OLD DOMINION UNIVERSITY
Research Foundation

ODU Research Foundation
4111 Monarch Way, Suite 204
Norfolk, VA 23508

An Open Letter to our Sponsors for Clinical Trials:

Thank you for selecting Macon & Joan Brock Virginia Health Sciences at Old Dominion University (ODU) for this study. The ODU Research Foundation will review your contract, and work towards concluding the clinical trial agreement with you shortly.

ODU, like other public research universities, is subject to an increasing number of state and federal regulations that are unique to higher education. As a result, most contracts provided by our sponsors require revisions before we can legally sign them.

For your convenience, we have attached a summary of the most common provisions negotiated in clinical trial agreements. Please note, if a sponsor's language deviates significantly from ODU's standard language, ODU Research Foundation is required to negotiate the language to align with institutional policies. If the parties are unable to agree upon mutually satisfactory language, ODU Research Foundation negotiators may be required to escalate the terms for additional review prior to finalizing, which would then require additional processing time.

To avoid unnecessary delays, the ODU Research Foundation will soon send you our proposed revisions in redline form. During the review process, the ODU Research Foundation will consult with ODU's Division of Research and Economic Development and Office of University Counsel regarding the agreement.

Should you have further questions regarding this process, you may contact the ODU Research Foundation Clinical Contract Team directly at: RFHSC-Clinical@odu.edu.

We look forward to working with you on this clinical trial agreement. If I can be of assistance, please do not hesitate to reach out me.

Thank you,

Richard Brammer

Digitally signed by Richard Brammer
Date: 2025.03.11 17:46:02 -04'00'

Richard Brammer
Deputy Executive Director/Sr. Director of Sponsored Programs
Old Dominion University Research Foundation
rbrammer@odu.edu

CONTRACT ISSUES CLINICAL TRIAL AGREEMENTS

Contracting Party	Old Dominion University (ODU) is the contract entity. ODU's name should appear in the Clinical Trial Agreement (CTA) as follows: "Old Dominion University whose business address is 5115 Hampton Blvd., Norfolk, VA 23529 ("Study Center"). The Principal Investigator is an employee of ODU and therefore is not named as a party to the CTA.
Contracting Party's Fiscal & Administrative Agent	University has entered into an agreement with the Old Dominion University Research Foundation (ODURF or "Affiliated Research Entity") which shall carry out certain delegated activities to support its research activities and to provide administrative and fiscal management services.
Contracting Party's Non-Physician staff	University will obtain the services of non-physician staff employed by ODURF for use in the Study, if required.
Medical Group	University has entered into an agreement with EVMS Medical Group ("Medical Group") to allow access to its facilities as necessary to conduct the Study.
Term of Agreement	For university accounting purposes, there must be an estimated termination date for the CTA.
Governing Law	As an agency in the Commonwealth, ODU cannot agree to the governing law of another state other than the Commonwealth of Virginia. In the alternative, ODU can remain silent on this provision.
Intellectual Property	ODU's standard approach is to agree that an invention arising out of a Sponsor-initiated clinical trial that 1) relates to, relies on, uses, or incorporates a Study Drug or Sponsor's Confidential Information; or (2) is anticipated by the relevant Protocol, shall be owned by Sponsor ("Sponsor Inventions"). Title to any inventions other than Sponsor Inventions ("Other Inventions") invented solely by Institution personnel shall reside with Institution. Other Inventions which are invented jointly by Institution and Sponsor personnel shall be owned jointly by the Parties. ODU retains the right to use all Inventions generated in the course of the Study for internal, noncommercial research, education and patient care purposes.
Study Data	ODU is committed to protecting the privacy of Study participants, and requires that Sponsors only use data obtained in accordance the IRB-approved Protocol with the consent of Study participants. ODU's standard language follows: "Study Data" shall mean all data and information generated by university as a result of conducting the Study in accordance with the IRB-approved Protocol. Data does not include original Study subject or patient medical records, research notebooks, source documents, or other routine internal documents kept in ODU's ordinary course of business operations, which shall remain the sole and exclusive property of ODU or medical provider. Sponsor shall have the right to use the Data in accordance with the signed

informed consent and authorization form, applicable laws, and the terms of this Agreement. For the avoidance of doubt, Data incidentally observed or recorded through quality assurance or safety monitoring procedures, and not specified in the Protocol, shall not be considered part of the Study Data and shall not be subject to Sponsor rights or use. Notwithstanding any licenses or other rights granted to Sponsor herein, but in accordance with the confidentiality and publication sections herein, ODU shall retain the right to use the Data and results for its publication, IRB, regulatory, legal, clinical, educational, and internal research purposes.

