INVESTIGATOR SPONSORED STUDY AGREEMENT

This Investigator Sponsored Study Agreement ("Agreement"), effective as of _____, 202_ ("Effective Date"), is entered into by and between Sanofi US Services Inc., 55 Corporate Drive, Bridgewater, NJ 08807, a Delaware corporation ("Sanofi"), and _____, a _____ organized and existing under the laws of _____ ("Institution"). Each of Sanofi and Institution are referred to herein as a "Party" or collectively as the "Parties."

WHEREAS, Sanofi is a research based pharmaceutical company with an interest in research projects related to the development or further investigation of pharmaceutical products, therapies for human disease, associated devices and biomarkers;

WHEREAS, Institution is an educational, healthcare and research facility with expertise in the area of health research;

WHEREAS, Principal Investigator is an employee or agent of Institution;

WHEREAS, Sanofi wishes to support a research project to be performed by and under the direction of _____ ("Principal Investigator") at Institution; and

WHEREAS, Principal Investigator wishes to perform such research, in accordance with the terms and conditions set forth in this Agreement.

NOW THEREFORE, in consideration of the promises and mutual covenants set forth herein, the Parties hereby agree as follows:

1. DEFINITIONS

A. "Affiliate" of a Party shall mean any person or entity directly or indirectly controlling, controlled by, or under common control with a Party, and for this purpose, "control," "controlling" and "controlled by" shall mean the ownership and control of more than fifty percent (50%) of the outstanding voting securities or interest in capital or profits of any person or entity.

B. "Invention" shall mean any invention or discovery that is made by Solely one or more employees, contractors, students, agents and/or, if applicable, Affiliates, of Institution as a result of the performance of the Study. As used in this definition of Invention, "Solely" shall mean without inventive contribution by Sanofi's employees, contractors, Affiliates or collaborators of Sanofi, as defined by the United States patent laws.

C. "Product" shall mean dupilumab, marketed in certain countries under the

tradename Dupixent™.

D. "Protocol" shall mean the protocol, attached hereto as Exhibit A, which may be amended upon mutual agreement in writing by the Parties and signed by a duly authorized representative of each Party.

E. "Study" shall mean the Institution initiated study to be performed under the direction of the Principal Investigator under this Agreement and as described in the Protocol, attached hereto in Exhibit A, as may be amended from time to time.

2. STUDY

A. Scope of Study**.** The scope of the Study to be performed under the direction of the Principal Investigator under this Agreement shall be as described in the Protocol, attached hereto as Exhibit A or any revisions of Exhibit A mutually agreed upon in writing in an amendment attached hereto and signed by a duly authorized representative of each Party. Institution shall cause the Principal Investigator and any employees, students, collaborators, agents and other persons involved in the Study to be made aware of and comply with Institution's obligations under this Agreement.

B. Subcontractors and Subsites. Institution may contract with (i) third parties in connection with the Study and (ii) other sites ("Subsites") to conduct the Study in accordance with the Protocol and the terms of this Agreement. Institution will be responsible for the acts, omissions, defaults or negligence of any subcontractors, Subsites or agents as if they were the acts, omissions, defaults or negligence of itself. Institution will ensure that, so far as possible, all duties and obligations it has under this Agreement will be included in any contract that it enters into with any subcontractor, Subsite or agent.

C. Compliance with Protocol and Applicable Law. The Study will be conducted in accordance with all applicable local laws including those specified in local Annex A hereto (i) the Protocol, (ii) this Agreement, (iii) all applicable provisions any and all federal, state and local laws, rules, regulations, orders and guidances including those specified in the local annex(es) attached hereto and all applicable Good Clinical Practice guidelines. If Sanofi is supplying any Product under this Agreement, Institution shall maintain accountability and traceability of Product under relevant statutes and regulations. Institution shall be the sole regulatory sponsor of the Study, and shall be solely responsible to perform all responsibilities of a regulatory sponsor under applicable laws, rules, regulations, orders and guidances (including, as applicable, Ethics Committees and Investigational Review Board ("IRB") approval, filing and maintenance of Investigational New Drug ("IND") applications and postings on clinicaltrials.gov or any other governmental website).

