COLLABORATIVE RESEARCH AGREEMENT

BETWEEN

ASTRAZENECA UK LIMITED AND [ACADEMIC MEDICAL CENTER]

THIS COLLABORATIVE RESEARCH AGREEMENT (hereinafter "**Agreement**") is entered into by and between **AstraZeneca UK Limited**, a company incorporated in England under no. 3674842 whose registered office is at 2 Kingdom Street, London, W2 6BD, England (hereinafter "**AstraZeneca")** and [NAME OF INSTITUTION**],** a [TYPE OF INSTITUTION] having an office at [INSERT ADDRESS] (hereinafter "**Academic Medical Center**" or "**AMC**") for the conduct of collaborative [preclinical] [OR] [clinical] research studies in the area of identification and testing of new disease indications for existing AstraZeneca drug candidates.

WHEREAS, AstraZeneca entered into a Memorandum of Understanding (the "**MOU**") dated [April __, 2014] with the National Institutes of Health's National Center for Advancing Translational Sciences ("**NCATS**"), the goal of which MOU is to encourage the discovery and exploitation of new therapeutic indications for existing drug candidates, and AstraZeneca is in possession of certain such drug candidates (e.g., AstraZeneca 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 an NIH Grant (as defined below) to perform studies related to AstraZeneca Compound; and

WHEREAS, the studies contemplated by this Agreement will be of mutual interest and benefit to AstraZeneca 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 AstraZeneca 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 Externally Sponsored Collaborative Research (ESCR) Agreement (as further defined below). Each Party will perform the work that is assigned to it in this Agreement, the Project Plan, and the ESCR Agreement (if any).

1.2 This Agreement and the ESCR 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 "**AstraZeneca Compound**" means [insert name of compound].

2.4 "**AstraZeneca Invention**" has the meaning provided in **Section 8.2.3**.

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

2.6 "**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 AstraZeneca, generally or with respect to any particular country, AstraZeneca will be deemed to have exercised Commercially Reasonable Efforts if AstraZeneca has exercised those efforts normally used by AstraZeneca, in the relevant country, with respect to a product or product candidate of similar modality owned or Controlled by AstraZeneca, or to which AstraZeneca 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.

2.7 "**Confidential Information**" means with respect to each Party, other than Exempt Information, any and all information or material in any form, including any documents, notes, analyses, studies, samples, drawings, flowcharts, databases, models, plans and software (including source and object codes), that the Disclosing Party or any of its Representatives discloses to the Receiving Party or any of its Representatives pursuant to this Agreement, that is 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.

2.8 "**Contact**" means the person nominated by AstraZeneca or AMC, respectively, to serve as such Party's contact for the Program as set forth in **Exhibit A**.

2.9 "**Debarred Person**" has the meaning provided in **Section 13.3**.

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

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

2.12 "**ESCR Agreement**" means the Externally Sponsored Collaborative Research Agreement between AstraZeneca and AMC for the conduct of any clinical trials which is attached to this Agreement in **Exhibit B**.

2.13 "**Exempt Information**" means information that: (i) the Receiving Party or any of its Affiliates possessed before the Disclosing Party or any of its Representatives 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 any of 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 any of its Affiliates without the use of the Disclosing Party's Confidential Information.

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

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

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

2.17 "**Indication**" means [insert definition].

2.18 "**IRB**" means Institutional Review Board.

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

2.20 "**Material**" has the meaning provided in **Section 5.4.**

2.21 "**MOU**" has the meaning provided in the Recitals.

2.22 "**Negotiation Period**" has the meaning provided in **Section 9.2.3**.

2.23 "**NIH**" means the U.S. National Institutes of Health.

2.24 "**NIH Grant**" means any award made under the NCATS Drug Rescue Program to AMC for Research Proposal [insert identifying information].

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

2.26 "**Party**" means AMC or AstraZeneca. "**Parties**" means AMC and AstraZeneca.

2.27 "**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.

2.28 "**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 AstraZeneca 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 the NIH Grant or by or on behalf of AstraZeneca or their respective Affiliates under this Agreement and which are authorized by this Agreement.

