MASTER CLINICAL TRIAL AGREEMENT
FOR INVESTIGATOR INITIATED CLINICAL TRIAL FOR MEMBER INSTITUTIONS
OF THE UNIVERSITY OF TEXAS SYSTEM
BY AND BETWEEN
NOVARTIS PHARMACEUTICALS CORPORATION
AND
THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO
THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER
THE UNIVERSITY OF TEXAS AT AUSTIN
THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON
THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

Effective Date: November 12, 2014 – November 12, 2019 (5 year Term)
MASTER CLINICAL TRIAL AGREEMENT
for Investigator Initiated Clinical Trial for Institution

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MASTER CLINICAL TRIAL AGREEMENT

This Master Clinical Trial Agreement ("Agreement") is entered into by and between The University of Texas Health Science Center at San Antonio, The University of Texas Health Science Center at Houston, The University of Texas Health Science Center at Tyler, The University of Texas at Austin, The University of Texas Medical Branch at Galveston, and The University of Texas Southwestern Medical Center, each with an office and place of business as set forth in Attachment C attached hereto, and each a member institution of The University of Texas System ("System") which is governed by the Board of Regents ("Regents") and located at 201 West 7th Street, Austin, Texas 78701 (each an "Institution"), and Novartis Pharmaceuticals Corporation, a corporation with its principal office and place of business at 59 Route 10, East Hanover, NJ 07936-1080, hereinafter referred to as "Novartis", the Institution and Novartis each being a "Party" and hereinafter collectively referred to as the "Parties". The place of business for the participating Institution in a Clinical Trial shall be outlined in the respective Attachment A. Clinical Trial Request From ("CTRF").

1. SCOPE OF WORK AND CLINICAL TRIAL REQUEST FORM

A. As the master form of contract, this Agreement allows the Parties to contract for multiple Clinical Trials ("Clinical Trial") through the execution of a Clinical Trial Request Form ("CTRF"). The terms and conditions of this Agreement shall apply to each CTRF that references this Agreement except as expressly modified therein. The specific requirements for each Clinical Trial shall be set forth in the CTRF for that Clinical Trial. Each CTRF shall be substantially in the form of Attachment A hereto and shall include the information noted thereon, including all referenced schedules and other attachments. For each Clinical Trial in which Institution participates, the Parties will execute a separate CTRF. The principal investigator ("Principal Investigator") shall indicate assent by signature on the relevant CTRF. Upon full execution of a CTRF by the Parties and signature in acknowledgement by the Principal Investigator, such CTRF shall automatically become incorporated into this Agreement. The place of business for the participating Institution in a Clinical Trial shall be outlined in the respective CTRF.

B. During the Term of this Agreement (as defined in Article 3), the Institution shall exercise its reasonable efforts to perform each Clinical Trial set forth in a protocol referenced in an executed CTRF that references this Agreement (each a "Protocol"). Each Clinical Trial shall investigate the safety, efficacy and/or related properties of one or more active ingredients (each a "Study Drug"), alone or in comparison to a placebo and/or one or more other active ingredients (each a "Comparator Drug"). It is understood that various formulations of the Study Drug and Comparator Drug may be used in a Clinical Trial and, except where the contrary is clear from the context, the terms "Study Drug" and "Comparator Drug" mean each formulation actually used in a Clinical Trial and each active ingredient thereof. For the avoidance of doubt, when a Study Drug or a Comparator Drug is a combination of two or more active ingredients, except where the contrary is clear from the context, each active ingredient and each combination shall also be deemed to be a Study Drug or Comparator Drug, as the case may be.

C. A copy of the budget for each Clinical Trial, including a payment schedule, shall be incorporated or attached to the CTRF. The total cost to Novartis for the completion of a Clinical Trial by Institution shall not exceed the amount set forth in the applicable Schedule A (attached to Attachment A). Payment includes all applicable overheads as stated in such Schedule A. Any payment(s) for partially completed enrolled patients will be prorated and will reference the Study number associated with that specific CTRF.
D. Payment shall be made to Institution according to Schedule A appended to the CTRF and incorporated therein by reference. All costs outlined on such Schedule A shall remain firm for the duration of the Clinical Trial covered by such CTRF, unless otherwise agreed to in writing by Institution and Novartis.

1. If Novartis is funding a specific Clinical Trial, then neither Institution nor the Principal Investigator shall directly or indirectly seek or receive compensation from patients or third-party payers for any treatment or services or materials ("Treatment") that are required by the Protocol and are paid for by Novartis. These Treatments shall include, but are not limited to, Study Drug, Comparator Drug or other drug provided by Novartis, patient screening, treatment visits, infusion, physician or nurse fee, diagnostic tests or Study Drug administration.

E. Checks will reference the Protocol Number, Principal Investigator, Milestone Condition of Payment, Date Completed, and Novartis PO Number and will be mailed to the address shown in Schedule A attached to the CTRF.

F. The Institution represents and certifies that its applicable policies are not inconsistent with this Agreement and that it will not enter into a CTRF if it or the Protocol is inconsistent with its applicable policies.

2. PRINCIPAL INVESTIGATOR

The Institution's principal investigator for a Clinical Trial shall be identified in the CTRF ("Principal Investigator"). The Principal Investigator shall be responsible for the direction of the Clinical Trial in accordance with applicable Institution policies. If, for any reason, (s)he is unwilling or unable to continue to serve as the Principal Investigator and a successor, acceptable to both the Institution and Novartis, is not available, the Clinical Trial may be terminated by Novartis in accordance with the provisions of Paragraph A of Section 13. The Principal Investigator shall agree in writing to the terms of a specific CTRF.

3. EFFECTIVE PERIOD; TERM OF THE AGREEMENT

The effective period of this Agreement shall be from November 12, 2014 through November 12, 2019 ("Term"). On a Clinical Trial-by-Clinical Trial basis, if a Clinical Trial is not completed within the Term this Agreement will survive until the completion of that specific Clinical Trial. The Parties may agree to extend the Term of this Agreement by written amendment to this Agreement.

4. RECORDKEEPING, REPORTING AND ACCESS

A. The Institution and the Principal Investigator shall notify Novartis of each Serious Adverse Event encountered in the Clinical Trial within twenty-four (24) hours of becoming aware of it. Each such notice shall be given by telefax, whether or not notification was initially given by telephone. If possible, each such notice shall be on a Novartis Serious Adverse Event Report form provided by Novartis together with instructions for its completion and transmission to Novartis (Attachment B of this Agreement). Paragraph C of this Section shall apply to both the original copy of each Serious Adverse Event Report form and the telefax confirmation sheet reflecting its transmission to Novartis.

B. It is agreed that regulatory authorities to the extent required by law, may, during regular business hours, arrange in advance with the Principal Investigator and Institution to:

(1) Inspect and copy all data and work products relating to the Clinical Trial.

C. The Institution and the Principal Investigator shall perform the following recordkeeping and reporting obligations in a timely fashion:
(1) Preparation and maintenance of complete, accurately written records, accounts, notes, reports and data of the Clinical Trial. Federal regulations require that copies of case report forms be retained by the investigator for a period of no less than two years following either the approval of the New Drug Application or the withdrawal of the Investigational New Drug Application.