D. Protocol Amendments, Informed Consent and Regulatory Filings. Institution shall submit (i) any proposed amendment or change to the Protocol and (ii) any proposed filings,

amendments or other submissions to the IRB, IND, Health Authority and/or Member State to Sanofi for scientific and medical review at least thirty (30) days prior to submission. If regulatory approval(s) is required, Institution shall provide Sanofi with a copy of the applicable IRB, Health Authority and/or Member State approval for the Study. Upon Sanofi's request, Institution shall provide Sanofi with any other proposed or submitted regulatory filings (e.g. IND) in connection with the Study. Institution shall be solely responsible for the proper submission of any such amendment or change to the Protocol to regulatory authorities and any filings, amendments or other submissions to the IRB, IND, Health Authority and/or Member State. If the Study includes human subjects, Institution will obtain from all subjects entered into the Study, a properly executed informed consent form that complies with all applicable laws, regulations, guidelines and IRB approval, which shall further state that Sanofi is supporting the Study and will have access to all resulting data, results and reports. For the avoidance of doubt, the parties will enter into a separate data protection agreement, on a form provided by Sanofi, prior to sharing any protected health information or personally identifiable information. Sanofi shall have no obligation to participate in the development of, or to review or comment on, any informed consent form.

E. Pharmacovigilance Reporting. Institution and Principal Investigator shall comply with all pharmacovigilance specifications, reporting and other obligations as set forth in Exhibit D.

F. Limited Rights to Use Sanofi Product. Any Product provided by Sanofi hereunder shall be used solely for the purposes of carrying out the Study and for no other purpose, and in accordance with the Protocol. Institution and Principal Investigator will not attempt to reverse engineer or sequence any biologic or determine the chemical structure of any Product, or chemically or biologically modify any Product supplied by Sanofi. No Product shall be transferred to any third party or to any other person not specifically engaged in the conduct of the Study. Neither the Principal Investigator or Institution will bill any person, program or organization for any Product received under this Agreement.

3. SANOFI SUPPORT

A. Financial Support. Sanofi shall pay Institution the Study support payments set forth in Exhibit B attached hereto. No other payment shall be paid by Sanofi to Institution except as otherwise approved in writing by Sanofi. Prior to payment by Sanofi, Institution must submit an invoice to Sanofi, no earlier than the applicable milestone date set forth in Exhibit B, which shall reference the applicable purchase order number provided by Sanofi to Institution (each, an "Invoice"). The preferred submission format for invoices is Sanofi's Electronic Data Capture System (iEnvision) iEnvision (envisionpharma.com) Alternatively, hard copy invoices shall be addressed to:

Sanofi US Services Inc.
PO Box 696410
San Antonio, TX 78269

United States

Approved Invoices shall be paid by Sanofi via within thirty (30) calendar days after Sanofi receives a proper Invoice from Institution which payment shall be sent to the following:

B. Supply of Sanofi Product and Placebo. Any Product and/or placebo provided by Sanofi hereunder will be provided at no cost and detailed in Exhibit C, Conditions of Product Supply, attached hereto. Sanofi will provide and Institution shall comply with the conditions of supply of any Product and/or placebo as set forth in Exhibit C. Sanofi's obligation to provide Product and placebo hereunder is subject to constraints on the availability of Product and placebo, including Sanofi's ability to manufacture the Product and to adequately supply the needs of the overall patient population.

C. Basis of Sanofi Study Support. Sanofi's support hereunder is not conditioned on any pre-existing or future business relationship between Sanofi and Institution or any investigator (including Principal Investigator) at Institution. Such support is also not conditioned on any business or other decisions any investigator (including Principal Investigator) or Institution has made, or may make, relating to Sanofi of Sanofi products.

4. MEETINGS AND REPORTS

A. Status Reports and Final Report. The Principal Investigator shall provide Sanofi two (2) status updates per year on key Study milestones as well as any proposed amendments to the Protocol, and shall also provide a written update at the time of invoicing for any milestone based payment that becomes due. Within six (6) months of the completion of the Study the Principal Investigator shall provide Sanofi with a written, detailed report of the data, results and conclusions of the Study ("Study Results"). Sanofi and its Affiliates shall have a perpetual, non-exclusive right to use Study Results, subject to the terms and conditions of Section 6.D.. For clarity, Sanofi support for the Study is contingent upon receipt of reports in this Section 4.A. Subject to mutual agreement, the Principal Investigator will have opportunity to present Study Results to Sanofi for review and discussion.

B. Electronic Capture Tool. The Principal Investigator shall upload reports, regulatory documents and Study Results for Sanofi's receipt by the methods reasonably designated by Sanofi, which may for example commercially available knowledge management platforms such as VisionTracker™.

C. Audit. During the term of this Agreement and for a period of three (3) years after termination or expiration of this Agreement, upon thirty (30) days' notice to Institution, Sanofi (or its appointed representatives) shall have the right, during normal business hours, to conduct an audit of Institution's operations and records but only to the extent these relate to the performance of the obligations undertaken by Institution and Principal Investigator under this Agreement, including applicable Good Clinical Practices, regulatory concerns, and handling of Product.

