

*This document is for discussion purposes only and does not constitute a binding agreement or letter of intent between the parties. Unless and until a definitive agreement is executed by the parties, neither party is under any legal obligation of any kind with respect to any transaction, except for the matters specifically agreed to in the confidentiality agreement between the parties. Until such a binding agreement is executed, either party may determine not to proceed with the proposed transaction at any time and for any reason.*

**COLLABORATIVE RESEARCH AGREEMENT  
BETWEEN**

**JANSSEN PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C. (THE  
COMPANY) AND ACADEMIC MEDICAL CENTER**

**THIS COLLABORATIVE RESEARCH AGREEMENT** (hereinafter “Agreement”) is entered into by and between **THE 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**, THE 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 and exploitation of new therapeutic indications and/or diagnostics for existing drug candidates, and THE 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 THE 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 with respect to a Person, any Person that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such first Person. “Control” and, with correlative meanings, the terms “controlled by” and “under common control with” mean (a) the power to direct the management or policies of a Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, resolution, regulation or otherwise, or (b) to own 50% or more of the outstanding voting securities or other ownership interest of such Person. “Person” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government
- 2.2 “AMC Invention” has the meaning provided in **Section 8.2.1**.
- 2.3 “CDA” means the Confidential Disclosure Agreement between THE 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 THE COMPANY, generally or with respect to any particular country, THE COMPANY will be deemed to have exercised Commercially Reasonable Efforts if THE COMPANY has exercised those efforts normally used by THE COMPANY, in the relevant country, with respect to a

- product or product candidate of similar modality owned or Controlled by THE COMPANY, or to which THE 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 any and all information or material including any documents, notes, analyses, studies, samples, drawings, flowcharts, databases, models, plans and software (including source and object codes), other than Exempt Information in any form which the Disclosing Party or its Affiliates discloses to the Receiving Party or its Affiliates pursuant to this Agreement, either marked “Confidential” or, if oral, declared to be confidential when disclosed and confirmed in writing within thirty (30) days of disclosure. The terms and conditions of this Agreement shall be considered Confidential Information of both Parties. “Exempt Information” means information that: (i) the Receiving Party or any of its Affiliates possessed before the Disclosing Party or its Affiliates disclosed it under this Agreement; or (ii) is or becomes publicly known (other than as a result of breach of this Agreement by the Receiving Party or its Representatives); (iii) the Receiving Party or any of its Affiliates obtains from a third party free of any confidentiality obligation to the Disclosing Party or its Affiliates with respect to such information; or (iv) is independently developed by or on behalf of the Receiving Party or its Affiliates without the use of the Confidential Information.
- 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 Field of New Therapeutic Indications and/or Diagnostics means 1) a method of treating an animal (including humans) with a COMPANY Compound for a disease or disorder that is not described in a patent or patent application which claims such COMPANY Compound or its use; or 2) is a diagnostic method using the COMPANY Compound to detect a disease or disorder; the status, progression or regression of a disease or disorder; or its location in the body of an animal (including humans) that is not described in a patent or patent application which claims such COMPANY Compound or its use.

- 2.11 “HIPAA” has the meaning provided in **Section 7.6**.
- 2.12 “IIR Agreement” means the Investigator Initiated Research Agreement between THE COMPANY and AMC for the conduct of any clinical trials which is attached to this Agreement in Exhibit B.
- 2.13 “Identifiable Private Information” means patient-identifying data from medical records or attached to patient specimens, to be obtained prospectively or from stored medical records or specimens, that can be linked to individual human subjects, either directly or indirectly through codes.
- 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 THE COMPANY. “Parties” means AMC and THE 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 “The COMPANY Compound” means [insert name of compound].
- 2.27 “The COMPANY Invention” has the meaning provided in **Section 8.2.3**.
- 2.28 “PHI” or “Protected Health Information” has the meaning provided in **Section 7.6**.
- 2.29 “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.
- 2.30 “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.
- 2.31 “Program” means all activities performed by or on behalf of AMC under the scope of an NIH Grant or by or on behalf of THE COMPANY or their respective Affiliates under this Agreement and which are authorized by this Agreement.
- 2.32 “Contact” means the person nominated by each of THE COMPANY and AMC to serve as that Party’s contact for the Program as set forth in **Exhibit A**.
- 2.33 “Project Plan” means the project plan appended to this Agreement in **Exhibit A** and incorporated herein by reference.
- 2.34 “Raw Data” means the primary quantitative and empirical data first collected by an Investigator from experiments and clinical trials conducted under the scope of this Agreement.
- 2.35 “Receiving Party” has the meaning provided in **Section 7.1**.
- 2.36 “Results” means the data and results arising from the Project Plan during the Term.
- 2.37 “Specific Success Criteria” are the specific success criteria listed in the Project Plan.
- 2.38 "Summary Data" means a summary of the Raw Data used to prepare an Annual Report to the FDA. Summary Data shall specifically exclude Identifiable Private Information.
- 2.39 “Technical Development” means any invention, discovery, composition, enhancement, technology, advancement, know-how, process, 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 but excludes Raw Data and Summary Data.

