**\*\*Items highlighted in yellow should be what the AI program inserts based on the fallback document.**

**Study Site Agreement**

This Study Site Agreement (the “**Agreement**”) is entered into as of the date of the last signature hereon, (the “**Effective Date**”) by and between Duke University, a tax-exempt research and educational institution located in Durham, North Carolina, acting for and on behalf of its Duke Clinical Research Institute (“**Duke**”)” and University of North Carolina at Chapel Hill on behalf of itself and its A~~a~~ffiliates , located at Tarheel Road, 27516\_ (“**Study Site**”) Duke and Study Site may be referred to herein each as a “Party” and collectively the “Parties”. Affiliate” means any corporation, company, partnership, joint venture or other entity which Controls, is Controlled by, or is under common Control with a person or entity. “Control” means (i) the ownership of more than fifty percent (50%) of the issued share capital or (ii) the legal power to direct or cause the direction of the general management and policies of the party in question.”

**WHEREAS**, Duke has entered into a contract with **Novo Nordisk Inc.** (an Affiliate of Novo Nordisk A/S of Denmark), having a business address at 800 Scudders Mill Road, Plainsboro, New Jersey 08536 (“**Novo Nordisk**” or “**Sponsor**”), to coordinate a clinical research study entitled *ARTEMIS - Effects of ziltivekimab versus placebo on cardiovascular outcomes in patients with acute myocardial infarction* (the “**Study**”), which shall be conducted according to Sponsor’s Protocol set forth above and attached hereto as **Exhibit A** (“**Protocol**”); and

**WHEREAS**, the Protocol shall be approved by Sponsor, Duke, Study Site and an appropriate Institutional Review Board (“**IRB**”); and

**WHEREAS**, Duke wishes to engage the Study Site to participate in the Study; and

**WHEREAS**, Study Site desires to participate in the Study with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, an employee of the Study Site, acting as and hereinafter referred to as “**Participating Investigator,**” on behalf of Study Site.

**NOW, THEREFORE**, in consideration of the mutual promises herein contained and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. **Performance of Study:**

1.1 Study Site agrees to conduct this Study in strict accordance with the Protocol (as it may be amended from time to time by the Sponsor), all applicable local, state, and federal guidelines relevant to the conduct of clinical protocols that are reflected in US state and federal regulations, including, but not limited to the Federal Food, Drug and Cosmetic Act and regulations of the United States Food and Drug Administration (“**FDA**”), the Health Insurance Portability and Accountability Act of 1996, as amended (“**HIPAA**”**)**, and the Guidelines for Good Clinical Practice adopted by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (“ICH GCP”), E6, to the extent adopted by the FDA, conditions imposed by the Study Site’s IRB and the written instructions of the Sponsor and Duke relative to the administration of the Protocol. The Parties agree to comply with and to conduct the Study in accordance with all applicable federal, state and local laws and regulations. All the terms of the Protocol and any further amendments to the Protocol are incorporated hereunder and are part of this Agreement.

1.2 Study Drug. Ziltivekimab (the “**Study Drug**”) and all other Materials supplied hereunder shall be used by the Participating Investigator(s) and Study Site only as specified in the Protocol. The Study Site agrees to (a) handle and store Study Drug as specified in the Protocol or by Sponsor in writing, (b) maintain records on use and disposition of the Study Drug and (c) dispose of Study Drug at the end of the Study according to Sponsor’s written instructions.

1.3 **Biological Samples.** The Parties will properly collect, retain, deliver, label and/or use biological samples (including but not limited to: any biologic material of human origin including, without limitation, tissues, blood, plasma, urine, spinal fluid, or other fluids derived from the Study subjects) from subjects enrolled in the Study solely according to the Protocol consistent with the Informed Consent Form provided by Duke, approved by Sponsor and the IRB, and signed by the Study subject (the “**ICF**”). Duke shall not attempt to identify, or contact any Study subject. Study Site shall ensure that the ICF and HIPAA Authorization signed by each Study subject grants Sponsor the right to use, transfer, and dispose of the Specimens strictly in accordance with the IRB-approved informed consent and HIPAA authorization, and applicable law.

1.4 **Supplies and Materials**. During the term of this Agreement, Duke and/or Sponsor may provide, or arrange for a third-party to provide, Study Site and/or Participating Investigator with certain materials, such as laboratory equipment or computer hardware or software, (collectively, “**Materials**”) if the Duke and/or Sponsor determines that the Materials are necessary to facilitate study timelines or Protocol compliance. Study Site agrees that Materials are to be used solely for the conduct of the Study and shall at all times remain the sole property of Sponsor or third-party provider, as applicable. Study Site agrees that if Materials provided are used for purposes other than effectuating and completing the Study, Duke and Sponsor reserve the right to terminate Study Site’s and Participating Investigator’s use of such Materials. Study Site agrees that any and all Materials provided by or on behalf of Sponsor shall be properly maintained by Study Site and Study Site personnel and kept in good operating condition, reasonable wear and tear excepted. Study Site and Study Site personnel shall coordinate and cooperate with Sponsor in the provision and/or return of such Material.

