

DATA SHARING AGREEMENT
For RESEARCH PROPOSAL _____

This DATA SHARING AGREEMENT (this “**Agreement**”) is effective as of _____, _____ (the “Effective Date”) between (the “Institution”), located at _____ and _____ (“**Study Sponsor**”) located at _____, and _____ (“Study Sponsor”) located at _____, regarding that certain **Research Proposal** submitted by _____ and approved by the **Independent Review Panel**.

BACKGROUND

WHEREAS, each Study Sponsor and its Affiliates (as defined below) are engaged in the business of researching, developing manufacturing and marketing prescription pharmaceuticals and have accumulated certain data in clinical studies conducted by Study Sponsor(s) and its Affiliates; and

WHEREAS, each Study Sponsor wishes to share data collected in clinical trials to support the free exchange of scientific information in accordance with standards found at <https://clinicalstudydatarequest.com>; and

WHEREAS, Institution desires to get access to and obtain a license to use certain data collected by each Study Sponsor accumulated in conduct of the clinical study/ies listed in **Exhibit A** (the “Clinical Studies”) in order to conduct certain analyses; and

WHEREAS, Institution’s Research Proposal involves the clinical trial data collected by each of the Study Sponsors identified above; and

WHEREAS, Study Sponsor(s), on its behalf and on behalf of its Affiliates, is willing to grant such a license and access to these data via a secure, password protected analysis system subject to the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of mutual promises, Study Sponsor(s) and Institution (each, a “Party” and collectively, the “Parties”) agree as follows:

1. DEFINITIONS

1.1 “**Affiliate**” means any person or entity which, directly or indirectly, is controlled by, controls, or is under common control with a Study Sponsor

1.2 “**Access System**” is a single shared Multi Sponsor environment that supports Researchers accessing the anonymized, patient-level clinical study data made available under this Agreement.

1.3 “**Analysis/Analyses**” refers to any and all analysis of the anonymized, patient-level data from the Clinical Studies, or any other source, as specifically described in the Research Proposal.

1.4 “**Analytical Tools**” includes, but is not limited to, any methodology, statistical methods, formulae or other methods or tools used in conducting the Analyses.

1.5 “**Independent Review Panel**” means the independent external review panel consisting of acknowledged experts which reviews the scientific merit of the request for data from the Clinical Studies, managed by the Wellcome Trust.

1.6 “**Lead Researcher**” means the researcher identified as the “Lead Researcher” in the Research Proposal or such other person that may be subsequently identified as a replacement Lead Researcher by the Institution in accordance with Section 2.4 of this Agreement.

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1.7 “**New Intellectual Property**” means all data, discoveries, developments, inventions (whether patentable or not), improvements, methods of use or delivery, processes, know-how, or trade secrets which are made by a Researcher as a result of the conduct of Analyses or as a result of the use of any information provided to Institution or a Researcher by a Study Sponsor under this Agreement.

1.8 “**Research Proposal**” means the research proposal as submitted by the Lead Researcher approved by the Independent Review Panel, including the plan for analyses of the anonymized, patient-level data from the Clinical Studies, or any other source, as described in detail in the research proposal, attached hereto as **Exhibit B**.

1.9 “**Researcher**” means each and any of the researchers listed in a Research Proposal or such other individuals that are employees, representatives and/or agents of Institution provided access to the data from the Clinical Studies.

1.10 “**Study Sponsor Confidential Information**” means all information (including, without limitation, anonymized patient-level data, research specifications or clinical trial/study protocols, reports, specifications, computer programs or models and related documentation, inventions (whether patentable or not), findings, results, know-how, trade secrets, or business or research plans) of a Study Sponsor or any of its Affiliates that is provided to or otherwise made available to the Institution or a Researcher in connection with this Agreement.

1.11 “**Study Sponsor Uses**” means any and all uses of or related to any Study Sponsor data or a compound which is owned or controlled by a Study Sponsor on or after the Effective Date, including the compound(s) used to generate the patient-level data, which would otherwise be an infringement of any New Intellectual Property. For the avoidance of doubt, a related use includes, but is not limited to, a diagnostic test applicable to a disease treated by the compound or the class to which it belongs.

2. DATA SHARING

2.1 Study Sponsor hereby grants to Institution a one-time non-exclusive, non-transferable license for use by Researchers of the anonymized, patient-level data from the Clinical Studies for the sole purpose of conducting the Analyses according to the Research Proposal and for no other purpose. Study Sponsor(s) will provide the Researcher(s) with access to these data via the Access System.

