FDP Fixed Price Clinical Trial Subaward Agreement

Pass-through Entity (PTE):		Subrecipient:	
PTE Principal Investigator (PI):		Subrecipient Principal Investigator (PI):	
PTE Federal Award No:	FAIN:		Federal Awarding Agency:
Federal Award Issue Date:	Total Amount of Federal Award to PTE $	CFDA No:	CFDA Title:
Study Title:			"Study"

Subaward Period of Performance: Start: End:	**Amount Funded This Action:**	**Subaward No.**
Estimated Project Period (if incrementally funded): Start: End:	Incrementally Estimated Total:	Is this Award R & D ☐ Yes or ☐ No
Check all that apply ☐ Reporting Requirements (Attachment 4)	☐ Subject to FFATA (Attachment 3B)	☐ Cost Sharing (Attachment 5)

Terms and Conditions

1) PTE hereby awards a fixed price subaward, as described above, to Subrecipient. The statement of work for this subaward is (check one) ☐ as specified in Subrecipient's proposal dated , or ☐ as shown in Attachment 5. In its performance of subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.

2) PTE shall provide funding in accordance with the Payment Schedule shown in Attachment 5. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include deliverables completed and milestone payment amount, subaward number, and certification, as required in 2 CFR 200.415 (a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments should be directed to the appropriate party's Financial Contact, as shown in Attachments 3A and 3B.

3) A final invoice, marked "FINAL" must be submitted to PTE's Financial Contact, as shown in Attachment 3A, NOT LATER THAN 60 days after subaward end date. PTE shall make the final payment to Subrecipient upon completion of all required deliverables and reports as indicated in Attachments 4 and 5.

4) PTE reserves the right to reject an invoice.

5) Matters concerning the technical performance of this subaward should be directed to the appropriate party's Principal Investigator, as shown in Attachments 3A and 3B. Technical reports are required as shown in Attachment 4.

6) Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this subaward agreement, and any changes requiring prior approval, should be directed to the appropriate party's Financial Contact, as shown in Attachments 3A and 3B. Any such changes made to this subaward agreement require the written approval of each party's Authorized Official, as shown in Attachments 3A and 3B.

7) Substantive changes made to this Subaward Agreement require the written approval of each party's Authorized Official as shown in Attachments 3A and 3B. The PTE may issue non-substantive changes to the Period of Performance and budget (check one): ☐ Bilaterally, or ☐ Unilaterally. Unilateral modifications shall be considered valid 14 days after receipt unless otherwise indicated by Subrecipient.

8) Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.

9) Either party may terminate this Subaward Agreement in accordance with Attachment 2B, Termination and Suspension terms and provide notice to the appropriate Financial Contact, as shown in Attachment 3A.

10) No-cost extensions require the approval of the PTE. Any requests for a no-cost extension should be addressed to and received by the Authorized Official Contact, as shown in Attachments 3A and 3B, not less than 30 days prior to the desired effective date of the requested change.

11) This Subaward Agreement is subject to the terms and conditions of the PTE Award and other special terms and conditions, as identified in Attachment 2A and 2B.

12) By signing this Fixed Price Clinical Trial Subaward Agreement Subrecipient makes the certifications and assurances shown in Attachments 1, 2A, and 2B.

13) Research Terms & Conditions – RESERVED

By an Authorized Official of Pass-through Entity:	By an Authorized Official of Subrecipient:
Name: Date	Name: Date
Title:	Title:

Attachment 1

Fixed Price Clinical Trial Subaward Agreement

Certifications and Assurances

By signing this Fixed Price Clinical Trial Subaward ("Subaward Agreement"), the Authorized Official of Subrecipient certifies, to the best of his/her knowledge and belief, that:

Certification Regarding Lobbying

1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the Subrecipient, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or intending to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the Subrecipient shall complete and submit Standard Form -LLL, "Disclosure Form to Report Lobbying," to the Pass-through Entity.