5. COSTS AND PAYMENT

A. Payment shall be made to the Institution in accordance with the CTRF and Schedule A appended hereto and incorporated herein as Attachment A. All costs set forth in Schedule A shall remain firm for the duration of the Clinical Trial, unless otherwise agreed to in writing by the Parties.

B. Novartis will have the right (a) to make public on its web site information relating to the Clinical Trial or this Agreement, including without limitation, the relevant name, city, and state of Institution (as applicable), the nature of the services performed pursuant to this Agreement, and any and all payments, reimbursements for expenses, or other transfers of value made in other than dollar form relating to this Agreement and (b) to otherwise disclose as Novartis determines or as may be required under applicable state or federal law or any Corporate Integrity Agreement, such information or any other information relating to this Agreement.

Furthermore, if a payment or other transfer of value is made under this Agreement, (i) on behalf of, at the request of, for the benefit or use of, or under the name of a US-based healthcare professional for whom Novartis would otherwise report payments if made directly to the US-based healthcare professional; or (ii) at the request of, or designated on behalf of, a US-based healthcare professional, then Novartis shall have the right to post and/or disclose the information referenced in the preceding sentence under the name of the Institution and/or the healthcare professional, as Novartis shall determine. Novartis shall also have the right to disclose this information to such healthcare professional's employer, or affiliated hospitals or institutions.

C. No amount paid or to be paid by Novartis as a result of this Agreement is intended to be, nor shall it be construed as, an obligation or inducement, either expressed or implied, to purchase, prescribe, promote, or otherwise support by Institution and any entity, which enters into an agreement to provide services hereunder, specific Novartis' products. The Parties acknowledge and confirm that no such expectations exist.

D. The Institution (and Institution will ensure that Principal Investigator) represent that they have reviewed and agree to meet and/or exceed each milestone deliverable dates attached hereto as Schedule A. In the event the Institution and Principal Investigator amend the Protocol and/or the Schedule A milestone delivery date (if applicable), the payment(s) will be revised as agreed to by the Parties.

6. CONFIDENTIAL INFORMATION

A. Neither the Institution nor the Principal Investigator shall disclose or use for any purpose other than the performance of the Clinical Trial any and all trade secrets, privileged records and other confidential or proprietary information disclosed to the Institution or the Principal Investigator by or on behalf of Novartis ("Novartis-disclosed Information") or developed and/or discovered by the Institution and/or the Principal Investigator using Novartis-disclosed Information, including, but not limited to, all written and electronic records, reports and data resulting from the performance of the Clinical Trial ("Institution Information"). For the avoidance of doubt, Institution Information shall not include any information developed and/or discovered by the Institution without use of Novartis-disclosed Information. Novartis-disclosed Information and Institution Information are hereinafter collectively referred to as "Confidential Information". This obligation of non-disclosure and non-use shall not apply to any:

(1) Confidential Information that is or becomes publicly available through no fault of the Institution or the Principal Investigator (including presentation or publication in accordance with the provisions of Section 7); and,
(2) Confidential Information that is already independently known to the Institution or the Principal Investigator as shown by prior written records, provided that the Institution or the Principal Investigator advises Novartis of this promptly upon the discovery that the Confidential Information is already independently known to the Institution; provided further, that Novartis provides Institution with written notice of breach and Institution shall have 30 days to offer evidence of prior independent knowledge; and,

(3) Confidential Information that at or after such time is disclosed to the Institution or the Principal Investigator on a non-confidential basis by a third-party with the legal right to do so;

(4) Confidential Information required to be released by any governmental entity with jurisdiction, provided that the Institution or the Principal Investigator, as the case may be, gives notice to Novartis at least ten (10) days (if reasonably possible, and, if not, as many days as is reasonably possible) prior to making such release of Confidential Information; and

(5) Confidential Information independently developed and/or discovered by Institution personnel other than the Principal Investigator and other Institution personnel participating in the performance of the Clinical Trial without reference to and/or use of Confidential Information, as evidenced by written contemporaneous documentation;

(6) Confidential Information disclosed to Institution’s IRB Committee and its members, provided that such IRB and its members are under a non-disclosure agreement substantially similar to that imposed on the Institution;

(7) Confidential Information disclosed in order to obtain informed consent from patients or subjects who may wish to enroll in the Clinical Trial, provided, however, that the Confidential Information will be disclosed only to the extent necessary and will not be provided in answer to unsolicited inquiries by telephone or to individuals who are not eligible Clinical Trial candidates.

B. In the event that the Institution or the Principal Investigator finds it necessary to disclose Confidential Information to a proper authority in order to defend its, his or her research against an allegation of fraud, the Institution or the Principal Investigator shall provide notice to Novartis of this, and Novartis and the Institution or the Principal Investigator, as the case may be, shall then agree on a mutually satisfactory method of disclosing such Confidential Information as necessary for this limited purpose.

C. Confidential Information developed and/or discovered by the Institution and/or the Principal Investigator in the conduct of the Clinical Trial, including, but not limited to, all written and electronic records, reports and data of and/or resulting from and/or relating to the performance of the Clinical Trial ("Institution Information") shall be disclosed to Novartis and Institution and Principal Investigator may: (a) present and publish such Institution Information in accordance with the provisions of Section 7; (b) use such Institution Information for non-commercial internal research, academic and patient care purposes prior to publication; and (c) use such Institution Information for any purpose after publication.

D. Institution or the Principal Investigator shall also be permitted to disclose Confidential Information for the purposes of emergency or immediate treatment of a Clinical Trial subject, provided that any such disclosure is limited to the extent reasonably necessary and provided further that Institution gives notice to Novartis prior to making such release of Confidential Information (if reasonably possible, and, if not, promptly after making such disclosure).
E. Institution shall comply with all applicable federal, state and local laws and regulations regarding the privacy of individually identifiable health information (including its collection, use, storage, and disclosure), including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the regulations promulgated thereunder, as may be amended from time to time.

F. If Novartis receives any protected health information ("PHI"), it shall abide with all applicable laws and regulations with respect to the privacy of individually identifiable health information it obtains from or on behalf of Institution and shall hold all such identifiable health information in confidence. Novartis shall not use the protected health information of a Clinical Trial subject for advertising, marketing, market research or to recruit subjects for additional studies except with the written consent of such Clinical Trial subject. This Section 6F shall survive expiration or termination of this Agreement.

G. The obligations of the Institution and the Principal Investigator under this Section shall survive the termination or expiration of this Agreement and/or a CTRF for a period of five (5) years.

7. PRESENTATIONS AND PUBLICATIONS

A. The presentation and publication of the results of the Clinical Trial in accordance with the provisions of this Section is permissible but no presentation or publication may disclose any Confidential Information without Novartis' prior written consent, which shall not be unreasonably withheld.