Lead Researcher agrees to restrict analysis of the Clinical Studies, and to cause all other Researchers to restrict analysis of the Clinical Studies, to the Analysis/Analyses specified in the Research Proposal, , and will not perform or allow other Researchers to perform any analysis that is not specified in the Research Proposal without prior written agreement from Sponsor(s).

a) Additional terms of use attached hereto as Exhibit C apply to the Access System and must be accepted by each Researcher before access will be granted to the System.

b) United States export laws and regulations apply to the Access System. Researcher agrees to comply with US and other applicable export and import laws and regulations. This includes but is not limited to attesting that the Researcher is not located in, under control of, or a national or resident of any country or region to which export of SAS software or the Access System is restricted by laws of the United States or other applicable laws and regulations.

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2.2 Prior to and during the course of the research project, Study Sponsor will process personal data of the Researchers and research team members according to data protection laws applicable to Study Sponsor ("Applicable Data Protection Laws").

Institution shall inform affected Researchers and research team members about processing of their personal data by Study Sponsor as described in the following and about their rights to enable Study Sponsor to comply with its information obligation under Applicable Data Protection Laws.

Categories of personal data that Study Sponsor is typically processing in connection with a research project are name, title, affiliation, email address and telephone number of the Researchers and research team members. The Study Sponsor will store and process the personal data for the following purposes: Processing the research proposal, including but not limited to managing the user accounts and providing data access.

2.3 Access to each Study Sponsor's data will be available to Institution for a twelve (12) month period. Study Sponsor(s) may extend Institution's access to its clinical data hereunder by written agreement of an authorized representative of each Study Sponsor.

2.4 Data provided by Study Sponsor(s) are Study Sponsor's(s') Confidential Information and may also contain copyrighted material of its licensors. This grant of a license shall not transfer any title or ownership rights in the Study Sponsor's(s') Confidential Information, and/or such copyrighted material, including any intellectual property embodied therein, and any content that is the property of a third party licensor, which title and ownership rights shall at all times remain with the Study Sponsor(s) or its third-party licensor/s. The clinical trial data provided hereunder is provided 'AS IS' and Study Sponsor(s) makes no representations or warranties regarding the suitability of the data provided to Institution for Analysis.

2.5 Institution shall provide Study Sponsor(s) prior written notice of any replacement of the Lead Researcher and/or the Statistician (or equivalent) as approved by the IRP and shall ensure that the replacement of either acknowledges and agrees to the terms of this Agreement. A Researcher's access to and usage of the Access System will be subject to compliance by such Researcher with the access and usage conditions set forth on the Access System, attached hereto as Exhibit C. Any Researcher may be denied access to the Access System and Institution shall be liable for any direct damages or liability arising from any non-compliance with the access and usage conditions. Study Sponsor(s) disclaim all liability to Institution or to any Researcher in connection with access to, or use of, the Access System.

2.6 Institution shall not, and will ensure that Researchers shall not:

- download, save, edit, photograph, print, or transfer the whole or any portion of the Study Sponsor's(s') Confidential Information from the Access System for either the approved use or for any other purpose;
- remove, bypass, circumvent, neutralise or modify any technological protection measures of the Access System; or
- share any username, password or other account details with a third party or otherwise provide a third party with access to the Researcher's or Institution's account to the Access System.

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Violations or attempted violations of this clause may result in the termination of data access and or legal action.

2.7 Institution and Researchers shall comply with applicable laws, regulations, codes, and guidelines, regarding handling, analysing and reporting analyses of clinical trial data.

2.8 Institution certifies that it is a holder of a valid WHO-Drug Dictionary license with the Uppsala Monitoring Centre. This is a condition for the transfer of data sets containing WHO Drug Dictionary codes. **(optional, but to be used if required by at least 1 sponsor)**

2.9 Institution shall inform each relevant Study Sponsor immediately, no later than within twenty-four (24) hours, (and may also inform any regulatory authority) of any information concluded from the research conducted pursuant to the Research Proposal that in the Lead Researcher's judgment could impact the risk-benefit assessment of Study Sponsor's(s') product, including but not limited to, any safety concerns, identified as part of the Analysis. Sponsor(s) pharmacovigilance contact details are provided in **Exhibit D**. The relevant Study Sponsor(s) may take action regarding such information, including informing regulatory authorities or healthcare providers, or otherwise making such information public, even in advance of publication of the Analysis by Institution. Promptly after a request, Institution shall provide access and reasonable assistance to Study Sponsor(s) to utilize and implement any Analytical Tools for the sole purpose of reproducing the Analysis.