3) The Subrecipient shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly. This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U. S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Debarment, Suspension, and Other Responsibility Matters

Subrecipient certifies by signing this Subaward Agreement that neither it nor any individual participating in this Subaward is presently debarred, suspended, declared ineligible or voluntarily excluded from participation in this research Study by any federal department or agency.

Audit and Access to Records

Subrecipient certifies by signing this Subaward Agreement that it complies with the Uniform Guidance, will provide notice of the completion of required audits and any adverse findings which impact this Subaward Agreement as required by parts 200.501-200.521, and will provide access to records as required by parts 200.336, 200.337, and 200.201 as applicable.

Attachment 2A

Fixed Price Clinical Trial Subaward Agreement

Prime Award Terms and Conditions

NIH

Agency-Specific Certifications/Assurances

1. By signing this Subaward Agreement, Subrecipient makes the certifications and assurances specified in the Research Terms and Conditions Subchapter D found at: (RESERVED)

General terms and conditions (as of the effective date of this Subaward Agreement):

1. Conditions on activities and restrictions on expenditure of federal funds in appropriations acts are applicable to this Subaward Agreement to the extent those restrictions are pertinent. This includes any recent legislation noted on the NIH Award Conditions website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-065.html
2. 45 CFR Part 75.
3. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the period of performance.
4. Interim Research Terms and Conditions found at: http://grants.nih.gov/grants/policy/NIH%20Interim%20Grant%20General%20Conditions.pdf and Agency Specific Requirements found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-065.html , except for the following:
   a. The right to initiate an automatic one-time extension of the end date provided by Article 25(c)(2) of the Research Terms and Conditions is replaced by the need to obtain prior written approval from the Pass-through Entity;
   b. The payment mechanism described in Article 22 and the financial reporting requirements in Article 52 of the Research Terms and Conditions and Article 8 of the Agency-Specific Requirements are replaced with Terms and Conditions (1) through (4) of this Subaward Agreement; and
   c. Any prior approvals are to be sought from the Pass-through Entity and not the Federal Awarding Agency.
5. Title to equipment costing $5,000 or more that is purchased or fabricated with research funds or Subrecipient cost sharing funds, as direct costs of the Study or program, shall unconditionally vest in the Subrecipient upon acquisition without further obligation to the Federal Awarding Agency subject to the conditions specified in 2 CFR Part 200.
6. Treatment of Program Income: ☐ Additive ☐ Other, [Pass-through Entity specify alternative from NIH Agreement]

NIH-Specific Requirements Promoting Objectivity in Research Applicable to Subrecipients (42 CFR Part 50 Subpart F)

a) 42 CFR Part 50.604 requires that institutions conducting PHS-funded research "*Maintain an up-to-date, written, enforced policy on financial conflicts of interest.*" Further, *"If the Institution carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Institutions (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this subpart by incorporating as part of a written agreement with the subrecipient terms that establish whether financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators."*

Subrecipient must designate herein whether the financial conflicts of interest policy of (check one):
☐ **PTE Institution or** ☐ **Subrecipient Institution will apply.**

If applying its own financial conflicts of interest policy, by execution of this Subaward Agreement, Subrecipient certifies that its policy complies with 42 CFR Part 50 Subpart F.

b) **Subrecipient shall report any financial conflict of interest to PTE's Administrative Representative, as designated on Attachment 3A.** Any financial conflicts of interest identified shall subsequently be reported to NIH. **Such report shall be made before expenditure of funds authorized in this Subaward Agreement and within 45 days of any subsequently identified financial conflicts of interest.**

Copy of Award Notice (See Attachment 6)

Special terms and conditions:

[WHILE SPECIAL TERMS AND CONDITIONS MAY NOT BE REQUIRED BY THE FUNDING AGENCY, Institutions may include the following 4 clauses. These clauses are optional and may be deleted if not applicable.]

1. ***Copyrights***

Subject to copyrights held by the publishing journal , Subrecipient ☐ grants / ☐ shall grant (check one) to Pass-through Entity an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted material (including any computer software and its documentation and/or databases) first developed and delivered under this Subaward Agreement solely for the purpose of and only to the extent required to meet Pass-through Entity's obligations to the Federal Government under its Prime Award.

