Exhibit B – Form Collaborative Research Agreement

COLLABORATIVE RESEARCH AGREEMENT
BETWEEN
SANOFI-AVENTIS U.S. INC. AND [ACADEMIC MEDICAL CENTER]

THIS COLLABORATIVE RESEARCH AGREEMENT (hereinafter "Agreement") is entered into by and between **sanofi-aventis U.S. Inc.,** a Delaware corporation having offices at 55 Corporate Drive, Bridgewater, NJ 08807 ("Company"); and **Academic Medical Center,** a [TYPE OF INSTITUTION] having an office at [INSERT ADDRESS] (hereinafter "AMC") for the conduct of collaborative preclinical and clinical research studies in the area of identification and testing of new disease indications for existing Company drug candidates.

WHEREAS, Company is a party to a Memorandum of Understanding (the "MOU") with the National Institutes of Health ("NIH") dated [insert date], the goal of which MOU is to encourage the discovery of new therapeutic indications and/or diagnostics for existing drug candidates, and Company is in possession of certain such drug candidates (e.g., the Company Compound, as defined below) and data related thereto; and

WHEREAS, AMC desires to expand its capabilities and leading expertise in education, research and/or clinical care, and AMC desires to apply for a NIH Grant (as defined below) to perform studies related to the Company Compound; and

WHEREAS, the studies contemplated by this Agreement will be of mutual interest and benefit to Company and AMC and the general public, and shall further the instructional and research objectives of AMC in a manner consistent with its status as a nonprofit research, education and healthcare institution; and

WHEREAS, the Parties desire to engage in a collaborative research program that will advance scientific knowledge and patient care with the objective of validating, in human clinical studies, a new disease indication for the Company Compound.

NOW THEREFORE, in consideration of the mutual premises and covenants set forth herein and intending to be legally bound the Parties hereby agree as follows:

1. Scope and Aims

1.1 This Agreement governs work performed in a collaborative research project in the form of a Project Plan (as defined below) which may include preclinical work or non-interventional clinical work or a Clinical Trial (as defined below) governed by an IIR Agreement (as defined below). Each Party will perform the work that is assigned to it in this Agreement, the Project Plan, and the IIR Agreement (if any).

1.2 This Agreement and the IIR Agreement (if any) shall be consistent with the terms and conditions of the NIH Grant.

2. Definitions

Unless the context otherwise requires, the following definitions shall have the following meanings:

2.1 "Affiliate" means any company, body or other organization directly or indirectly controlling, controlled by, or under common control with a Party to this Agreement where "control" is defined as the direct or indirect holding of a majority of the stock entitled to vote (or other voting interest) or to otherwise appoint and remove the management of the company, body or organization.

2.2 "AMC Invention" has the meaning provided in **Section 8.2.1**.

2.3 "CDA" means the Confidential Disclosure Agreement between Company and AMC dated [insert date] and incorporated herein by reference.

2.4 "Clinical Trial" means any study performed under this Agreement which includes human subjects and the use of the Company Compound.

2.5 "Commercially Reasonable Efforts" means, with respect to the efforts to be expended by a Party with respect to any objective, those reasonable, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances. With respect to any efforts relating to the development, regulatory approval, manufacture or commercialization of a Product by Company, generally or with respect to any particular country, Company will be deemed to have exercised Commercially Reasonable Efforts if Company has exercised those efforts normally used by Company, in the relevant country, with respect to a product or product candidate of similar modality owned or controlled by Company, or to which Company has similar rights, which product or product candidate is of similar market potential in such country, and is at a similar stage in its development or product life cycle as the Product, taking into account all factors in effect at the time such efforts are to be expended. It is expressly understood that the use of Commercially Reasonable Efforts may result in ceasing the development, regulatory approval, manufacture or commercialization of a Product. Further, to the extent that the performance of a Party's obligations hereunder is adversely affected by the other Party's failure to perform its obligations hereunder, the impact of such performance failure will be taken into account in determining whether such Party has used its Commercially Reasonable Efforts to perform any such affected obligations.

2.6 "Confidential Information" means, with respect to each Party, all know-how or other information, including proprietary information and materials (whether or not patentable) regarding or embodying such Party's technology, products, business information or objectives, that is communicated by or on behalf of the Disclosing Party to the Receiving Party or its permitted recipients, on or after the date of the existing Confidential Disclosure Agreement between the Parties regarding the

disclosure of information as contemplated by the MOU but only to the extent that such know-how or other information in written form is marked in writing as "confidential" at the time of disclosure, and such know-how or other information disclosed orally or in non-tangible form is (a) identified by the Disclosing Party as "confidential" at the time of disclosure and (b) within 30 days thereafter, the Disclosing Party provides a written summary of such know-how or other information marked as "confidential". Confidential Information does not include any know-how or other information that (a) was already known by the Receiving Party (other than under an obligation of confidentiality to the Disclosing Party) at the time of disclosure by or on behalf of the Disclosing Party, (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party, (c) became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party, other than through any act or omission of the Receiving Party in breach of its obligations under this Agreement, (d) was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to the Receiving Party or (e) was independently discovered or developed by or on behalf of the Receiving Party without the use of any Confidential Information belonging to the Disclosing Party. The terms and conditions of this Agreement shall be considered Confidential Information of both Parties.

2.7 "Disclosing Party" has the meaning provided in **Section 7.1**.

2.8 "Effective Date" means [insert date], subject to the contingency of **Section 15.2**.

2.9 "Existing Technologies" has the meaning provided in **Section 8.1**.

2.10 "HIPAA" has the meaning provided in **Section 7.6**.

2.11 "IIR Agreement" means the Investigator Initiated Research Agreement which may be negotiated between Company and AMC for the conduct of any clinical trials.

2.12 "IND Application" has the meaning provided in **Section 9.2.1**.

2.13 "Indication" means [insert definition]

2.14 "IRB" means Institutional Review Board.

2.15 "Joint Invention" has the meaning provided in **Section 8.2.2**.

2.16 "Program Advisory Committee" or "PAC" has the meaning provided in **Section 4.1**.

2.17 "Material" has the definition provided in **Section 5.3.**

2.18 "MOU" has the meaning provided in the Recitals.

