COLLABORATIVE RESEARCH AGREEMENT

BETWEEN

GLAXOSMITHKLINE, LLC AND [ACADEMIC MEDICAL CENTER]

THIS COLLABORATIVE RESEARCH AGREEMENT (hereinafter "Agreement") is entered into by and between GlaxoSmithKline, LLC, a Delaware Corporation with a place of business at One Franklin Plaza, 200 N. 16th Street, Philadelphia, Pennsylvania 19101 (hereinafter "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. Company and AMC may be referred to herein individually as a "Party" and collectively as the "Parties."

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, when associated with a Party to this Agreement, any entity which controls, is controlled by, or is under common control with, that Party. In this context, "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, remove, or otherwise direct the management or policies of that Party.

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

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

2.8 "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 thirty (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.

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

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

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

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

2.13 "IIR Agreement" means the Investigator Initiated Research Agreement between Company and AMC for the conduct of any clinical trials which is attached to this Agreement in **Exhibit B**.

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

2.15 "Indication" means [insert definition]

2.16 "IRB" means Institutional Review Board.

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

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

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

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

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

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

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

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

2.25 "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.

2.26 "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 Advisory Committee" or "PAC" has the meaning provided in Section 4.1.

2.31 "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**.

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

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

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

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

2.36 "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.

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

2.38 "Third Party" means any person other than a Party to this Agreement or any Affiliate of either Party to this Agreement.

3. Term

3.1 Term. This Agreement is effective [insert 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; NIH Steering 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;

4.1.5 attempt to resolve any disputes on an informal basis; and

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

4.2 Responsibilities of each PAC 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 Sr. 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**.

4.7 Steering Committee of the NIH Grant. The Parties anticipate that NIH will convene a Steering Committee to provide feedback to NIH on each grant recipient's project. The Steering Committee is expected to include: the Program Director(s)/Principal Investigator(s), key personnel, the pharmaceutical company collaborator or consultant as an ex officio member, the NIH Project Scientist, the NIH Program Official, and external scientist(s). The Steering Committee will:

4.7.1 Participate in monitoring scientific progress of the Project Plan, assessing recruitment, progress of the go/no go milestones, and assessing whether go/no go criteria have been met.

4.7.2 Meet quarterly (in person or by video or audio teleconference) to monitor progress on the research project plan and to address issues or activities that impact the project. At least one in-person meeting is expected to be held annually in the Washington, D.C. area to allow attendance of NIH staff.

4.7.3 Hold teleconferences to address operational issues on a monthly basis, or as dictated by the needs of the study.

4.7.4 Establish workgroups for specific tasks as the Steering Committee deems appropriate. The workgroups will make recommendations to the Steering Committee.

4.7.5 Ensure timely publication of abstracts and scientific articles to make results of projects and inventions available, including negative data regarding new indications.

4.7.6 Participate in monitoring of intellectual property arising from the project.

5. Governance and Management

5.1 Progress Reports. The Principal Investigator is responsible for submission of required NIH reports, including the annual progress report, invention statement, and interim progress report upon completion of the first stage of the NIH grant. The Principal Investigator will provide periodic progress reports of research accomplishments, roadblocks, and milestones, monthly recruitment updates, and other standard reports requested by the NIH Steering Committee.

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 Materials (defined below) 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 no Materials are contemplated to be transferred from AMC to Company. The Parties agree that the Company Compound, and other compounds, materials, biological samples, and other physical property (altogether, the "Material") of Company may be provided to AMC hereunder and shall be used by AMC solely for the purpose of the Project Plan and solely in the laboratories or clinics of AMC by personnel described in the Project Plan. The GSK Materials are and shall remain the sole and exclusive property of the Company. Accordingly, any and all Material of Company will be treated as Confidential Information of Company in accordance with **Article 7**. Any transfer of Material by Company to AMC's site shall require the prior written consent of both Parties in the form of **Exhibit C1** (for the transfer of Material not derived from human tissue) or **Exhibit C2** (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 AMC by secure means. All such Material shall remain the property of the Company and will be surrendered to Company promptly, or destroyed, upon Company's written request to AMC for such return or destruction. No license, express or implied, is granted to AMC 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, and as such 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 by an IIR Agreement in the form set out in **Exhibit B** and such other special and supplemental terms as the Parties determine are necessary and appropriate at that time.