B. A manuscript of each proposed presentation and publication shall be submitted to Novartis for review prior to submission to anyone who is not employed by the Institution and under an obligation of non-disclosure and non-use at least substantially identical to that imposed on the Principal Investigator by this Agreement in order to permit Novartis to (1) evaluate the manuscript for accuracy, (2) ascertain whether Confidential Information is being improperly disclosed, (3) provide information which may not have yet been made available by Novartis and (4) provide input for consideration regarding the content and/or conclusion(s) of the manuscript. These provisions are in recognition of Novartis' rights and responsibility to provide peer input regarding the scientific content and conclusions of the manuscript. Novartis shall be afforded a review period of fifteen (15) Working Days for manuscripts not exceeding two (2) double-spaced pages in length (or the equivalent thereof) and forty-five (45) Working Days for all other manuscripts. A Working Day is any day other than a Saturday, Sunday or Federal holiday.

C. At the request of Novartis, any Confidential Information contained therein shall be excused from the manuscript and reasonable consideration to all other input received from Novartis shall be given. The author(s) shall make all final decisions regarding the contents of the proposed presentation or publication except as relates to the improper disclosure of Confidential Information; provided, however, that Institution is allowed to disclose certain Confidential Information to support the conclusions drawn by the authors and Institution agrees to consider any additional input of Novartis prior to finalizing the language in such publication.

D. If the Clinical Trial includes authoring or production of articles or other publications, Institution shall, and shall ensure that its employees, subcontractors and agents shall (1) comply with the International Committee of Medical Journal Editors ("ICMJE") criteria concerning authorship and disclosure of relationships with industry; and (2) disclose in any manuscript, journal submission, and elsewhere as appropriate or required, any potential conflict of interest, including any financial or personal relationships with Novartis, the names of any individuals who have provided editorial support for any manuscripts or other publications, and all funding sources for the study or publication.

E. Principal Investigator will make every reasonable effort to provide Novartis with a written summary of the results of the Clinical Trial, including but not limited to safety assessments, no later than nine (9) months after the last Protocol visit of the last Clinical Trial subject remaining under Clinical Trial treatment.
8. INTELLECTUAL PROPERTY

A. (a) Notwithstanding any other provision of this Agreement, neither the Institution nor the Principal Investigator shall acquire any rights of any kind in any Study Drug, Comparator Drug or other drug of Novartis, or any use thereof, as a result of the performance of the Clinical Trial other than the rights expressly described in this Section 8. (b) Neither Party transfers to the other any rights to any inventions, patent applications, patents, trademark applications, trademarks, copyright applications, copyrights or data or any other proprietary rights except as expressly set forth in this Agreement. (c) Inventorship and when an invention is deemed to have been made shall be determined in accordance with United States patent law. (d) Except as set forth in this Section 8A(d), each Clinical Trial Invention (as defined in Paragraph 8G below) shall be disclosed to Novartis within six (6) months of the date that it was disclosed to Institution's Office of Technology Commercialization. Notwithstanding the foregoing, Novartis agrees that Institution shall not be obligated to track any Clinical Trial Inventions made with Biological Samples (as defined in Section 24 below) collected during and/or as a result of the performance of the Clinical Trial, and shall only disclose any such Clinical Trial Inventions to Novartis to the extent that Institution becomes aware of such Clinical Trial Inventions and such Clinical Trial Inventions are disclosed to Institution's Office of Technology Commercialization.

B. (a) All Clinical Trial Inventions made solely by the Principal Investigator and/or one or more other individuals under an obligation to assign inventions to the Institution shall be owned by the Institution. (b) The Institution shall make all decisions concerning, and shall bear all expenses of, the patenting of, and the maintenance of patents on, each Clinical Trial Invention that it owns and shall own the resulting patent applications and issued patents ("Institution Patent Rights"). (c) As used in this Agreement: (i) The term "patents" includes United States and foreign patents (including reissue patents), extensions thereof and Supplemental Protection Certificates based thereon, the term "patent applications" includes applications for all of the foregoing, the terms "trademark applications" and "trademarks" include, respectively, United States and foreign trademark applications and trademarks, the term "copyright applications" includes applications for United States and foreign copyrights, and the term "copyrights" includes United States, foreign and common law copyrights. (ii) The term "Clinical Trial Inventions" means inventions resulting from (x) the performance of the Clinical Trial related to the Study Drug, or a Novartis drug in the same therapeutic class, (y) the performance of the Clinical Trial using Biological Samples of Clinical Trial subjects collected pursuant to the Protocol, and (z) any use thereof for the treatment of patients made by the Principal Investigator and/or one or more other individuals that have assigned or are under an obligation to assign inventions to the Institution, alone or jointly with one or more others.

C. (a) All Clinical Trial Inventions made by the Principal Investigator and/or one or more other individuals that have assigned or are under an obligation to assign inventions to the Institution jointly with one or more individuals that have assigned or are under an obligation to assign inventions to Novartis are hereby jointly owned by the Institution and Novartis ("Joint Inventions"). Each Joint Invention shall be the subject of good faith negotiations between the Parties. The Parties shall jointly make all decisions regarding the patenting thereof, shall jointly own all patent applications and patents resulting therefrom ("Joint Patent Rights") and shall jointly make all decisions regarding the maintenance of Joint Patent Rights, unless otherwise agreed to by the Parties. (b) Each joint owner of each Joint Patent Right may exercise its rights without any accounting to the other joint owner in accordance with the provisions of 35 USC 262 as of the date of this Agreement (which shall also apply to foreign Joint Patent Rights). (c) If, however, the Parties cannot reach agreement concerning the patenting of a Joint Invention and/or the maintenance of a Joint Patent Right and one Party wants to file and/or prosecute one or more patent applications and/or to maintain one or more patent applications or patents that the other Party does not want to file, prosecute and/or maintain, the Party that wants to do so may do so at its own expense; the patent applications and patents in question shall be owned by that Party. Any patent applications and patents covering Joint Inventions owned by Novartis shall be deemed to be Novartis Patent Rights, and any patent applications and patents covering Joint Inventions owned by the Institution shall be deemed to be Institution Patent Rights.
At the request and expense of the Party assuming ownership in accordance with this Subparagraph (c), the other Party, the Principal Investigator and the (or other) individuals that have assigned or are under an obligation to assign inventions to said other Party shall assist the owner in the preparation and prosecution of such patent application(s) and shall execute all documents reasonably deemed necessary by the owner for the filing thereof and/or for the vesting in the owner of title thereto. (d) The Institution shall have an irrevocable, non-exclusive, royalty-free, paid-up, worldwide license thereto under each Novartis Patent Right, solely for Institution’s internal research, academic and patient care purposes.