2.19 "NIH Grant" means any award made under the NIH-Industry Program: Discovering New Therapeutics Uses for Existing Molecules.

2.20 "NIH" means the U.S. National Institutes of Health.

2.21 "Option" has the meaning provided in **Section 9.2.1**.

2.22 "Party" means AMC or Company. "Parties" means AMC and Company.

2.23 "Patent" means any patent, certificate of invention, inventors certificate, utility model or similar forms of protection, or other form of protection (including applications, divisionals, continuations, continuations-in-part, and substitutions thereof; all foreign patent applications corresponding to the preceding applications or directly or indirectly claiming priority to or from any of the foregoing; and all U.S. and foreign patents granted on any of the preceding applications, including extensions, reissues, and reexaminations), granted anywhere in the world covering an invention which is a Technical Development.

2.24 "Company Compound" means [insert name of compound].

2.25 "Company Invention" has the meaning provided in **Section 8.2.3**.

2.26 "PHI" or "Protected Health Information" has the meaning provided in **Section 7.6**.

2.27 "Principal Investigator" or "PI" means [insert name of AMC scientist]. The Principal Investigator will be responsible for the conduct of the Program in accordance with this Agreement.

2.28 "Product" means a pharmaceutical product in any jurisdiction in the world, containing the Company Compound, as approved by the appropriate regulatory authority of that jurisdiction for the diagnosis, treatment or prevention of human or animal diseases.

2.29 "Program" means all activities performed by or on behalf of AMC under the scope of an NIH Grant or by or on behalf of Company or their respective Affiliates under this Agreement and which are authorized by this Agreement.

2.30 "Program Contact" means the person nominated by each of Company and AMC to serve as that Party's contact for the Program as set forth in **Exhibit A**.

2.31 "Project Plan" means the project plan appended to this Agreement in **Exhibit A** and incorporated herein by reference.

2.32 "Receiving Party" has the meaning provided in **Section 7.1**.

2.33 "Results" means the data and results arising from the Project Plan during the Term.

2.34 "Specific Success Criteria" are the specific success criteria listed in the Project Plan.

2.35 "Technical Development" means any invention, discovery, composition, enhancement, technology, advancement, know-how, process, data, device, machine, material, software or any other information arising from the Program, including any such development protectable by patent, copyright, or other protection under the law and in which a Party has an ownership interest.

2.36 "Term" has the meaning provided in **Section 3.1**.

3. Term

3.1 Term. This Agreement is effective as of the Effective Date and unless terminated in accordance with the provisions of **Section 12** herein shall remain in full force and effect for a period of [insert duration] years (the "Term") or until the completion of the work under the Project Plan, whichever occurs first. The Agreement may be extended by a period of time as the Parties may agree, by a written amendment to this Agreement signed by both Parties.

4. Program Advisory Committee

4.1 Program Advisory Committee. The Parties recognize, because of the contributions made to the Program by NIH's National Center for Advancing Translational Sciences ("NCATS") as a result of the NIH Grant, that NCATS has an interest in the activities of the work under this Agreement. Accordingly, as provided in **Section 1.2**, nothing in this Agreement may be construed to conflict with or supersede the rights and requirements of the NIH under the terms and conditions of the NIH Grant or by operation of law or regulation. The Parties will establish a program advisory committee (the "Program Advisory Committee" or "PAC") comprising two (2) Contacts, one from each of AMC and Company, and up to four (4) additional members from each of AMC and Company. The names of the initial Contacts for each of Company and AMC are set out in **Exhibit A**. The PAC will:

4.1.1 review and make recommendations regarding changes to the Project Plan based on emerging data as requested by the NIH Grantee;

4.1.2 monitor and facilitate the timely progress of the Project Plan;

4.1.3 monitor and consider the protection of intellectual property arising from results of the Project Plan, as necessary, and specifically prior to public disclosures;

4.1.4 address such other matters relating to the activities of the Parties under this Agreement as either Party may bring before the PAC, including any matters that are expressly for the PAC to decide as provided in this Agreement; and

4.1.5 attempt to resolve any disputes on an informal basis.

4.1.6 align with and communicate with the steering committee of the NIH Grant.

4.2 Responsibilities of each Contact. Each Contact will:

4.2.1 alternate chairing of PAC meetings.

4.2.2 ensure alignment of their respective organizations on the objectives; the AMC Contact will work with the PI and the AMC to ensure alignment on the objectives, including any proposed changes to the Project Plan or objectives, with NIH.

4.2.3 organize and circulate a written agenda in advance of PAC meetings;

4.2.4 prepare and promptly circulate minutes of the PAC meetings, clearly setting out the decisions of the PAC and the follow-up actions of each Party resulting from the meeting.

Furthermore, the Contacts from Company and AMC will make decisions on those day to day aspects of the Program which are not otherwise within the remit of the PAC. The Contacts will bear overall accountability to their respective organizations for the conduct of the Program.

4.3 Replacement of Contacts. Each Party's Contact may only be replaced by the written agreement of the other Party, such agreement not to be unreasonably withheld or delayed.

4.4 Meetings. The Contacts will convene meetings of the PAC at least every three (3) months at such times and places as agreed by the Parties. The Contacts may attend the meetings in person or by audio teleconference or by video teleconference. Each Party may invite additional employees who are not PAC Members to PAC meetings at such Party's discretion. Each Party shall be responsible for all of its own expenses in participating in the PAC meetings. The Parties shall endeavor to schedule meetings of the PAC at least three (3) months in advance.

4.5 Decision-Making. Decisions of the PAC must be unanimous; each Party has one vote to be given by its Contact. If agreement cannot be reached and the PAC must

have a decision to avoid any delay or prioritization of work, the Co-Chairs may refer the matter to their respective senior management: [Insert Position] of AMC and the Vice President of Company Research and Development.

4.6 Limits on PAC Authority. Each Party shall retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion shall be delegated to or vested in the PAC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. The PAC shall not have the power to amend, modify or waive compliance with this Agreement (other than as expressly permitted hereunder). Notwithstanding anything herein to the contrary, neither Party shall require the other Party to (i) breach any obligation or agreement that such Party may have with or to a third party or (ii) perform any activities that are materially different or greater in scope or more costly than those provided for in the approved Project Plans then in effect. It is outside the scope of the PAC's authority to negotiate license agreements under **Section 9.2**.