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

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

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

2.35 "**Representatives**" means, with respect to a Party, its Affiliates and its and their respective directors, officers, employees, contractors, consultants, advisors and agents.

2.36 "**Research Documentation**" means any and all documents, records, accounts, notes, reports (including, without limitation, the progress reports and the final report prepared pursuant to **Article 5**) and other data relating to the Program, whether in written, electronic, video or other tangible form created by AMC or by a third party on behalf of AMC.

2.37 "**Senior Negotiator**" has the meaning provided in **Section 9.2.3**.

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

2.39 "**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.

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

2.41 "**Third Party Disclosure**" has the meaning provided in **Section 7.2**.

3. Term

3.1 Term. This Agreement is effective as of the Effective Date and unless terminated in accordance with the provisions of **Section 12** herein shall remain in full force and effect for a period of three (3) 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. Governance, Management and Oversight

4.1 Program Advisory Committee. The Parties recognize, because of the contributions made to the Program by 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 AstraZeneca, and up to four (4) additional members from each of AMC and AstraZeneca. The names of the initial Contacts for each of AstraZeneca 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 be consulted to assess whether a Technical Development is sufficiently developed to warrant the submission of a patent application (provided that, before giving notice of an intent to file a patent application under **Section 8.4.1** or **8.6.1** (as applicable), a Party must request a consultation with the PAC and provide the PAC with such opportunity to conduct an assessment of the relevant Technical Development, and the PAC must meet within twenty (20) days of the applicable AMC consultation request for such assessment);

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;

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

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 cooperative agreement 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; and
- 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 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; and

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 AstraZeneca 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 AstraZeneca, such agreement not to be unreasonably withheld or delayed. The AstraZeneca Contact may be replaced by written notification to AMC.

4.4 PAC Meetings. The Contacts will convene meetings of the PAC, unless agreed otherwise, at least once 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 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 PAC 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 Vice President, Emerging Innovations Unit, Scientific Partnering and Alliances of AstraZeneca.

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. Reporting and Conduct of the Program

5.1 Recordkeeping. AMC will implement recordkeeping procedures consistent with accepted good preclinical and clinical laboratory practice standards and consistent with the requirements of the AMC's relevant Institutional Review Board so that all relevant program Research Documentation is complete, current, accurate, organized and legible, and shall be prepared and maintained in a manner acceptable for the collection of data for submission to, or review by, regulatory authorities and in full compliance with all applicable laws. AMC shall maintain the Research Documentation for this Program separate from all other records kept by each Researcher for other programs. Without limiting the generality of the foregoing, AstraZeneca is available to work with AMC to ensure that the Program's recordkeeping procedures include Research Documentation that shall provide the level of detail to support the filing and prosecution of patent applications for any inventions discovered, created, conceived or reduced to practice in the conduct of the Program.

5.2 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 each 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. The Principal Investigator will provide the AstraZeneca Contact with scientific content of such NIH reports.

5.3 Final Report. AMC shall cause the Principal Investigator to furnish to AstraZeneca 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.

5.4 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 5.4**, unless the Parties mutually agree otherwise. The Parties agree that AstraZeneca 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**. Except for transfer of AstraZeneca Compound under the ESCR Agreement in **Exhibit B**, 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 AstraZeneca. All such Material shall be transferred to the other Party by secure means. All such Material shall remain the property of the transferring Party and will be surrendered to the transferring Party promptly or destroyed after the transferring Party provides to the other Party a written request for such return or destruction. No license, express or implied, is granted to the other Party in respect of such supplied Material other than as expressly stated in this Agreement.

5.5 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 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 ESCR 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 AstraZeneca 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. AstraZeneca will provide no funding or compensation 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 or other third party where the other third party holds no financial or intellectual property interest in the project.

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. The Receiving Party will disclose the Disclosing Party's Confidential Information only to its officers, employees and any permitted subcontractors 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. Notwithstanding the foregoing in this **Section 7.1**, the Receiving Party, without prior written consent of the Disclosing Party, may disclose Disclosing Party's Confidential Information (i) to the NIH as necessary to support a grant application and under the terms of the NIH Grant, subject to applicable laws, regulations and NIH policies concerning confidentiality, or (ii) as necessary to practice its rights under **Article 9**, provided however that such disclosure to a third party other than the NIH under this clause (ii) is made under a confidentiality agreement substantially similar to the confidentiality provisions of this Agreement.