D. (a) Novartis and its affiliates are hereby granted an irrevocable, non-exclusive, royalty-free, paid-up, sub-licensable, worldwide license under each Institution Patent Right. (b) In the case of each Institution Patent Right and Joint Patent Right, Novartis shall have, in addition to the non-exclusive license granted in Subparagraph (a) of this Paragraph and Novartis’ rights as a joint owner under Subparagraph (b) of Paragraph C, an exclusive option to first negotiate an exclusive (subject to Institution’s irrevocable, non-exclusive, royalty-free, paid up, worldwide license to any such Clinical Trial Invention or Joint Invention for Institution’s internal research, academic, and patient care purposes), sub-licensable, worldwide license under such Institution Patent Right or Joint Patent Right. The option shall expire ninety (90) days after Novartis receives a written offer to enter into negotiations for an exclusive license and, in case not previously disclosed to Novartis a written disclosure of an Institution Patent Right or Joint Patent Right, unless exercised in writing by Novartis within said option period. Upon exercise of an option, the Parties shall negotiate in good faith for an exclusive license which shall provide for payment by Novartis of a lump sum and/or a royalty to be negotiated. If terms are not agreed upon within six (6) months after the option is exercised, Novartis’ rights under the option shall expire, and the Institution shall be free to license other parties (subject to the non-exclusive license granted to Novartis and its affiliates or Novartis’ rights as a joint owner, as the case may be). If Novartis does not obtain an exclusive, royalty-bearing license under any Institution Patent Right, but retains a non-exclusive royalty-free license thereto, then in accordance with any applicable law Institution may grant an equivalent non-exclusive royalty-free license to any person requesting such license.

E. Novartis, its affiliates and all other corporations and other entities authorized to do so by Novartis or an affiliate of Novartis may incorporate the reports and data resulting from the performance of the Clinical Trial into patent applications filed by or on behalf of Novartis and its affiliates and into regulatory filings in the United States and all other countries and regions for one or more Study Drugs, Comparator Drugs and/or other drugs. Neither the Institution nor the Principal Investigator shall have any ownership, license or access rights in, or to, any regulatory filing or any Study Drug, Comparator Drug or such other drug based upon the inclusion of such written and electronic records, reports and/or data in any regulatory filing(s). In addition, Novartis, its affiliates and all other corporations and other entities authorized to do so by Novartis or an affiliate of Novartis may utilize such written and electronic records, reports and data for all other purposes, including, but not limited to (i) Marketing and/or sale of any drug, but only after the presentation or publication thereof by, or with the permission of, the Principal Investigator or one (1) year from the conclusion of the effective period of the specific CTRF, whichever comes first, and (ii) internal research and development.

F. The Institution represents and certifies that: (i) The Principal Investigator and all other individuals participating in the performance of a Clinical Trial (other than any individuals that have assigned or are under an obligation to assign their rights in inventions and written and electronic records, reports and data of and/or resulting from and/or relating to the performance of the Clinical Trial to Novartis) have assigned or are under an obligation to assign all Clinical Trial Inventions to the Institution; and (ii) it has the authority to grant all of the rights granted in this Section.

G. NOVARTIS MAKES NO WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO NON-INFRINGEMENT OF ANY THIRD PARTY INTELLECTUAL PROPERTY RIGHTS. UNDER NO CIRCUMSTANCES SHALL EITHER PARTY BE LIABLE IN ANY MANNER FOR CONSEQUENTIAL, INCIDENTAL, SPECIAL AND/OR INDIRECT DAMAGES.
9. PUBLICITY

A. Neither Party shall use the other Party's name, nor issue any public statement about this Agreement, without the prior written permission of the other Party, except as required by law (and, in such case, only with prior notice to the other Party (if reasonably possible, and, if not, as many days as is reasonably possible)). The preceding sentence shall not apply to presentations and publications in accordance with the provisions of Section 7. Such prior permission shall not be unreasonably withheld. In order for the Institution to satisfy its reporting obligations, it may disclose the amount of funding, Study Drug(s) and/or Comparator Drug(s) received from Novartis for the Clinical Trial.

B. Novartis strongly encourages the Institution and/or the Principal Investigator to post the Clinical Trial on www.ClinicalTrials.gov and/or one or more other Internet clinical trial registries in accordance and in compliance with all applicable laws and regulations and the requirements and guidelines of each Internet clinical trial registry on which the Clinical Trial is posted. Each such posting shall comply with all applicable requirements of this Agreement including, but not limited to, those of Sections 6 (Confidential Information), 7 (Presentations and Publications) and 18 (Conformance with Law); however, to the extent that Paragraph A of this Section is deemed to require Novartis' consent for any such posting, such consent is hereby given. Novartis, however, will not post the Clinical Trial on www.ClinicalTrials.gov or on any other Internet clinical trial registry.

10. APPLICABLE LAW

This Agreement shall be governed by the laws of the State of Texas without regard to any conflict of laws provisions.

11. NOTICE

A. Any notice required or permitted by this Agreement shall be in writing and delivered by hand or sent by registered or certified mail, postage prepaid, return receipt requested, or by nationally recognized overnight delivery service, delivery charges prepaid, in each case addressed to the Party to receive such notice at the address set forth below or such other address as is subsequently specified in writing in accordance with this Section. Such notice shall be deemed given or provided as of the date of such delivery or sending.

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<tr>
<th>IF TO NOVARTIS:</th>
<th>IF TO THE INSTITUTION:</th>
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<tbody>
<tr>
<td>Robert Stevens</td>
<td>See Administrative Contacts in Attachment C</td>
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<tr>
<td>Director US Medical Sourcing, US Medical and DRA Novartis Pharmaceuticals Corporation 59 Route 10 East Hanover, NJ 07936 Phone: 862 778-7576 E-Mail: <a href="mailto:Robert.stevens@novartis.com">Robert.stevens@novartis.com</a></td>
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B. Any notice relating to a Clinical Trial or a Clinical Trial Request Form shall be given as set forth in Section 2 of the Clinical Trial Request Form.

C. Upon conclusion of a Clinical Trial, if the Institution is unable to communicate with and/or contact one of the Novartis personnel referenced above or in the Clinical Trial Request Form, the Institution shall telephone 1-888-669-6682 (1-888-NOW-NOVA) to obtain the appropriate contact information.
12. INDEMNIFICATION & INSURANCE

A. To the extent authorized by the constitution and laws of the State of Texas, Institution shall indemnify and hold harmless Novartis and its affiliates and their respective officers, directors, employees and agents (collectively "Novartis Indemnitees") against and from any and all claims, actions, suits, proceedings and investigations arising out of, or in connection with, the Clinical Trial including, without limitation, reasonable attorney's fees incurred in connection with the defense and/or settlement of any such claim, action, suit, proceeding and/or investigation as such costs or expenses are incurred, whether before or after a judgment is rendered.

B. The Institution represents and certifies that it maintains a policy or program of insurance or self-insurance, or financial resources at levels sufficient to support its indemnification obligations assumed herein.

C. Institution, as a member institution of System, is an agency of the State of Texas and is self-insured pursuant to The University of Texas System Professional Medical Liability Benefit Plan, under the authority of Section 59.01, Texas Education Code. Institution has and will maintain in force during the term of this Agreement adequate insurance to cover its indemnification obligations hereunder.

D. (a) SUBJECT TO THIS SECTION 18D, EACH STUDY DRUG, COMPARATOR DRUG AND OTHER MATERIAL PROVIDED BY NOVARTIS IN ACCORDANCE WITH THIS AGREEMENT IS PROVIDED "AS IS", AND NOVARTIS MAKES NO WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, CONCERNING IT OR ITS MERCHANTABILITY OR FITNESS FOR ANY PURPOSE WHATSOEVER. UNDER NO CIRCUMSTANCES SHALL EITHER PARTY BE LIABLE IN ANY MANNER FOR CONSEQUENTIAL, INCIDENTAL, SPECIAL AND/OR INDIRECT DAMAGES. 
(b) Any advice furnished by Novartis is given gratis. Novartis assumes no obligation or liability for the advice given or the results obtained, and any such advice shall not constitute a warranty as to any matter, all such advice being given and accepted at the recipient's risk.