5. Governance and Management

5.1 Progress Reports. Progress reports on the work under the Project Plan will be submitted to the PAC at least semi-annually or more frequently if required under the Project Plan. The Principal Investigator shall be responsible for preparation of such progress reports. Such reports will detail progress on the Project Plan.

5.2 Final Report. AMC shall cause the Principal Investigator to furnish to Company a comprehensive report within thirty (30) days after the completion of the Term, describing in detail the work and Technical Developments accomplished on the studies described in the Project Plan.

5.3 Transfer of Material. The transfer of Material from one Party to the other Party will be governed by the terms and conditions of this **Section 5.3**, unless the Parties mutually agree otherwise. The Parties agree that the Company Compound, and other compounds, materials, biological samples, and other physical property (altogether, the "Material") of each Party may be provided to the other Party and used by the other Party solely for the purpose of the Project Plan and solely in the laboratories or clinics of that Party by personnel described in the Project Plan. Accordingly, any and all Material of a Party will be treated as Confidential Information of that Party in accordance with **Article 7**. Any transfer of Material or other physical property by one Party to the other Party's site shall require the prior written consent of both Parties in the form of **Exhibit B1** (for the transfer of Material not derived from human tissue) or **Exhibit B2** (for the transfer of Material derived from human tissue). Detailed records of all such transferred items will be kept by AMC and Company. All such Material shall be transferred to the other Party by secure means. All such Material shall remain the property of the transferring Party and will be surrendered to the transferring Party promptly or destroyed after the transferring Party provides to the other Party a written request

for such return or destruction. No license, express or implied, is granted to the other Party in respect of such supplied Material other than as expressly stated in this Agreement.

5.4 Project Clinical Trials. For any Clinical Trial or non-interventional clinical study included in the Project Plan, the terms and conditions governing that component of the Project Plan shall be governed to the maximum extent possible under this Agreement, and the specifics of such work shall be as set forth in the Project Plan, and in any applicable protocol, IND, and IRB approval. The Parties agree that such Clinical Trial will be performed in compliance with all applicable laws and regulations. AMC will sponsor any such Clinical Trials and any non-interventional clinical studies, meaning the AMC will be responsible for filing the IND and obtaining appropriate IRB approvals. For each such AMC-sponsored Clinical Trial, the terms of this Agreement will be supplemented, if applicable, by an IIR Agreement and such other special and supplemental terms as the Parties determine are necessary and appropriate at that time.

6. Funding and Resources

6.1 Company will provide to AMC the Materials and information described in **Exhibit A**.

6.2 Each Party will each bear any costs, expenses, or other charges of whatever nature incurred by such Party and which are not expressly detailed in the Project Plan. Company will provide no funding to AMC for the work under this Agreement and the Parties anticipate that AMC will obtain funding for AMC's work under the Project Plan solely from the NIH Grant.

7. Confidentiality

7.1 The Party receiving the Confidential Information (the "Receiving Party") of the other Party (the "Disclosing Party") agrees to maintain the Disclosing Party's Confidential Information with at least the same degree of care it holds its own information and in any case not less than a reasonable degree of care. The Receiving Party will not use the Disclosing Party's Confidential Information except in connection with the Program, including disclosure to the NIH under the NIH Grant application and terms of any award, or as necessary to practice its rights under **Article 9**. The Receiving Party will disclose the Disclosing Party's Confidential Information only to its officers, employees, consultants, Affiliates and any permitted sub-contractors concerned with the Program or the conduct of work under the Project Plan, but will neither disclose the Confidential Information to any third party nor use the Confidential Information for any other purpose. Other provisions of this **Article 7** notwithstanding, a Receiving Party may disclose to third parties ("Third Party Disclosure") Confidential Information of the Disclosing Party as required by law or regulation, provided that the Receiving Party provides reasonable advance written notice to the Disclosing Party of such Third Party

Disclosure so that the Disclosing Party may seek a protective order or other remedy. If the Disclosing Party fails to obtain a protective order or waives compliance with the relevant provisions of the Agreement, the Receiving Party will disclose only that portion of the Confidential Information which its legal counsel determines it is required to disclose.

7.2 The Receiving Party's obligations of nondisclosure and the limitations upon the right to use the Confidential Information shall not apply to the extent the receiving Party can demonstrate the Confidential Information:

7.2.1 is or becomes publicly known through no fault or omission of the Receiving Party or an Affiliate of the Receiving Party; or

7.2.2 was at the time of receipt already in the possession of the Receiving Party or an Affiliate of the Receiving Party without obligation of confidentiality to the Receiving Party; or

7.2.3 was or is received by the Receiving Party or an Affiliate of the Receiving Party from a third party under no obligation of confidentiality to the Disclosing Party; or

7.2.4 has been released from such obligation by the prior written consent of the Disclosing Party; or

7.2.5 is independently developed by or on behalf of the Receiving Party or an Affiliate of the Receiving Party without the use of the Disclosing Party's Confidential Information.

7.3 All obligations relating to the non-disclosure of Confidential Information shall expire five (5) years from the date of completion or earlier termination for any reason of the relevant Project.

7.4 Technical Developments will be treated as Confidential Information of the Party(ies) owning such Technical Developments.

7.5 On expiration or earlier termination of this Agreement, the Receiving Party will, at the written request of the Disclosing Party, return or destroy (at the Disclosing Party's sole discretion) all Confidential Information of the Disclosing Party then in its possession or control and all copies of it save that the Receiving Party:

7.5.1 may retain a single copy of the Disclosing Party's Confidential Information for the sole purpose of ascertaining its ongoing rights and responsibilities in respect of such information; and

7.5.2 will not be required to surrender or destroy any computer files stored securely by the Receiving Party, its Affiliates and permitted sub-

contractors that are created during automatic system back-up or retained for legal purposes by the legal division of the Receiving Party and its Affiliates.

