution will delete such Sponsor’s Confidential Information only to the extent such deletion does not preclude the complete and accurate presentation and interpretation of the Research Results. Sponsor will have the right to require that any publication or presentation concerning the work performed hereunder acknowledge Sponsor’s support.
   2. The first Publication of the results of the Study will be made in conjunction with the presentation of a joint multi-center Publication of the Research Results with the principal investigators from all sites contributing data, analyses, and comments (“**Multi-center Publication**”). However, Institution may individually proceed with a Publication in accordance with this section upon the first occurrence of one of the following: (i) a Multi-center Publication is published; (ii) no Multi-center Publication is submitted within twelve (12) months after conclusion, abandonment, or termination of the Study at all sites (“**Multi-center Publication Period**”); or (iii) Sponsor confirms in writing there will be no Multi-center Publication. If no Multi-center Publication occurs within the Multi-center Publication Period or the Multi-center Publication is otherwise abandoned, upon request by Institution, Sponsor will provide Institution access to the aggregate Study data from all Study sites.
   3. If the Institution, through its Principal Investigator, is identified to participate in the Multi-center Publication: (i) Institution will have the opportunity to review the aggregate multi-center Study data, upon request; and (ii) consistent with the International Committee of Medical Journal Editors (“**ICMJE**”) regulations, Institution will have adequate opportunity to review and provide input on any Multi-center Publication prior to its submission for publication. Institution also retains the right, on behalf of its Principal Investigator, to decline to be an author on any Multi-center Publication.
2. **Use of Name**
   1. Neither Institution nor Sponsor may use the name, trademark, logo, symbol, or other image or trade name of the other Party or its employees and agents in any advertisement, promotion, or other form of publicity or news release or that in any way implies endorsement without the prior written consent of an authorized representative of the other Party whose name is being used. Such approval will not be unreasonably withheld.
   2. Institution and Sponsor understand that the amount of any payment made hereunder may be disclosed and made public by the other Party as required by law or regulation, including the Patient Protection and Affordable Care Act of 2010, provided that the disclosure clearly designates the payment as having been made to Institution for research and not to the physician.
   3. Institution may acknowledge the Sponsor’s support, including but not limited to financial support as may be required by academic journals, professional societies, funding agencies, and applicable regulations. Notwithstanding anything to the contrary in this Agreement, Institution may publically post information about the Study to appear on Institution’s clinical trials directory/website; including, Sponsor’s name, the Study title, and the Study period, and funding amount.
3. **WARRANTY**

THE PARTIES MAKE NO EXPRESS WARRANTIES AND DISCLAIM ANY IMPLIED WARRANTIES AS TO ANY MATTER RELATING TO THIS AGREEMENT, INCLUDING, INVENTIONS, OR ANY OTHER WORK PRODUCT OR THE PERFORMANCE OF OR RESULTS OF THE STUDY; THE AVAILABILITY OF LEGAL PROTECTION FOR RESEARCH RESULTS, INVENTIONS, OR ANY OTHER WORK PRODUCT OF THE STUDY; OR THE VALIDITY OR ENFORCEABILITY OF ANY INTELLECTUAL PROPERTY PROTECTION THAT MAY BE OBTAINED PURSUANT TO THIS AGREEMENT. THE PARTIES PROVIDE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE FOR ANY RESEARCH RESULTS OR INTELLECTUAL PROPERTY RIGHTS. THE PARTIES MAKE NO ASSURANCES THAT THE USE OF RESEARCH RESULTS OR INTELLECTUAL PROPERTY RIGHTS WILL NOT INFRINGE ANY PATENT RIGHTS OR OTHER PROPRIETARY RIGHTS OF A THIRD PARTY.