E. Novartis shall indemnify, hold harmless, and subject to the statutory duties of the Texas State Attorney General defend Institution, System, and their Regents, officers, directors, agents and employees of Institution including the Principal Investigator (collectively the "Institution Indemnitees") from any and all claims, actions or suits for personal injury or death (each, a "Loss") directly arising out of the Novartis' use of the results of the Clinical Trial, provided however:

(1) that the Clinical Trial is conducted in accordance with the Protocol, all written instructions of Novartis which Principal Investigator has confirmed receipt of, all applicable laws and regulations and Good Clinical Practice regulations; and,

(2) that such Loss does not arise in any way out of the negligence or willful misconduct of any Institution Indemnitee, or any other person other than an employee, agent, officer, or representative of Novartis; and,

(3) that Novartis is promptly notified in writing no later than ten (10) days after any complaint, claim or injury relating to any Loss; and,

(4) that, subject to the statutory duties of the Texas State Attorney General, Novartis shall have the sole right to select defense counsel and to direct the defense or settlement of any such claim or suit; and,

(5) that all Institution Indemnitees shall cooperate fully with Novartis and counsel in the investigation and defense of any Loss, claim or suit, and that any Institution Indemnitee shall have the right to representation by separate counsel but only at the sole cost and expense of such Institution Indemnitee.

G. Novartis warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support its indemnification obligations assumed herein. Upon request, Novartis shall provide evidence of such insurance.
H. In the event that the Clinical Trial results in physical injury to a Clinical Trial subject, Novartis will not provide coverage for the costs of such injury.

I. Deviations from the terms of the Protocol that may arise out of necessity do not constitute negligence or willful malfeasance provided that the Institution promptly provides notice to Novartis of any such deviations.

J. Study Subject Safety. Institution and Novartis shall promptly notify each other of any significant new findings developed during a Clinical Trial and thereafter that may (i) adversely affect the safety, well-being, or medical care of Clinical Trial subjects, (ii) affect the willingness of a Clinical Trial subject to continue participation in the Clinical Trial, or (iii) alter the IRB's continuing approval of the Clinical Trial. Institution shall promptly notify the IRB of any such events. When Clinical Trial subject safety or medical care could be directly affected by Clinical Trial results, Institution shall be free to provide the Clinical Trial results to Clinical Trial subjects in accordance with IRB policy. Novartis agrees to provide to Institution urgent safety information in accordance with International Conference on Harmonization ("ICH") E6 Guidelines (section 5.17) and FDA IND regulations (21 CFR § 312.32).

13. TERMINATION OF THIS MASTER AGREEMENT OR TERMINATION OF A SPECIFIC CLINICAL TRIAL

A. (a) This Master Agreement may be terminated by either Party for any safety and/or efficacy concerns by written advance notice given to the other Party. (b) A specific Clinical Trial may be terminated by Novartis by a 30-day written notice given to the Institution if, for any reason, the Principal Investigator is unwilling or unable to continue to serve as such and a successor, acceptable to both Parties, is not available. (c) The effective date of any termination in accordance with this Paragraph shall be ten (10) days from the date the notice is given unless a later date is specified in the notice.

B. This Master Agreement may be terminated by either Party with or without cause, other than those specified in Paragraph A, Subsection (a) of this Section, by written notice given to the other Party. The effective date of the termination shall be thirty (30) days from the date the notice is given unless a later date is specified in the notice.

C. In the event that either Party shall materially breach a Clinical Trial under this Agreement and a corresponding CTRF, the Parties shall give written notice to each other specifying such breach with reasonable detail. If either party fails to cure such breach within thirty (30) calendar days of its receipt of such notice, then the responsible non-offending party may terminate the Clinical Trial.

D. (a) Immediately upon receipt of a notice of termination, the Institution and the Principal Investigator shall cease entering patients into the Clinical Trial. (b) Upon the effective date of the termination, the Institution and the Principal Investigator shall, to the extent medically permissible, cease the treatment in accordance with the Protocol, of all Clinical Trial subjects already entered into the Clinical Trial unless further treatment is medically necessary as agreed to by Novartis and the Institution.

E. Within sixty (60) days of the effective date of the termination of CTRF, the Institution shall return to Novartis any funds paid by Novartis that were not expended or irrevocably committed by the Institution prior to said date.

F. Termination of this Agreement or a CTRF by either party shall not affect the rights and obligations of the Parties accrued prior to the effective date of such termination. The rights and obligations under Sections 4 Recordkeeping, Reporting and Access, 6 Confidential Information, 7, Presentations and Publications, 8 Intellectual Property, 9 Publicity, 10 Applicable Law, 11 Notice, 13 Indemnification & Insurance, 15, Assignments and Subcontracts by the Institution, 17, Delivery To Novartis or Destruction of Unused Materials, 18 Conformance with Law, Regulations and Accepted Practices and 19 Debarment shall survive the termination or expiration of this Agreement.
14. ENTIRE AGREEMENT AND SEVERABILITY

A. This Agreement represents the entire understanding of the Parties with respect to the subject matter hereof. In the event of any inconsistency between this Agreement and a Clinical Trial Request Form, the terms of the Clinical Trial Request Form shall govern with respect to the conduct of the Clinical Trial and the treatment of the Clinical Trial subjects in connection therewith; in all other respects, the terms of this Agreement shall prevail. In the event of any inconsistency between this Agreement or a Clinical Trial Request Form and the Protocol, the terms of this Agreement or the Clinical Trial Request Form, as the case may be, shall govern.

B. The invalidity or unenforceability of any term or provision of this Agreement or a Clinical Trial Request Form shall not affect the validity or enforceability of any other term or provision of either this Agreement or the Clinical Trial Request Form.

15. ASSIGNMENTS AND SUBCONTRACTS BY THE INSTITUTION

Neither this Agreement nor any rights and obligations hereunder may be assigned or subcontracted by the Institution without the written consent of Novartis; such consent will not be unreasonably withheld.

16. CHANGES TO THE PROTOCOL

If, at any time, changes in the Protocol in a specific Clinical Trial appear desirable, such changes may be made by the Institution and the Principal Investigator with the prior written consent of any applicable Institutional Review Board and Novartis.

17. DELIVERY TO NOVARTIS OR DESTRUCTION OF UNUSED MATERIALS

Within thirty (30) days following completion or termination of the Clinical Trial, all unused Study Drug(s), Comparator Drug(s), devices, case report forms (whether or not completed) and other materials that were furnished to the Institution by or on behalf of Novartis shall, at Novartis' expense, be returned to Novartis or, if Novartis so directs, destroyed.