2.40 “Term” has the meaning provided in **Section 3.1**.

### **3. Term**

3.1 Term. The Agreement is effective from 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 THE COMPANY, and up to four (4) additional members from each of AMC and THE COMPANY. The names of the initial Contacts for each of THE 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 will be consulted to assess, within twenty (20) days of the consultation request, if a Technical Development is sufficiently developed to warrant the submission of a patent application before the AMC provides notification of intent to file.
- 4.1.5 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

4.1.6 attempt to resolve any disputes on an informal basis.

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

4.1.7.1 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:

- Participate in monitoring scientific progress of the UH2 and UH3 research project plan, assessing recruitment, progress of the go/no go milestones, and assessing whether go/no go criteria have been met.
- 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.
- Hold teleconferences to address operational issues on a monthly basis, or as dictated by the needs of the study.
- Establish workgroups for specific tasks as the Steering Committee deems appropriate. The workgroups will make recommendations to the Steering Committee.
- Ensure timely publication of abstracts and scientific articles to make results of projects and inventions available, including negative data regarding new indications.
- Participate in monitoring of intellectual property arising from the project.

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 THE 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. The AMC Contact may only be replaced by the written agreement of THE COMPANY, such agreement not to be unreasonably withheld or delayed. The COMPANY Contact may be replaced by written notification to the AMC.
- 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 unless agreed otherwise. The Contacts may attend the meetings in person or by audio teleconference or by video teleconference. Each Party may invite additional employees involved in the Program 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 Contacts may refer the matter to their respective senior management: [Insert Position] of AMC and [Insert Position] of THE COMPANY.
- 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. 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 Steering Committee.

- 5.2 Final Report. AMC shall cause the Principal Investigator to furnish to THE 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 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 THE 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. AMC shall not conduct any research on Materials collected or created by using the COMPANY Compound (e.g., blood, plasma, cell extracts, tissue samples from animals or humans) other than that set forth in the Program or Clinical Trial Agreement. 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 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.

## 6. Funding and Resources

- 6.1 THE 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 Approved Project Plan. THE 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 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 without written permission of the Disclosing Party. 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 COMPANY shall have the right to disclose Summary Data on a COMPANY Compound to third parties for the purpose of evaluating and discussing entering into a business relationship with such third party related to the COMPANY Compound, provided that the third party has executed a confidentiality agreement with terms that are substantial equivalent or more stringent than the terms of confidentiality and nonuse as provided in this **Article 7**.
- 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, Raw Data and Summary Data 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 (except Raw Data and Summary Data) 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, 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 THE COMPANY regarding payments made to members of the medical or scientific community, or in accordance with applicable laws or regulations, THE 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 THE 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 THE 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 THE 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 THE COMPANY (“AMC Invention”),
- 8.2.2 Shall belong jointly to AMC and THE COMPANY, if the inventors are one or more employees of AMC and one or more employees of THE COMPANY (“Joint Invention”),
- 8.2.3 Shall belong to THE COMPANY, if the inventors are one or more employees of THE COMPANY and none of the inventors are employees of AMC (“The COMPANY Invention”).
- 8.3 AMC and THE 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 THE 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 THE COMPANY shall have the right to review all patent applications on AMC Inventions and provide AMC with substantive comments. AMC shall also consult with THE COMPANY regarding the countries in which such patent applications should be filed, and AMC will file applications in those countries where THE COMPANY requests that AMC should file. AMC, at its option and at its expense, may file in countries where THE COMPANY does not request that AMC should file such applications.
- 8.4.2 THE 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 THE COMPANY requests or agrees that Patents should be filed, prosecuted and maintained. THE COMPANY may request that AMC employ THE COMPANY’S preferred patent agents in such countries as THE

COMPANY requests that AMC should file, and AMC shall do so where reasonable possible and agrees that THE COMPANY may be directly invoiced by such agents. At THE COMPANY's request AMC will direct its agents to copy THE COMPANY on patent applications which THE COMPANY designates at THE COMPANY's expense. THE 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 or paying 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.