3. CONFIDENTIALITY

3.1 Institution shall ensure that Study Sponsor's(s') Confidential Information is kept confidential and is not used for any purposes other than the purpose(s) described in this Agreement. Neither Institution nor any of the Researchers shall disclose Study Sponsor's(s') Confidential Information to third parties or to any other Study Sponsors without the prior written approval of Study Sponsor(s) except as necessary for the purpose(s) described in this Agreement and under a written agreement by the third party or other Study Sponsor(s) (with the exception of regulatory authorities notified of Analysis results) to be bound by obligations at least as restrictive as those set forth in this Agreement in terms of maintaining the confidentiality of Study Sponsor Confidential Information. For sake of clarity, Institution shall ensure that in the Research project each Study Sponsor's Confidential Information will not be disclosed to any other Study Sponsors without a prior written approval of the concerned Study Sponsor(s). Institution shall safeguard Study Sponsor's(s') Confidential Information with the same standard of care that the Study Sponsors generally apply and all general applicably industry standard for safeguarding Confidential Information. At any time upon the request of relevant Study Sponsor, all tangible expressions, in any media, of Study Sponsor's(s') Confidential Information in Institution's or a Researcher's possession shall be delivered to the relevant Study Sponsor or, at the relevant Study Sponsor's option, destroyed.

3.2 The obligations of confidentiality and limited use under this Section shall not extend to any information: (i) which is or becomes publicly available, except through breach of this Agreement (ii) which Institution or a Researcher can demonstrate that it possessed free of any obligation of confidence prior to, or developed independently from, disclosure under this Agreement; (iii) which a Researcher or Institution receives from a third party which is not legally prohibited from disclosing such information; or (iv) which Institution or a Researcher is required by law to disclose, provided that the other party is notified of any such requirement with sufficient time to seek a protective order or other modifications to the requirement.

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3.3 The obligations of this Section shall survive this Agreement for a period of fifteen (15) years after the Effective Date.

4. INTELLECTUAL PROPERTY [version for multi-sponsor agreements]

4.1 Study Sponsor's(s') Confidential Information and all tangible expressions, in any media, of Study Sponsor's(s') Confidential Information are the sole property of such Study Sponsor.

4.2 All New Intellectual Property shall be the sole property of Institution; however, Institution will notify each Study Sponsor, promptly and in writing, of any New Intellectual Property in accordance with the Confidentiality Terms in Section 3 of this Agreement. Institution hereby grants to each Study Sponsor a perpetual, non-exclusive, fully-paid up, royalty-free, irrevocable, worldwide, unrestricted license under any New Intellectual Property for Study Sponsor Uses, with the right to sublicense through multiple tiers. Institution further grants an exclusive (for Single Sponsor exercised option) or co-exclusive (for Multi Sponsor exercised option) always even as to Institution, option to each Study Sponsor, to be exercised within twelve (12) months from notice of the New Intellectual Property to negotiate in good faith a co-exclusive (even as to Institution), fee-bearing, worldwide license with the right to sublicense through multiple tiers to any New Intellectual Property which Institution may have or obtain. In order to negotiate the co-exclusive license in accordance with the Confidentiality Terms of Section 3 of this Agreement, Institution shall only share a summary of the New Intellectual Property. However, if Institution needs to provide any other Study Sponsor's Confidential Information within the summary of the New Intellectual Property, the Institution shall request the written authorisation of the concerned Study Sponsor(s), which shall not be illegitimately withheld. If additional assistance from the Institution is requested beyond the rights provided by the non-exclusive license, Institution will provide reasonable assistance to each Study Sponsor, upon commercially reasonable terms that are at least as favorable to the Study Sponsor as the terms agreed with any other licensee for such assistance, to facilitate Study Sponsor in fully utilizing any New Intellectual Property. For sake of clarity, "co-exclusive" rights shall not provide exclusivity of one Study Sponsor against the other(s), but shall preclude Institution from granting licenses to third parties.