7.6 To the extent that either Party provides to the other Party Protected Health Information ("PHI") as that term is defined in the Health Insurance Portability and Accountability act of 1996 and applicable regulations from time to time promulgated there under ("HIPAA"), both parties shall, to the extent applicable, comply with HIPAA, and to the extent applicable, the Party obtaining the PHI from any patient or study subject agrees to obtain a HIPAA authorization or an IRB waiver (or both, as needed or required) prior to using or disclosing such patients' or subjects' PHI to the other Party. Each Party will only use and disclose PHI in a manner consistent with HIPAA requirements, and as otherwise may be permitted or required by applicable law, the subject's signed authorization or the waiver. Each Party also agrees to use appropriate safeguards to prevent any unauthorized disclosures of subjects' PHI.

7.7 Other Sections of this **Article 7** notwithstanding, as part of any disclosure policy that may be implemented from time to time by Company regarding payments made to members of the medical or scientific community, or in accordance with applicable laws or regulations, Company may publicly disclose any fact related to the content of this Agreement, the name of AMC, the name of any researcher accepting funding under this Agreement, as well as the compensation provided by Company to AMC hereunder.

8. Intellectual Property Ownership and Patents

8.1 All rights, title and interest in and to any inventions or technologies of AMC or of Company, respectively, existing on or before the Effective Date, and all rights, title and interest in and to any inventions or technologies developed by AMC or Company outside the Program hereunder (altogether, the "Existing Technologies") shall be the exclusive property of the respective party.

8.2 Ownership of Technical Developments (and the Patents, if any, which claim such Technical Developments) shall be determined according to the origin of the Technical Developments, and, in case of inventions, by inventorship (as defined under U.S. patent law at the time the invention is made), i.e.:

8.2.1 Shall belong to AMC, if the inventors are one or more employees of AMC and none of the inventors are employees of Company ("AMC Invention"),

8.2.2 Shall belong jointly to AMC and Company, if the inventors are one or more employees of AMC and one or more employees of Company ("Joint Invention"),

8.2.3 Shall belong to Company, if the inventors are one or more employees of Company and none of the inventors are employees of AMC ("Company Invention").

8.3 AMC and Company will each disclose to the other Party all inventions discovered under this Agreement and owned by the disclosing Party promptly after becoming aware of such inventions.

8.4 Patents on AMC Inventions

8.4.1 AMC shall have the right to file patent applications covering any AMC Invention. AMC shall give Company written notice of its intent to file such patent applications at least forty-five (45) days in advance of the intended filing date, and Company shall have the right to review all patent applications on AMC Inventions and provide AMC with substantive comments. AMC shall also consult with Company regarding the countries in which such patent applications should be filed, and AMC will file applications in those countries where Company requests that AMC should file. AMC, at its option and at its expense, may file in countries where Company does not request that AMC should file such applications. AMC shall provide to Company a yearly update on the status of all such Patents and Patent applications. AMC will provide to Company forty-five (45) days' advance written notice of AMC's intention to abandon any Patent on a AMC Invention, and Company will have the right to continue prosecution of such Patent or patent application at Company's sole expense and in the event Company decides to continue with such prosecution the Parties agree to negotiate licensing such Patent to Company pursuant to the provisions of Section 9.2.

8.4.2 Company shall reimburse AMC for all costs of filing, prosecuting, responding to opposition (including interference proceedings), and maintaining Patents on AMC Inventions in countries where Company requests or agrees that Patents should be filed, prosecuted and maintained. In the event Company requests that AMC employ Company's preferred ex-US patent agents in such countries, AMC shall do so where reasonably possible, and agrees that Company may be directly invoiced by such agents. Company may, upon sixty (60) days written notice, request that AMC discontinue filing, prosecuting, responding to opposition, or maintaining Patents in any such country and, upon expiration of such sixty (60) day period, discontinue reimbursing AMC for the costs of filing, prosecuting, responding to opposition or maintaining such Patent in any country. Subject to the foregoing, AMC will be free to continue, at its own expense at the end of such sixty (60) day period, to file, prosecute, respond to opposition and/or maintain such Patent.

8.5 Patents on Company Inventions. Company shall have the right to file patent applications covering any Company Invention. Company shall be solely responsible for the prosecution and maintenance of all Patent applications and Patents claiming Company Inventions and all costs related thereto.

8.6 Patents on Joint Inventions.

8.6.1 AMC and Company shall confer regarding the filing of patent applications on Joint Inventions. Company shall have the right to file patent applications covering any Joint Invention using either its own counsel, if agreed to by the Parties, or outside counsel reasonably acceptable to both Parties. AMC agrees that Company may employ its preferred ex-US patent agents for such filing, and otherwise employ all reasonable cost-savings measures. Company shall give AMC notice of its intent to file any patent application at least sixty (60) days in advance of its filing date. AMC shall have the right to review all patent applications on Joint Inventions and to provide Company with substantive comments. Company will notify AMC of its intention to abandon any Patent on a Joint Invention and AMC will have right to continue prosecution of such Patent at AMC's sole expense. Subject to the preceding sentence and to **Section 8.6.3**, Company shall be solely responsible for filing, prosecuting, responding to oppositions (including interference proceedings) and maintaining all Patents claiming Joint Inventions and all costs related thereto. Subject to the grant of licenses herein and the exercise of the option under **Section 9.2,** each Party shall be free to exploit, either itself or through the grant of licenses to third parties (which third party licenses may be further sublicensed), rights in any Joint Inventions, including any patents directed thereto, throughout the world without restriction, without the need to obtain further consent from or provide notice to the other party, and without any duty to account or otherwise make any payment of any compensation to the other party.

8.6.2 Company shall consult with AMC regarding the countries in which patent applications claiming Joint Inventions should be filed, and Company will file applications in those additional countries where AMC requests Company to do so. Company, at its option and at its expense, may initially select the list of countries in which to file, and may file in countries where AMC does not request that Company file such Patent applications.

8.6.3 AMC shall reimburse Company for all costs of filing, prosecuting, responding to opposition (including interference proceedings), and maintaining Patent applications and Patents on Joint Inventions filed under **Section 8.6.2** in additional countries where AMC requests that Patent applications be filed, prosecuted and maintained. AMC may, upon sixty (60) days written notice, request that Company discontinue filing,

prosecuting, responding to opposition, or maintaining Patent applications or Patents in any such country and, upon expiration of such sixty (60) day period, may discontinue reimbursing Company for the costs of filing, prosecuting, responding to opposition or maintaining such Patent application or Patent in any country. Subject to the foregoing, Company will be free to continue, at its own expense at the end of such sixty (60) day period, to file, prosecute, respond to opposition and/or maintain such Patent application or Patent.