8.4.3 AMC shall consult with THE COMPANY in connection with the continued prosecution of Patents on AMC Inventions and shall take into consideration the reasonable comments of THE COMPANY, including without limitation incorporating any such comments subject to AMC's approval.

8.4.4 AMC shall provide to THE COMPANY a yearly update on the status of all such Patents and Patent applications. AMC will provide to THE COMPANY forty-five (45) days' advance written notice of any deadline for taking action should AMC have decided to otherwise allow the Patent to go abandoned, and THE COMPANY will have the right to continue prosecution of such Patent or patent application at THE COMPANY's sole expense.

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

8.6 Patents on Joint Inventions.

8.6.1 AMC and THE COMPANY shall confer regarding the filing of patent applications on Joint Inventions. THE COMPANY shall have the right to file patent applications covering any Joint Invention using THE COMPANY'S preferred patent agents. THE 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 THE COMPANY with substantive comments. THE COMPANY will provide to the AMC forty-five (45) days' advance written notification of any deadline for taking action should THE COMPANY have decided to otherwise allow

the Patent to go abandoned, and AMC will have right to continue prosecution of such Patent at AMC's sole expense. Subject to the preceding sentence and to **Section 8.6.4**, THE 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.

- 8.6.2 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.
- 8.6.3 THE COMPANY shall consult with AMC regarding the countries in which patent applications claiming Joint Inventions should be filed, and THE COMPANY will file applications in those additional countries where AMC requests THE COMPANY to do so. THE 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 THE COMPANY file such Patent applications.
- 8.6.4 AMC shall reimburse THE 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 8.6.3** in additional countries where AMC requests that Patent applications be filed, prosecuted and maintained. AMC may, upon sixty (60) days written notice, request that THE 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 THE COMPANY for the costs of filing, prosecuting, responding to opposition or maintaining such Patent application or Patent in any country. Subject to the foregoing, THE 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.
- 8.6.5 Patents on Joint Inventions after THE COMPANY Declines to Exercise Option. In the event that THE 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 THE 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, THE COMPANY shall retain any rights it may have as a joint owner under existing US patent law and as provided in **Section 8.6.2**.

- 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 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 THE COMPANY with respect to any Joint Inventions arising under this agreement, that THE COMPANY represents only itself, and not AMC, and that AMC is represented by its own counsel. Neither THE 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 THE COMPANY and THE COMPANY's Affiliates a non-exclusive, world-wide, perpetual, , 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 1) for only internal research, and development purposes in the Field of New Therapeutic Indications and/or Diagnostics; and 2) for all research and development outside the Field of New Therapeutic Indications and/or Diagnostics. The foregoing licenses shall be without the right to transfer or grant sublicenses to any third party (except to contractors performing work solely for the benefit of THE COMPANY or THE COMPANY's Affiliates and under obligations of confidentiality and non-use similar to those of this Agreement), unless THE COMPANY receives the express written permission of AMC to do so.
- 9.1.2 THE COMPANY grants to AMC and AMC's Affiliates a non-exclusive, world-wide, perpetual, royalty-free, fully paid-up license under THE 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 THE COMPANY. Collaborations with for-profit entities are expressly excluded from the license granted in this **Section 9.1.2.**

9.1.3 THE 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 THE COMPANY's rights in Materials provided by THE 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 THE COMPANY and THE 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 THE 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 THE COMPANY or THE COMPANY's Affiliates under the Program.

## 9.2 Commercial Option and Licenses

9.2.1 For each Project Plan in addition to the rights granted under 9.1.1, AMC hereby grants to THE COMPANY the exclusive option to acquire (i) a worldwide, bearing a royalty or other appropriate financial terms as agreed to by the parties under **Article 9.2.2**, exclusive license to Technical Development owned by the AMC, AMC Invention and/or Joint Invention or non-exclusive license to Technical Development owned by the AMC and/or AMC Invention, 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, 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"). THE COMPANY and its Affiliates must exercise the Option by providing written notice to AMC within six (6) months after written notification by AMC to THE COMPANY of the corresponding Technical Development AMC Invention or Joint Invention which is described in sufficient written detail to allow for analysis of the merits of such Technical Development or invention or within six (6) months of