4.3 If a Study Sponsor exercises its option to negotiate an exclusive or co-exclusive license, Study Sponsor and Institution will exclusively (for Single Sponsor exercised option) or co-exclusively (for Multi Sponsor exercised option) negotiate in good faith, for up to twelve (12) months or such mutually agreeable longer period, regarding commercially reasonable terms for an exclusive or co-exclusive, worldwide, fee-bearing license, including the right to sublicense, for the Single or Multi Study Sponsor(s) and its/their Affiliates to make, have made, use, import, sell or otherwise dispose of the subject matter of the New Intellectual Property or products incorporating the subject matter of the New Intellectual Property subject to any non-exclusive licenses granted in section 4.2. In the event that none of the Study Sponsors exercises the option to negotiate an exclusive or co-exclusive license, or in the event Institution and Study Sponsor or Study Sponsors fail to agree to commercially reasonable exclusive license terms following good faith negotiation, Institution may negotiate further non-exclusive license terms with third parties. Any such terms shall be consistent with the non-exclusive license granted to Study Sponsor in Section 4.2 above. Should any terms be agreed with a third party in accordance with this section, then for five (5) years after the Effective Date, Institution will notify each Study Sponsor, within thirty (30) days of the effective date of any such agreement, of the identity of the third party.

4.4 Institution agrees to obtain written agreements with all Researchers which assign, without additional consideration, all rights, title and interests in New Intellectual Property to Institution for subsequent licensing to all Study Sponsors.

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4.5 Study Sponsors shall have no further obligations resulting from the assignment and/or exploitation of any New Intellectual Property.

4.6 The obligations of this Section shall survive termination of this Agreement.

4. INTELLECTUAL PROPERTY [version for single-sponsor agreements]

4.1 Study Sponsor's(s') Confidential Information and all tangible expressions, in any media, of Study Sponsor's(s') Confidential Information are the sole property of the Study Sponsor.

4.2 All New Intellectual Property shall be the sole property of Institution; however, Institution will notify each Study Sponsor, promptly and in writing, of any New Intellectual Property. Institution hereby grants to each Study Sponsor a perpetual, non-exclusive, fully-paid up, royalty-free, irrevocable, worldwide, unrestricted license under any New Intellectual Property for Study Sponsor Uses, with the right to sublicense through multiple tiers. Institution further grants an exclusive option, to be exercised within one hundred eighty (180) days from notice of the New Intellectual Property to negotiate in good faith an exclusive, fee-bearing, worldwide license with the right to sublicense through multiple tiers to any New Intellectual Property which Institution may have or obtain. If additional assistance from the Institution is requested beyond the rights provided by the non-exclusive license, Institution will provide reasonable assistance to each Study Sponsor, upon commercially reasonable terms that are at least as favorable to the Study Sponsor as the terms agreed with any other licensee for such assistance, to facilitate Study Sponsor in fully utilizing any New Intellectual Property.

4.3 If a Study Sponsor exercises its option to negotiate an exclusive license, Study Sponsor and Institution will exclusively negotiate in good faith, for up to one hundred eighty (180) days or such mutually agreeable longer period, regarding commercially reasonable terms for an exclusive, worldwide, fee-bearing license, including the right to sublicense, for the Study Sponsor and its Affiliates to make, have made, use, sell or otherwise dispose of the subject matter of the New Intellectual Property or products incorporating the subject matter of the New Intellectual Property subject to any non-exclusive licenses granted in section 4.2. In the event that the Study Sponsor does not exercise its option to negotiate an exclusive license, or in the event Institution and Study Sponsor fail to agree to commercially reasonable exclusive license terms following good faith negotiation, Institution may negotiate further non-exclusive license terms with third parties. Any such terms shall be consistent with the non-exclusive license granted to Study Sponsor in Section 4.2. Should any terms be agreed with a third party in accordance with this section, then for five (5) years after the Effective Date, Institution will notify Study Sponsor(s), within thirty (30) days of the effective date of any such agreement, of the identity of the third party.

4.4 Institution agrees to obtain written agreements with all Researchers which assign, without additional consideration, all rights, title and interests in New Intellectual Property to Institution for subsequent licensing to Study Sponsor(s).

4.5 Study Sponsor shall have no further obligations resulting from the assignment and/or exploitation of any New Intellectual Property.

4.6 The obligations of this Section shall survive termination of this Agreement.

5. PUBLICATION

5.1 Institution consents that the title of the Research Proposal, name of the Lead Researcher, affiliation, funding source, potential conflicts of interest, lay summary of the proposed Research , and requested

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studies (all as provided by the Researcher in the Research Proposal) will be posted on clinicalstudydatarequest.com after the Data Sharing Agreement is executed.