8.6.4 Patents on Joint Inventions after Company Declines to Exercise Option. In the event that Company declines to exercise its option to acquire a worldwide-royalty-bearing, exclusive license to a Joint Invention under **Section 9.2**, or such option expires without Company having acquired such a license under the Option, then AMC, to the extent no patent applications covering such Joint Invention have already been filed, shall have the right, but not the obligation, to file patent applications covering such Joint Invention, exercisable at AMC's sole election; in such circumstances, if AMC proceeds with patenting Joint Inventions, Company shall retain any rights it may have as a joint owner under existing law.

8.7 Each Party undertakes on behalf of itself, its directors, officers, employees, Affiliates and permitted subcontractors to do such further acts and execute or obtain execution of such documents as may be reasonably necessary to give effect to each Party's rights under this **Article 8**.

8.8 AMC will have such policies and procedures in place so as to cause all personnel affiliated with AMC (including permitted students and subcontractors used by AMC), including the Program Contact and AMC's members of the Program Advisory Committee, to vest all Technical Development and Patents created by such AMC personnel in the name of AMC.

8.9 It is understood with respect to patent filing, prosecution or maintenance activities conducted by Company with respect to any Joint Inventions arising under this agreement, that Company represents only itself, and not AMC, and that AMC is represented by its own counsel. Neither Company, nor any of its Affiliates or sub-licensees, nor any of their employees or agents shall be liable for any act or omission with respect to such activities.

9. Licenses

9.1 Research and Educational Licenses.

9.1.1 AMC grants to Company and Company's Affiliates a non-exclusive, world-wide, perpetual, non-cancelable, royalty-free, fully paid-up license under AMC's rights in Technical Developments, including its rights in

AMC Inventions and Patents covering such AMC Inventions, to use the Technical Developments for internal research and development purposes only. The foregoing license shall be without the right to transfer or grant sublicenses to any third party (except to contractors performing work solely for the benefit of Company or Company's Affiliates and under obligations of confidentiality and non-use similar to those of this Agreement), unless Company receives the express written permission of AMC to do so.

9.1.2 Company grants to AMC and AMC's Affiliates a non-exclusive, world-wide, perpetual, non-cancelable, royalty-free, fully paid-up license under Company's rights in Technical Developments, including its rights in Company Inventions and Patents covering such Company Inventions, to use the Technical Developments for internal research and educational purposes only, which shall include collaborations between AMC and other non-profit and government entities. The foregoing license shall be without the right to transfer or grant sublicenses to any third party (except to contractors performing work solely for the benefit of AMC or AMC's Affiliates and under obligations of confidentiality and non-use similar to those of this Agreement), unless AMC receives the express written permission of Company. Collaborations with for-profit entities are expressly excluded from the license granted in this **Section 9.1.2**.

9.1.3 Company grants to AMC and AMC's Affiliates a non-exclusive, world-wide, royalty-free, fully-paid license (without the right to transfer or grant sublicenses) during the Term under Company's rights in Materials provided by Company to AMC under the Program to use such Materials under the Program. This license includes the right to sublicense only to contractors doing work for the benefit of AMC or AMC's Affiliates under the Program.

9.1.4 AMC grants to Company and Company's Affiliates a non-exclusive, world-wide, royalty-free, fully-paid license (without the right to transfer or grant sublicenses) during the Term under AMC's rights in Materials provided by AMC to Company under the Program to use such Materials under the Program. This license includes the right to sublicense only to contractors doing work for the benefit of Company or Company's Affiliates under the Program.

9.2 Commercial Option and Licenses

9.2.1 For each Project Plan, AMC hereby grants to Company and its Affiliates the exclusive option to acquire (i) a worldwide, royalty-bearing, exclusive or non-exclusive license, including the right to grant sublicenses under an exclusive commercial license, to make, use, sell, offer for sale, import and export Products, under all of AMC's right, title and interest in AMC

Technical Developments, AMC Inventions and AMC's interest in Joint Inventions, including Patents covering any of the foregoing which arise from the work performed under that Project Plan and (ii) the associated investigational new drug application (the "IND Application") (each, an "Option"). Company and its Affiliates must exercise the Option by providing written notice to AMC within six (6) months after written notification by AMC to Company of the corresponding Technical Development or Invention or within six (6) months of completion of the Project Plan under which the Technical Development or Invention arose, whichever is later, *provided, however*, that if AMC gives notice to Company of its intent to file a patent application under **Section 8.4.1** and if Company does not request AMC to file the patent application in any specific countries, then the Option will expire six (6) months from the date AMC first notifies Company of AMC's intent to file the patent application. Company's failure to timely exercise such option shall cause such option to lapse and expire.

9.2.2 The terms and conditions for any license elected pursuant to the Option shall be commercially reasonable and shall be negotiated in good faith between the Parties.

9.2.3 Company and AMC shall negotiate in good faith for a period not to exceed six (6) months from the date of Company's exercise of the Option plus any extensions of time as agreed by the Parties (altogether the "Negotiation Period") to reach agreement on the terms and conditions of the license agreement related to the Options(s). If the Parties have not reached agreement on the terms and conditions of the license agreement under Section 9.2 by the end of the sixth (6^{th}) month after the election by Company of the Option, and the Parties do not have an agreement to extend the Negotiation Period, AMC may license its interests in such AMC Invention or AMC Technical Developments (subject to any non-exclusive licenses that were granted to Company pursuant to this Agreement) to any third party on any terms it desires, in its sole discretion. Such licenses shall not include any rights to Company owned intellectual property or Company Confidential Information.

9.3 Additional License Terms.

9.3.1 Each exclusive license agreement granting rights from AMC to Company and which results from Company's exercise of the Option will contain a provision requiring Company to use Commercially Reasonable Efforts to commercialize a Product or a service (as applicable) in the United States and other countries if mutually agreed to by AMC and Company.