7.2 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 is required to disclose.

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

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 subcontractors 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 AstraZeneca regarding payments made to members of the medical or scientific community, or in accordance with applicable laws or regulations, AstraZeneca 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 any compensation or item of value provided by AstraZeneca 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 AstraZeneca, 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 AstraZeneca 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 Representatives of AMC and none of the inventors are Representatives of AstraZeneca ("**AMC Invention**"),

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

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

8.3 AMC and AstraZeneca 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 Subject to consultation with AstraZeneca, including through the PAC in accordance with **Section 4.1.4**, AMC shall have the right to file patent applications covering any AMC Invention. AstraZeneca shall have the right to review all patent applications on AMC Inventions and provide AMC with substantive comments. Accordingly, AMC shall provide AstraZeneca with a draft of any such application at least forty-five (45) days in advance of the intended filing date (unless an earlier filing is authorized in writing by the AstraZeneca Contact for such application). AMC shall also consult with AstraZeneca regarding the countries in which such patent applications should be filed, and AMC will file applications in those additional countries where AstraZeneca requests AMC to do so. AMC, at its option and at its expense, may initially select the list of countries in which to file, and may file in countries where AstraZeneca does not request that AMC file such patent applications.

8.4.2 AstraZeneca shall reimburse AMC for all costs of filing, prosecuting, responding to opposition (including interference proceedings), and maintaining Patents and patent applications on AMC Inventions filed under **Section 8.4.1** in additional countries where AstraZeneca requests that patent applications be filed, prosecuted and maintained. AstraZeneca may request that AMC employ AstraZeneca's preferred patent agents in such additional countries as AstraZeneca requests that AMC should file, and AMC shall do so where reasonably possible and agrees that AstraZeneca may be directly invoiced by such agents. AstraZeneca 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 or patent application 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 or patent application.

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

8.4.4 AMC shall provide to AstraZeneca a yearly update on the status of all such Patents and patent applications. AMC will provide to AstraZeneca 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 AstraZeneca will have the right to continue prosecution of such Patent or patent application at AstraZeneca's sole expense.

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

8.6 Patents on Joint Inventions.

8.6.1 AMC and AstraZeneca shall confer regarding the filing of patent applications on Joint Inventions, including through the PAC in accordance with **Section 4.1.4**. AstraZeneca shall have the right to file patent applications covering any Joint Invention using AstraZeneca's preferred patent agents. AstraZeneca 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 AstraZeneca with substantive comments. AstraZeneca will provide to AMC forty-five (45) days' advance written notification of any deadline for taking action should AstraZeneca 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**, AstraZeneca 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** (if any)**,** 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 AstraZeneca shall consult with AMC regarding the countries in which patent applications claiming Joint Inventions should be filed, and AstraZeneca will file applications in those additional countries where AMC requests AstraZeneca to do so. AstraZeneca, 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 AstraZeneca file such patent applications.

8.6.4 AMC shall reimburse AstraZeneca for all costs of filing, prosecuting, responding to opposition (including interference proceedings), and maintaining Patents and patent applications 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 AstraZeneca discontinue filing, prosecuting, responding to opposition, or maintaining Patents or patents applications in any such country and, upon expiration of such sixty (60) day period, may discontinue reimbursing AstraZeneca for the costs of filing, prosecuting, responding to opposition or maintaining such Patent or patent application in any country. Subject to the foregoing, AstraZeneca 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 or patent application.

8.6.5 <u>Patents on Joint Inventions after AstraZeneca Declines to Exercise Option.</u> In the event that AstraZeneca 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 AstraZeneca 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, AstraZeneca shall retain any rights it may have as a joint owner under **Sections 8.2.2** and **8.6.2**.

