Clinical Supply Agreement

**between\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and the**

**Division of Cancer Treatment and Diagnosis, NCI**

**AGREEMENT**

The following agreement serves as the basis for the distribution of [collaborator’s agents\_\_\_\_\_\_\_\_\_\_by NCI for ­­­­DCTD supported clinical trials

**Article 1. Definitions**

"*Affiliates*" means any corporation or other business entity controlled by, controlling, or under common control with Collaborator (see "Collaborator"). For this purpose, a business entity shall be deemed to “control” another business entity if it (a) owns, directly or indirectly, fifty percent (50%) or more of the outstanding voting securities or other ownership interest of such other business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity), or (b) otherwise possesses, directly or indirectly, the power to direct the management or policies of such other business entity, whether through the ownership of voting securities or by contract relating to voting rights or corporate governance.

"*Agent*" means \_\_\_\_\_\_\_\_\_\_\_, proprietary to\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

“*Annual Report”* means a brief report of the progress of an IND-associated investigation which the IND sponsor is required to submit to the FDA within 60 days of the anniversary date that the IND went into effect (pursuant to 21 CFR 312.33).

“*Clinical Data and Results*” means all information, data, and results developed or obtained in connection with clinical trials conducted within the scope of this Agreement.

"*Collaborator*" means \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_doing business as\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, a corporation organized and existing under the laws of the State of \_\_\_\_\_\_\_\_\_\_\_\_\_\_ having a principal place of business at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and its Affiliates.

“*Cooperative Group*” means the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and other such groups in similar structure organized to conduct studies by a collective group of investigators located at various institutions.

"*CTEP*" means the Cancer Therapy Evaluation Program, DCTD, NCI.

"*DCTD*" means the Division of Cancer Treatment and Diagnosis, NCI.

*“DHHS”* means the Department of Health and Human Services.

"*FDA*" means the Food and Drug Administration, DHHS.

"*Government*" means the U.S. Government and any of its agencies.

"*Human Subjects*" means individuals whose physiologic or behavioral characteristics and responses are the objects of study in a research project. Under the Federal regulations for the protection of human subjects, human subjects are defined as living individuals about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information (45 CFR 46.102(f)).

"*NCI*" means the National Cancer Institute, NIH, DHHS.

*“NIH”* means the National Institutes of Health, PHS, DHHS.

*“PHS”* means the Public Health Service, DHHS.

*“PMB”* means Pharmaceutical Management Branch, CTEP, DCTD, NCI.

"*Proprietary / Confidential Data*" means confidential scientific, business or financial data, provided that such data:

* + 1. are not publicly known or available from other sources who are not under a confidentiality obligation to the source of the information;
    2. have not been made available by its owners to others without a confidentiality obligation;
    3. are not already known by or available to the receiving Party without a confidentiality obligation; and
    4. do not relate to potential hazards or warnings associated with the production, handling or use of the subject matter of this Agreement.

If any one or more of the above provisions of this definition are not met, the relevant information shall no longer be considered proprietary.

"*Raw Data*" means the primary quantitative and empirical data first collected by the intramural and extramural investigators from experiments and clinical trials conducted under the scope of this Agreement.

"*Regulatory Affairs Branch*" means the Regulatory Affairs Branch, CTEP, DCTD, NCI.

"*Summary Data*" means a summary of the Raw Data which will be made available to DCTD, which summary is used by DCTD to prepare an Annual Report to the FDA.

**Article 2. Adverse Events**

Cooperative Group shall report all serious or unexpected Grade 4 and Grade 5 adverse events that emerge during this Study using AdEERS as described in the protocol. In the event that Collaborator informs the FDA of any serious or unexpected adverse events, Collaborator must notify the NCI at the same time.