1.5 The Parties agree that any deviation from the Protocol will not constitute a breach of this Agreement if the deviation was, in the Participating Investigator’s medical opinion, necessary for the Study subject’s immediate physical well-being. Study Site shall notify Duke as soon as possible in the event of such a deviation.

2. **Participating Investigator:**

2.1 The Study Site represents that the Participating Investigator shall be responsible for performing the Study at Study Site and for supervising all personnel performing portions of the Study.

2.2 In the event the Participating Investigator becomes unable to perform any of the activities in the Study or complete the Study for any reason, Duke and Study Site may mutually agree to a substitute Participating Investigator, who shall be an employee of Study Site, in which event this Agreement shall continue in full force and effect. If Duke and Study Site cannot agree on a substitute Participating Investigator, Duke may terminate this Agreement as provided herein.

2.3 Study Site agrees not to engage the services or use the facilities of any third party (each, a "Third-Party Institution"), including, but not limited to, sub-investigators and study coordinators, in conducting any Study-related services under this Agreement.

3. **Payment/Funds Availability/Reimbursement:**

3.1 In consideration of the work to be performed under this Agreement, Sponsor through its third-party vendor (“**Payment Administrator**”), will provide financial support for the Study as set forth in the Budget and Payment Schedule attached hereto as **Exhibit B** and will provide such funds to Payment Administrator for the purpose of paying all compensation due Study Site pursuant to Exhibit B. Payment Administrator will administer such funds and shall make all payments to Study Site in accordance with the payment schedule included in Exhibit B. Study Site acknowledges and agrees Payment Administrator will have access to this Agreement in order to issue payments.

If the Protocol is amended and such amendment causes a change to the Study procedures conducted, which requires a modification to the Study Budget due to increased costs to Study Site, the Parties agree to negotiate in good faith ~~and~~ ~~execute~~ an amendment to Exhibit B to account for such changes.

3.2 **Funds Availability and Reimbursement:**

All funds to support Study Site’s performance of the Study will be paid by the Sponsor to Payment Administrator, and Study Site shall have no recourse against Duke for failure by Sponsor to make payments in accordance with the terms hereof. These amounts, which are inclusive of overhead and all applicable taxes, represent the fair market value of the covered costs associated with the Study and have not been determined in a manner that takes into account the volume or value of any referrals or business. Study Site agrees that: (a) all claims that the Study Site submits for reimbursement to any federal healthcare program or third party payor for any procedure that involves any materials (including, but not limited to, Study Drug) provided by or on behalf of Sponsor at no cost to Study Site will accurately reflect the provision of those materials by or on behalf of Sponsor; and (b) Study Site shall not seek reimbursement from any federal healthcare program or third party payor for any of the amounts paid by Payment Administrator on behalf of Sponsor.

For all payment queries and to submit invoice, please contact:

Invoices and inquiries:

**americas@ctp.solutions.iqvia.com**

Subject: EX6018-4979

ARTEMIS\_Site Number in Footer

Participating Investigator Name

Study Site agrees that in order to receive timely payments, Study Site must reference and comply with the invoicing guidelines provided by Payment Administrator.

4. **IRB Approval / Informed Consent/HIPAA Authorization:**

Study Site shall ensure that the Participating Investigator(s) obtains the approval of the Protocol and related ICF, which has been previously approved by Duke and Sponsor, from the IRB or similar committee formally designated by the Study Site to review biomedical research, in conformance with 21 CFR Part 56. The Study Site shall ensure that each Study subject shall give his/her informed consent to such participation by signing the ICF in accordance with the Study Site’s informed consent policies and in conformance with **21 CFR Part 50**, and that a copy of the written ICF be given to each Study subject or the Study subject’s legal representative. The Study Site shall provide Duke with a copy of the Protocol and ICF approved by the IRB. No change to the Protocol and/or the ICF will be made without prior written approval by Sponsor, Duke and the IRB except when such change is necessary to eliminate apparent immediate hazard to Study subjects, or to comply with applicable local, state or federal law, in which case Study Site agrees to notify Duke and the IRB immediately.

The Study Site shall further ensure that each subject enrolling in the Study shall execute a HIPAA Authorization form (the “**HIPAA Authorization**”) approved by Duke, Sponsor and the IRB in advance, permitting the use and disclosure of the subject’s protected health information (“**PHI**”) (as that term is defined under 45 C.F.R. § 160.103) as contemplated under the Study. The Parties agree to treat all PHI in accordance with any ICF and/or HIPAA Authorization signed by Study subject.

5. **Confidentiality:**

5.1 Study Site agrees that all information, data, clinical or technical, including the Protocol and any forms or reports relating to this Study is Sponsor’s confidential information (“**Confidential Information**”)and shall not be disclosed to any third parties other than Duke, Sponsor or its designee or used for any purpose other than the conduct of the Study, except as and to the extent required by law. All Confidential Information disclosed pursuant to this Agreement will be identified in writing as “Confidential” at the time of disclosure to the extent reasonably practicable. However, information which is orally or visually disclosed, or written information that is not marked as “Confidential” shall be considered confidential if a reasonable person knowledgeable in the field of clinical research or medical practice would conclude it was confidential. The obligations set forth in this Section 5.1 will continue for five (5) years following the close of the Study at all Study sites.