2. ***Data Rights***

Subrecipient grants to Pass-through Entity the right to use Data created in the performance of this Subaward Agreement solely for the purpose of and only to the extent required to meet Pass-through Entity's obligations to the Federal Government under its Prime Award.

3. ***Automatic Carry Forward: As this is a fixed price subaward agreement, carry forward of unexpended funds is automatic.***

4. ***In accordance with 48 CFR 3.908 Pilot Program for Enhancement of Contractor Employee Protections. Subrecipient is hereby notified that they are required to:***

   a. ***Inform their employees working on any Federal award that they are subject to the whistleblower rights and remedies of the pilot program;***
   b. ***Inform their employees in writing of employee whistleblower protections under 41 U.S.C §4712 in the predominant native language of the workforce; and;***
   c. ***Contractors and grantees will include such requirements in any agreement made with a subcontractor or subgrantee***

[Should additional special terms and conditions be mandated by local policies and procedures, they may be added at this point. Additional terms and conditions should be strictly limited to those absolutely required. Please do not include indemnification, law and venue clauses, as public institutions can never accept these conditions.]

(To be considered/modified on a case by case basis if applicable)
The Invoicing and Payment Terms as referenced on the face page of this Subaward Agreement are revised as follows:

Study drug will be provided to Subrecipient ☐ at no cost to them/ ☐ at cost [PTE to choose]. Subrecipient assures by signing this Subaward Agreement, (i) that the drug provided will be used only for the Study identified on the Subaward Agreement Study Title field above; (ii) that the drug provided will be used only in accordance with the IRB approved protocol ("Protocol"); and (iii) that the drug is only dispensed to Study subjects who have signed the approved informed consent form. Subrecipient will further ensure that the drug is properly handled, secured and stored, and that the drug is not transferred, misbranded, sold, administered, handled or used by any unauthorized third party. Except as specified by the Protocol, Subrecipient will not modify the drug in any way including changing the container or closure.

The drug provider ☐ will/ ☐ will not reimburse for Study related Subject injury (if affirmative above, see attached letter from drug provider).

Attachment 2B

Fixed Price Clinical Trial Subaward Agreement

Special Terms and Conditions

Data Use /Ownership

"Data" shall mean all data and information generated by Subrecipient as a result of conducting the Study in accordance with the Protocol. Data does not include original Study subject or patient medical records, research notebooks, source documents, or other routine internal documents kept in the Subrecipients's ordinary course of business operations, which shall remain the sole and exclusive property of the Subrecipient or medical provider. Subrecipient shall own and have the right to use the Data in accordance with the signed informed consent and authorization form, applicable laws, and the terms of this Subaward Agreement. Notwithstanding any licenses or other rights granted to Subrecipient herein, but in accordance with the Confidentiality and Publication sections herein, Subrecipient shall retain the right to use the Data and results for its publication, IRB, regulatory, legal, clinical, educational, and internal research purposes.

Use of Name

Neither party may use the name, trademark, logo, symbol, or other image or trade name of the other party or its employees, students and agents in any advertisement, promotion, or other form of publicity or news release or that in any way implies endorsement without the prior written approval of an authorized representative of the party whose name is being used. Such approval will not be unreasonably withheld.

Subrecipient will acknowledge the PTE's support, including but not limited to financial support as may be required by academic journals, professional societies, funding agencies, and applicable regulations. Notwithstanding anything herein to the contrary, Subrecipient shall have the right to post PTE's name, the Study Title, and the Period of Performance, and funding amount, on Subrecipient publicly accessible lists of research conducted by the Subrecipient.

Monitoring and Clinical Trial Auditing

Any site visits by PTE and/or its authorized designee (e.g., Study monitor) will be scheduled in advance for times mutually acceptable to the parties during normal business hours. PTE's and/or authorized designee's access is subject to reasonable safeguards to ensure confidentiality of medical records and systems.