Article 3. Drug Information and Supply

Collaborator agrees to provide to DCTD, without charge, appropriately labeled Agent(s) for distribution by CTEP for the protocol in sufficient quantity to complete the Protocol(s). The Agent shall have a minimum shelf life of one year. The contact person for DCTD will be Mr. Skip Hall, Chief, Pharmaceutical Management Branch (Telephone Number 240-276-6575). The DCTD, NCI shall provide, without charge, the Agent to the U.S. Participating Investigators of the Study only to be used solely for the treatment of patients registered to the Study, pursuant to the Protocol. The NCI requires the Study Participating Investigators to store the Agent properly in a secure location with limited access to prevent theft or misuse. DCTD require sites to maintain NCI Investigational Agent Accountability Records as described in the NCI Investigator Handbook. Once the Study is completed or closed to accrual and treatment, Participating Investigators will be required to return to the NCI Clinical Repository any un-dispensed packages of Agent. Previously dispensed Agent packages, whether partial or full packages, will not be returned to the NCI Clinical Repository and must be destroyed locally in accordance with the Participating Investigator’s institutional disposal policy. The NCI will destroy all expired or unused Agent remaining at the end of NCI’s collaboration with Collaborator in accordance with Federal or State Regulations and DCTD policy, unless requested by Collaborator to return the Agent to Collaborator, at the Collaborator’s expense.

The Pharmaceutical Management Branch (PMB), CTEP, DCTD, NCI professional staff will provide pharmaceutical management and coordination for the acquisition, inventory control, and distribution authorization for the Agent distributed for the Study. Collaborator will bear the costs for the storage, distribution, inventory management, and final Agent disposition through an independent NCI Contractor, currently, Fisher BioServices, 627 Lofstrand Lane, Rockville, MD 20850 (“Fisher”) (Tax ID# 54-1348241), as long as the contract between the NCI Contractor and NCI is active. The Collaborator will enter into a Work Order agreement with Fisher BioServices for these services for each Agent or Protocol and the Work Orders will be made a part hereof as Attachments.

Agent should be shipped directly to:

NCI Clinical Repository, Fisher BioServices, 627 Lofstrand Lane, Rockville, MD 20850

Attn: Jeff Eggers (301-762-1772)

Collaborator will bear the costs for Clinical Drug Request receipt and processing (which includes ensuring that all NCI Investigator registration documents are in place before shipment), and Investigator Brochure distribution (if applicable) through an independent NCI Contractor, currently, EDJ Associates, 13873 Park Center Road, Suite 301, Herndon, VA 20171, as long as the contract between the NCI Contractor and NCI is active. The Collaborator will enter into a Work Order agreement with EDJ for these services for each Agent or Protocol and the Work Orders will be made a part hereof as Attachments.

**Article 4. Proprietary/ Confidential Data**

Any preclinical or formulation data considered proprietary by Collaborator will be treated as such by DCTD. DCTD shall treat in confidence any of Collaborator's written infor­mation about the Study that is stamped "Confidential" for a period of three (3) years from the date of disclosure, unless Collaborator informs DCTD that the Confidential Information is still secret and confidential, and DCTD concurs, in which case the obli­gations hereof shall extend for a further period of two (2) years. Any proprietary information which is orally disclosed must be reduced to writing and marked "Confidential" within thirty (30) days of such disclosure. Such Proprietary Data shall not include information or data exempted from the definition of “Proprietary Data” under Article 1. Primary data will, upon request by Collaborator, be returned to Collaborator by DCTD. However, summaries of all such studies will be retained in the DCTD files. Notwithstanding the foregoing with respect to Multiparty data and subject to the terms of Article 4, it is the intention of the NCI that except as may be required by the Freedom of Information Act or other applicable law or court order that all data derived from clinical trials at a DCTD-sponsored institution will be made fully, and exclusively available for use by Collaborator in obtaining regulatory approval for the Agent(s). The data will be made available to DCTD in summary form (Summary Data).

**Article 5. Publications and Commercialization**

The DCTD investigators maintain the full right to present and publish the data at such time and place as they see fit. Manuscripts from all clinical trials involving Agent or those to which Collaborator has specifically committed resources should have advisory review and comment by Collaborator prior to submission for publication. The amount of time required for the review shall not exceed thirty (30) days. The publication or other disclosure shall be delayed for up to an additional thirty (30) days upon written request by either Party to this Agreement as necessary to preserve U.S. or foreign patent or other intellectual property rights.