5.5 Data Integrity. Each Party shall use best efforts to maintain records in sufficient detail and in a good scientific and detailed manner reflecting its activities under this Agreement obtained therefrom to properly reflect all work done and results achieved in performing the Project Plan. Each Party acknowledges the importance to the other Party of ensuring that its activities under this Agreement are performed in accordance with the following guidelines:

5.5.1 data are being generated using sound scientific techniques and processes;
5.5.2 data are being accurately recorded in accordance with good scientific practices by persons conducting the Project Plan hereunder;
5.5.3 data are being analyzed appropriately without bias in accordance with good scientific practices;
5.5.4 data and results are being stored securely and can be easily retrieved, and
5.5.5 data trails exist to easily demonstrate and/or reconstruct key decisions made during the conduct of the Project Plan and conclusions reached with respect to the Project Plan.

6. Funding and Resources

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

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") will 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 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 comply with HIPAA to the extent that HIPAA applies to that Party (but this Agreement does not by contract impose HIPAA requirements on a Party), 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 (if applicable to that Party), 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 (if any) 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 sole and 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 within thirty (30) days after becoming aware of such inventions.

8.4 Patents on AMC Inventions

8.4.1 AMC shall have the right, but not the obligation, to file patent applications covering any AMC Invention. Except as stipulated in **Section 8.4.2**, AMC shall be solely responsible for the prosecution and maintenance of all Patent applications and Patents claiming AMC Inventions and all costs related thereto. 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 may also consult with Company regarding the countries in which such patent applications should be filed. In the event Company requests that AMC employ Company's preferred ex-U.S. patent agents in such countries, AMC shall consider doing so. AMC shall provide to Company a yearly update on the status of all such Patents and Patent applications. AMC will provide to Company sixty (60) days' advance written notice of AMC's intention to abandon any Patent on an AMC Invention, and Company will have the right to continue prosecution of such Patent or patent application at Company's sole expense, including reimbursing AMC for patent prosecution expenses previously incurred by AMC on such Patent or application. The Parties agree to negotiate licensing such Patent to Company under the provisions of **Section 9.2**.

8.4.2 If Company exercises an Option under section 9, then Company shall reimburse AMC for all expenses previously incurred in the 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.

8.5 Patents on Company Inventions. Company shall have the right, but not the obligation, 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 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** and **Section 9.3,** 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 Abandons Filing or Declines to Exercise Option. In the event that Company decides to abandon filing of the Joint Inventions, or 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 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 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 hereby 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 hereby 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 hereby 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 hereby 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 the exclusive option to acquire (i) a worldwide, royalty-bearing, exclusive or non-exclusive license, at Company's sole discretion, including the right to grant sublicenses under such 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 any 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 receipt of 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 Consideration terms for any license elected pursuant to the Option shall specifically include, but will not be limited to, provisions that:

[Specific financial terms mutually agreeable to the Parties to be inserted here].

9.2.3 If the Parties do not agree (having negotiated in good faith) upon an exclusive license to any AMC Invention or AMC Technical Developments in accordance with **Section 9.2** by the end of the fifth (5^{th}) month after the election by Company of the Option, then each Party shall at that time refer further negotiations to a member of its senior management selected by that Party (each, a "Senior Negotiator"). For AMC, the initial Senior Negotiator shall be the Vice Chancellor of Research or an equivalent position. For Company the initial Senior Negotiator shall be the VP of Research. The Senior Negotiators shall continue negotiations on the terms of the license agreement for a period of up to one (1) month (the "Negotiation Period"). If the Senior Negotiators have not reached agreement on revised consideration by the end of the Negotiation Period, each Party shall submit its final proposed consideration. Fair market value consideration (which shall not be less than final proposal by Company or greater than the final proposal by AMC) shall be determined by non-binding arbitration in accordance with the procedures of the American Arbitration Association ("AAA"), provided that the non-binding arbitration decision shall be rendered no later than twenty-one (21) days after the filing of the request for arbitration, absent mutual agreement of the Parties for an extension of time. Each Party shall bear its own costs of the arbitration. On determination of such fair market value consideration, Company shall have the right to enter into the proposed license on the

basis of such revised consideration or to rescind the exercise of its Option. If Company rescinds the exercise of its Option, then (i) the Option will immediately lapse and expire, and (ii) AMC will be free to license the subject AMC Technical Developments, AMC Inventions or AMC's interest in Joint Inventions (but not the rights to Company solely-owned intellectual property or Company Confidential Information) to any Third Party(ies) as AMC desires, provided these terms are not more favorable than those offered to Company.