Upon becoming aware of an audit or investigation by a regulatory agency with jurisdiction over the Study, Subrecipient agrees to provide PTE with prompt notice of the audit or investigation. If legally permissible or allowable by the regulatory agency and permissible in accordance with the Subrecipient's policy, PTE may be available or request to be present with approval from auditor during such audit, but PTE agrees not to alter or interfere with any documentation or practice of Subrecipient. Subrecipient shall be free to respond to any regulatory agency inquiries and will provide PTE with a copy of any formal response or documentation to the regulatory agency regarding the Study.

Confidentiality

It is anticipated that in the performance of this Agreement, the parties may need to disclose information which is considered confidential. The rights and obligations of the parties with respect to such information are as follows:

"Confidential Information" refers to information of any kind which is disclosed by one party, "the Discloser", to the other party, "the Recipient", for purposes of conducting the Study which:

a) by appropriate marking, is identified as confidential and proprietary at the time of disclosure;
b) if disclosed orally, is identified in a marked writing within thirty (30) days as being confidential; or
c) parties will make reasonable efforts to mark Confidential Information as stated in (a) and (b) above. However, to the extent such marking is not practicable, then in the absence of written markings, information disclosed (written or verbal) that a reasonable person familiar with the Study would consider to be confidential or proprietary from the context or circumstances of disclosure shall be deemed as such. Notwithstanding the foregoing, Data and results generated in the course of conducting the Study are not Confidential Information for publishing purposes.

Subject to Publication Section, parties agree, for a period of three (3) years following the termination or expiration of this Subaward Agreement, to use reasonable efforts, no less than the protection given their own confidential information, to use Confidential Information received in accordance with this Section.

Parties agree to use Confidential Information solely as allowed by this Subaward Agreement, and for the purposes of conducting the Study. Parties agree to make Confidential Information available only to those of its, or its affiliated hospitals' employees, personnel, agents, consultants, and vendors, and approved subcontractors, as applicable, who require access to it in the performance of this Study, and are subject to similar terms of confidentiality.

The obligation of nondisclosure does not apply with respect to any of the Confidential Information that:

a) is or becomes public knowledge through no breach of this Subaward Agreement;

b) is disclosed by a third party entitled to disclose such information without known obligation of confidentiality;

c) is already known or is independently developed without use of the Discloser's Confidential Information as shown by the Recipient's contemporaneous written records;

d) is necessary to obtain IRB approval of Study or required to be included in the written information summary provided to Study subject(s) and/or informed consent form;

e) is released with the prior written consent of the Discloser; or

f) is required to support the medical care of a Study subject.

The Recipient may disclose the Discloser's Confidential Information to the extent that it is required to be produced pursuant to a requirement of applicable law, IRB, government agency, an order of a court of competent jurisdiction, or a facially valid administrative, Congressional, or other subpoena, provided that Recipient, subject to the requirement, order, or subpoena, promptly notifies the Discloser. To the extent allowed under applicable law, the Discloser may seek to limit the scope of such disclosure and/or seek to obtain a protective order. Recipient will disclose only the minimum amount of Confidential Information necessary to comply with law or court order as advised by its legal counsel.

No license or other right to a party's Confidential Information is created or granted hereby, except the specific right to conduct the Study as set forth by Protocol and under terms of this Subaward Agreement, nor shall any license or other right with respect to the subject matter hereof be created or granted except by the prior written agreement of the Parties duly signed by their authorized representatives.

Upon Discloser's written request, Recipient agrees to return all Confidential Information supplied to it by the Discloser pursuant to this Subaward Agreement except that Recipient may retain a duplicate original in a secure location for purposes of identifying and satisfying its obligations and exercising its rights under this Subaward Agreement.

Parties may disclose the existence of this Subaward Agreement and any additional information necessary to ensure compliance with applicable Federal, State and Institutional policies, regulations, and laws.

HIPAA/PHI

There ☐ will ☐ will not be personal health information (PHI) or personally identifiable information (PII) involved in this Study.

PTE shall be provided with patient information as allowed by law and will maintain the confidentiality of all such patient information, unless specifically required to disclose such information by law.