5. PUBLICATION

Publication of Study Results is one of the primary missions of Institution. Sanofi agrees that Institution shall be permitted to present at symposia, national or regional meetings, and to publish the Study Results in abstracts, posters, journal articles, theses or dissertations (each, a "Publication"); provided, however, that Institution agrees to submit to Sanofi for its prior review and comment, any Publication utilizing the Study Results at least thirty (30) calendar days prior to the proposed date for submission of such Publication. Sanofi reserves the right to remove Sanofi Confidential Information (as defined in Section 11.A.) from any Publication. Additionally, Sanofi may delay any Publication for up to an additional sixty (60) calendar days in order to file a patent application or take such other measures as Sanofi deems necessary to establish and preserve its proprietary rights. Proper acknowledgment will be made for the support and contributions of each Party to the Study Results being published and acknowledgment of the contributions of Sanofi or any collaborator of Sanofi (including, if applicable, Regeneron Pharmaceuticals) of any Product in accordance with generally accepted scientific standards.

6. INTELLECTUAL PROPERTY

A. Background Technology. Nothing contained in this Agreement shall affect, either directly or by implication, estoppel, or otherwise, the pre-existing rights of either Party in intellectual property developed outside of this Agreement. All such intellectual property shall remain the property of its owner and the option granted to Sanofi in this Agreement shall not apply to such intellectual property.

B. Ownership of Inventions. Inventions shall be solely owned by Institution.

C. Non-exclusive License. Sanofi and its Affiliates are hereby granted a perpetual, worldwide, non-exclusive, sublicensable, fully-paid up, royalty-free license to Institution's interest in any Invention and the Study Results.

D. Sanofi Option to Inventions. Each Party shall promptly notify the other Party, in writing and in confidence, of any Invention of which it becomes aware. Institution hereby grants to Sanofi and its Affiliates an exclusive option to negotiate a worldwide, sublicensable, exclusive license, to Institution's interest in each Invention. Such option shall be for a six (6) month period commencing on the filing date of the priority application claiming any such Invention. If Sanofi

or one of its Affiliates elects to exercise its option, the Parties shall endeavor in good faith six (6) months following the date of such exercise ("Negotiation Period") to negotiate the terms of a license, including terms common in such industry-institution licenses. The Negotiation Period may be extended by mutual written agreement of the Parties. In the event that the Parties fail to reach agreement on license terms within the Negotiation Period, including any extensions thereof, then all of Institution's rights to such Invention shall remain with Institution without further obligation to Sanofi and Institution shall thereafter be free to negotiate and enter into a license with any third party. No payments associated with patent costs will be due to Institution unless Sanofi exercises its option for an exclusive license hereunder.

E. Prosecution. Institution shall be responsible for the preparation, filing, prosecution and maintenance of Institution Inventions. Institution shall appoint patent counsel and control the prosecution. During any period in which Sanofi holds an active option or license to an Institution Invention, Sanofi shall have the right to comment upon and advise Institution as to the preparation, filing, prosecution and maintenance of the applicable patent applications. Institution's counsel shall provide copies to Sanofi of all official correspondence (including, but not limited to, applications and office actions), as well as any Institution responses thereto, in a timely fashion.

7. INDEMNIFICATION

A. Indemnification by Sanofi. The Study supported by Sanofi is not designed, sponsored, or managed by Sanofi and therefore Sanofi provides no indemnification for Study design, implementation or injury as a result of the Study. Notwithstanding the foregoing sentence, Sanofi hereby agrees to indemnify, defend, and hold harmless Institution, its Affiliates, and their respective trustees, officers, directors, agents, successors, employees, students and permitted assigns (collectively, the "Institution Indemnified Parties"), from and against any and all losses, expenses, costs (including reasonable attorneys' fees), liabilities, damages, claims, suits or proceedings (each a "Claim") brought by a third party arising out of (i) Sanofi's use of the Study Results or Inventions, (ii) the gross negligence, willful misconduct, fraud or misrepresentation by Sanofi, (iii) any manufacturing defect in the Product provided by Sanofi pursuant to Section 3.B and Exhibit C, if applicable, and (iv) Sanofi's material breach of this Agreement or applicable law or regulation; provided, however, Sanofi's indemnification obligations hereunder shall not apply to the extent that such Claim is attributable to any Institution Indemnified Party's (x) negligence or wrongful acts or omissions, willful malfeasance, fraud or misconduct, (y) failure to use the Product in accordance with the Protocol, or (z) material breach of this Agreement or applicable law or regulation.