18. CONFORMANCE WITH LAW, REGULATIONS AND ACCEPTED PRACTICE

A. The Institution shall perform the Clinical Trial in conformance with all applicable Federal, state and local government laws and regulations, including, but not limited to, the Federal Food, Drug and Cosmetic Act, the Health Insurance Portability and Accountability Act of 1996 and regulations of the FDA and other Federal agencies, generally accepted standards of Good Clinical Practice, the Protocol and ICH guidelines governing the performance of clinical trials. In its activities in connection with the Clinical Trial, Novartis agrees to comply with all applicable laws and regulations.

B. (a) If the Institution, or any independent Institutional Review Board utilized by the Institution, commences an investigation of, or takes any action against, the Principal Investigator in connection with the performance of the Clinical Trial or any other clinical trial, whether or not for Novartis, (whereby such investigation or action of another clinical trial could affect the Principal Investigator's continued participation in a specific Novartis Clinical Trial) the Institution shall notify Novartis within forty-eight (48) hours of the commencement of the investigation or the taking of action or, in the case of an investigation or action taken by an Institutional Review Board, within forty-eight (48) hours of becoming aware of the commencement of the investigation or the action taken. (b) If the FDA or a regulatory agency of any other country or region commences an investigation of, or takes any action against, the Institution and/or the Principal Investigator in connection with the performance of a Clinical Trial or any other clinical trial, whether or not for Novartis, (whereby such investigation or action of another clinical trial could affect the Principal Investigator's continued participation in a specific Novartis Clinical Trial) the Institution and/or the Principal Investigator shall notify Novartis within forty-eight (48) hours of becoming aware of the commencement of the investigation or the action taken.
C. All shipments of diagnostic specimens obtained as the result of the performance of the Clinical Trial shall comply with all applicable Federal regulations including, but not limited to, 49 CFR Part 173, such as 49 CFR 173.199 (if applicable).

D. Novartis represents and warrants that it is in compliance with all applicable federal, state and local legal requirements relating to the manufacture and distribution of each Study Drug, Comparator Drug, or other material provided under this Agreement.

19. DEBARMENT

The Institution hereby certifies that (i) it has not been debarred under Subsection (a) or (b) of Section 306 of the Federal Food, Drug and Cosmetic Act (21 USC 335a) and no person who has been debarred under Subsection (a) or (b) of Section 306 of said Act will be employed by it in the performance of the Clinical Trial or in connection with any work to be performed for or on behalf of Novartis, (ii) no person on any of the following FDA Clinical Investigator Restriction Lists - Disqualified/Totally Restricted List, Restricted List and Adequate Assurances List - will participate in the performance of the Clinical Trial, (iii) it has not been convicted of an offense related to any Federal or State healthcare program, including (but not limited to) those within the scope of 42 U.S.C. § 1320a-7(a); or (iv) it has not been excluded, suspended or is otherwise ineligible for Federal or State healthcare program participation, including (but not limited to) persons identified on the General Services Administration’s List of Parties Excluded from Federal Programs or the HHS/OIG List of Excluded Individuals/Entities; or is otherwise ineligible for Federal or State healthcare program participation. The Institution further certifies that if, at any time after execution of this Agreement, it becomes aware that it or any person employed by it who participated, or is participating, in the performance of the Clinical Trial or any clinical trial for Novartis or any other company is on, or is being added to, the FDA Debarment List or any of the three (3) FDA Clinical Investigator Restriction Lists, it will provide notice of this to Novartis within forty-eight (48) hours of its becoming aware of this. Such notice will be sent in writing to: Novartis Pharmaceuticals Corporation, Attn: Ethics and Compliance, 59 Route 10, East Hanover, NJ 07936-1080.

20. ADDITIONAL COMPLIANCE OBLIGATIONS

A. If Institution or Principal Investigator, or any employee, subcontractor or agent of Institution and Principal Investigator involved with the performance of the Clinical Trial is or during the term of this Agreement subsequently becomes, a member of, affiliated with, or an employee of an educational or not-for-profit institution, healthcare institution, medical committee, or other medical or scientific organization and is required by such institution, committee, or organization to disclose any proposed or current agreements for the research contemplated herein, Institution will ensure that said employee, subcontractor or agent will, make such disclosure(s) in accordance with the policies and procedures of such institution, committee, or organization, and will obtain prior written approval of this Agreement by such institution, committee, or organization, if required. The obligation to make the disclosures and obtain the approvals contemplated above shall extend beyond the termination or expiration of this Agreement for such period of time as required by such institution, committee, or organization. If and to the extent that the procedures or disclosure requirements of any institution, committee, or organization referenced above require disclosure of Confidential Information to such institution, committee, or organization, Institution will notify Novartis of such requirement reasonably in advance of making such disclosure, to the extent not prohibited by the policies of such institution, committee, or organization.
B. If any employee, subcontractor or agent of the Institution or Principal Investigator involved with the performance of the Clinical Trial is currently or during the term becomes a member of a committee that sets formularies of covered medicines (e.g., formulary committee or Pharmacy & Therapeutics committee) or develops clinical practice guidelines or treatment protocols or standards, such person shall comply with the disclosure requirements of the respective committee(s) and, at minimum, shall follow the procedures of such committee and disclose to such committee that such person(s) provide services to Novartis related to clinical research activities relating to the Study Drug. The obligation to disclose to such committee as contemplated in this Section 20 shall extend for two (2) years beyond the termination or expiration of this Agreement, or a longer period of time as required by such committee. If and to the extent that the procedures or the disclosure requirements of any committee(s) referenced above of which such person is a member requires disclosure of Confidential Information to such committee(s), Institution will notify Novartis of such requirement reasonably in advance of making such disclosure, to the extent not prohibited by the policies of such committee.

21. MISCELLANEOUS

A. Nothing in this Agreement will limit or prohibit Institution or any of its personnel, including the Principal Investigator, from conducting any research or from performing research for or with any entity or person, including any other outside sponsors. Novartis acknowledges that this provision is intended to preserve the academic freedom and integrity of Institution and its faculty and to ensure that Institution and its faculty are not regarded as exclusive researchers for Novartis.

B. Institution is an agency of the State of Texas and, under the constitution and the laws of the State of Texas, possesses certain rights and privileges, is subject to certain limitations and restrictions, and only has such authority as is granted to it under the constitution and laws of the State of Texas. Notwithstanding any provision hereof, nothing in this Agreement is intended to be, nor will it be construed to be, a waiver of the sovereign immunity of the State of Texas or a prospective waiver or restriction of any of the rights, remedies, claims, and privileges of the State of Texas. Moreover, notwithstanding the generality or specificity of any provision hereof, the provisions of this Agreement as they pertain to Institution are enforceable only to the extent authorized by the constitution and laws of the State of Texas.

22. SUBSITES/SUBCONTRACTORS

To the extent that Institution utilizes any sub-sites or subcontractors in the conduct of the Clinical Trial, Institution shall enter into an agreement with each such sub-site or subcontractor, that will be in full force and effect at all times throughout the term of this Agreement unless terminated in accordance with its terms. Institution represents and certifies that any such sub-site or subcontractor shall be obligated by its agreement with the Institution to comply with the requirements of this Agreement as applicable.