Notwithstanding the foregoing, Study Site may disclose Confidential Information to those of its employees, agents, representatives, or third parties (“**Representatives**”); provided that, to protect Confidential Information, Study Site agrees to: (a) limit dissemination of Confidential Information to only those Representatives having a “need to know” such information (b) advise all such Representatives who receive Confidential Information of the confidential nature of such information; (c) have agreements with its Representatives sufficient to enable them to comply with the confidentiality and non-use obligations contained herein; and (d) use at least the same degree of care that Study Site uses to protect its own confidential and proprietary information of a similar nature, but in no event less than a reasonable standard of care. Study Site shall be and shall remain responsible and liable for any breach of these provisions by Representatives.

5.2 Specifically excepted from Confidential Information is all information that: (a) was previously known by the Study Site as evidenced by its competent prior written records; (b) is publicly disclosed except by breach of this Agreement either prior to or subsequent to the Study Site's receipt of such information; (c) is rightfully received by the Study Site from a third party without an express obligation of confidentiality; or (d) is independently developed by personnel of the Study Site without use of the Confidential Information as evidenced by competent prior written records.

5.3 Nothing set forth herein shall operate to prohibit or prevent Study Site from disclosing Confidential Information pursuant to any judicial or government request, requirement or order, provided that Study Site takes reasonable steps to provide Sponsor with sufficient prior notice in order to allow Sponsor to contest such request, requirement or order.

5.4 Notwithstanding anything to the contrary, Confidential Information shall not include the original source patient medical records owned by Study Site.

6. **Record-Keeping/Retention**:

Study Site agrees to maintain complete and up-to-date Study records including, without limitation, case report forms (“**CRFs**”), Study Drug and reconciliation documentation and the Study Site file, which includes all Study-related correspondence, all in accordance with applicable laws, regulations and FDA guidelines.

6.1 Study Site shall contact Sponsor in writing and follow Sponsor’s written instructions six (6) months prior to the destruction of records, the removal of records to another location or in the event of accidental loss or destruction of any Study records. At the end of the applicable retention period, Sponsor may, at its own cost and expense, either (a) receive the original data and records for further storage by Sponsor or a third party, where Study Site will allow a reasonable timeframe for the records transfer to occur before the destruction of records or (b) upon agreement with Study Site, arrange for further storage by Study Site.

6.2 Study Site shall:

(a) keep Duke informed of the Study status; and

(b) maintain and promptly provide, upon request, to Duke or its designee (i) complete and accurate records of the Study as required by the Protocol, and (ii) completed CRFs in the form specified by Sponsor; and

(c) maintain complete and up-to-date medical records of Study subjects.

6.3 Study Site shall retain all Study records for the longer of:

(a) Twenty-five (25) years following completion of the Study; or

(b) Two (2) years following the termination or withdrawal of the health regulatory agency exemption (e.g., Investigational New Drug (IND) application, or Investigational Device Exemption application) under which this Study was conducted; or

(c) The period required by local, state and federal laws, regulations and FDA Guidances.

7. **Disclosures Laws.**

7.1 Study Site acknowledges that Sponsor is subject to regulatory and compliance requirements in connection with contracting with and tracking payments to Healthcare Professionals, Healthcare Organizations and Patient Organizations (collectively “**HCPs**”), including the EFPIA disclosure requirements, as further detailed below.

Study Site agrees to provide Sponsor, through Duke, with all details and information reasonably required by Sponsor for the purpose of observing Sponsor’s regulatory and compliance requirements for contracting and tracking payments to HCPs.

Under applicable laws and regulations Sponsor may be required to report to governmental institutions or similar organizations certain payments and other transfers of value made directly/indirectly to physicians and hospitals, and that payments related to the Study may fall within the reporting scope. Furthermore, the HCPs should acknowledge that such receiving organizations/institutions may intend to publish such data on a publicly-available website.

7.2 **EFPIA Disclosure Requirements**.

Study Site acknowledges that Sponsor may, in accordance with the joint ‘Principles for Responsible Clinical Trial Data Sharing’ by EFPIA and PhRMA (found at: www.efpia.eu or www.phrma.org), share the Clinical Trial report, related clinical documents, and patient-level Data with third party requestors, subject at all times to compliance with the Applicable Laws and the ICF.

8. **Audits/Inspections/Reporting**

8.1 Personnel from Duke or Sponsor, or their respective representatives (“**Auditor**”), may visit Study Site periodically at mutually agreed, reasonably convenient times, to monitor and/or audit the Study Site facilities and conduct quality audits, responsible sourcing audits, business ethics audits and audits to verify compliance of the terms of this Agreement. Study Site agrees to make all Study documents and Study subjects’ medical records available for comparison. During audits the Study Site shall ensure such access and shall provide reasonable assistance to Duke or Sponsor free of charge in scheduling and carrying out such visits and shall ensure that any Third-Party Institution or other third party will proceed accordingly. During these visits such Auditors may examine documents, facilities, records and any other relevant resources, and the controls and procedures, applicable to the Study, to the extent strictly necessary and to the extent it does not infringe, expose or in any way compromise the Study Site’s security and confidentiality obligations to its patients. Moreover, Duke and/or Sponsor may conduct audits remotely. During such remote audits Study Site is expected to provide documents, or access to documents, electronically as applicable.