B. Indemnification by Institution. Institution hereby agrees to indemnify, defend, and hold harmless Sanofi, its Affiliates, and their respective officers, directors, agents, successors, employees and permitted assigns (collectively, the "Sanofi Indemnified Parties"), from and against any and all Claims arising out of Institution's or Principal Investigator's (i) use of Study Results or Inventions, (ii) gross negligence, willful misconduct, fraud or misrepresentation; (iii) failure to

use the Product in accordance with the Protocol, and (iv) material breach of this Agreement or applicable law or regulation, provided, however, Institution's indemnification obligations hereunder shall not apply to the extent that such Claim is attributable to any Sanofi Indemnified Party's (x) negligence or wrongful acts or omissions, willful malfeasance, fraud or misconduct, (y) supply of Product having manufacturing defects, or (z) material breach of this Agreement or applicable law or regulation.

C. Notification of Claims. The Party seeking indemnification hereunder ("Indemnified Party") shall notify the other Party ("Indemnifying Party") in writing of any asserted claim as soon as practicable. Failure to provide such notice, which substantially prejudices the Indemnifying Party's ability to defend such claim or action, may invalidate any obligation of indemnification. The Indemnified Party must authorize and permit the Indemnifying Party to exercise sole control of the defense and disposition of any claim or action, including all decisions related to litigation, appeal or settlement; provided, however, that the Indemnifying Party shall not settle any claims or actions that would be deemed to confess wrongdoing on the part of the Indemnified Party without the prior written consent of the Indemnified Party, which consent shall not be unreasonably withheld. Notwithstanding the foregoing, the Indemnified Party shall nevertheless be entitled to retain separate counsel at its own cost to participate in such matter; however, the Indemnifying Party shall have sole case management authority. Each Party hereto shall cooperate with the other in every reasonable way to facilitate the defense of any such claim.

8. REPRESENTATIONS

A. Mutual Representations. Each Party represents to the other that (i) it is an organization duly organized, validly existing and in good standing under the laws of its state or country of formation; (ii) it has the right and authority to execute and deliver this Agreement and to perform its obligations contemplated hereunder; (iii) this Agreement is a legal, valid and binding agreement of the Party and enforceable against it; (iv) the execution and delivery of this Agreement will not, to each Party's knowledge, violate any statute, regulation, law or any other restriction upon the Party; (v) it has secured all requisite authorizations and approvals necessary for the execution, delivery and performance of this Agreement; and (vi) it is not subject to any restrictive obligations imposed by any third party which would prevent or impair its ability to enter into this Agreement or fulfill its obligations hereunder, nor will it knowingly enter into any agreement with any other party that would in any way prevent it from performing its obligations under this Agreement.

B. Institution Representations. Additionally, Institution represents and covenants to Sanofi as follows:

(i) neither it nor any individual employed or engaged by Institution in connection with the Study have ever been and are not currently (a) under investigation for debarment or debarred pursuant to federal, regional, state law, local law or regulation; (b) excluded by government agency from participation in any government sponsored or

controlled health care program; or (c) otherwise disqualified or restricted by the any regulatory authority, nor will Institution knowingly utilize any debarred, excluded or disqualified personnel to perform the Study hereunder;

(ii) it will notify Sanofi immediately in the event any investigation or proceeding for debarment, exclusion or disqualification is initiated against Institution or any individual employed or engaged by Institution that is performing the Study hereunder;

(iii) it shall perform the Study in compliance in all material respects with all applicable federal, regional, state and local laws, rules and regulations;

(iv) it has notified Sanofi of all encumbrances integral to the conduct of the Study that could reasonably impact Sanofi's decision to enter into this Agreement;

(v) it shall use reasonable efforts to perform the Study in accordance with the terms and conditions of this Agreement;

(vi) it is the sole sponsor of the Study;

(vii) it has not and will not receive any financial support or other renumeration from any third party (other than from Sanofi as set forth in this Agreement) in connection with the Study; and

(viii) it shall not knowingly infringe any patent or other proprietary right of any third party in its conduct of the Study or by providing the Study Results pursuant to this Agreement.

C. Disclaimer of Warranties. EXCEPT AS OTHERWISE SET FORTH IN THIS AGREEMENT, INSTITUTION'S CARRYING OUT OF THE STUDY HEREUNDER, AND PROVISION OF STUDY RESULTS HEREUNDER, IS DONE "AS-IS" WITH NO REPRESENTATION OR WARRANTY OF ANY KIND, AND EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, INSTITUTION HEREBY DISCLAIMS ANY AND ALL WARRANTIES (INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE) TO THE MAXIMUM EXTENT PERMISSIBLE BY LAW.