Abstracts presented by NCI investigators will be sent to Collaborator for courtesy notification at least 3 days prior to submission for courtesy review and comment.

**Article 6. Use of Name**

Collaborator may use, refer to, and disseminate reprints of scientific, medical, and other published articles which disclose the name of DCTD or NCI consistent with U.S. copyright laws, provided such use does not constitute an endorsement of any commercial product or service by DCTD or NCI. Collaborator shall take every step possible to ensure that references to the articles are accurate, and shall explicitly state that any such reference does not claim, infer, or imply an endorsement or recommendation of the product by the Investigator or the NCI, NIH, PHS, or DHHS. Collaborator shall not use the name of DCTD or NCI or any of the foregoing in any advertising, packaging, or promotional material in connection with Agent except with the written permission of DCTD or NCI, or as may be required by law. Collaborator-issued press releases that reference or rely upon the work of NCI under this Agreement shall be made available to CTEP at least seven days prior to publication for review and comment, except when the press release is issued in response to a governmental order or directive that does not allow time for such prior review. In that case, the press release will be sent prior to issuance.

**Article 7. Liability**

No indemnification for any loss, claim, damage, or liability is intended or provided by either Party under this Agreement. Each Party shall be liable for any loss, claim, damage, or liability that said Party incurs as a result of said Party's activities under this Agreement, except that DCTD, as an agency of the United States, assumes liability only to the extent as provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171 Sections 2671-2680).

**Article 8. Governing Law**

This Agreement shall be governed by and construed in accordance with Federal law as construed by the Federal Courts of the District of Columbia.

**Article 9. Severability**

The terms of this Agreement are severable. If any item or provision of this Agreement shall to any extent be invalid or unenforceable, the remainder of this Agreement shall not be affected, and each remaining item and provision of this Agreement shall be valid and shall be enforceable to the fullest extent permitted by law.

**Article 10. Survivability**

The provisions of this Agreement as they relate to confidentiality and Agent supply shall survive the expiration or earlier termination of this Agreement.

**Article 11. Compliance with DHHS Regulations**

DCTD and Collaborator agree to comply with all Department of Health and Human Services regulations relating to Human Subject use, and all Public Health Service policies relating to the use and care of laboratory animals.

**Article 12. Travel and Other Interactions**

As part of the conduct of the Study, the participation of DCTD staff may be required at selected scientific or development meetings, as mutually agreed by DCTD and Collaborator. As part of this Agreement, it is agreed that Collaborator will provide for the transportation and associated costs for attendance of DCTD staff in such activities. Selection of participating DCTD staff must be based on choices mutually acceptable to both Collaborator and DCTD. Both Collaborator and DCTD must agree that the activities would be appropriate under this Agreement, and acceptance of Collaborator's support of DCTD's participation in the activities will be contingent upon appropriate DCTD approval. Other interactions which materially assist the development of potentially important new therapies will also be possible. Again, mutual agreement and appropriate DCTD approval will be necessary, according to the terms of this Agreement. However, notwithstanding anything to the contrary, this Agreement does not represent a Cooperative Research and Development Agreement (CRADA, under the Federal Technology Transfer Act, 15 U.S.C. 3701 et seq.) Travel costs are limited by the Federal Travel Rules and Regulations for all government staff whether paid for by government funds or private Collaborators.

**Article 13. Termination**

A. This Agreement expires on the earlier to occur of the completion of the research or five (5) years from the date of execution of this Agreement. Said expiration date may be changed by mutual agreement and written amendment of this Agreement.

B. This Agreement may be terminated at any time by the mutual written consent of the Parties.

C. Either Party may unilaterally terminate the Agreement at any time by giving written notice to the other Party at least sixty (60) days prior to the desired termination date.

D. On expiration or earlier termination of this Agreement, Collaborator will supply enough of each Agent to complete the clinical study(ies) ongoing or approved, pursuant to the provisions of Article 3.