Study Site also agrees to cooperate with representatives of the FDA or any other regulatory agency in the event of an inspection of this Study, and will provide the regulatory agency representatives access to the above-described records. In the event Study Site becomes aware that a regulatory agency desires to audit the Participating Investigator, the Study Site or the Study, the Party having such knowledge shall notify Duke and Sponsor promptly by telephone and in writing pursuant to Section 26 (Notices) of this Agreement.

8.2 During and for a period of at least two (2) years after the completion of the Study, Duke shall promptly, which should not exceed thirty (30) days, report to Study Site and Participating Investigator 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 Study Site shall ensure that the Participating Investigator communicate these findings to each Study subject and the IRB.

9. **Indemnification/Liability**:

9.1 Duke shall have no obligation to indemnify the Participating Investigator, Study Site or the Study Site’s agents, employees or representatives for any loss, injury or harm resulting from the Study.

9.2 Sponsor indemnification is provided under separate letter attached hereto as **Exhibit C**.

10. **Insurance:**

Study Site represents and warrants that it has a sufficient general and professional liability insurance program, to fully cover its and the Participating Investigator’s responsibilities within this Agreement.  The Parties agree that such insurance coverage is not less than $3,000,000 per occurrence, $5,000,000 annual aggregate for each of general and professional liability.  Study Site agrees to provide Duke with evidence of the amounts of such coverage upon request.  If Study Site’s insurance coverage is reduced below the aforementioned limits or canceled during the Study, Study Site shall promptly notify Duke in writing, pursuant to Section 26 (Notices) of this Agreement.

11. **Warranties and Applicable Disclaimers:**

Study Site understands and agrees that any Study Drug to be investigated is experimental in nature and that no warranty, either express or implied, is made by Sponsor or Duke regarding the Study Drug.

Study Site warrants to the best of its knowledge that Study Site’s performance of the Study does not infringe rights of any third party, including all intangible rights. In the event Study Site wishes to use any third party’s intellectual property, Study Site is responsible for obtaining all necessary rights and licenses from any such third party.

12. **Debarment Certification**:

The Study Site certifies that:

(i) neither it nor any of its employees conducting research in connection with this Agreement, including the Participating Investigator, is presently, and in the last five (5) years:

(a) been debarred, or received a warning or other regulatory letter alleging violations, pursuant to provisions of the Generic Drug Enforcement Act of 1992 (the “Act”) or any other applicable law, rule or regulation of any authority having jurisdiction over the Study; or

(b) listed on the FDA debarment list found at http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/default.htm, or the Office of Inspector General’s List of Excluded Individuals/Entities at https://oig.hhs.gov/exclusions/exclusions\_list.asp,

(ii) it will not use in any capacity, in connection with the work to be performed under this Agreement, any individual who has been:

(a) debarred, excluded or disqualified by any regulatory agency;

(b) the subject of a disqualification proceeding nor has been disqualified as a clinical investigator pursuant to agency rules;

(c) has been terminated from any investigation or research project by a sponsor for clinical or medical misconduct; or

(d) the subject of any litigation, arbitration, or mediation involving the practice of medicine, or any other proceedings by any board of medical examiners that has imposed any restriction or limitation on the practice of medicine by Study Site or such Study staff.

(e) has been excluded from participation in any government healthcare program, debarred from or under any other federal program, convicted of any offense defined in 42 U.S.C. Section 1320a-7, otherwise deemed ineligible for participation in healthcare programs, nor is aware of any pending actions that would give rise to any such ineligibility

If at any time after execution of this Agreement, the Study Site, the Participating Investigator or any other Study staff is debarred, excluded or disqualified or receives a notice of initiation of disqualification, the Study Site will promptly notify Duke in writing, pursuant to Section 26 (Notices) of this Agreement.

13. **Intellectual Property**:

It is recognized and understood that certain pre-existing inventions and technologies are the separate property of Sponsor, Duke or Study Site and are not affected by this Agreement, and no Party shall have any claims to or rights in such separate inventions and technologies.

**Ownership Rights**. In return for the consideration given to the Study Site hereunder, Sponsor shall be the sole and exclusive owner of all right, title and interest in and to: (a) any inventions, technologies, know-how, ideas, processes, techniques, algorithms, discoveries, improvements, biologics, pharmaceuticals, products, concepts, designs, prototypes, samples, models, technical information, materials, drawings, trade secrets and specifications that (i) are conceived, by Study Site or Study Site personnel (either solely or jointly with employees and/or agents of Sponsor or Affiliates of Sponsor) arise from the Study and represent a reduction to practice of Sponsor’s documented prior conception or (ii) otherwise contain, incorporate or relate to the Study Drug or Confidential Information (collectively, “Inventions”); and (b) Study data.

Study Site shall, and shall cause Study Site personnel to fully and promptly disclose in writing to Sponsor any Inventions, and Study Site, on behalf of itself and Study Site personnel, hereby assigns to Sponsor: (i) all of its intellectual property and proprietary rights, title and interest in and to the Inventions and Study data; and (ii) all rights of action and claims for damages and benefits arising due to past and present infringement of said rights.