9. LIMITATION OF LIABILITY

NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OF ANY KIND, REGARDLESS OF THE FORM OF ACTION WHETHER IN CONTRACT, TORT (INCLUDING WITHOUT LIMITATION NEGLIGENCE), STRICT LIABILITY, OR OTHER

LEGAL OR EQUITABLE THEORY, EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES; PROVIDED, HOWEVER, THIS LIMITATION OF LIABILITY SHALL NOT BE CONSTRUED TO LIMIT A PARTY'S LIABILITY WITH RESPECT TO ITS INDEMNIFICATION OBLIGATIONS SET FORTH IN SECTION 7 OR WITH RESPECT TO ANY BREACHES OF A PARTY'S OBLIGATIONS OF CONFIDENTIALITY SET FORTH IN SECTION 11.

10. PUBLICITY

No Party shall use the other Party's name, trademark, service mark, or logo, or that of its Affiliates, or any adaptation thereof, or the name of the Principal Investigator or other researcher(s) of the other Party in any advertising, promotional or sales literature without the prior written approval of the other Party. This restriction shall not apply to: (i) usage permitted in accordance with the terms of this Agreement; (ii) annual or other periodical reports prepared by either Party in the normal course of business; and (iii) any information required by law to be disclosed. In addition, the Parties may acknowledge Sanofi's support for the Study being conducted under this Agreement.

11. CONFIDENTIALITY

A. Sanofi Confidential Information. Institution acknowledges and agrees that any data, know-how, documents, materials or information of any type whatsoever, in whatever form or medium, whether or not marked as "confidential" and/or "proprietary", including but not limited to, any information concerning or relating to the property, products, research, technology, and business and affairs of Sanofi or its Affiliates, that is disclosed or provided by or on behalf of Sanofi to Institution in connection with the Study, and which is not Institution Confidential Information (as defined in Section 11.B.) shall be deemed to be confidential information of Sanofi (collectively, "Sanofi Confidential Information"). Study Results are not considered Sanofi Confidential Information, but are subject to the requirements set forth in Section 5 regarding publication.

B. Institution Confidential Information. Sanofi acknowledges and agrees that any data, know-how, documents, materials or information of any type whatsoever, in whatever form or medium, whether or not marked as "confidential" and/or "proprietary", including but not limited to, any information concerning or relating to the property, products, research, technology, and business and affairs of Institution or its Affiliates, that is disclosed or provided on behalf of Institution to Sanofi in connection with the Study, and which is not Sanofi Confidential Information shall be deemed to be confidential information of Institution (collectively, "Institution Confidential Information"). "Confidential Information" means Sanofi Confidential Information and Institution Confidential Information.

C. Restrictions on Use of Confidential Information. Except as otherwise expressly provided herein, the Party receiving Confidential Information ("Receiving Party") from the other Party ("Disclosing Party") shall (i) hold such Confidential Information in strict confidence; (ii) not disclose such Confidential Information to any third party, except in the case of Institution, to its Affiliates, agents, bona fide collaborators and subcontractors who have a need to know in order to conduct the Study; and except in the case of Sanofi, to Affiliates, agents, subcontractors and bona fide research, development and/or commercialization collaborators, provided, however, that such third parties agree in writing to abide by the confidentiality provisions at least as stringent as those set forth herein; (iii) use such Confidential Information only as necessary to conduct the Study and not for any other purpose, subject to Sanofi's rights to use the Study Results and Inventions under the Agreement; (iv) upon termination of this Agreement, destroy or return to the Disclosing Party, at the Disclosing Party's option, all tangible Confidential Information in its possession and in the possession of any Affiliates, agents and subcontractors, subject to the Receiving Party's right to retain one (1) copy of the Confidential Information in its secure file as a record of its obligations under this Agreement and further provided that back-up copies of electronic documents that are created by the Receiving Party in the ordinary course of business will remain within the Receiving Party's electronic systems until deleted in the ordinary course of business and in accordance with applicable laws and regulations; and (v) protect Confidential Information received from disclosure with at least that degree of care used by the Receiving Party in dealing with its own confidential information of a similar nature and shall take reasonable steps to minimize the risk of an unauthorized disclosure of Confidential Information.