1. **Sponsor Indemnification and Limitation of Liability**
   1. Sponsor will indemnify, defend, and hold harmless the Institution, its Principal Investigator, Study Personnel, affiliated hospital, and each of its trustees, officers, directors, governing bodies, subsidiaries, affiliates, investigators, employees, IRB members, agents, successors, heirs and assigns (individually “**Institution Indemnitee,**” and collectively referred to as "**Institution Indemnitees**"), from and against any third party claims, loss, damage, cost and expense of claims and suits (including reasonable attorney’s fees) ("**Claims**"), alleged to be caused by or arising from the conduct of the Study, use of the Study Drug, Study Device, Study Materials, or from the use of the Study Data and Study Results, regardless of the legal theory asserted.
   2. Sponsor will have no obligation to provide such indemnification to the extent that such Claim is solely caused by an Institution Indemnitee’s: (1) material deviation from the specifications and directions set forth in the Protocol; (2) failure to comply with all Applicable Laws in the performance of the Study, or (3) negligent acts or omissions during the conduct of the Study and within the scope of the Institution Indemnitee’s employment by Institution.
   3. Institution’s reasonable deviations from the Protocol or Sponsor’s written instructions for reasons of Study Subject safety that arise out of medical necessity and emergent circumstances will not nullify Sponsor’s indemnification obligations hereunder.
   4. Institution will give notice to Sponsor promptly upon receipt of written notice of a Claim for which indemnification may be sought under this Agreement; provided, however, that failure to provide such notice will not relieve Sponsor of its indemnification obligations except to the extent that the Sponsor’s ability to defend such Claim is materially, adversely affected by such failure. Sponsor will not make any settlement admitting fault or incur any liability on the part of the Institution or Institution Indemnitee without Institution Indemnitee’s prior written consent, such consent not to be unreasonably withheld or delayed. The Institution Indemnitee will cooperate with Sponsor in all reasonable respects regarding the defense of any such Claim, at Sponsor’s expense. The Institution Indemnitee is entitled to retain counsel of its choice at its own expense. In the event a Claim falls under this indemnification clause, in no event will the Institution Indemnitee compromise, settle or otherwise admit any liability with respect to any Claim without the prior written consent of the Sponsor, and such consent not to be unreasonably withheld or delayed.
2. **Institution Liability**

Institution assumes any and all risks of personal injury and property damage attributable to the negligent acts or omissions of the Institution and the trustees, officers, employees, servants, and agents thereof while acting in the scope of their employment by the Institution. The Institution affirms that it is self-funded for liability insurance, both public and property, with such protection being applicable to the Institution’s trustees, officers, employees, servants and agents while acting within the scope of their employment by the Institution. Nothing contained herein will be construed or interpreted as (1) denying to either Party any remedy or defense available to such Party under the laws of the State of Florida; (2) the consent of the Institution, the State of Florida, or their agents and agencies to be sued; or (3) a waiver of the sovereign immunity of the Institution, the State of Florida, and their agents and agencies beyond the waiver provided in Section 768.28, Florida Statutes.

1. **Limitation of Liability**

EXCEPT FOR LIABILITY ARISING UNDER TERMS RELATED TO CONFIDENTIAL INFORMATION, INVENTIONS, AND INDEMNIFICATION, IN NO EVENT WILL ANY PARTY HEREUNDER BE LIABLE TO ANY OTHER PARTY HEREUNDER FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES ARISING FROM OR IN RELATION TO THIS AGREEMENT, THE PROTOCOL, OR THE STUDY DRUG, STUDY DEVICE, OR STUDY MATERIALS (WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY, BY STATUTE OR OTHERWISE).

1. **Subject Injury**

Sponsor will pay for reasonable and necessary costs of medical services incurred by a Study Subject in the diagnosis and treatment of any injury that is determined by the Principal Investigator to be solely attributable to the use of the Study Drug, Study Device, or Study Materials or any Study-required procedure under the Protocol (“**Subject Injury**”); provided such injury is not caused in any way by failure to adhere to the Protocol or this Agreement, or the negligence or misconduct of Institution, Principal Investigator or Study Personnel; provided, however, that Institution’s reasonable deviations from the Protocol for reasons of Study Subject safety that arise out of medical necessity and emergent circumstances will not nullify Sponsor’s obligations under this section.

1. **Insurance**
   1. Institution Insurance.Institution participates in the State Risk Management Trust Fund administered by the Department of Financial Services, Division of Risk Management of the State of Florida, for worker’s compensations, general liability and fleet automobile liability insurance. The program provides financial protection for bodily and personal injury and property damage arising from the operations of the Institution. The combined limits for general liability and fleet automobile liability coverage amount to $200,000 per person per claim and $300,000 per occurrence. Nothing herein will be construed as a waiver of the sovereign immunity of the Institution, the State of Florida, and their agents and agencies beyond the waiver provided in Section 768.28, Florida Statutes.
   2. Sponsor Insurance. All insurance coverages maintained by Sponsor hereunder will (a) be maintained in amounts commensurate for similarly situated entities undertaking similar activities and providing similar good and services and as otherwise required by Applicable Laws and this Agreement, (b) include coverage for contractually assumed liability and for clinical studies liability, (c) have aggregate limits sufficient to cover Sponsor’s financial and indemnification obligations hereunder.
   3. Upon written request, either Party will provide evidence of its insurance or self-insurance acceptable to the other Party. A Party’s inability to meet its insurance obligation constitutes material breach of this Agreement.
2. **Dispute Resolution**