8.7 Each Party undertakes on behalf of itself and its Affiliates, Representatives 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 the Contact and AMC's members of the Program Advisory Committee as well as permitted students, subcontractors and other Representatives used by AMC, 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 AstraZeneca with respect to any Joint Inventions arising under this agreement, that AstraZeneca represents only itself, and not AMC, and that AMC is represented by its own counsel. Neither AstraZeneca, nor any of its Affiliates or sublicensees, nor any of their Representatives 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 AstraZeneca and AstraZeneca'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 AstraZeneca or AstraZeneca's Affiliates and under obligations of confidentiality and non-use similar to those of this Agreement), unless AstraZeneca receives the express written permission of AMC to do so.

9.1.2 AstraZeneca grants to AMC and AMC's Affiliates a non-exclusive, world-wide, perpetual, non-cancelable, royalty-free, fully paid-up license under AstraZeneca's rights in Technical Developments, including its rights in AstraZeneca Inventions and Patents covering such AstraZeneca 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 AstraZeneca. Collaborations with for-profit entities are expressly excluded from the license granted in this **Section 9.1.2**.

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

9.2 Commercial Option and Licenses

9.2.1 For each Project Plan, AMC hereby grants to AstraZeneca the exclusive option to acquire (i) a worldwide, royalty-bearing, exclusive or non-exclusive license, including the right to grant sublicenses under an exclusive commercial license, to make, have made, 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**"). AstraZeneca and its Affiliates must exercise the Option by providing written notice to AMC within six (6) months after written notification by AMC to AstraZeneca 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 AstraZeneca of its intent to file a patent application under **Section 8.4.1** and if AstraZeneca does not request or agree that AMC should file the patent application in certain specific countries, then solely with respect to such specific countries, the Option will expire six (6) months from the date AMC first notifies AstraZeneca of

AMC's intent to file a patent application. AstraZeneca's failure to timely exercise an 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 invention or IND Application relative to the previous investments made by AstraZeneca 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:

9.2.2.1 for exclusive licenses, provide for a royalty of up to [insert %] on net sales for the specific indication of each Product whose manufacture, use or sale for such specific indication is covered by or requires the practice of any AMC Technical Development, which is owned by AMC alone or owned jointly with AstraZeneca (*e.g.*, any AMC Invention or Joint Invention); and

9.2.2.2 for non-exclusive licenses, provide for a royalty of up to [insert %] of net sales for the specific indication of each Product whose manufacture, use or sale for such specific indication is covered by or requires the practice of any AMC Technical Development, which is owned by AMC alone (*e.g.*, any AMC Invention); and

9.2.2.3 permit AMC to use the licensed AMC Technical Development(s) (including Patents thereon) for research, academic, or other non-commercial purposes.

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 AstraZeneca 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 AstraZeneca the initial Senior Negotiator shall be the Vice President of Research for the applicable therapeutic area or an equivalent position. 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 be either the final proposal by AstraZeneca or 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, AstraZeneca 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 AstraZeneca 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 AstraZeneca solely-owned intellectual property or AstraZeneca Confidential Information) to any third party or parties as AMC desires, provided these terms are not more favorable than those offered to AstraZeneca.

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

9.3 Additional License Terms.

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

9.3.2 Any license granted to AstraZeneca 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 AstraZeneca and which results from AstraZeneca'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.

10. Indemnification

10.1 AstraZeneca agrees to hold harmless, indemnify and defend AMC from all third party liabilities, demands, damages, expenses and losses arising out of: (i) use by

AstraZeneca or by any third party acting on behalf of or under authorization from AstraZeneca, of information or materials received from AMC, or (ii) any use, sale or other disposition by AstraZeneca or by any third party acting on behalf of or under authorization from AstraZeneca 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 AstraZeneca prompt notice of any claim it receives and such failure materially prejudices AstraZeneca with respect to any claim or action which AstraZeneca's obligation pursuant to this Section applies. AstraZeneca, 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 AstraZeneca 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 AstraZeneca or (ii) if AstraZeneca fails to give AMC prompt notice of any claim it receives and such failure materially prejudices AMC with respect to any claim or action which AMC's obligation pursuant to this Section applies. AMC, in its sole discretion, shall choose legal counsel, shall control the defense of such claim or action and shall have the right to settle same on such terms and conditions it deems advisable.