5.2 Institution consents that the Statistical Analysis Plan (as provided by the Researcher in the Research Proposal) will be posted on clinicalstudydatarequest.com after the research is published.

5.3 Institution also agrees to disclose the results of the Analysis in a scientific journal, within one (1) year of completing the Analysis, in a manner consistent with the publication plan set forth in the Research Proposal (a "Publication"), with such Publication appropriately including citations or register identification numbers for the studies used in the analysis, disclosing the strengths and weaknesses of the Analysis methodology and providing a link to www.ClinicalStudyDataRequest.com. Institution may use Study Sponsor's name solely for that purpose. If for any reason the Analysis cannot be disclosed in a manner consistent with the publication plan, a brief summary of any activity performed, any outcome of the Analysis, and reason for non-completion, as applicable, should be disclosed on an open access journal or publishing platform with a link provided on www.ClinicalStudyDataRequest.com.

5.4 Institution shall ensure compliance with the additional provisions regarding publication of the results of the Analyses set forth in Exhibit E.

5.5. Institution agrees that all Publications will acknowledge the appropriate Sponsor(s) and www.ClinicalStudyDataRequest.com as sources of data and may use their names and the CSDR logo for that purpose.

5.6 The obligations of this Section 5 shall survive termination of this Agreement.

6. INDEPENDENT CONTRACTOR

The relationship of the parties is that of independent contractors. Neither party is the partner, joint venturer, or agent of the other and neither party has authority to make any statement, representation, commitment, or action of any kind which purports to bind the other without the other's prior written authorization.

7. ASSIGNMENT

A Study Sponsor may assign its rights and duties under this Agreement without Institution's consent. Any assignment of any rights or obligations under this Agreement by Institution is valid only upon the prior written consent of Study Sponsor(s). To the extent permitted above, this Agreement shall be binding upon and inure to the benefit of the parties and their permitted successors and assigns.

8. REPRESENTATIONS AND WARRANTIES

8.1 Institution represents and warrants that it does not have, and will not enter into, any legal or contractual obligations that would prevent it from complying with its obligations under this Agreement, including without limitation, the obligations of Section 4, without the written approval of Study Sponsor.

8.2 Institution shall be responsible for the compliance of the Lead Researcher and any other Researcher to the terms of this Agreement.

8.3 Lead Researcher will obtain any regulatory or ethics approvals necessary to conduct the Research Proposal.

9. DATA PROTECTION

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Institution acknowledges the importance of data privacy of individuals to whom accessed data may relate, and commits to comply with all applicable federal, state and local laws and regulations relating to data protection and the privacy of subject health information, not to attempt to identify subjects, and not to combine accessed data with other sources of data that would lead to the identification of any individual.

10. TERM AND TERMINATION

10.1 The term of this Agreement shall commence on the Effective Date and continue through completion of the Research Proposal. Certain provisions of this Agreement survive termination of this Agreement as expressly set forth herein.

10.2 Institution's or a Researcher's use of any of Study Sponsor's(s') Confidential Information or Intellectual Property in violation of any law or of any terms or limitations imposed by this Agreement shall be a violation of this Agreement and Study Sponsor may immediately terminate the rights granted under this Agreement unless earlier terminated as set forth in 10.3 below.

10.3 Study Sponsor(s) may, in addition to any other rights and remedies available to Study Sponsor(s), terminate this Agreement by giving Institution written notice of such termination in the event Institution or any Researcher materially breaches any of the terms and conditions of this Agreement and fails to cure such breach or default as promptly as practicable and, in any event, not more than thirty (30) days after respective Study Sponsor gives Institution written notice specifying the details thereof. Notwithstanding the foregoing, in the event that any breach is not reasonably capable of cure within the thirty (30) day period, it shall be sufficient if Institution promptly commences appropriate action to cure and diligently pursues such action until complete.

11. GOVERNING LAW; VENUE

This Agreement shall be interpreted and governed exclusively by the laws of the country and, as applicable, the government subdivision, in which the Study Sponsor is located (as set forth at the beginning of this Agreement), without reference to its rules of conflict of law. Any dispute arising under or in connection with this Agreement shall be subject to the exclusive jurisdiction of the competent courts of that country or government subdivision.