23. OTHER SOURCES OF SUPPORT

To the extent that Institution or Principal Investigator intends to seek additional support for the Clinical Trial, including financial support and/or supply of an additional drug to be used in the Clinical Trial, Institution shall notify Novartis. Institution agrees and represents that it has not and shall not enter into any other agreement relating to this Clinical Trial which will in any way interfere with Institution’s or Principal Investigator’s ability to meet any obligations to Novartis under this Agreement or in any way interfere with rights granted to Novartis under this Agreement.
24. BIOLOGICAL SAMPLES

A. "Biological Samples" include, without limitation, blood, serum, fluid and tissue biopsy samples collected from a clinical trial patient enrolled in the Clinical Trial and accompanying CTRF. Biological Samples further include, without limitation, any tangible material directly or indirectly derived from such blood, fluid or tissue samples, such as: genes, gene fragments, gene sequences, proteins, protein fragments, protein sequences, probes, DNA, RNA, cDNA libraries, plasmids, vectors, expression systems, cells, cell lines, organisms, antibodies or other biological substances; and any constituents, progeny, mutants, variants, derivatives, replications, reagents or chemical compounds thereof or derived therefrom.

B. (1) Institution's Collection, Retention and Use of Biological Samples.

Institution will collect, retain and use Biological Samples in as required by the Clinical Trial and CTRF. Institution may collect and/or reserve additional quantities of Biological Samples ("secondary Biological Samples") for use in research not described in the Clinical Trial ("non-Protocol research"), provided that (a) such collection complies with all applicable laws, regulations and acceptable clinical trial practices, including, but not limited to, patient privacy and informed consent laws in the country in which the Clinical Trial is being conducted, and (b) no Confidential Information or any other information which links the secondary Biological Samples to any Confidential Information is available to investigator(s) for such non-Protocol research (for example, without limitation, Institution may annotate such secondary Biological Samples with Clinical Trial subject demographic information (e.g., age, gender and clinical diagnosis), but not with information related to administration of, or response to, or adverse events associated with, a Study Drug).

(2) Novartis' Receipt and Use of Biological Samples.

Novartis shall receive pre-determined quantities of Biological Samples from Institution, as set forth in the Clinical Trial, for use in research as generally described in the protocol, provided that such research complies with all applicable laws and regulations, including, but not limited to, patient privacy and informed consent laws in the country in which Biological Samples were collected. Using the same unique identifier ("Study Subject Number") utilized to identify the original Biological Sample, Novartis will disclose and provide to the Principal Investigator in a timely manner upon written request all raw data generated by Novartis in support of the primary objectives of the Clinical Trial, as specified in and required by the protocol, and which is derived from Biological Samples ("Biological Samples Raw Data"). Novartis agrees to make reasonable efforts to disclose and provide such Biological Samples Raw Data to Institution, upon written request to Novartis, within one year after completion of the Clinical Trial, or for multicenter studies, within one year after completion of the Clinical Trial at all sites. For sake of clarity, Institution agrees not to perform experiments with or analyze Biological Samples Raw Data which are pre-obligated and/or encumbered in some manner. Such Biological Samples Raw Data (i) shall be treated by Institution as Confidential Information under this Agreement; (ii) Institution agrees to maintain the patient's confidential information as set forth in the informed consent document that corresponds to the Protocol; (iii) the Principal Investigator may use such Biological Samples Raw Data for the purpose of generating, for non-commercial purposes, a manuscript to be published in a scientific peer-reviewed journal;
(iv) Institution may use such Biological Samples Raw Data for its own internal non-commercial research and academic purposes, (v) Institution may disclose such Biological Samples Raw Data to other academic investigators outside Institution for non-commercial collaborative research and academic purposes, provided that investigators outside Institution and any institution to whom such investigators may have an obligation to assign inventions or other intellectual property rights enter into a "proprietary data transfer agreement" acceptable to both Novartis and Institution, and Institution will identify in writing to Novartis any such Biological Samples Raw Data provided to other academic investigators at the time it is provided, and (vi) all publications relating to the Biological Samples Raw Data and all data, information and inventions resulting from the use of Biological Samples Raw Data shall be in performance of the Clinical Trial and subject to all provisions of this Agreement.

C. In the event that Principal Investigator desires to conduct further research in collaboration with Novartis with respect to such Biological Samples Raw Data, Novartis agrees to consider any such request. Any such further research agreed upon by Novartis shall be subject to the terms of a separate research agreement.

(THIS SPACE INTENTIONALLY LEFT BLANK)
IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate by proper persons thereunto duly authorized.

NOVARTIS PHARMACEUTICALS CORPORATION

By: ____________________________
   (signature)

Name: Cathryn Clary, M.D.

Title: Head US Medical and Chief Scientific Officer

Date: 12/02/2014

THE UNIVERSITY OF TEXAS AT AUSTIN

By: ____________________________
   (signature)

Name: Susan W. Servick, Ph.D.

Title: Director, Sponsored Projects

Date: 11/6/2014

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: ____________________________
   (signature)

Name: ____________________________

Title: ____________________________

Date: ____________________________

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

By: ____________________________
   (signature)

Name: ____________________________

Title: ____________________________

Date: ____________________________
IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate by proper persons thereunto duly authorized.

NOVARTIS PHARMACEUTICALS CORPORATION

By:  
(signature)

Name: Cathryn Clary, M.D.
Title: Head US Medical and Chief Scientific Officer
Date: 12/02/2014

THE UNIVERSITY OF TEXAS AT AUSTIN

By:  
(signature)

Name: __________________________
Title: __________________________
Date: __________________________

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By:  
(signature)

Name: Chris G. Green, CPA
Title: Director, Office of Sponsored Programs
Date: 14 November 2014

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

By:  
(signature)

Name: __________________________
Title: __________________________
Date: __________________________
IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate by proper persons thereunto duly authorized.

NOVARTIS PHARMACEUTICALS CORPORATION

By: Cathryn Clary

(signature)

Name: Cathryn Clary, M.D.

Title: Head US Medical and Chief Scientific Officer

Date: 12/02/2014

THE UNIVERSITY OF TEXAS AT AUSTIN

By: ______________________

(signature)

Name: ______________________

Title: ______________________

Date: ______________________

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

By: ______________________

(signature)

Name: ______________________

Title: ______________________

Date: ______________________

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

By: ______________________

(signature)

Name: Karen S. Niemeier

Title: Director, Contracts

Office of Sponsored Projects

Date: 11/20/2014
THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT TYLER

By: ____________________________
   (signature)

Name: __________________________

Title: __________________________

Date: __________________________

Cathryn M. Clary, M.D.
Head, US Medical & Chief Scientific Officer
Novartis Pharmaceuticals Corporation

12/02/2014

THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON

By: ____________________________
   (signature)

Name: __________________________

Title: __________________________

Date: __________________________

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

By: ____________________________
   (signature)

Name: Angela R. Charboneau Wishon, J.D.
   Vice President for
   Research Administration

Title: __________________________

Date: 11-17-2014
ATTACHMENT A: Clinical Trial Request Form

THE UNIVERSITY OF TEXAS (NAME THE MEDICAL CENTER)

This Clinical Trial Request Form shall be binding upon the undersigned upon its execution by the duly authorized representatives of the Parties and the Principal Investigator as of the day and year last written below. It is subject to the terms of the Master Clinical Trial Agreement for Investigator Initiated Clinical Trial for Institutions dated October 13, 2014 entered into by the Parties.