9.3.2 Subject to 9.2.2., any license granted to Company for inventions covering diagnostic research tools which results from the exercise of any Option will be non-exclusive.

9.3.3 AMC will have the right under all circumstances to grant a license for AMC Technical Developments to not-for-profit research institutions and the United States Government to use AMC Technical Developments for research and teaching purposes only and not for use in the manufacture, distribution or sale of products. Nothing herein shall affect the United States Government's rights under the Bayh Dole Act, including the Government license under 35 U.S.C. § 202.

10. Indemnification

10.1 Company agrees to hold harmless, indemnify and defend AMC from all third party liabilities, demands, damages, expenses and losses arising out of: (i) use by Company or by any third party acting on behalf of or under authorization from Company, of information or materials received from AMC, or (ii) any use, sale or other disposition by Company or by any third party acting on behalf of or under authorization from Company of products made by use of information or materials received from AMC; provided, however, that the foregoing shall not apply (i) if the claim is found to be based upon the negligence, recklessness or willful misconduct of AMC or (ii) if AMC fails to give Company prompt notice of any claim it receives and such failure materially prejudices Company with respect to any claim or action which Company's obligation pursuant to this Section applies. Company, in its sole discretion, shall choose legal counsel, shall control the defense of such claim or action and shall have the right to settle same on such terms and conditions it deems advisable.

Unless otherwise prohibited by applicable law, AMC agrees to hold harmless, indemnify and defend COMPANY from all third party liabilities, demands, damages, expenses and losses arising out of: (i) any breach of any obligation in this Agreement and (ii) the inaccuracy or breach of any representation or warranty made by AMC in this Agreement provided, however, that the foregoing shall not apply to the extent (i) the claim is found to be based upon the negligence, recklessness or willful misconduct of COMPANY or (ii) COMPANY fails to give AMC prompt notice of any claim it receives and such failure materially prejudices AMC with respect to any claim or action which AMC's obligation pursuant to this Section applies. AMC, in its sole discretion, shall choose legal counsel, shall control the defense of such claim or action and shall have the right to settle same on such terms and conditions it deems advisable.

10.2 No Warranty. ANY INFORMATION, RESULTS, MATERIALS, SERVICES, RESOURCES, INTELLECTUAL PROPERTY OR OTHER PROPERTY OR RIGHTS GRANTED, GRANTED ACCESS TO, OR PROVIDED BY COMPANY TO AMC PURSUANT TO THIS AGREEMENT (HEREIN THE

"INTELLECTUAL PROPERTY") ARE ON AN "AS IS" BASIS. COMPANY MAKES NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, AS TO ANY MATTER INCLUDING, BUT NOT LIMITED TO, WARRANTY OF FITNESS FOR PARTICULAR PURPOSE, MERCHANTABILITY, EXCLUSIVITY, ACCURACY, INTEGRATION, OR RESULTS OBTAINED FROM INTELLECTUAL PROPERTY, INCLUDING BUT NOT LIMITED TO, ANY USE OF ANY INTELLECTUAL PROPERTY MADE OR CREATED UNDER THE AGREEMENT, NOR SHALL COMPANY BE LIABLE TO AMC FOR INDIRECT, SPECIAL, OR CONSEQUENTIAL DAMAGES INCLUDING, BUT NOT LIMITED TO, LOSS OF PROFITS OR INABILITY TO USE, USE PROPERLY, OR USE WITHOUT ERRORS, SAID INTELLECTUAL PROPERTY OR ANY APPLICATIONS AND DERIVATIONS THEREOF. COMPANY MAKES NO WARRANTIES OF ANY KIND WITH RESPECT TO FREEDOM FROM PATENT, TRADEMARK, OR COPYRIGHT INFRINGEMENT, INFORMATIONAL CONTENT, ACCURACY, INTEGRATION, OR THEFT OF TRADE SECRETS AND DOES NOT ASSUME ANY LIABILITY HEREUNDER FOR ANY INFRINGEMENT OF ANY PATENT, TRADEMARK, OR COPYRIGHT ARISING FROM THE USE OF THE INTELLECTUAL PROPERTY OR RIGHTS GRANTED OR PROVIDED BY IT HEREUNDER. AMC AGREES THAT IT WILL NOT MAKE ANY WARRANTY ON BEHALF OF COMPANY EXPRESSED OR IMPLIED, TO ANY PERSON CONCERNING THE APPLICATION OF, ACCURACY OF, OR THE RESULTS TO BE OBTAINED WITH THE INTELLECTUAL PROPERTY, OR WITH RESPECT TO ANY OTHER MATTER

11. Publication

11.1 The Parties acknowledge that inadvertent publication of the results arising under any Project Plan may jeopardize patent protection. Notwithstanding the foregoing, Company acknowledges the importance of publications to the reputation of AMC and its faculty members. The provisions of this **Section 11** are intended to promote and ensure timely publication of results of Projects, inventions and Technical Developments, while protecting patent rights and Confidential Information.

11.2 In the event AMC wants to publish or present any or all of the Technical Developments, it shall submit to Company the manuscript, abstract or other proposed publication at least thirty (30) days prior to submission and, in the case of poster boards or other presentations, at least thirty (30) days prior to the presentation itself (the "Initial Review Period"). Company shall timely review the proposed publication, and may, together with AMC, revise the manuscript or other proposed publication to ensure protection of Company's Confidential Information. Upon Company's request, AMC shall delay submission or publication for up to an additional thirty (30) days (the "Supplemental Review Period") if Company deems it reasonably necessary to enable AMC or Company (as the case may be) to apply for Patent protection covering any Technical Development disclosed in the

proposed publication. In exercising its rights under this Section, Company will not unreasonably withhold or delay consent.

12. Termination

12.1 AMC may suspend or terminate all or any portion of any human subject research that it is conducting upon written notice to Company if AMC determines in its reasonable discretion that such action is necessary for patient safety or in the event any approval required by the IRB, the FDA, the NIH or any other federal or state agency is terminated, expired, withdrawn or suspended. Either Party may suspend or terminate all or any portion of any human subject research that is being conducted by AMC under the Project Plan upon written notice to AMC if the Party determines in its reasonable discretion that such action is necessary for patient safety.