HIPAA

ODU understands that Sponsors must be able to review original data and may come into contact with Protected Health Information ("PHI"). ODU requires Sponsors to maintain PHI in a manner consistent with HIPAA regulations. The following language clarifies the expectations and responsibilities of the Parties when handling PHI As Study Data obtained by Sponsors under either an informed consent form ("ICF") or HIPAA authorization ("Authorization").

"Institution shall comply with applicable laws and regulations, as amended from time to time, including without limitation, 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. Sponsor shall collect, use, store, access, and disclose PHI collected from Study subjects only as permitted by the IRB approved informed consent form ("ICF") or HIPAA authorization form obtained from a Study subject. Sponsor's ability to review the Study subjects' Study-related information contained in the Study subject's medical record shall be subject to reasonable safeguards for the protection of Study subject confidentiality and the Study subjects' informed consent form or HIPAA authorization form. Sponsor shall not attempt to identify, or contact, any Study subject unless permitted by the informed consent form."

Confidentiality

ODU is an agency in the Commonwealth of Virginia and is subject to Virginia Freedom of Information Act laws. ODU strongly recommends that Sponsors mark their written confidential information as "CONFIDENTIAL" and if disclosures are in oral or a non-tangible format, such communications should be summarized in writing (and marked as "CONFIDENTIAL") within thirty (30) days of the oral communication.

With respect to ongoing confidentiality obligations, ODU agrees to a five (5) year survival period upon the termination of the CTA. As a public institution, ODU shall not be prevented from disclosing the existence of this Agreement or the identities of the parties.

Publication

ODU is precluded from accepting contractual restrictions which conflict with its commitment to academic freedom with respect to education, research, service, and patient care. In order to safeguard its tax-exempt status and to meet AAHRPP accreditation standards, ODU research

agreements ensure that its investigators retain the right to independently publish its results from its conduct of a Study. ODU suggests the following language:

"Institution shall be free to publish, present, or use any Data and results arising out of its performance of the Protocol (individually, a "Publication"). At least thirty (30) days prior to submission for Publication, Institution shall submit to Sponsor for review and comment any proposed oral or written Publication ("Review Period"). Institution will consider any such comments in good faith but is under no obligation to incorporate Sponsor's suggestions. The Review Period for abstracts or poster presentations shall be thirty (30) days. If during the Review Period, Sponsor notifies Institution in writing that: (i) it desires patent applications to be filed on any inventions disclosed or contained in the disclosures, Institution will defer Publication for a period not to exceed sixty (60) days, to permit Sponsor to file any desired patent applications; and (ii) if the Publication contains Sponsor's Confidential Information and Sponsor requests Institution in writing to delete such Sponsor's Confidential Information, the Institution agrees to delete such Sponsor's Confidential Information only to the extent such deletion does not preclude the complete and accurate presentation and interpretation of the Study results.

If this Study is part of a multi-center clinical trial, Institution agrees that the first Publication of the results of the Study shall be made in conjunction with the presentation of a joint multi-center Publication of the Study results with the Principal Investigators from all sites contributing Data, analyses, and comments. However, Institution may publish the Data and Study results individually upon first occurrence of one of the following: (i) multi-center Publication is published; (ii) no multi-center publication is submitted within eighteen (18) months after conclusion, abandonment, or termination of the Study at all sites; or (iii) Sponsor confirms in writing there will be no multi-center Publication.

If no multi-center Publication occurs within eighteen (18) months of the completion of the Study at all sites, upon request by Institution, Sponsor shall provide access to the aggregate Data from all Study sites to Institution.

Indemnification

ODU requires all Sponsors to indemnify and hold harmless ODU, its trustees, Principal Investigator, officers, agents and employees from any and all liabilities, claims, actions or suits made by third parties arising from ODU's proper performance of the clinical trial, as well as the Sponsor's use of the Study data, results and inventions arising out of the Study, and the negligence or willful misconduct of the Sponsor (and the CRO, if applicable). As an agency of the Commonwealth, ODU is not permitted to indemnify outside parties, except under limited circumstances for claims arising out of Institution's (including its employees') gross negligence or wrongful acts. *See VA Code 2.2-1837.*

Insurance

To support the sponsor's indemnification obligations the sponsor must maintain a sufficient level of insurance (e.g., $3 million dollars per occurrence). ODU's insurance details can be accessed through this link to University of Virginia Liability Self-Insurance Plan.

Arbitration

As an agency of the Commonwealth, ODU cannot waive its right to available legal remedies, and will not agree to submit to either mandatory or binding dispute resolution alternatives (e.g., arbitration or mediation).

Disclaimer of Warranties

Clinical trial research is experimental by nature and ODU disclaims any express or implied warranties based on either its research activities or outcomes.

EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, UNIVERSITY MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED WITH REGARD TO THE SERVICES TO BE PERFORMED HEREUNDER STUDY INFORMATION OR INVENTIONS. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT SPONSOR'S USE OF THE STUDY INFORMATION OR RESULTS OR INVENTIONS WILL NOT INFRINGE ANY THIRD-PARTY PATENT, COPYRIGHT, TRADEMARK, OR OTHER THIRD-PARTY PATENT RIGHTS. STUDY CENTER MAKES NO REPRESENTATION AS TO THE USEFULNESS OF THE STUDY INFORMATION OR RESULTS OR INVENTIONS. IF SPONSOR CHOOSES TO EXPLOIT THE STUDY INFORMATION, RESULTS, RESEARCH OR INVENTIONS IN ANY MANNER WHATSOEVER, SPONSOR DOES SO AT ITS OWN RISK.

Adverse Events

ODU requires that the Sponsor report to ODU adverse events the Sponsor becomes aware of during and after the clinical trial. Sample language follows:

The Sponsor must promptly report to ODU any and all findings that could affect the safety or medical care of Research subjects or their willingness to continue participation in the Research, alter the conduct of the Research, or alter ODU's institutional review board's approval of the Research. Such findings shall include, but not be limited to, any study-related illness, adverse event, or injury that results in a claim for payment for treatment. The Sponsor acknowledges and agrees that ODU may be required to report such findings to 1) the appropriate federal government authorities as may be required under applicable federal law or regulation and 2) the Research subjects. During the Research and after the conclusion of the Research, the Sponsor will continue to inform ODU of observed Research study drug(s) or device(s) effects so ODU, if appropriate, can inform the IRB, Research subjects, or both.

Limitation of Liabilities

ODU is subject to statutes restricting its ability to contractually accept liabilities over and above the amount allocated by the treasury. ODU must

specifically exclude any contingent unlimited liability. ODU's standard clause follows:

INSTITUTION SHALL NOT BE LIABLE TO SPONSOR FOR INDIRECT, SPECIAL, CONSEQUENTIAL, PUNITIVE, INCIDENTAL OR OTHER DAMAGES (INCLUDING ATTORNEY FEES, LOST REVENUE, PROFITS, USE, DATA OR OTHER ECONOMIC LOSS OR DAMAGE) HOWEVER CAUSED AND REGARDLESS OF THEORY OF LIABILITY (WHETHER FOR BREACH OR IN TORT, INCLUDING NEGLIGENCE) ARISING FROM, RELATED TO, OR CONNECTED WITH SPONSOR'S USE OF RESEARCH DATA, RESULTS, INVENTIONS, COPYRIGHTABLE WORKS, TANGIBLE RESEARCH PROPERTY, OR ANY OTHER RESEARCH RESULTS PROVIDED BY INSTITUTION, EVEN IF UNIVERSITY WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

Subject Injury

ODU will not agree to bill government or government sponsored insurance for subject injuries arising out of clinical research studies position: Sample language follows:

"The Sponsor shall pay for reasonable and necessary medical expenses incurred by Research Subjects in the Research study for any medical care, including diagnosis, treatment and hospitalization for any adverse reaction, illness or injury sustained by the Research Subject(s) arising from the Research study drug, device or research procedures; provided, however, the foregoing shall not apply to the extent the expenses, illness or injury arise from (i) the failure by ODU to adhere to the material terms of the Protocol or Sponsor's written instructions concerning use of the Research study drug, device or procedure or any applicable FDA or governmental requirements, (ii) the negligence or willful malfeasance of any Institution Indemnitee, (iii) the Research Subject's pre-existing condition, and/or (iv) the natural progression of an underlying pre-existing condition not caused by the administration or use of the Research study drug, device or procedure."

ODU shall not submit any claims, invoices, or requests for reimbursement to any third party, including, without limitation, private insurance companies, governmental agencies, or other payers, for medical treatment, services, or expenses incurred in connection with injuries sustained by subjects during the Study. All costs and liabilities associated with the diagnosis and treatment of such subject injuries shall be borne solely by the Sponsor. In the event there is a discrepancy between the subject injury provisions in the IRB-approved ICF and this Agreement, the Parties shall cooperate to resolve any inconsistencies through negotiation and mutual agreement, and if required, a signed amendment.

Payment	**Make Checks Payable to:** Old Dominion University Attn: Jennifer Rickards, Grant Accountant Old Dominion University 2004 Rollins Hall Norfolk, VA 23529 ODUGAGrants@odu.edu 757-683-5023
Tax ID Number	54-6000884
Signature Line	**Old Dominion University** Authorized Official: Dr. Ken Fridley, Vice President for Research
Administrative Contact	Old Dominion University Research Foundation Attn: Richard Brammer 4111 Monarch Way, Suite 204 Norfolk, VA 23510 Email: RFHSC-Clinical@odu.edu Phone: (757) 683-4293 Cc: s4robins@odu.edu