D. Exceptions to Confidential Information. Notwithstanding the foregoing, Confidential Information shall not include information which: (i) is or hereafter becomes available to the public other than by reason of any breach hereof; (ii) was already known to the Receiving Party, prior to the date of disclosure; (iii) is disclosed to the Receiving Party by a third party who has the right to disclose such information without any obligations of confidentiality; (iv) is developed by or on behalf of the Receiving Party independently, without reliance on Confidential Information received hereunder, as demonstrated by written records; or (v) is otherwise required to be disclosed by the Receiving Party in order to comply with applicable legal requirements of a public authority, law, rule of court or regulation; provided that, (a) the Receiving Party promptly notifies the Disclosing Party of the obligation to disclose in order to allow the Disclosing Party to object or seek a protective order; (b) the Receiving Party only discloses the minimum amount of Confidential Information that is necessary to comply with the required disclosure; and (c) such information remains Confidential Information in accordance with the terms of this Section 11 for all other purposes.

E. Restricted Period. These restrictions upon disclosure and use of Confidential Information shall continue during the Term and for a period of five (5) years thereafter.

12. INDEPENDENT CONTRACTOR

Neither Party shall be or be deemed to be employees or agents of the other. Neither Party is authorized to act as an agent for the other for any purposes and shall not act on behalf of the other Party or enter into any contract, warranty or representation as to any matter.

13. NOTICES

Any notices to be given hereunder shall be sufficient if signed by the Party giving same and either:

(i) mailed certified mail return receipt requested, or

(ii) made by overnight delivery.

If to Sanofi:

_____

_____

_____

With a copy to:

Sanofi US Services Inc.
55 Corporate Drive
Bridgewater, NJ 08807
Attention: General Counsel

If to Institution:

_____

_____

_____

Attn: _____

Notices mailed shall be deemed given on the date postmarked on the envelope. Notices sent by overnight carrier shall be deemed given on the date received by such carrier, as indicated on the shipping receipt.

14. TERM AND TERMINATION

A. Term. This Agreement shall be effective as of the Effective Date and shall continue in full force and effect for _____ years from the Effective Date ("Term") unless earlier terminated in accordance with this Section 14, or extended upon mutual written agreement of the Parties.

D. Termination. Either Party may terminate this Agreement (a) immediately upon written notice to the other Party if necessary to protect the health, safety or welfare of subjects enrolled in the Study, (b) a material breach of this Agreement by the other Party upon thirty (30) days written notice to the other Party, or (c) upon thirty (30) days written notice to the other Party, for convenience at either Party's sole discretion.

E. Effects of Termination. Upon termination, Institution will immediately stop enrolling subjects into the Study and determine the appropriate manner to cease conducting Study procedures and administration of Product to subjects already in the Study. All unused Product at the time of Study completion or termination shall be returned to Sanofi as directed by Sanofi.

15. ENTIRE AGREEMENT; MODIFICATION

This Agreement, including any exhibits and Annex A attached hereto, constitutes the entire understanding and agreement between the Parties with respect to the subject matter covered herein and supersedes any and all prior agreements, understandings, covenants, promises, warranties and representations, oral or written, express or implied, between the Parties that relates to the subject matter hereof. This Agreement may not be amended or supplemented in any way except in writing, dated and signed by authorized representatives of each Party.

16. INSURANCE

A. Institution Coverage. Institution shall, at its own expense, provide and keep in full force and effect during the Term and for a period of two (2) years following the date of termination, the following kinds and minimum amounts of insurance, or self-insurance, as permitted by law:

(i) Commercial general liability insurance which shall include bodily injury, property damage, independent contractor coverage, completed operations or products coverage, blanket contractual, and broad-form property damage with limits of at least $2,000,000 per occurrence and in aggregate.

(ii) Professional liability insurance covering the Principal Investigator with limits of at least $1,000,000 per occurrence and $3,000,000 in aggregate.

B. Sanofi Coverage. Sanofi shall maintain general liability (including products

liability insurance) with minimum limits of $1,000,000 per occurrence and $3,000,000 in the aggregate to cover its indemnification obligations under this Agreement.

C. Evidence of Coverage. Upon written request of either Party, the other Party shall provide copies of certificates of insurance, evidencing the coverage required hereunder.

17. SURVIVORSHIP

The provisions of Sections 2.B., 2.C., 4.A., 4.C., 5, 6, 7, 9, 10, 11, 12, 13, 16, 17, 18, 19, 20, 21 and 22 shall survive any expiration or termination of this Agreement.

18. GOVERNING LAW

This Agreement and all claims relating to or arising out of this Agreement, or the breach thereof, whether based in contract, tort or otherwise, shall be governed and construed in accordance with the laws of the state or country designated as the Institution's address in the first paragraph of this Agreement without regard to its conflict of laws, rules or principles.