9.2.4 For the avoidance of doubt, if for any reason Company does not obtain an exclusive license to any AMC Invention or AMC Technical Developments of the Option, AMC may license its interests in such AMC Invention or AMC Technical Developments to any Third Party on any terms it desires, in its sole discretion, provided that if licensed exclusively the terms are not more favorable than those offered to Company. Such licenses shall not include rights to Company solely-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 Any license granted to Company for inventions covering diagnostic research tools which results from the exercise of any Option will be 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 Indemnification by Company. Company will hold harmless, indemnify and defend AMC from and against any and all Third Party claims, liabilities, demands, damages, expenses (including reasonable attorneys' fees) 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 hereunder, 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.

10.2 Indemnification by AMC. Unless otherwise prohibited by applicable law, AMC assumes all liability for claims or damages that may arise from AMC's, its Affiliates, or any Third Parties acting on behalf of or under authorization from AMC, use, handling, storage, distribution, administration in humans and/or disposal of the Materials, and for any activities related to the Materials. Further, unless otherwise prohibited by applicable law, AMC shall hold harmless, indemnify and defend the Company from all Third Party liabilities, demands, damages, expenses and losses arising out of: (i) any breach of any obligation in this Agreement by AMC, (ii) the inaccuracy or breach of any representation or warranty made by AMC in this Agreement 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 the Company or (ii) if the 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.

10.3 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 Project Plans, 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 forty-five (45) 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. GSK may be acknowledged, consistent with academic standards, in all such publications by coauthorship or acknowledgement, as is appropriate.

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. Company 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 Company 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 or no 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 license granted to Company under **Article 9.2** will terminate upon the effective date of such Agreement termination, provided, however, that Company will be allowed to sell all inventory of Product then in its possession or distribution pipeline. Upon such termination, rights in the AMC Inventions and AMC Technical Developments which were the subject of the license 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.

12.3.1 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, upon the effective date of termination, 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, 5.3, 12.3, 12.4, 15.2, 15.5, 15.7, 15.8, 15.9, 15.10, 15.11, 15.12**, and **15.13**.

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 To the extent the Project Plan utilizes any non-human animals, the Company and AMC agree that the care, handling and use in research and development activities hereunder of any non-human animals by or on behalf of the Company or AMC shall comply with all relevant statutes, legislation, regulations and guidelines for the care, welfare and ethical treatment of animals used in research in the country where the Evaluation shall be performed. In conducting any research involving the use of animals, the Company and AMC each further agrees to use best efforts to comply with the "3R" Principles-- reducing the number of animals used, replacing animals with non-animal methods whenever possible and refining the research techniques used. All work should be conducted in adherence to the core principles for animals on research studies identified below. Local customs, norms, practices or laws may be additive to the core principles, but the Company and AMC each agrees to comply, at a minimum, with these core principles:

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13.4.1 Access to species appropriate food and water;
13.4.2 Access to species specific housing, including species appropriate temperature and humidity levels;
13.4.3 Access to humane care and a program of veterinary care;
13.4.4 Ability to demonstrate species specific behavior;
13.4.5 Adherence to principles of replacement, reduction and refinement in the design of *in vivo* studies; Project protocol reviewed and approved by the Company's Institutional Animal Care and Use Committee (IACUC);
13.4.6 Commitment to minimizing pain and distress during *in vivo* studies, and
13.4.7 Work performed by appropriately trained staff.

13.5 Unless otherwise required or prohibited by law, the Company and AMC each hereby represents and warrants to the other that, to the best of its knowledge, in relation to the Project Plan:

13.5.1 it does not employ engage or otherwise use any child labor in circumstances such that the tasks performed by any such child labor could reasonably be foreseen to cause either physical or emotional impairment to the development of such child;

13.5.2 it does not use forced labor in any form (prison, indentured, bonded or otherwise) and its employees are not required to lodge papers or deposits on starting work;

13.5.3 it provides a safe and healthy workplace, presenting no immediate hazards to its employees. Any housing provided by the Company or AMC to its employees is safe for habitation. the Company and AMC each provides access to clean water, food, and emergency healthcare to its employees in the event of accidents or incidents at the Company's or AMC's workplace;

13.5.4 it does not discriminate against any employees on any ground (including race, religion, disability or gender);

13.5.5 it does not engage in or support the use of corporal punishment, mental, physical, sexual or verbal abuse and does not use cruel or abusive disciplinary practices in the workplace;

13.5.6 it pays each employee at least the minimum wage, or a fair representation of the prevailing industry wage, (whichever is the higher) and provides each employee with all legally mandated benefits;

13.5.7 it complies with the laws on working hours and employment rights in the countries in which it operates; and

13.5.8 it is respectful of its employees right to join and form independent trade unions and freedom of association.