**Article 13. Clinical Supply Agreement Amendments**

Upon mutual agreement of both parties, this Agreement may be amended as necessary to ensure the Agreement accurately reflects the terms and scope of the collaborative research project. The Amendment shall be in writing signed by both the authorized representative of Collaborator and the Director of the DCTD.

**SIGNATURES**

This Agreement, and any Amendments hereto, provides the basis for mutually satisfactory co-development of Agent as an anti-cancer agent.

By executing this Agreement, each of the undersigned represents and confirms that he or she is fully authorized to bind the identified entity to its terms. Each of the undersigned expressly certifies or affirms that the contents of any statement made or reflected in this document are truthful and accurate.

**Agreed to and Accepted by:**

***For the National Cancer Institute:***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

James Doroshow, M.D. Date

Director, Division of Cancer Treatment and Diagnosis

*Address correspondence related to this Agreement to:*

Sherry S. Ansher, Ph.D.

Associate Chief

Agreement Coordination Group

Regulatory Affairs Branch

Cancer Therapy Evaluation Program, DCTD

National Cancer Institute, NIH

9609 Medical Center Drive 5W-526

Rockville, MD 20850

Telephone: 240-276-6580

***For the Collaborator:***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Signature) Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Printed Name and Title)

Address:

Budget for Agent in support of Protocol

Collaborator contact for this Protocol/Agent is

Collaborator agrees to pay Fisher a total of \_\_\_\_\_\_\_\_\_\_\_ to cover the costs defined in this agreement. The cost is based on providing support for a planned accrual of \_\_\_\_\_\_\_ patients over a period of \_\_\_\_ years and Agent storage and distribution for \_\_\_\_ years. Additional Agent costs in support of increased patient accrual shall be invoiced to Collaborator at a fee structure substantially similar to that described below in this paragraph.

Collaborator agrees to pay the amount invoiced for the Work Order period of performance upon execution of the Work Order agreement and receipt of an invoice from Fisher (Fisher BioServices, 627 Lofstrand Lane, Rockville, MD 20850 Tax ID# 54-1348241). Payment will be due within thirty (30) days of receipt of the invoice. Work Order agreements will be executed with and Invoices will be sent to Collaborator on the following schedule:

Period of Performance (date range) $\_\_\_\_\_\_

Period of Performance (date range) $\_\_\_\_\_\_

Period of Performance (date range) $\_\_\_\_\_\_

Period of Performance (date range) $\_\_\_\_\_\_

Period of Performance (date range) $\_\_\_\_\_\_

Total $\_\_\_\_\_\_\_

Any questions regarding the Fisher invoices should be directed to Rodney Howells, PMB at [rodneyh@mail.nih.gov](mailto:rodneyh@mail.nih.gov) or 240-276-6575.

Collaborator agrees to pay EDJ a total of XXXX to cover the costs defined in this agreement. Additional costs in support of increased patient accrual shall be invoiced to Collaborator at a fee structure substantially similar to that described below in this paragraph.

Collaborator agrees to pay the amount invoiced for the Work Order period of performance upon execution of the Work Order agreement and receipt of an invoice from EDJ, 13873 Park Center Road, Suite 301, Herndon, VA 20171 (“EDJ”) (Tax ID# 54-1934561). Payment will be due within thirty (30) days of receipt of the invoice. Work Order agreements will be executed with and Invoices will be sent to Collaborator on the following schedule:

Period of Performance (date range): $\_\_\_\_\_\_

Period of Performance (date range): $\_\_\_\_\_\_

Period of Performance (date range): $\_\_\_\_\_\_

Period of Performance (date range): $\_\_\_\_\_\_

Period of Performance (date range): $\_\_\_\_\_\_

Any questions regarding the EDJ invoices should be directed to Matt Boron, PMB at [boronm@mail.nih.gov](mailto:boronm@mail.nih.gov) or 240-276-6575.