19. SEVERABILITY; WAIVER

The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement. Any delay or waiver by a Party to declare a breach or seek any remedy available to it under this Agreement or by law will not constitute a waiver as to any past or future breaches or remedies.

20. ASSIGNMENT

Institution may not assign or transfer this Agreement or any part hereof without the express written consent of Sanofi. Sanofi may assign its rights and obligations under this Agreement without the consent of Institution.

21. EXCUSABLE DELAYS

Neither Party will be responsible for any failure or delay in performance of this Agreement if the failure or delay is due to an event beyond the reasonable control and without the fault or negligence of the Party seeking to excuse performance, including without limitation, pandemic, epidemic, acts of God, acts of terrorism, war, labor disputes and strikes, fire, flood, riot, unforeseen delays in third-party provided transportation or communications ("Force Majeure Event"). Any

Party seeking to excuse or delay performance due to a Force Majeure Event under this Section 21 will provide detailed written notice to the other Party of the nature and anticipated duration of the delay. A Party claiming the benefit of a Force Majeure Event shall use reasonable efforts to avoid or overcome the causes affecting performance and diligently fulfill all outstanding obligations within thirty (30) calendar days. In the event that any such Force Majeure Event continues for in excess of sixty (60) calendar days, either Party shall have the right to terminate this Agreement upon thirty (30) calendar days' notice to the other Party; provided that, if the Force Majeure Event ceases within such thirty (30) day period, this Agreement shall remain in full force and effect upon prior written notice to the other Party.

22. TRANSPARENCY REQUIREMENTS

Sanofi is committed to transparency in its interactions with healthcare professionals and healthcare organizations/institutions consistent with applicable laws in countries in which Sanofi has Affiliates. Information relating to payments or other transfers of value "covered recipients" under or related to this Agreement will be collected and reported as required under applicable federal, regional, state and local laws and regulations. To the extent that any payments or transfers of value pursuant to this Agreement fall outside the "research" as defined in the applicable laws and regulations, they will be reported as required consistent with applicable laws and regulations. Institution represents that no portion of any payment made under this Agreement is or will be passed on to: any healthcare professional according to applicable law, including any physician (Medical Doctor (MD), Doctor of Osteopathic Medicine (DO), MD or DO Fellow, Dentist, Dental surgeon, Podiatrist, Optometrist, or Chiropractor), licensed in the U.S. ("Physician"). Salary paid to a Physician shall not be considered to include amounts passed on under this Agreement if the amount of the salary is determined without consideration of the amounts paid under this Agreement and Institution has not used and will not use any portion of payments made under this Agreement in determining the amount of non-salary compensation to any Physician.

Signature page follows.

EXHIBIT A

PROTOCOL

EXHIBIT B

FINANCIAL COMPENSATION

EXHIBIT C

CONDITIONS OF PRODUCT SUPPLY

EXHIBIT D

PHARMACOVIGILANCE

1. DEFINITIONS

Adverse Event of Special Interest (AESI): An adverse event of special interest is an adverse event (serious or non-serious) of scientific and medical concern specific to the Sponsor's product or program, regardless of causality, for which ongoing monitoring and rapid communication by the Investigator to the Sponsor may be appropriate. Such events may require further investigation in order to characterize and understand them. AESIs may be added or removed during a study by protocol amendment.

New safety finding: Any (other than reportable individual case safety report (ICSR)) safety issue that may require expedited reporting because providing information that may lead to a change in the known risk-benefit balance for the product and as mentioned, but not limited to, in the following regulatory texts: Europe: Good Pharmacovigilance Practices, modules VI and VII; and US: FDA: 21 CFR Parts 312 Investigational New Drug Application- Section 312.32, (c) (1) IND safety reports.

Treatment Emergent Adverse Event (TEAE): Any adverse event, regardless of relatedness, that occurs while the patient is taking the study drug.

Related Adverse Event, i.e. Adverse Drug Reaction (ADR): There is a reasonable possibility according to the sponsor that the product may have caused the event.

Serious adverse event (SAE): any untoward medical occurrence that at any dose:

- Results in death
- Is life threatening, (Note: the term "life-threatening" refers to an event/reaction in which the patient was at risk of death at the time of the event/reaction; it does not refer to an event/ reaction which hypothetically might have caused death if it were more severe)
- Requires inpatient hospitalization or results in prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect

Unexpected related Adverse Event, i.e. Unexpected Adverse Drug Reaction (UADR): An adverse reaction (considered serious or nonserious), in which the nature or severity is not consistent with the applicable product information (e.g., Principal Investigator's brochure for an unapproved investigational medicinal product or package insert/summary of product characteristics for an approved product). An expected ADR with a fatal outcome should be considered unexpected unless the local/regional product labelling specifically states that the ADR might be associated with a fatal outcome.