Study Site shall execute such documents (and shall cause Study Site personnel to execute such documents) and shall take such other action (and shall cause Study Site personnel to take such other action), at Sponsor’s request and expense (which expense shall be the reasonable and actual documented expenses incurred), as may be reasonably necessary or appropriate to establish, register, record, perfect, preserve, or otherwise effectuate Sponsor’s ownership rights in and to the Inventions and Study data throughout the world.

**License**. Subject to the other provisions of this Agreement, Study Site and Participating Investigator shall have the right to use the Study Site’s own Study data for its own internal noncommercial research and teaching purposes, which shall include publication in accordance with Section 14 but shall not, in any event, include performing activities for, with or on behalf of any for-profit entity.

14. **Academic Publications:**

14.1 Study Site acknowledges that the Study has been designed as a multicenter study and that the data generated from Study Site’s evaluation may not be sufficient to draw meaningful conclusions. For these reasons, Study Site shall not first individually publish, present or otherwise publicly disclose the results of the Study, but rather shall participate in a joint, multicenter publication of the Study results coordinated by Duke. Study Site expressly acknowledges and agrees that the initial and sole right to make publications regarding the combined results of the Study shall rest solely with Sponsor, and that Study Site and Study personnel shall provide reasonable assistance to Sponsor to effectuate such publication.

Study Site and its author(s) shall give Sponsor appropriate credit for any direct contribution made by them, and shall acknowledge Sponsor’s support in all publications and presentations.

However, at the earlier of publication of such joint publication, or if such joint publication is not submitted for publication within twelve (12) months) of Study completion or termination at all sites, Study Site has the right to individually produce and submit a proposed publication, based on Study Site’s Study results, subject to the prior review of Sponsor as described herein.

Study Site shall, and shall require Participating Investigator to, submit any Publication utilizing data generated from this Study to Sponsor for prior review, at least sixty (60) days before such Publication is actually presented, or is submitted for presentation or publication.

Sponsor shall advise Study Site and/or Participating Investigator, as applicable, in writing of any information contained therein which is Confidential Information (other than Study data) or which may impair Sponsor’s ability to obtain patent protection, and Sponsor shall have the right to require Study Site and Participating Investigator to remove specifically identified Confidential Information (other than Study data) and to delay the proposed Publication for up to an additional sixty (60)days to enable Sponsor to seek appropriate patent protection.

Except as provided above, Sponsor shall not have any editorial rights over such Publication, and Study Site and Participating Investigator shall be entitled to determine the authorship and general content (including scientific conclusions and professional judgment) of any such Publication in accordance with appropriate scientific and academic customs.

14.2 Prior to enrollment of the first subject in the Study, Duke shall ensure that the Sponsor registers the Study with www.clinicaltrials.gov, or any equivalent registry, including all information required by the Uniform Requirements for Manuscripts Submitted to Biomedical Journals of the International Committee of Medical Journal Editors in effect as of the date of initiation of the Study (see [www.icmje.org](http://www.icmje.org)).

15. **Use of Name:**

No Party shall, without the prior written consent of the affected Party, use in advertising, publicity or otherwise, the name, trademark, logo, symbol or other image of the affected Party or Sponsor, except for internal reporting requirements. Study Site may disclose the Sponsor’s financial support of the Study as may be required by academic journals and funding agencies.

16. **Press Releases and Public Notices:**

Study Site agrees that they shall not issue, nor allow their employees or agents to issue, any press release, nor initiate any communication of information regarding the Study, written or oral, to the communications media without the prior written consent of Sponsor and Duke. Any written or video or other communications material regarding the Study provided to the Participating Investigator or Study Site by Sponsor or Duke shall not be disseminated to the communications media by the Participating Investigator or Study Site without the prior written consent of Sponsor and Duke.

17. **Effective Date and Term:**

This Agreement shall become effective upon the Effective Date and shall remain in full force and effect until the completion of the Study and satisfaction of all obligations set forth herein unless earlier terminated as set forth below.

18. **Termination of Agreement/Participation:**

Study Site may terminate this Agreement due to the breach or default of Duke by giving thirty (30) days written notice to Duke pursuant to Section 26 (Notices) of this Agreement, provided, however, that such termination shall not take effect if Duke cures such breach or default during the thirty (30) day notice period. Either Party has the right to terminate this Agreement upon thirty (30) days prior written notice to the other Party if the Participating Investigator is unable to complete the Study and the Parties are unable to agree upon a successor. Duke may terminate this Agreement upon thirty (30) days written notice to the Study Site for any reason. Upon termination, Study Site shall promptly deliver all Study data identified as a deliverable in the Protocol to Duke. In the event of such premature termination, other than due to Study Site’s breach of this Agreement, Study Site will be compensated pursuant to Exhibit B herein for all activities properly completed in accordance with the Protocol through the date of termination. Study Site acknowledges that enrollment of subjects into the Study is competitive. Study Site further acknowledges that Duke reserves the right to end subject enrollment under this Agreement when Sponsor determines the desired number of Study subjects for all clinical trial sites has been reached.

19. **Survival:**

Any terms which, by their intent or meaning are intended to survive, will survive termination or expiration of this Agreement. No termination hereunder will constitute a waiver of any rights or causes of action that either Party may have based upon events occurring prior to the termination date.