completion of the Project Plan under which the Technical Development, AMC Invention or Joint Invention arose, whichever is later, *provided, however*, that if AMC gives written notice to THE COMPANY of its intent to file a patent application under **Section 8.4.1** described in sufficient written detail to allow for analysis of the merits of such invention and if THE 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 THE COMPANY of AMC's intent to file the patent application. THE 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 will consider the relative contribution of the any AMC Invention, Joint Invention or AMC Technical Developments (e.g. IND application) relative to the previous investments made by THE COMPANY in developing the Material, and in the subsequent investments required to develop a marketed product. Terms 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<sup>th</sup>) month after the election by THE 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 THE 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 THE 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"). The arbitrator shall have a meeting within ten (10) days from the appointment of the arbitrator with both parties to hear a presentation of their position and may request a written submission of their positions at the time of the meeting. Within fourteen (14) days the conclusion of that meeting the arbitrator shall provide a non-binding arbitration decision. These deadlines may be extended by mutual agreement between the parties. Failure of the arbitrator to meet these deadlines shall not affect

validity of the arbitrator's decision. No discovery shall be taken or authorize in this arbitration proceeding. The choice of law that will be applied in this arbitration is the law of the State of New Jersey. The arbitrator's decision shall not assess fees or award money damages of any kind (e.g. exemplary or punitive damages). The decision shall be treated as jointly owned Confidential Information of the parties, unless the parties mutually agree otherwise. Each Party shall bear its own costs of the arbitration. On determination of such fair market value consideration, THE 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 THE 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 THE COMPANY solely-owned intellectual property or THE COMPANY Confidential Information) to any third party or parties as AMC desires, provided these terms are not more favorable than those offered to THE COMPANY.

- 9.2.4 For the avoidance of doubt, if for any reason THE 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 THE COMPANY. Such licenses shall not include rights to THE COMPANY solely-owned intellectual property or THE COMPANY Confidential Information.

### 9.3 Additional License Terms.

- 9.3.1 Each exclusive license agreement granting rights to AMC Invention from AMC to THE COMPANY and which results from THE COMPANY's exercise of the Option will contain a provision requiring THE COMPANY to use Commercially Reasonable Efforts to commercialize a Product or a service (as applicable) in the United States or other countries if mutually agreed to by AMC and THE COMPANY.
- 9.3.2 Any license granted to THE COMPANY for inventions covering diagnostic research tools which results from the exercise of any Option will be non-exclusive.
- 9.3.3 Each exclusive license agreement granting rights from AMC to THE COMPANY and which results from THE COMPANY's exercise of the Option will contain a provision allowing AMC to retain the right to use AMC Technical Developments for its research and teaching purposes and the right to sublicense these rights to not-for-profit research institutions for research

and teaching purposes only and not for use in the manufacture, distribution or sale of products.

#### 9.4 Data Rights

9.4.1 The Raw Data generated under this Agreement are considered the property of the Party that generates the data. Analysis of the Raw Data will be conducted by AMC in accordance to the statistical methods delineated in the Clinical Trial or Project Plan. In addition to any other reports or data made available to them hereunder, THE COMPANY shall be provided on a timely basis:

- (a) Annual copies of all final Summary Data reports;
- (b) Annual patient accrual status report (Site ID, Investigator, patients: enrollment status, total screened, in screening, failed screening, total enrolled, enrolled failure, active, complete, dropped); and
- (c) Annual overview of the progress of any Clinical Trials (Proposed timelines for start-up and completion of such Clinical Trial).

9.4.2 The data generated in Clinical Trials conducted by AMC are the property of AMC. THE COMPANY shall have complete access to all de-identified Raw Data, Summary Data and results generated under this Agreement that are in the possession and control of AMC. Summary Data will be made fully available to THE COMPANY for its own analyses and for its application for FDA approval. THE COMPANY shall have the right to use such de-identified data for internal research, development and commercialization (including disclosing such data to Affiliates consistent with **Article 7**) and to use and disclose such de-identified data to satisfying FDA or health authorities' reporting requirements and obtaining regulatory approval of the COMPANY Compound. Furthermore, THE COMPANY may assign any data or reports provided under this Agreement to any Affiliate or a third party in the event of any acquisition of rights to COMPANY Compound, Product or sell, merger or divestiture of the business which includes COMPANY Compound or Product.

9.4.3 COMPANY will receive Identifiable Private Information only if necessary for purposes of satisfying FDA or health authorities' reporting requirements, and for internal research purposes directly related to obtaining regulatory approval of COMPANY Compound.