The Parties will attempt to cooperatively resolve any and all disputes and/or claims that arise under this Agreement by first engaging the appropriate administrative officials of each Party who will negotiate in good faith to seek a cooperative resolution. For any dispute related to this Agreement that the Parties cannot resolve by mutual agreement within thirty (30) days, the Parties will submit formal mediation in Gainesville, Florida, failing which either Party may pursue any remedies legally available.

1. **Term and Termination**
   1. This Agreement will commence on the Effective Date and will terminate upon the completion of the Parties’ Study-related activities under the Agreement, unless terminated early as further described in this section.
   2. This Agreement may be terminated:
      1. by either Party immediately upon written notice if necessary to protect the rights, safety, or welfare of Study Subjects, or if the IRB otherwise disapproves the Study. If the Study is terminated under this section, Sponsor will pay for all reasonable and necessary costs required to bring the Study to a medically safe closure.
      2. by either Party immediately if, in that Party’s judgment or that of the Principal Investigator, the IRB, or the FDA, it is determined to be inappropriate, impractical, or inadvisable to continue the Study or the IRB otherwise disapproves the Study.
      3. by either Party for a material breach by the other Party, which breach is not cured within thirty (30) days following receipt of written notice thereof; provided that immediate action in deviation from the Protocol taken to prevent injury that is a direct result of a Study Subject’s participation in the Study will not be considered a material breach of this Agreement.
      4. by either Party upon thirty (30) days’ written notice.
      5. by Institution upon sixty (60) days’ written notice if circumstances beyond its control preclude continuation of the Study.

* + 1. upon thirty (30) days’ written notice if the Principal Investigator becomes unavailable to direct the conduct of the Study and the Parties after a good faith effort are unable to identify a mutually acceptable successor. Failure of Institution to find a replacement Principal Investigator after diligent efforts will not be considered a breach of this Agreement.
    2. upon thirty (30) days’ written notice to the other Party if amendments made to the Protocol substantially change or alter the original conduct of the Study approved and agreed to by the Parties, or which make it no longer feasible for Institution to continue to perform the Study.
    3. upon fifteen (15) days’ written notice if after diligent efforts Institution is unable to reach the enrollment goal at the Institution. Failure of Institution to reach an enrollment goal after diligent efforts will not be considered a breach of this Agreement
    4. upon fifteen (15) days’ written notice if either Party becomes insolvent, is dissolved, or liquidated, makes a general assignment for the benefit of its creditors, files or has filed against it a petition in bankruptcy, or has a receiver appointed for it or a substantial part of its assets.

1. **Return of Study Drug and Materials**

Upon termination of this Agreement, Institution will return to Sponsor at Sponsor’s expense, all non-disposable and unused disposable Study Drug, Study Device, and Study Materials, as well as all copies of manuals and other printed or reproduced documents (including information stored on machine-readable media) provided by Sponsor to Institution or Principal Investigator.

1. **Survival**

Termination of this Agreement by either Party will not affect the rights and obligations of the Parties accrued prior to the effective date of such termination. Any provision of this Agreement that by its nature and intent remains valid after termination will survive termination.

1. **Subcontract**

If applicable, Institution has the right to subcontract to other sites to conduct the Study in accordance with the Protocol with terms consistent with this Agreement and with written approval of the Sponsor which approval will not be unreasonably withheld. If Institution subcontracts any Study-related duties, Institution will contract with such subcontractors incorporating terms substantially similar to the terms herein. Such subcontracts may be provided to the Sponsor upon written request. The Sponsor has the right to subcontract to a third-party CRO or Academic Research Organization (“**ARO**”) and assign Study-related duties and rights to any Sponsor affiliate. If Sponsor subcontracts any Study-related duties and rights, Sponsor remains responsible for any of those duties and rights.

1. **Notices**

*If to Institution: If to the Sponsor:*

Office of Clinical Research XXXXXXXX, Inc.