10.2 No Warranty. ANY INFORMATION, RESULTS, MATERIALS, SERVICES, RESOURCES, INTELLECTUAL PROPERTY OR OTHER PROPERTY OR RIGHTS GRANTED, GRANTED ACCESS TO, OR PROVIDED BY ASTRAZENECA TO AMC PURSUANT TO THIS AGREEMENT (HEREIN THE "**INTELLECTUAL PROPERTY**") ARE ON AN "AS IS" BASIS. ASTRAZENECA 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 ASTRAZENECA 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. ASTRAZENECA 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 ASTRAZENECA 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, AstraZeneca 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 Programs, 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 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 AstraZeneca Contact to the Program Advisory Committee shall secure timely AstraZeneca review of the proposed publication. AstraZeneca may, together with AMC, revise the manuscript or other proposed publication to ensure protection of AstraZeneca's Confidential Information. Upon AstraZeneca's request, AMC shall delay submission or publication for up to an additional thirty (30) days (the "**Supplemental Review Period**") if AstraZeneca deems it reasonably necessary to enable AMC or AstraZeneca (as the case may be) to apply for Patent protection covering any Technical Development disclosed in the proposed publication. At AstraZeneca's reasonable request, Recipient shall discuss with AstraZeneca's Representatives comments or recommendations that AstraZeneca may have with regard to the Technical Developments proposed for publication or presentation. In exercising its rights under this Section, AstraZeneca 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 AstraZeneca 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 the other Party 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 AstraZeneca under **Section 12.2.3**, then any Option granted to AstraZeneca under **Section 9.2** will terminate upon the effective date of such Agreement termination. Upon such termination, rights in the AMC Technical Developments which were the subject of the Option will revert to AMC. In the event that AMC declares that it will not exercise its right to commercialize or license its interests in such AMC 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, have made, use, sell, offer for sale, import and export such an AMC Technical Developments.

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

12.4 The following Articles and Sections shall survive the expiration or termination for any reason of this Agreement: Articles 2, 7, 8, 9, 10, 11, and 13; and Sections 5.1, 5.3, 12.3, 12.4, 14.2, 15.1, 15.4, 15.5, 15.6, 15.7, 15.8, 15.9, 15.10, 15.11, and 15.12. [***Note to Draft: Confirm cross-references prior to execution.***]

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 represents that it has not has been debarred and is not subject to debarment or otherwise been disqualified or suspended from performing scientific or clinical investigations or otherwise subjected to any restrictions or sanctions by the FDA, or any other governmental or regulatory authority or professional body with respect to the performance of scientific or clinical investigations (a "**Debarred Person**"), and Recipient shall not use in any capacity, in connection with the Program, any Debarred Person.

13.4 Each Party warrants that it shall obtain from each of its Representatives who are performing research activities under the Program, or who otherwise have access to any Confidential Information, rights to any and all Technical Developments that relate to the Program, such that the other Party and its Affiliates shall receive the licenses and other rights granted hereunder without additional consideration.

13.5 AMC warrants that it will conduct all work involving animals with standards consistent with (a) AstraZeneca's Global Policy Bioethics on "Using Animals in Research Studies," as the same may be amended from time to time and made available on the website of AstraZeneca and its Affiliates (see http://www.astrazeneca.com/Responsibility/Research-ethics), and (b) 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.

13.6 Insofar as the Program involves the use of human biological samples, AMC represents and warrants that it has the adequate facilities and relevant permissions and ethical approvals for the collection of human biological samples and that, unless such samples were obtained anonymously or were subsequently anonymised, it has obtained or will obtain, as applicable, explicit informed consent of the subjects who have provided the samples to utilise such samples in research and that their use within the Program is within the scope of such consent. In the event that human biological samples are obtained from sources other than AMC, AMC shall ensure that it has been granted the right to freely use such samples in carrying out the Program and that the human biological samples have been obtained in compliance with all applicable laws and regulations. AMC agrees that, insofar as the Program involves the use of human biological samples, the Research shall be conducted in accordance with AstraZeneca's Global Policy Bioethics on "Genetic Information and Human Biological Samples," as the same may be amended from time to time and made available on the website of

AstraZeneca and its Affiliates (see http://www.astrazeneca.com/Responsibility/Research-ethics).