Invoices by Fisher and EDJ Associates should be sent to:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Attachment A

|  |  |  |  |
| --- | --- | --- | --- |
| WORK ORDER Date: | | | |
| [Collaborator Name]  [Street Address]  [City, ST ZIP Code]  [Phone]  Fax [000-000-0000]  [E-mail address]  (“Collaborator”) | | To | Fisher BioServices, Inc.  627 Lofstrand Lane  Rockville, MD 20850  301-762-1772  Contact:  E-mail:  (“Fisher”) | | JoB: | Collaborator:  Clinical Supply Agreement #  Protocol:  Agent: |
|  | | | | | | |
| Period of Service | description | | | | | |
| Month/Day/Year to  Month/Day/Year  (Period of Service shall not exceed 12 months) | Provide the following Services for the referenced Agent, Protocol and Clinical Supply Agreement in accordance with the terms set forth in the Clinical Supplies Agreement (CSA) between the Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI) and the Collaborator: | | | | | |
|  | * Receive, inspect contents and condition of shipment, reconcile discrepancies with packing lists, note condition of materials received, inspect labeling and inventory Collaborator’s agent following NCI-Clinical Repository (NCI-CR) standard operating procedures (SOPs). * Enter Agent inventory into NCI’s proprietary inventory database for tracking each unit of Agent from receipt to final disposition. * Provide Agent storage services at the Agent's required storage conditions and provide continuous monitoring of such storage conditions to guarantee and document conti­nuous proper storage following NCI-CR SOPs. * NCI-registered investigators will place orders with CTEP pursuant to an NCI-sponsored study under the CSA. Upon authorization by CTEP, retrieve Agent from inventory and ship to authorized investigators following NCI-CR SOPs. * Provide final disposition services for Agent (destruction or return to the manufacturer) of any non-distributed Agent and destruction of any Agent returned to the NCI-CR from clinical trial sites in accordance with all local, state and federal regulations. * Provide Quality Assurance to ensure compliance with internal operating procedures and applicable Local, State and Federal Regulations. * Invoice for service costs for the period of service as outlined in the Clinical Supply Agreement between Collaborator and CTEP, DCTD, NCI and defined in this Work Order.   **CONFIDENTIALITY**    **Confidential Information**  “Confidential Information” shall mean any proprietary, confidential and/or non-public business, technical, procedural, or financial information (whether or not patentable or copyrightable, and whether or not currently patented or copyrighted) which is owned or controlled by either Party or obtained in the course of the performance of this Work Order, and anything solely derived therefrom or that is derived through observation or examination of the disclosing Party’s facilities or operations. This Work Order shall govern without regard to the manner of preparation, transmittal or storage of such Confidential Information, including but not limited to physical devices or materials, electronic devices or media, magnetic media, optical media or any other method.  **Disclosure and Use**  Each Party agrees to treat any Confidential Information obtained from the other Party (the “Disclosing Party”) as the confidential and exclusive property of the Disclosing Party. The Party receiving such Confidential Information (the “Receiving Party”) agrees not to disclose any of the Confidential Information to any third-party without first obtaining the written consent of the Disclosing Party. The Receiving Party agrees that it will use the Confidential Information for the purposes of satisfying the obligations under this Work Order, and for no other purpose without the prior written consent of the Disclosing Party. The Receiving Party agrees to hold such Confidential Information in strict confidence for ten (10) years after the date of the applicable Work Order and shall protect Disclosing Party’s information with the same level of care it uses to protect its own Confidential Information. The Receiving Party shall disclose Confidential Information to its employees, officers, directors, and representatives only on a need-to-know basis and only if the foregoing Parties are bound and obligated by provisions of confidentiality. Upon the completion or earlier termination of this Work Order, each Party will promptly return to the other Party all of the Confidential Information.  **Exclusions**  The provisions of Disclosure and Use section shall not apply to information which (i) is or becomes generally available to the public other than as a result of a breach of this Work Order by the Receiving Party; (ii) was in the Receiving Party’s possession prior to receipt from the Disclosing Party as evidenced by the Receiving Party’s contemporaneously written records; provided that the source of such information was not known to the Receiving Party to be bound by an obligation of confidentiality (contractual, legal, fiduciary or otherwise) to the Disclosing Party or any other party with respect to such information; (iii) is received by the Receiving Party from a third party on a non-confidential basis, unless the Receiving Party knows that the third party is bound by an obligation of confidentiality (contractual, legal, fiduciary or otherwise) to the Disclosing Party or any other party with respect to such information; or (iv) is or was independently developed by the Receiving Party without reference to or reliance upon the Confidential Information received from the Disclosing Party as evidenced by the Receiving Party’s contemporaneously written records.  **Disclosures Required by Law**  Notwithstanding anything to the contrary contained in this Work Order, Confidential Information may be disclosed by a Receiving Party as required by applicable law, legal process or stock exchange rule, provided the Receiving Party notifies the Disclosing Party prior to such disclosure, except where impracticable or prohibited by law, so as to afford the Disclosing Party a reasonable opportunity to object or seek an appropriate protective order with respect to such disclosure. Notwithstanding the foregoing, Receiving Party may only disclose that information which it is legally required to disclose.  **Property Ownership**  All materials, documents, data and information supplied to Fisher or prepared or developed by Fisher exclusively in the performance of the Services which constitute improvements to the Drug Product pursuant to this Work Order or any SOW (except for Fisher procedural manuals and personnel data and computer software or technology developed by Fisher), or resulting exclusively from the Services provided hereunder shall be the sole and exclusive property of Collaborator and Collaborator shall have the right to make whatever use it deems desirable of any such materials, documents, data and information; provided that Fisher may retain copies of such materials as may be required by applicable laws and regulations. All other materials, documents, data and information shall be and remain Fisher’s sole and exclusive property.  **Indemnification**  Collaborator is advised that the following indemnification terms will be applicable with each Order:   1. Collaborator agrees to indemnify Fisher against personal injury to any employee of Fisher directly or indirectly caused by the Agent provided by Collaborator, Fisher’s performance of, or involvement with, the Agent or its obligations under this Work Order, the negligence gross negligence or intentional misconduct or inaction of Collaborator in the performance of its obligations under an Order; provided that if such Loss or Claim hereof arises in whole or in part from Fisher’s negligence, gross negligence or intentional misconduct or inaction, then the amount of such Loss that Collaborator shall indemnify Fisher for pursuant to this Section shall be reduced by an amount in proportion to the percentage of Fisher’ responsibilities for such Loss as determined by a court of competent jurisdiction in a final and non-appealable decision or in a binding settlement between the parties. 2. Upon receipt of notice of any Claim which may give rise to a right of indemnity hereto, Fisher shall give written notice thereof to the Collaborator (with a copy to CTEP) with a Claim for indemnity. Such Claim for indemnity shall indicate the nature of the Claim and the basis therefore. Collaborator shall not, in defense of any such Claim, except with the consent of Fisher, consent to the entry of any judgment or enter into any settlement which does not include, as an unconditional term thereof, the giving by the claimant or plaintiff to Fisher of a release from all liability in respect thereof. After notice to Fisher of the Collaborator’s election to assume the defense of such Claim, Collaborator shall be liable to Fisher for such legal or other expenses subsequently incurred by Fisher in connection with the defense thereof at the request of Collaborator. As to those Claims with respect to the which Collaborator does not elect to assume control of the defense, Fisher will afford Collaborator an opportunity to participate in such defense, at the Collaborator’s own cost and expense, and will not settle or otherwise dispose of any of the same without the consent of Collaborator. 