20. **Relationship of Parties:**

Study Site is operating as an independent contractor under this Agreement and not as an agent or employee of Sponsor or Duke.

21. **Conflict of Interest:**

Study Site, by signing below, warrants and represents that neither it, the Participating Investigator nor any of the Participating Investigator’s immediate family (defined as spouse and children) have any real or perceived conflict of interest in the execution of this Study (e.g., stock or other equity in companies which manufacture agents being tested in this Study) and that participation herein does not conflict with any other obligation to third parties.

22. **Anti-Corruption Representation and Warranty:**

Study Site represents, warrants and covenants, as of the Effective Date to and through the expiration or termination of this Agreement, that it has not and will not, directly or indirectly, offer, promise, authorize, solicit, pay, or give anything of value (including money) to: influence public officials to gain an improper advantage; and induce anyone, including public officials, to violate Anti-Corruption Legislation. “**Anti-Corruption Legislation**” means, as may be applicable, the United Nations Convention Against Corruption, the U.S. Foreign Corrupt Practices Act, the UK Bribery Act, any applicable national laws and regulations implementing the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, and any applicable laws and regulations prohibiting public or commercial bribery, extortion, kickbacks or other unlawful or improper means of conducting business.

23. **Data Protection Laws.** In accordance with Data Protection Laws, Sponsor, may collect, share, process or use certain personal data, as defined in the Data Protection Laws. “Data Protection Laws” means applicable data protection laws, including the regulation 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of Personal Data and on the free movement of such data, and repealing the EU Directive and any applicable laws implementing it and or any later amendments hereof. For clarity, the Parties acknowledge and agree that nothing contained in this Section 23 shall be construed to obligate Study Site or Participating Investigator to comply with any law or regulation not otherwise applicable to Study Site or Participating Investigator.

24. **Assignment**:

This Agreement may not be assigned by Study Site without the prior written consent of Duke.

25. **General Provisions**:

25.1 **Entire Agreement**. This Agreement together with the Exhibits and the Protocol, constitutes the entire understanding between the Parties with respect to the subject matter and supersedes any prior negotiations, representations, agreements and understandings regarding the subject matter.

25.2 **Modifications**. This Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by the Parties.

25.3 **No Waiver**. The failure of any Party to insist upon strict performance of any provision of this Agreement or to exercise any right hereunder shall not constitute a waiver of that provision or right under this Agreement or of any other provision or right hereunder.

25.4 **Severability**. If any provision of this Agreement is declared invalid, illegal or unenforceable, such provision shall be severed and all remaining provisions shall continue in full force and effect.

25.5 **Governing Law**. This Agreement shall be construed and enforced in accordance with the laws of the State of North Carolina.

25.6 **Due Authorization**. The persons executing this Agreement represent that they have the full power and authority to enter into this Agreement on behalf of the entities that they represent.

25.7 **Force Majeure**. If either Party shall be delayed or hindered in, or prevented from, the performance of any act required hereunder for any reason beyond such Party’s direct control, including but not limited to, strike, lockouts, labor troubles, governmental or judicial actions or orders, riots, insurrections, war, acts of God, inclement weather or other reason beyond the Party’s control (a “**Disability**”) then such Party’s performance shall be excused for the period of the Disability. Any Study timelines affected by a Disability will be extended for a period equal to the delay. The Party affected by the Disability shall notify the other Party of such Disability as provided for herein.

25.8 **Third Party Beneficiary**. Each Party expressly acknowledges and agrees that Sponsor shall be a third-party beneficiary of this Agreement and shall be entitled to enforce the provisions hereof that affect it by all remedies available at law or in equity.

25.9 **Counterparts and Electronic Signature**. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same Agreement. Delivery of an executed signature page to the Agreement by facsimile transmission or PDF will be as effective as delivery of a manually signed counterpart.

25.10 **Conflict of Terms**. In the event of any conflict between the terms and conditions of this Agreement and the Protocol or between this Agreement and any of its Exhibits, the terms and conditions of the Protocol shall control with respect to matters of the clinical conduct of the Study, and the terms of this Agreement shall control with respect to all other matters.

26. **Notices**:

Any notices to be given hereunder shall be given by personal delivery, by certified mail, return receipt requested, or by recognized express courier with signature and delivery confirmation. Notice shall be deemed to have been given on the next business day if personally delivered or upon three (5) business days if delivered certified or express mail. Notice shall be given to the respective Party at the addresses listed below.

To Duke:

DCRI

Attention: 8559 ARTEMIS PROJECT LEADER

300 West Morgan Street, Suite 800

Durham, NC 27701

Phone: (919) 668-8300

ARTEMIS\_trial@duke.edu

**With a copy to:**

DCRI, Contracts Management

Attention: ARTEMIS 8559

300 West Morgan St., Suite 800

Durham, NC 27701

Phone: (919) 668-8300

To Sponsor: Novo Nordisk Inc.

Attn: Strategic Resource Management

Reference EX6018-4979

Strategic Operations

800 Scudders Mill Road  
Plainsboro, New Jersey 08536

**with a copy to:**

Novo Nordisk, Inc.  
Attn: Legal Department

Reference EX6018-4979

800 Scudders Mill Road  
Plainsboro, New Jersey 08536

Fax: (609) 919 - 7741

To Study Site:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

To Participating Investigator:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[*Signatures appear on following page*]

The Parties have consented to the terms of this Agreement by signing below.