Attention: Brian J. Sevier, PhD, Director

Ruth K. and Shepard Broad Building

1300 Center Drive, Room 106 Attn: XXXXXX

PO Box 100158 XXXXXXXXXXX

Gainesville, FL  32611-0158

Phone:  352-273-5946

Notice Email: [OCR-contracting@ahc.ufl.edu](mailto:OCR-contracting@ahc.ufl.edu)

Financial Email: [OCR-Financials@ahc.ufl.edu](mailto:OCR-Financials@ahc.ufl.edu)

1. **Independent Contractor**

Institution will be deemed to be an independent contractor, and not an agent or employee of Sponsor, for all purposes and for all services to be provided under this Agreement. Institution will not have authority to make any statements, representations, or commitments of any kind, or to take any action that is binding upon Sponsor, except as expressly provided for in this Agreement or authorized in writing by Sponsor.

1. **Clinical Trial Registry**

Sponsor will comply with all Applicable Laws regarding the conduct of the Study. Sponsor has obtained and will maintain all necessary FDA and other governmental approvals required to conduct the Study. Sponsor will register the Study on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) as required by Applicable Laws prior to enrollment of the first Study Subject.

1. **Non-referral/Anti-corruption Language**

Institution and Sponsor do not intend to induce or encourage the unlawful referral of subjects or business between the Parties, and there will not be any requirement under this Agreement that either Party, its employees, or affiliates, including its medical staff, engage in any unlawful referral of subjects to, or order or purchase products or services from, the other Party.

Institution and Sponsor employees, who are involved in the conduct of the Study, will not offer, pay, request or accept any bribe, inducement, kickback or facilitation payment, and will not make or cause another to make any offer or payment to any individual or entity for the purpose of influencing a decision for the benefit of the other Party.

1. **Force Majeure**

Neither Party will be liable for the failure to perform its obligations under this Agreement if such failure arises out of circumstances beyond that Party’s reasonable control, including but not limited to strikes, labor or civil unrest or disturbances, lock outs, riots, wars, fires, floods, hurricanes, tornadoes, or other severe weather disturbances or natural disasters. As soon as circumstances permit and such Party is reasonably able to do so, the Party invoking this clause will notify the other Party in writing concerning its inability to perform and will make every reasonable effort to fulfill its obligations under this Agreement. Such delay or inability to perform will not constitute a breach of this Agreement.

1. **Counterparts**

This Agreement may be signed in counterparts, each of which will be deemed an original and all of which together will constitute one and the same agreement. Signatures submitted by PDF or other electronic means have the same force and effect as wet signatures and are valid and binding upon the Parties.

1. **Amendments**

This Agreement may be amended only by a written agreement signed by the Parties.

1. **Waiver**

Failure to enforce any right hereunder, regardless of the length of time such failure continues, will not constitute a waiver of that or any other right unless the Party failing to enforce such right specifically acknowledges a waiver in writing.

1. **Debarment**

The Institution certifies that to its knowledge neither it, nor any of its Study Personnel is currently debarred, suspended, or excluded under the Federal Food, Drug and Cosmetic Act, as amended, or disqualified under the provisions of 21 CFR §312.70. In the event that any Study Personnel become debarred or disqualified during the term of this Agreement or within one (1) year after termination of the Study, Institution will to promptly notify Sponsor after learning of such event. Institution is not excluded from a federal health care program, including Medicare and Medicaid. In the event Institution becomes excluded during the term of this Agreement or within one (1) year after termination of the Study, Institution will promptly notify Sponsor after learning of such exclusion.

1. **Severability**

If any provision of this Agreement is held to be illegal, invalid, or unenforceable by a court of competent jurisdiction, the Parties will, if possible, substitute a legal, valid, and enforceable substitute provision which is as similar in effect to the deleted provision as possible. The remaining portion of this Agreement will remain valid and effective for the term remaining unless the provision that is found illegal, invalid, or unenforceable goes to the essence of this Agreement.

1. **Choice of Law**

This Agreement is governed and construed in accordance with the laws of the State of Florida. The Parties will bring any action in connection with this Agreement in courts of competent jurisdiction in Alachua County, Florida.

1. **Entire Agreement**

This Agreement is the entire understanding between the Parties with respect to its subject matter and supersedes any prior or contemporaneous discussions, representations, or agreements, whether written or oral, of the Parties regarding this subject matter.

IN WITNESS WHEREOF, each of the Parties has caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

<<Sponsor>>

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

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

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

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_University of Florida Board of Trustees

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

Brian Sevier, Ph.D.

Director, Office of Clinical Research

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_