12.2 Either Party may terminate this Agreement:

12.2.1 if the other Party commits a material breach of a material term of this Agreement which, if capable of remedy, remains unremedied by the breaching Party for sixty (60) days following written requirement by the non-breaching Party to the breaching Party to cure the same; or

12.2.2 if the other Party becomes insolvent, the subject of bankruptcy proceedings, enters into an arrangement with its creditors, or any circumstance analogous to the foregoing; or

12.2.3 at will and for any reason upon delivery to the other Party sixty (60) days advance written notice of such termination.

12.3 Effect of Termination.

12.3.1 If this Agreement is terminated by AMC under **Section 12.2.1** or by Company under **Section 12.2.3**, then any Option granted to Company under **Article 9.2** and not yet exercised will terminate upon the effective date of such Agreement termination. Upon such termination, rights in the AMC Inventions and AMC Technical Developments which were the subject of any unexercised Option will revert to AMC. In the event that AMC declares that it will not exercise its right to commercialize or license its interests in such AMC Invention or AMC Technical Developments to any third party, then AMC, to the extent it is legally able, will grant to NIH a license (with right to sublicense) to make, use, sell, offer for sale, import and export such AMC Invention or AMC Technical Developments. For the avoidance of doubt it is recognized and understood by the Parties that the provisions of this Section 12.3.1 shall have no effect on any licenses that have already been granted to Company under this Agreement which shall remain in full force and effect.

12.3.2 If this Agreement is terminated by Company under **Section 12.2.1** or by AMC under **Section 12.2.3**, then any license granted to Company under **Article 9.2** will become perpetual and irrevocable.

12.4 The following Articles and Sections shall survive the expiration or termination for any reason of this Agreement: **Articles 2, 7, 8, 9, 10, 11**, and **13**; and **Sections 5.2, 12.3, 12.4, 15.1, 15.4, 15.6, 15.7, 15.8, 15.9, 15.10, 15.11**, and **15.12**.

13. Representations and Warranties

13.1 Each Party warrants that the activities conducted by such Party under this Agreement shall conform to the specifications and the current material applicable standards, laws, regulations, recognized ethical standards, and procedures of the appropriate regulatory and oversight agencies.

13.2 Each Party represents that it has the right, authority and necessary licenses to enter into and perform its obligations under this Agreement in accordance with all applicable governmental laws, rules and regulations.

13.3 Each Party certifies that it is not debarred under subsections 306(a) or (b) of the Federal Food, Drug, and Cosmetic Act and will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement.

13.4 AMC warrants that it will conduct all work involving animals with standards consistent with those used by The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International). In addition, AMC will observe any and all statutes and applicable governmental regulations that bear upon animal welfare, care and use of the jurisdiction(s) in which AMC's facilities are located.

14. Monitoring and Audits

14.1 Upon reasonable notice and during regular business hours, AMC will permit Company representatives access to the premises, facilities, study records, investigators, and research staff employed in connection with and Project Plan as required to monitor study conduct and/or animal care and welfare. Monitoring by Company does not relieve AMC of any of its obligations under this Agreement.

14.2 The work performed under this Agreement may be subject to inspection by regulatory agencies worldwide, including, without limitation, the FDA and USDA. Regulatory inspections may occur after completion of the Program and may include auditing of study records.

14.2.1 Notification. AMC will notify Company as soon as reasonably possible if the site is inspected or scheduled to be inspected by a regulatory agency in relation to the Program. If AMC has reasonable advance notice of an inspection which involves a Company Compound, Company will have a right to participate in the inspection.

14.2.2 Cooperation. AMC will cooperate with regulatory agency or Company representatives in the conduct of inspections and audits and will ensure that study records are maintained in a way that facilitates such activities.

14.2.3 Resolution of Discrepancies. AMC will promptly resolve any discrepancies that are identified between study data and source documentation, or deviations from animal care and use standards.

14.2.4 Inspection Findings and Responses. AMC will promptly forward to Company copies of any inspection findings (e.g. Establishment Inspection Report, FDA Form 483 or USDA Inspection Report) that it receives from any regulatory agency in relation to the Program. Whenever feasible, AMC will also provide Company with an opportunity to prospectively review and comment on AMC's responses to regulatory agency inspections in regard to the Program.

14.2.5 Animal Care & Welfare Inspections. AMC will promptly forward to Company copies of any inspection findings or notices that AMC receives from AAALAC International or any regulatory agency in relation to the animal care and use program at AMC's facilities that occurs at any time during the term of this Agreement.

15. General Provisions

15.1 Notices. Notices to be given under this Agreement shall be in writing and sent to the Parties as follows:

If to Company, to: [INSERT CONTACT AND ADDRESS]

With copy to: sanofi-aventis U.S. Inc.
55 Corporate Drive
Bridgewater, NJ 08807
Attention: Vice President & General Counsel U.S. R&D Division

If to AMC, to:
[INSERT CONTACT AND ADDRESS]

With copy to:
[INSERT CONTACT AND ADDRESS]

Any such notice will be validly given if delivered in person, by certified mail, return receipt requested, by courier or by confirmed facsimile transmission, and shall be deemed effective on receipt.

15.2 Contingent upon Execution of Grant Agreement. This Agreement will not be in force and effect until such time as AMC and NIH have executed the NIH Grant and received concurrence from NIH that the terms and conditions of this Agreement are consistent with NIH policies. Changes to any terms or conditions of this Agreement or to the Project Plan which are requested by NIH during the review process must be approved by Company and AMC in writing before they are effective.

15.3 Execution in Counterparts. This Agreement may be executed in two counterparts (including by facsimile or electronic copies), each of which shall be deemed an original, and both of which together shall constitute one and the same instrument.

15.4 No Waiver. No waiver is made or given unless in writing and signed on behalf of the Party making such waiver. Any waiver granted on one occasion shall not be deemed a waiver given on any other or subsequent occasion. All rights of the Parties are cumulative.

15.5 Assignment. Neither Party may assign this Agreement in whole or in part without the prior written consent of the other Party, save that Company may make such assignment to any Affiliate or may make such assignment in the event of any acquisition, merger or other valid business reconstruction without such consent of AMC.