12. OPERATIONAL AUDITS (optional, but to be used if required by at least 1 sponsor)

Upon prior written notice, one or more of the Sponsor or its/their designee, including Governmental authorities, or third party auditors, shall be permitted access to any facility or systems at which the Research is being performed and to the data and records maintained by Institution, the Lead Researcher and all Researcher(s) with respect to the Research for the purposes of:

- (a) verifying compliance with the provisions of this Agreement, in particular the sections two (2), three (3) and five (5) and any applicable privacy data protection requirements.
- (b) verifying the integrity of confidential data provided by Sponsor(s), examining the systems that process, store, support, and transmit such data, and confirming the security of confidential data processed by Researcher.

The findings of the audit can be used by Sponsors to terminate the agreement, to inform the relevant Authorities and to engage liability of the Institution in case of breach of the sections (2), three (3) and/or five (5) and any applicable privacy data protection requirements or laws and regulations.

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The Sponsors will coordinate their audit activities to avoid multiple audits. Sponsors reserve the right to perform one common audit per year at the maximum unless there is an urgent need to perform an audit. Sponsors agree that the purpose of the audit right is not for one Sponsor to get access to the anonymized data to the other Sponsors and the confidentiality obligation will be applicable in case of performance of an audit.”

13. ENTIRE AGREEMENT

This Agreement represents the entire and integrated agreement between the parties and supersedes all prior negotiations, representations or agreements, either written or oral, regarding its subject matter.

14. COUNTERPARTS

This Agreement may be executed in two or more counterparts, each of which shall be considered an original instrument. Each counterpart will be considered a valid and binding original, and all counterparts taken together shall constitute one and the same agreement. Faxed copies and scanned copies of original signatures shall be deemed as effective as original signatures. Once signed, any reproduction of this Agreement made by reliable means (e.g., photocopy, facsimile, scan) is considered an original.

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IN WITNESS WHEREOF, the parties have executed this Agreement by their duly authorized officers or representatives on the date set forth below, effective as of the Effective Date.

Study Sponsor:
By:
Name:
Title:
Date:

Study Sponsor:
By:
Name:
Title:
Date:

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Institution:
By:
Name:
Title:
Date:

<u>Acknowledged and Agreed to by the Lead Researcher:</u>
By:
Name:
Title:
Institution:
Date:

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<u>Acknowledged and Agreed to by the Statistician:</u> (optional, but to be used if required by at least 1 sponsor)
By:
Name:
Title:
Institution:
Date:

Attachments:

- Exhibit A – Clinical Studies Listing
- Exhibit B – Research Proposal
- Exhibit C – Access System Additional Terms of Use
- Exhibit D – Study Sponsor PV Contact Information
- Exhibit E – Additional Study Sponsor Publication Provisions

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Exhibit A – Clinical Studies Listing

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Exhibit B – Research Proposal

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Exhibit C – Access System Additional Terms of Use

Access System Additional Terms of Use – the Export classification (ECCN) of Clinical Trial Data Transparency 5D002.c).

<https://mseportal.ondemand.sas.com/ctdt/help/view/CTDT%20Terms%20of%20Use%20for%20Researchers%20Final%2011Aug2015.pdf>

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Exhibit D – Study Sponsor PV Contact Information

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Exhibit E

Additional Study Sponsor Publication Provisions

Publication Terms:

(to be used if required by at least 1 sponsor)

Lead Researcher shall submit to Study Sponsor(s) a copy of any proposed Publication (or a brief summary if for any reason the Analysis cannot be disclosed in a manner consistent with the publication plan) at least thirty (30) days prior to submission to a scientific congress or journal to give Study Sponsor the opportunity for input regarding medical and scientific accuracy, supplementary scientific information, to object to any inclusion of Study Sponsor's(s') Confidential Information and to review for patentable subject matter. Lead Researcher is not required to accept Study Sponsor's comments regarding medical and scientific accuracy and supplementary scientific information. Researcher/Institution is required to make changes for purposes of protecting Sponsor's Intellectual Property, if requested by Sponsor.

Please submit the manuscript to the following recipients:....

(to be used if required by at least 1 sponsor)

Lead Researcher shall submit to Study Sponsor(s) a copy of any proposed Publication (or a brief summary if for any reason the Analysis cannot be disclosed in a manner consistent with the publication plan) within five (5) days after submission to a scientific congress or journal.

Please submit the manuscript to the following recipients:.....