13.6 Each of the Company and AMC hereby agrees that it is responsible for controlling its own supply chain and that it will encourage compliance with ethical standards and human rights by any subsequent supplier of goods and services that are used by the Company or AMC, as applicable, when performing its obligations under this Agreement. Each of the Company and AMC will ensure that it has ethical and human rights policies and an appropriate complaints procedure to deal with any breaches of such policies.

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 the Project Plan as required to monitor study conduct and compliance with the terms of this Agreement and/or any IIR Agreements, and/or animal care and welfare, and/or ethical human standards. 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. In the event of an unscheduled inspection by a regulatory agency in relation to the Program, AMC will notify the Company as soon as reasonably possible but in no event more than one (1) business day after the inspection. In the event of a scheduled inspection by a regulatory agency in relation to the Program, AMC will notify the Company as soon as reasonably possible but in no event less than five (5) business days before the inspection. 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, within three (3) business days of receipt, 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.

14.3 Additional monitoring and auditing requirements are stated in **Exhibit B**.

15. General Provisions

15.1 Anti-Bribery and Anti-Corruption Practices. AMC shall comply fully at all times with all applicable laws and regulations, including but not limited to applicable anti-bribery laws and anti-corruption laws of the territory in which the AMC conducts business with the Company.

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

If to Company, to:

With copy to:

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.

15.3 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.

15.4 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.

15.5 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.

15.6 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.

15.7 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.

15.8 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.

15.9 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.

15.10 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.

15.11 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.

15.12 Choice of Law. This Agreement shall be governed in all respects by the laws of the State [insert].

15.13 Consultancy. Both Parties agree that each is responsible for the acts of its own employees within the scope of their employment pursuant to all relevant and applicable laws and regulations. Notwithstanding the above, Company agrees that in the event a AMC faculty or staff member serves Company in the capacity of consultant, officer, employee, board member, advisor, or other designation, pursuant to a contract or otherwise outside of this Agreement, when acting outside of this Agreement such AMC faculty or staff member shall serve in his or her individual capacity, as an independent contractor, and not as an agent or representative of AMC, that AMC exercises no authority or control over such faculty or staff member while acting in such capacity, that AMC receives no benefit from such activity, that neither Company nor the faculty or staff member may use AMC resources in the course of such service and that AMC makes no representations or warranties under such contracts and otherwise assumes no liability or obligation in connection with any such work or service undertaken by such faculty or staff member. Company further agrees that any breach, error, or omission by a AMC faculty or staff member acting in the capacity set forth above

in this Section shall not be imputed or otherwise attributed to AMC, and shall not constitute a breach of this Agreement by AMC.

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]		**[Company]**	
Signed:	…….	Signed:	……..
Printed Name:		Printed Name:	
Position:		Position:	
Date:	…….	Date:	…….....

Signed: ……..

Printed Name: ……..

Position: …….

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 B – IIR Agreement Template

Exhibit C1 – Proforma for Transfer from One Party to the Other of Materials, Reagents and Any Other Physical Property Not Derived from Human Tissue

To be completed by AMC's Program Contact and signed by both AMC's Program Contact and Company's Program Contact

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 the Program Contacts on behalf of:

Academic Medical Center		**[Company]**	
Signed:	……..	Signed:	…….
Print name:	……..	Print name:	…….
Date:	……..	Date:	……..

Exhibit C2 – Proforma for Transfer from One Party to the Other of Materials, Reagents and Any Other Physical Property Derived from Human Tissue

To be completed by AMC's Program Contact and signed by both AMC's Program Contact and Company's Program Contact

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 the Program Contacts on behalf of:

Academic Medical Center		**[Company]**	
Signed:	……..	Signed:	…….
Print name:	……..	Print name:	…….
Date:	……..	Date:	……..