15.6 Independent Entities. Each Party acknowledges that it is entering into this Agreement solely on its own behalf, and will perform any and all of its obligations or work under this Agreement as an independent entity. Nothing under this Agreement shall create any other relationship between the Parties including without limitation one of principal and agent, employer and employee, or partnership.

15.7 Entire Agreement. This Agreement incorporates all Exhibits and constitutes the entire agreement and understanding between the Parties in respect of the subject matter hereof and replaces in its entirety any prior discussions, negotiations, agreements or other arrangements in relation to the subject matter, whether written or oral, all of which are replaced by the terms of this Agreement. No amendment or modification of this Agreement shall be valid or binding unless made in writing and signed by authorized representatives of both parties.

15.8 Use of Names. Subject to **Section 7.7**, except as required by law or by NIH for its public databases on awards, such as RePORT, neither Party may use the name of the other Party in any public announcement, advertising, or other public disclosure without first gaining the written consent of the other Party.

15.9 Severability. When possible, each provision of this Agreement will be interpreted in such manner as to be effective, valid, and enforceable under applicable law, but if any provision of this Agreement is held to be invalid or unenforceable under applicable law, such provision will be held invalid or unenforceable without invalidating the remainder of such provision or of this Agreement. The Parties will make a good faith effort to replace the invalid or unenforceable provision with a valid one, which in its economic effect is most consistent with the invalid or unenforceable provision.

15.10 Authorized Representatives. The signatories to this Agreement confirm that they are authorized by their respective organizations to enter into this Agreement. Both Company and AMC represent and warrant to each other that they will perform this Agreement in compliance with all applicable laws, ordinances and regulations by which they are bound and in so doing they will not to the best of their knowledge breach the terms of any other agreement to which they are a party.

15.11 Choice of Law. This Agreement shall be governed in all respects by the laws of the State of New Jersey without reference to its conflict of laws provisions.

IN WITNESS WHEREOF the Parties have caused this Agreement to be executed by the hands of their duly appointed representatives on the day and date first written above.

[Academic Medical Center]		**SANOFI-AVENTIS U.S. INC.**	
Signed:	…….	Signed:	……..
Printed Name:		Printed Name:	
Position:		Position:	
Date:	…….	Date:	…….....

Exhibit A – Project Plan

N.b.: The Project Plan will include at least the following:

- Descriptive Title
- List of Key Contributors
- Statement of the Hypothesis for the Mechanism (target) and Indication
- Background Information that Support and Refute the Hypothesis
- Target Product Profile – What specific patients will benefit? How exactly will they benefit? How this will be notably superior to what is now or soon to be available to them? Number of such patients in US? Number of new cases? Current therapy options (rough cost of each)?
- Detailed Plan for Validating the Indication/Target Pair Hypothesis
    - Specific Aims – including rationale and 'Go / No Go' decision criteria for:
        - Preclinical Studies – if needed
        - Clinical Study
    - Justification for the Decision Criteria
    - Assessment of operational feasibility and resources needed for execution
    - Capabilities of the relevant labs/groups – evidence that the decisive studies can be performed by the key contributors
- Specific Success Criteria
- Project Advisory Committee Composition
- Appendix 1: Overall Project Decision Tree – with criteria for each decision
- Appendix 2: Clinical Study Outline
- Appendix 3: Budget – aligned with Specific Aims and milestones (decision points) in the Project Decision Tree
- Appendix 4: Proposed Timelines and Milestones
- Appendix 5: NIH Biosketch of the Principle Investigator(s)

Exhibit B1 – Proforma for Transfer from One Party to the Other of Materials, Reagents and Any Other Physical Property Not Derived from Human Tissue

Transfer #:	[insert unique number assigned by AMC's Program Contact]
Transferor:	[insert the name of the Party transferring items to the other Party (either Company or AMC as the case may be)]
Transferee:	[insert the name of the Party receiving items from the other Party (either AMC or Company as the case may be)]
AMC contact Person:	[insert name of individual]
Company contact Person:	[insert name of individual]
Items to be transferred:	[insert a detailed description of items to be transferred]
Purpose of transfer:	[insert a detailed description of why the transfer is taking place]
Date of transfer:	[insert the effective date of the transfer]
Applicable Terms:	This transfer is governed by the terms and conditions of the Collaborative Research Agreement between Company and [AMC] dated [insert date].

Agreed and accepted by:

Academic Medical Center		**SANOFI-AVENTIS U.S. INC.**	
Signed:	……..	Signed:	…….
Print name:	……..	Print name:	…….
Date:	……..	Date:	……..

Exhibit B2 – Proforma for Transfer from One Party to the Other of Materials, Reagents and Any Other Physical Property Derived from Human Tissue

Transfer #:	[insert unique number assigned by AMC's Program Contact]
Transferor:	[insert the name of the Party transferring items to the other Party (either Company or AMC as the case may be)]
Transferee:	[insert the name of the Party receiving items from the other Party (either AMC or Company as the case may be)]
AMC contact Person:	[insert name of individual]
Company contact Person:	[insert name of individual]
Items to be transferred:	[insert a detailed description of items to be transferred] Transferor represents and warrants that all applicable laws, regulations and governmental guidelines were complied with in the collection and handling of the Material; that collection of the Material was approved by either an Institutional Review Board ("IRB") or included in an open IND that complies with applicable federal regulations for such a body; that an informed consent ("Informed Consent") was obtained from each donor; that the transfer of Material from the Transferor to the Transferee and the uses described in this Proforma are consistent with and within the scope of either the IRB approval or IND and Informed Consent; and the that Transferor has the legal right to provide the Materials and is not infringing on the property rights of any third party. The Transferor will provide the Transferee with a copy of the language of the informed consent documents, if necessary.
Purpose of transfer:	[insert a detailed description of why the transfer is taking place]
Date of transfer:	[insert the effective date of the transfer]
Applicable Terms:	This transfer is governed by the terms and conditions of the Collaborative Research Agreement between Company and [AMC] dated [insert date].

Agreed and accepted by:

Academic Medical Center		**SANOFI-AVENTIS U.S. INC.**	
Signed:	……..	Signed:	…….
Print name:	……..	Print name:	…….
Date:	……..	Date:	……..