3. The obligations of the Collaborator under this Indemnification Article shall survive the expiration or termination of this Work Order. Further, a breach by Fisher of its obligations under this Work Order or any CSA shall not relieve the Collaborator of its obligations under this Article unless such breach was solely responsible for the Loss or Claim as determined by a court of competent jurisdiction in a final and non-appealable decision or in a binding statement between the parties.   **DEFAULT / LIMITATION OF LIABILITY**  **Default**.  If Fisher is in default of its material obligations under this Work Order, then Collaborator shall promptly notify Fisher in writing of such default. Fisher shall have a period of 45 days from the date of receipt of such notice within which to cure such default. If such default cannot be cured, then Collaborator may, at its option: (i) require Fisher to repeat the Services at Fisher’s cost within a mutually agreeable time period; or (ii) obtain a refund from Fisher of all fees paid by the Collaborator for the Services resulting in default; or (iii) terminate the relevant Work Order under which the default arose, in which event Collaborator’s sole remedy shall be: (a) in the case where such default has not rendered the Services invalid, to obtain a reduction in or rebate of the fees paid for the subject Services an amount equal to the difference between (1) aggregate fees paid for the subject Services and (2) the value of the work properly performed; and (b) in the case where such default renders the Services invalid, to obtain a refund of aggregate fees paid for the subject Services.  **Product Loss.**  Collaborator agrees and acknowledges that the commercial value and/or cost of replacement or remanufacture of any Agent provided to Fisher for any purpose is a matter that, as between Collaborator and Fisher, is within the sole and exclusive knowledge of Collaborator. Accordingly, Collaborator agrees and acknowledges that it is solely responsible to insure such items against damage or loss. Collaborator further agrees and acknowledges that under no circumstances shall Fisher be liable for loss or damage to any such items, even if due to Fisher’s negligent actions or inactions.  **LIMITATION OF LIABILITY.**  EXCEPT AS SET FORTH IN SECTION “PRODUCT LOSS”, NOTWITHSTANDING ANYTHING TO THE CONTRARY, AND IRRESPECTIVE OF ANY INSURANCE COVERAGE THAT MAY BE AVAILABLE UNDER THIS WORK ORDER OR OTHERWISE, UNDER NO CIRCUMSTANCES SHALL FISHER BE LIABLE TO COLLABORATOR, IN CONNECTION WITH ANY PROJECT, IN AN AMOUNT THAT, IN THE AGGREGATE, EXCEEDS THE TOTAL OF ALL FEES PAID TO FISHER BY COLLABORATOR FOR THE PROJECT. FURTHER, UNDER NO CIRCUMSTANCES SHALL COLLABORATOR BE ENTITLED TO RECOVER FROM FISHER OR ITS AFFILIATES ANY INCIDENTAL, INDIRECT, PUNITIVE, EXEMPLARY, CONSEQUENTIAL (INCLUDING LOST SALES, PROFITS OR OPPORTUNITY COSTS) OR SPECIAL DAMAGES, REGARDLESS OF LEGAL THEORY, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.  **Insurance**  Fisher does not assume any property rights, risk of loss, or interest in the Agents provided by the Collaborators. Collaborators are responsible to insure the Agent(s) for the full replacement value at all times.  **Invoicing and Payment**  Fisher will submit invoices to the Collaborator in accordance with the pricing schedule agreed to in the CSA. Payments may be made either by check or electronic funds transfer, at the option of Collaborator to Fisher. Collaborator will be required to make payment within 30 days of the date of the invoice. Collaborator shall make payment, in advance of the work being performed. If payment is not received by Fisher, Fisher shall not be obligated to perform work for the Collaborator until the payment is received.  **Assignment**  Neither Party shall assign this Work Order to any other person or entity without the prior written consent of the other, and any purported assignment without such consent shall be void. This Work Order shall be binding upon and shall inure to the benefit of the Parties hereto and their respective permitted assigns.  **Term**  The term of this Work Order shall commence on the last date signed below and shall be coterminous with the CSA that this Work Order is made a part hereof. | | | | | |
|  |  | | | | | |

Submitted: Accepted:

BY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ BY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

TITLE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ TITLE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_

DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| [Name]  [Your Collaborator Name]  [Street Address]  [City, ST ZIP Code]  [Phone}  [Fax}  [E-mail Address] | Fisher BioServices, Inc.  627 Lofstrand Lane  Rockville, MD 20850  301-762-1772  Contact:  E-mail |

Invoice for the Referenced Period of Service should be sent to:

[Name]

[Your Collaborator Name]

[Street Address]

[City, ST ZIP Code]

[Phone}

[Fax}

[E-mail Address]