Record Retention

Subrecipient shall retain and preserve a copy of the Study-related financial and programmatic records, supporting documents, statistical records and all other records pursuant to record retention requirements as provided in 2 CFR 200.333 and 45 CFR 46.

Inventions, Discoveries and Patents

The determination of rights in ownership and disposition of inventions resulting from the performance of the Statement of Work ("Subject Inventions") and the administration of patents will be in accordance with 37 CFR 401 and the terms of this Subaward Agreement. Subrecipient shall disclose promptly to PTE any patentable Subject Inventions pursuant to the reporting requirements provided in Attachment 4.

Publication

Prior to enrollment of the first subject in the Study, PTE agrees to ensure that the Study is fully registered on www.clinicaltrials.gov in accordance with the requirements of the International Committee of Medical Journal Editors (ICMJE) and Public Law 110-85 (42USC282). Results of this Study will be reported in compliance with applicable laws. Each party shall have the right to publish and disseminate information derived from the performance of the Statement of Work under this Subaward Agreement. Qualification for authorship shall be in keeping with generally accepted criteria. Subrecipient shall provide PTE with a copy of any proposed publication for review and comment at least thirty (30) days prior to submission. Activities, reports and publications resulting from this grant must adhere to the Acknowledgement standards set by the NIH. (http://grants.nih.gov/grants/acknow.htm#requirements)

☐ This Study is part of a multi-center clinical trial. The Subrecipient agrees that the first Publication of the results of the Study shall be made in conjunction with the presentation of a joint multi-center Publication of the Study results with the Principal Investigators from all sites contributing Data, analyses, and comments. However, Subrecipient may publish the Data and Study results individually in accordance with this Publication section upon first occurrence of one of the following: (i) multi-center Publication is published; (ii) no multi-center publication is submitted within twelve (12) months after conclusion, abandonment, or termination of the Study at all sites; or (iii) PTE confirms in writing there will be no multi-center Publication.

If no multi-center Publication occurs within twelve (12) months of the completion of the Study at all sites, upon request by Subrecipient, PTE agrees to provide Subrecipient access to the aggregate Data from all Study sites.

Electronic Signatures and Records

The parties of this agreement accept facsimile, electronic, and/or PDF signatures in lieu of original signatures which comply with 2 CFR 200.335.

Human Subjects

Both parties shall comply with all applicable federal laws, regulations and policy statements, including but not limited to 21 CFR Parts 50 and 56, 45 CFR Part 46, and HIPAA. Subrecipient further agrees to conduct all federally-funded human subjects research under their DHHS Federal Wide Assurance number as provided in Attachment 3B and in accordance with all provisions contained therein.

Insurance

PTE and Subrecipient agree that sufficient general and professional liability insurance/malpractice insurance or self-insurance exists and shall be maintained to cover liability from the performance of their respective responsibilities hereunder. Parties agree that upon request evidence of adequate insurance will be provided.

Warranty

Neither party makes any warranty, express or implied, including, without limitation, any implied warranty of merchantability or any implied warranty of fitness for a particular purpose with respect to any research activity or article supplied by it or its Principal Investigator in connection with this Protocol, nor with respect to any patent, trademark, know-how, tangible research property, information or data provided to the other party hereunder, and each party hereby disclaims the same.

Safety Reporting

If monitoring is required for the Study, the PTE will send Subrecipient Principal Investigator any monitoring findings and data safety monitoring committee reports that (i) affect the safety and welfare of current or former Study subjects, or (ii) influence the conduct of the Study. Subrecipient and/or Subrecipient Principal Investigator will communicate such findings to the IRB and Study subjects, as appropriate.