**Duke University**:

By

Name: David Hill

Title: Director, Finance DCRI

Date:

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_:**

By my signature below I attest that I am authorized to represent the Study Site

in legally binding contracts.

By

Name:

Title:

Date:

# EXHIBIT A

**PROTOCOL**

*(sent under separate cover letter)*

# EXHIBIT B:

**BUDGET AND PAYMENT TERMS**

**Protocol Number**: EX6018-4979

**Protocol Title:** *ARTEMIS - Effects of ziltivekimab versus placebo on cardiovascular outcomes in patients with acute myocardial infarction*

1. **Site Fees**

All fees listed in this Exhibit B are inclusive of Study Site overhead/F&A/IDC if applicable.

|  |  |
| --- | --- |
| **COMPLETION REQUIRED FOR PAYMENTS** | |
| **Payee Name (As Reflected on currently filed W-9):** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**TABLE 1 –**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Initial Fees*** | ***Description*** | ***Amount*** | Payment After |
| Administrative Start Up Fee (Non-refundable, one-time fee) |  | $3,000.00 | Upon Study Site receipt of activation letter by Duke |
| ***Study Site Fees*** |  | | |
| Local IRB Fees | Reimbursement for costs incurred by Local/ Institutional IRB, if applicable. Study Sites utilizing Sponsor -chosen central IRB will have IRB fees paid directly by Sponsor. | Actual costs | Upon Sponsor third-party vendor receipt of Invoice, inclusive of supporting documentation |
| Reimbursable Recruitment Fees. Requires Duke’s prior written approval. | Fees for activities and associated expenses related to recruiting Study subjects | Up to $2,500.00\* | Upon invoice from Study Site with supporting documentation; may also include IRB approval. |
| Reimbursable Retention Fees. Requires Duke’s prior written approval. | Fees for retention related expenses and activities. | Up to $5,000.00\* | Upon Invoice from Study Site with supporting documentation; may also include IRB approval |
| Patient/Caregiver Meals and Lodging Expense (for travel greater than 50 miles roundtrip).\*\* Requires Duke’s prior written approval. | Study Site is eligible for reimbursement of Subject and/or Caregiver lodging and meal expense for subjects who reside outside of 50-mile roundtrip of the treatment site.  If expenses are less than the amount specified, Sponsor will only reimburse for the actual cost of the lodging and/or meals. | Not to exceed up to $350.00/night. | Upon invoice from Study Site with presentation of verifiable documentation and valid receipt(s) of expense(s). |
| SAEs and AEs requiring additional data collection. | Study Site is eligible for reimbursement of all Adverse Events of Special Interest requiring additional data collection (AESIs), Serious Adverse Events (SAEs), and all events requiring adjudication, as applicable. | $150.00 per reportable event. | Upon invoice and verification of appropriate event recording and receipt of proper documentation. Payment will be issued for each AESI/SAE or adjudicated event upon the Study Site’s completion of all follow-up information and Duke’s acceptance of the documentation and Study Site invoice. |
| Unscheduled On-site Visit – Hypersensitivity Central Lab Sample Collection (Initial or Follow up), as applicable |  | $816.75 per visit. | Upon Invoice from Study Site with supporting documentation. |
| Hypersensitivity Central Lab Collection at Scheduled On-site Visit, as applicable (Initial or Follow up) |  | $265.00 per visit. | Upon Invoice from Study Site with supporting documentation. |
| Unscheduled Visit | For reasonable and medically necessary unscheduled onsite visits | Up to $901.75. | Upon Invoice from Study Site with supporting documentation (source document and/or progress note of visit required to be submitted with invoice). Subject to review and approval by Duke. |
| Lost to Follow up Contact Attempts as identified by Sponsor or Duke at End of Study. Only applicable for patients that have been deemed potentially lost -to-follow-up at the time of the Trial Stop Date. |  | Up to $580.00 per patient. | Upon Invoice from Study Site with supporting documentation; subject to review and approval by Duke. |

\*Study Site may be eligible for additional reimbursement of this item beyond the initial allotment of funds, if prior approval is obtained in writing from the appropriate Duke trial team member before the spend occurs.

\*\*Any subject travel, meals, and lodging arranged and paid by the Sponsor’s designated third-party travel reimbursement vendor, Colpitts, will not be eligible for separate reimbursement to Study Site or Study subjects. If subject travel reimbursements are to be handled by the Study Site, additional Study subject travel beyond the Subject Stipend will be reimbursed only with the Study Site obtaining prior approval from Duke in writing from the appropriate Duke team member **before** the travel occurs. The mode of travel approved will be the least expensive unless otherwise authorized. Car mileage reimbursement will be made based in accordance with the current IRS Federal Business Mileage rate.