2. OBLIGATIONS AND RESPONSIBILITIES OF THE INSTITUTION

The Institution shall be responsible for ensuring submission of required expedited and periodic reports to the appropriate Regulatory Authority (RA), the Ethics Committee and investigators of each country participating in the ISS/ESC (based on applicable regulations).

The Institution shall be responsible for preparing its own periodic reports for clinical studies as required under the applicable regulations (e.g. ICH E2F for DSUR) as amended from time to time.

Any periodic reports (e.g. Development Safety Update Report (DSUR)), shall be transmitted to Sanofi by the Institution at the time of submission to Regulatory Authority.

The study reports of any ISS/ESC must contain a section describing safety data and a summary of safety conclusions and must be made available for review by Sanofi before it's finalization.

The Institution must provide to Sanofi, upon request, results of any relevant supplementary and/or complementary exams performed to obtain the final diagnosis of any ADR, AE or SAE (e.g., hospital discharge summary, autopsy, consultation).

The Institution is responsible for providing new safety finding of Sanofi Product received from Sanofi to the investigators and Ethics Committee in each country participating in the Study.

Specific country regulations may be more stringent in terms of requirements than the present document. In those cases, all provisions must be applied in accordance with local regulatory requirements.

The reference safety information (RSI) to be used by the Institution for evaluation of expectedness of adverse events shall be the current approved product label available in the country (for an approved indication)/ the Investigator Brochure (for an unapproved indication).

The Institution must transmit the following information in English to the Sanofi Pharmacovigilance contact (please refer to section 4):

- For interventional Studies with all products including vaccines, the Institution must transmit to Sanofi all SAEs and AESIs regardless of Investigator's causality, within 1 business day
- For non-interventional studies with a design based on primary data collection, the Institution must transmit to Sanofi
    - within 1 business day: All SAEs (including study procedure related SAEs) and AESIs, all exposure during pregnancy, if any
    - For drugs: within 7 business days : All non-serious AE related to the product
    - For vaccines: within 7 business days : All non-serious AE related to the vaccine, except those mentioned as "very common" in (RSI) of the vaccine under investigation.
- For Disease registry, the Institution must transmit to Sanofi all ADRs within 1 business day

- For studies based on secondary use of data, the investigator sponsor must transmit at any time of the analysis and at the latest the time of study report to Sanofi safety signals or conclusions with potential safety impact if any.

3. DEAR INVESTIGATOR LETTER (DIL) PROCESS

DIL Documents / Definitions:

The DIL file of the SUSAR may contain several SUSARs and is made of three components:

- The DIL cover letter: the sponsor's opinion statement that the reported SUSAR does or does not warrant a change in the clinical program is provided within the DIL cover letter
- The DIL Information Table
- SUSAR Individual Case Safety Report(s) (ICSR) (i.e., CIOMS I report(s)).

The DIL file of a "New Safety Finding" consists of a specific DIL cover letter and any related supporting documentation in the context of safety findings or emergency issues which may significantly impact the patient safety, the conduct of the study or alter the current benefit risk ratio of a product.

Note: DILs are generated for pre-marketed or recently approved products only per Sanofi procedure (< 3 years from International Birth Date (IBD)).

Sanofi will inform the Institution on the safety.

Sanofi will inform the Institution on the safety of the product by providing them the Dear Investigator Letter (DIL) files containing SUSAR Individual Case Safety Report(s) (ICSR) (i.e., CIOMS I report(s)) or periodic safety reports (Semi Annual Safety Reports- SASRs) or new safety findings documents on a timely manner.

Transmission of DIL to investigators starts at the time of contract signature. The DIL documents and/or SASR are provided to Investigators until the last Subject or Patient is completed as per Protocol.

New Safety Findings pertaining to safety of product originating from pre-clinical studies, or clinical studies, must be transmitted within 1 business day from Sanofi to Institution Study.

4. SANOFI PHARMACOVIGILANCE CONTACT

For global products except vaccines:
Email: CL-CPV-Receipt@sanofi.com
Or
Fax: to +33 1 60 49 70 70

For vaccines:
E-mail: PV.outsourcing@sanofi.com
or
Fax +33 (0) 4 37 37 71 32

ANNEX A

ADDITIONAL PROVISIONS BASED ON APPLICABLE LOCAL LAWS