13.7 AMC and its Representatives will not offer, pay, request or accept any bribe, inducement, kickback or facilitation payment, and will not make or cause another to make any offer or payment to any individual or entity for the purpose of influencing a decision for the benefit of AstraZeneca.

14. Monitoring and Audits

14.1 Upon reasonable notice and during regular business hours, AMC will permit AstraZeneca 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 AstraZeneca 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. Regulatory inspections may occur after completion of the Program and may include auditing of study records.

14.2.1 Notification. AMC will notify AstraZeneca 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 an AstraZeneca Compound, AstraZeneca will have a right to participate in the inspection.

14.2.2 Cooperation. AMC will cooperate with regulatory agency or AstraZeneca 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 AstraZeneca copies of any inspection findings that it receives from any regulatory agency in relation to the Program. Whenever feasible, AMC will also provide AstraZeneca 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 AstraZeneca 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 AstraZeneca, to:

AstraZeneca UK Limited
2 Kingdom Street
London, W2 6BD
England
Facsimile: [ ]
Email: [ ]
Attention: General Counsel

With copies to:

Donald Frail, Ph.D.
Vice President, Emerging Innovations Unit, SP&A
AstraZeneca Pharmaceuticals LP
35 Gatehouse Drive
Waltham, MA 02451
Facsimile: [ ]
Email: [ ]

and

Craig D. Wegner, Ph.D.
Executive Director, Emerging Innovations Unit, SP&A
AstraZeneca Pharmaceuticals LP
35 Gatehouse Drive
Waltham, MA 02451
Facsimile: [ ]
Email: [ ]

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, by confirmed facsimile transmission or by confirmed electronic mail, 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 AstraZeneca 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 AstraZeneca may make such assignment to any Affiliate or may make such assignment to any successor in interest to all or substantially all of the business to which this Agreement relates without such consent of AMC. For clarity, AstraZeneca may transfer any of its rights to any Technical Developments to any of its Affiliates (*e.g.*, AstraZeneca AB). AstraZeneca shall always have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates.

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. Notwithstanding anything to the contrary in this **Section 15.8**, to the extent any public announcement, advertising, or other public disclosure is made with the consent of the Parties, a Party may thereafter disclose such information without the prior 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 AstraZeneca 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 Delaware, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

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, AstraZeneca agrees that in the event an AMC faculty or staff member serves AstraZeneca 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 AstraZeneca 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. AstraZeneca 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.

[*Remainder of page intentionally left blank. Signatures follow.*]

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]		**AstraZeneca UK Limited**	
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
- Contacts (as defined in the Agreement) for each of AMC and AstraZeneca
- 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 the U.S. and/or worldwide? 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: Biosketch of the Principle Investigator(s)

Exhibit B – ESCR Agreement Template

[To be provided.]

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 AstraZeneca'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 AstraZeneca or AMC as the case may be)]
Transferee:	[insert the name of the Party receiving items from the other Party (either AMC or AstraZeneca as the case may be)]
AMC contact Person:	[insert name of individual]
AstraZeneca 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 AstraZeneca and [AMC] dated [insert date].

Agreed and accepted by the Program Contacts on behalf of:

[**Name of AMC**]		**AstraZeneca UK Limited**	
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 AstraZeneca'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 AstraZeneca or AMC as the case may be)]
Transferee:	[insert the name of the Party receiving items from the other Party (either AMC or AstraZeneca as the case may be)]
AMC contact Person:	[insert name of individual]
AstraZeneca 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 AstraZeneca and [AMC] dated [insert date].

Agreed and accepted by the Program Contacts on behalf of:

[Name of AMC]		**AstraZeneca UK Limited**	
Signed:	……..	Signed:	…….
Print name:	……..	Print name:	…….
Date:	……..	Date:	……..