### **10. Indemnification**

10.1 THE 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 THE COMPANY or by any third party acting on behalf of or under authorization from THE COMPANY, of information or materials received from AMC, or (ii) any use, sale or other disposition by THE COMPANY or by any third party acting on behalf of or under authorization from THE 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 THE COMPANY prompt notice of any claim it receives and such failure materially prejudices THE COMPANY with respect to any claim or action which THE COMPANY's obligation pursuant to this Section applies. THE 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 THE COMPANY from all third party liabilities, demands, damages, expenses and losses arising out of: (i) any breach of any obligation in this Agreement (ii) the inaccuracy or breach of and 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 THE 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 THE COMPANY TO AMC PURSUANT TO THIS AGREEMENT (HEREIN THE "INTELLECTUAL PROPERTY") ARE ON AN "AS IS" BASIS. THE 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 THE 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. THE 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 THE 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, THE COMPANY acknowledges the importance of publications to the reputation of AMC and its faculty members. The provisions of this **Article 11** are intended to promote and ensure timely publication of results of Projects, inventions and Technical Developments, Raw Data and Summary Data 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, Raw Data, or Summary Data ,it shall submit to the Program Advisory Committee 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”). THE COMPANY Contact to the Program Advisory Committee shall secure timely COMPANY review of the proposed publication. THE COMPANY may, together with AMC, revise the manuscript or other proposed publication to ensure protection of THE COMPANY’s Confidential Information. Upon THE COMPANY’s request, AMC shall delay submission or publication for up to an additional thirty (30) days (the “Supplemental Review Period”) if THE COMPANY deems it reasonably necessary to enable AMC or THE COMPANY (as the case may be) to apply for Patent protection covering any Technical Development, Raw Data and Summary Data disclosed in the proposed publication. In exercising its rights under this Section, THE 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 THE 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 THE COMPANY under **Section 12.2.3**, then i) any license granted by AMC to THE COMPANY for AMC Inventions under **Article 9.1.1**; ii) the COMPANY's rights to Options under 9.2; and iii) any license granted to THE COMPANY under **Article 9.2** will terminate upon the effective date of such Agreement termination, provided, however, that THE COMPANY will be allowed to sell all inventory of Product then in its possession or distribution pipeline. 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.
- 12.3.2 If this Agreement is terminated by THE COMPANY under **Section 12.2.1** or by AMC under **Section 12.2.3**, then i) any license granted by THE COMPANY to AMC for COMPANY Inventions under **Article 9.1.2** shall terminate upon the effective date of such Agreement termination; ii) AMC shall immediately make all necessary disclosures and offer the Option provided under **Article 9.2** to COMPANY; and iii) any license granted to THE 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, 5, 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 THE 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 THE 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 THE 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, THE COMPANY will have a right to participate in the inspection.
  - 14.2.2 Cooperation. AMC will cooperate with regulatory agency or THE 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 THE 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 THE 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 THE 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 Notices. Notices to be given under this Agreement shall be in writing and sent to the Parties as follows:

If to THE COMPANY, to:

[INSERT CONTACT AND ADDRESS]

With copy to:

[INSERT CONTACT AND ADDRESS]

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 THE 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 THE COMPANY may make such assignment to any Affiliate or may make such assignment in the event of any acquisition (COMPANY Compound, Product or the business which includes COMPANY Compound or Product), merger or other valid business reconstruction of such company or business 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 THE 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 [insert]
- 15.12 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, THE COMPANY agrees that in the event a AMC faculty or staff member serves THE 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 THE 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. THE 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**

**THE 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 THE 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 THE COMPANY or AMC as the case may be)]

Transferee: [insert the name of the Party receiving items from the other Party (either AMC or THE COMPANY as the case may be)]

AMC contact Person: [insert name of individual]

THE 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 THE COMPANY and [AMC] dated [insert date].

Agreed and accepted by the Program Contacts on behalf of:

**Academic Medical Center**

**THE 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 THE 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 THE COMPANY or AMC as the case may be)]

Transferee: [insert the name of the Party receiving items from the other Party (either AMC or THE COMPANY as the case may be)]

AMC contact Person: [insert name of individual]

THE 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 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 THE COMPANY and [AMC] dated [insert date].

Agreed and accepted by the Program Contacts on behalf of:

**Academic Medical Center**

**THE COMPANY**

Signed: .....

Signed: .....

Print name: .....

Print name: .....

Date: .....

Date: .....