1. **PER PATIENT FEES**

**TABLE 2 –**

|  |  |
| --- | --- |
| **Visit Payment Schedule** | **Payment Per Patient Per Visit Completed \*\*\*** |
| Visit 1 (Hospitalization) – Screening | $1,967.00 |
| Visit 2 (Hospitalization) – Randomization | $2,917.50 |
| Visit 3 | $1,627.25 |
| Phone Visit 4 | $611.75 |
| Visit 5 | $1,503.25 |
| Visit 6 | $1,760.75 |
| Visit 7 | $1,327.25 |
| Visit 8 | $1,861.25 |
| Phone Visit 9 | $852.75 |
| Visit 10 | $1,819.25 |
| Phone Visit 11 | $852.75 |
| End of Treatment | $1,912.75 |
| Follow up | $1,376.25 |
| **Per Patient Cost (inclusive of Site overhead)** | **$20,389.75** |

|  |  |
| --- | --- |
| **Phone Visits Converted to On-Site Clinic Visits** | **Payment Per Patient Per Visit Completed**\*\* |
| Visit 4 | $836.25 |
| Visit 9 and/or Visit 11 | $967.25 |

\*\*Payment will not be provided for both a Phone Visit and an On-site Visit for the same Visit. If it is deemed appropriate or necessary for the patient to be on-site for visit 4, 9, or 11 only the On-Site Clinic Visit cost will be paid.

\*\*\* The total amount of each payment will be determined by data entered into the Electronic Data Capture system (EDC). A completed visit includes the proper completion of all protocol activities and delivery to Sponsor of complete and accurate CRF data for that visit

Per patient fees are inclusive of dry ice expenses, patient stipend amount, and retention efforts, as applicable.

For any on-site clinic visit outlined in the above Table 2 that is converted to a phone visit, if allowed locally, the payment amount provided will be **$787.75**.

Should the event rate be lower than anticipated, visits will continue as stated in the protocol. Payments for completed, repeat visits will be the same as the initial visit rate listed in Table 2.

1. Enrollment. Study Site and Participating Investigator shall use reasonable efforts to recruit and enroll up to **fifteen** (**15**) evaluable Study subjects into the Study within a reasonable timeframe after commencement of the Study at Study Site and in accordance with the Protocol. Notwithstanding the foregoing, the enrollment requirement may be changed at the sole discretion of Sponsor or Duke through written communication from Sponsor or Duke.

**Additionally, Study Site and Participating Investigator may be authorized to enroll additional Study subjects over the above stated amount upon prior written permission of the Sponsor or Duke.**

1. SCREEN FAILURE PAYMENTS

To be qualified for payment, screen failures must be monitored and verified by Sponsor. Reimbursement will be made for validated and Sponsor approved screen failures unrelated to medical history as set forth in this agreement.

Study Site will be reimbursed up to a maximum of seven (7) confirmed screen failures over the duration of the Study at the rate of Visit 1 as specified within Table 2. Any additional screen failures must be approved for payment in writing by Sponsor/Duke.

**STUDY PAYMENT TERMS**

1. Premature Termination. In the event a subject terminates or is terminated early from the Study, Study Site will be paid for visits completed in accordance with the Table 2 – Visit Payment Schedule set forth in this Exhibit B.

In the event of premature termination of this Study, Study Site will be paid for milestones completed in accordance with the milestone payment schedule set forth in this Exhibit B.

If Study Site’s participation is terminated because of failure to enroll any patients, Study Site/Participating Investigator will not be entitled to reimbursement or payment for any costs that were incurred prior to such termination, except to the extent such costs as set forth expressly in this Agreement as upfront, non-refundable payments, such as initial non-refundable fees and IRB fees incurred directly by Study Site, or those costs that are approved in writing by Duke.

1. Subject Stipends. Any payment(s) of stipends to subjects shall be made by the Study Site directly to the subject(s).
2. Payment Schedule. Payments are processed monthly. The monthly payment cutoff date for EDC entry is the 25th of each month. If the data is entered after the 25th of the month the visit will be paid in the subsequent payment cycle. The cutoff date for pass through invoices is the 10th of the month.
3. Incomplete Data and Protocol Deviation. Sponsor reserves the right to withhold payment for any subject (a) for whom complete data has not been obtained, or (b) who has deviated from the Protocol resulting in invalid data. The foregoing does not include deviations related to patient safety.
4. Final Payment. Payment Administrator shall reconcile and reimburse Study Site, or other appropriate payee, any remaining amounts upon:
5. Verification of completed subject visits;

ii. Final acceptance by Sponsor of all CRF/eCRF pages;

iii. Resolution of all data clarifications issued; and

iv. Satisfaction of all other applicable conditions set forth in this Agreement.

Study Site/Participating Investigator will have thirty (30) days after the receipt of the final payment to dispute any payment discrepancies and to submit any final invoices for pass-through expenses.

1. Refunding Payments. In the event that either Study Site or Payment Administrator determines that Study Site received any excess payment, the Party discovering such overpayment shall notify the other Party and Study Site shall refund the excess funds to Payment Administrator within thirty (30) days of such determination.

All refund checks from Study Site must be mailed to:

Clinical Financial Services, LLC dba IQVIA Clinical Trial Payments

101 N Independence Mall East

Attn: Box 3101

Philadelphia, PA 19106

Please include complete study number (EX6018-4979), Study Site number and Participating Investigator name.

# (End of Exhibit B)

**EXHIBIT C**

**Sponsor Letter of Indemnification**