1. CLINICAL TRIAL INFORMATION

   Site No.:

   Principal Investigator:

   Study No.:

   Brief Description of the Clinical Trial
   [Protocol Title]:

   Is this Clinical Trial part of a
   Multi-center Study? [Yes or No]

   Effective Period
   Start Date:
   Termination Date:

   Number of Patients to be Enrolled:

2. NOTICE

   A. Any notice required or permitted by this Clinical Trial Request Form shall be in writing and delivered by hand or sent by registered or certified mail, postage prepaid, return receipt requested, or by nationally recognized overnight delivery service, delivery charges prepaid, in each case addressed to the Party to receive such notice at the address set forth below or such other address as is subsequently specified in writing in accordance with this Section. Such notice shall be deemed given or provided as of the date of receipt. For the avoidance of doubt, a writing provided by E-mail shall not be deemed to comply with the notice requirements of this Clinical Trial Request Form.
IF TO NOVARTIS:
All payment queries and all invoices must include the following information:
(Refer to Schedule A):
1. Project (Study Drug)
2. Protocol number
3. Center number
4. Principal Investigator’s name
5. PO number (if available)

For Agreement Matters:
{Insert the Contract Manager’s name}
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080
862-778-xxxx (Tel)
973-781-xxxx (Fax)

For Payment and Clinical Trial Related Matters:
{Insert the Clinical Trial Leader’s name}
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080
862-778-xxxx (Tel)
973-781-xxxx (Fax)

IF TO THE INSTITUTION:
For Technical Matters:
{Insert the name, address, phone and fax numbers of the Institution’s Technical Matters Person (usually the Principal Investigator)}

For Administrative Matters:
{Insert the name, address and telephone and telefax numbers of the Institution’s representative for administrative matters (usually a grants officer, attorney, executive or other person authorized to receive and act upon legal notices who is located at the official address)}

B. Upon conclusion of the Clinical Trial, if the Institution is unable to communicate with and/or contact one of the appropriate personnel referenced above, the Institution shall telephone 1-888-699-6692 (1-888-NOW-NOVA) to obtain the appropriate contact information.

3. MODIFICATIONS AND ADDITIONAL TERMS FOR THIS CLINICAL TRIAL

[CAUTION: The provisions of this Section 3 supersede any conflicting provisions of the Master Clinical Trial Agreement and must be approved in writing by Institution and the Office of General Counsel of The University of Texas System. The Parties agree and acknowledge that this Section 3 will only be used for Clinical Trial-specific revision on a case-by-case basis. The Parties further agree and acknowledge that this Section 3 is not intended to be used to revise terms or conditions that are applicable to all Clinical Trials and that the Master Clinical Trial Agreement will be duly revised for such revisions.]

If this Clinical Trial Request Form requires the Clinical Trial to be performed beyond the expiration or termination date of the Master Clinical Trial Agreement, then the terms of the Master Clinical Trial Agreement that would otherwise expire shall remain in effect until the expiration or termination of this Clinical Trial Request Form.
4. LIST OF ATTACHMENTS AND PROTOCOL

Protocol: {Insert the Number and Title of the Protocol}
Schedule A – Attached
Copy of Master Clinical Trial Agreement – On file at the Institution and Novartis

5. COSTS AND PAYMENT

A. Payment shall be made to the Institution in accordance with the Schedule A appended hereto and incorporated herein by reference.

B. Each check will be made payable to (insert the precise name of the Institution to whom the check(s) will be made payable), will reference the Protocol number and will be mailed to the address set forth in Schedule A. The Institution's Tax Identification Number is {Insert the Tax Identification Number of the Institution}.

REST OF PAGE INTENTIONALLY LEFT BLANK
IN WITNESS WHEREOF, the Parties have executed this Clinical Trial Request Form in duplicate by proper persons thereunto duly authorized.

NOVARTIS PHARMACEUTICALS CORPORATION

By: ______________________________
    (signature)

Name: ______________________________

Title: ______________________________

Date: ______________________________

THE UNIVERSITY OF TEXAS (NAME THE MEDICAL CENTER)

By: ______________________________
    (signature)

Name: ______________________________

Title: ______________________________

Date: ______________________________

PRINCIPAL INVESTIGATOR

I have read this Clinical Trial Request Form and the Master Clinical Trial Agreement, and I understand and accept my obligations hereunder.

By: ______________________________
    (signature)

Name: ______________________________
    (print or type name)

Title: ______________________________

Date: ______________________________
ATTACHMENT B

SAE REPORT – IIRP

Please fax to IMS within 24 hours
FAX: 1-888-299-4565
If you encounter problems with the fax transmission please call
(862) 778-8470 or (862) 778-8724

CONTACT INFORMATION

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STUDY INFORMATION (please print)

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CAUSALITY

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WAS THIS REPORT SENT TO THE FDA? □ NO □ YES Date

INVESTIGATOR SIGNATURE:

Date
## Attachment C
### Administrative Contact Person and Address for Each Institution

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Institution</th>
<th>Address</th>
<th>Phone</th>
<th>Fax</th>
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<tr>
<td>David Hawkins</td>
<td>Associate Director</td>
<td>The University of Texas at Austin</td>
<td>North Office Bldg., Suite 5.300</td>
<td>512-471-6424</td>
<td>512-471-6564</td>
<td>74-6000203</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Austin, TX 78712</td>
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</tr>
<tr>
<td>Angela R. Charboneau Wishon, J.D.</td>
<td>Vice President for Research Administration</td>
<td>The University of Texas Southwestern Medical Center</td>
<td>5323 Harry Hines Blvd., Dallas, TX 75390-9105</td>
<td>214-648-6449</td>
<td>214-648-4474</td>
<td>75-6002868</td>
</tr>
<tr>
<td>Chris Green</td>
<td>Director, Office of Sponsored Programs</td>
<td>The University of Texas Health Science Center at San Antonio</td>
<td>7703 Floyd Curl Dr, Mail Code 7828</td>
<td>210-567-2340</td>
<td>210-567-8107</td>
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<td>San Antonio, TX 78229-3900</td>
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<tr>
<td>Karen Niemeier</td>
<td>Director, Contracts</td>
<td>The University of Texas Health Science Center at Houston</td>
<td>7000 Fannin Street, Suite 1006, Houston, TX 77030</td>
<td>713-500-3999</td>
<td>713-383-3746</td>
<td>74-1761309</td>
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<tr>
<td>David Anderson</td>
<td>Director, Office of Pre-Award Services</td>
<td>The University of Texas Health Science Center at Tyler</td>
<td>11937 U.S. Hwy. 271, Tyler, TX 75708-3154</td>
<td>903-877-7486</td>
<td>903-877-7558</td>
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<tr>
<td>Angela Cook</td>
<td>Director, Office of Clinical Research</td>
<td>The University of Texas Medical Branch at Galveston</td>
<td>301 University Boulevard, Galveston, TX 77555-0158</td>
<td>409-772-1978</td>
<td>409-772-1968</td>
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