Termination and Suspension

Either party may terminate this Subaward Agreement with thirty (30) busines days written notice. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance 2 CFR 200, or 45 CFR 75, Appendix IX, "Principles for Determining Cost Applicable to Research & Development under Grants and Contracts with Hospitals", as applicable. This Study may be suspended or terminated in whole or in part immediately if the Subrecipient fails to comply with the terms and conditions of the Federal award; or at any time for any reason by the Subrecipient or PTE when, in their judgment or that of the Principal Investigator, Subrecipient Principal Investigator, the PTE's IRB, the Subrecipient's IRB, Scientific Review Committee, if applicable, or the Federal Awarding Agency , it is determined to be inappropriate, impractical, or inadvisable to continue, in order to protect the Study subjects' rights, welfare and safety, or the IRB otherwise disapproves the Study in accordance with the terms of this Agreement

This study may be terminated or suspended immediately in whole or in part in the event that the Federal Awarding Agency reduces or terminates funding for the prime award.

Notwithstanding the above, any party may, in addition to any other available remedies:

a) immediately terminate this Subaward Agreement upon the other party's material failure to adhere to the Protocol, except for deviation required to protect the rights , safety, and welfare of Study subjects; and/or

b) terminate this Subaward Agreement upon the other party's material default or breach of this Subaward Agreement, provided that the defaulting/breaching party fails to remedy such material default, or breach of this Subaward Agreement within thirty (30) business days after written notice thereof;

In the event that this Subaward Agreement is terminated or suspended prior to completion of the Study, for any reason, Subrecipient shall:

a) notify the IRB that the Study has been terminated or suspended;

b) cease enrolling subjects in the Study;

c) cease treating Study subjects under the Protocol as directed by PTE to the extent medically permissible and appropriate;

d) terminate, as soon as practicable, all other Study activities; and cooperate with PTE to provide for an orderly wind-down of the Study;

e) cease spending on the Subaward Agreement pending resolution of the suspension;

f) provide adequate documentation to allow both parties to facilitate an orderly close out of the projects; and

g) provide the information necessary for the PTE to meet its obligations to the Federal Awarding Agency.

If for any reason the Subrecipient Principal Investigator as indicated in Attachment 3B (or personnel considered essential for the work) is unavailable to direct the performance of the work under this Subaward Agreement, Subrecipient shall notify PTE. If the parties are unable to identify a mutually acceptable successor, this Subaward Agreement may be terminated by either party upon thirty (30) days written notice.

Subject Material

"Original Subject Material" means any biologic material of human origin including, without limitation, tissues, blood, plasma, urine, spinal fluid, or other fluids derived from the Study subjects in accordance with and pursuant to Subrecipient's performance of the Protocol.

☐ This clinical trial does not include the transfer of Subject Material.

☐ This clinical trial includes the transfer of Subject Material. All transfers of Subject Material hereunder shall be documented by execution by both parties or respective Principal Investigators of a Transfer Record consistent with the one attached to this Subaward Agreement as Attachment 7.

For the purposes of this Subaward Agreement, "Subject Material" shall include the Original Subject Material plus Unmodified Derivatives, and Progeny where Unmodified Derivatives means substances created by PTE which constitute an important unmodified functional sub-unit or expression product of the Original Subject Material and Progeny means unmodified descendant from the Original Subject Material.

Subrecipient agrees to make the Subject Material available to the PTE in accordance with the Protocol for the purposes of the Study. The Subject Material provided by Subrecipient shall remain the property of Subrecipient and may be used by the PTE, central laboratory, or their contracted party for the performance of the Study only as allowed by the Study subject's informed consent form or pertinent institutional review board(s). PTE agrees that any use of Subject Materials, other than as allowed by the Study subject's informed consent form, will require additional IRB review and approval. Any substances created by PTE which contain/incorporate any form of the Subject Material (a "Modification") shall be owned by PTE; provided, however, that the Subrecipient shall retain ownership of any form of the Subject Material contained therein.

PTE agrees to use the Subject Material in a safe manner and in compliance with all applicable laws and regulations, including, but not limited to current EPA, FDA, USDA and NIH guidelines. The Subject Material is supplied solely for research purposes, for use in animals and/or in vitro. Except as provided herein, nothing in this Subaward Agreement shall be construed as granting any rights to PTE, by license or otherwise, to any Subject Material. At the completion of the Study or termination of this Subaward Agreement, PTE will discontinue its use of the Subject Material and will, upon direction of the Subrecipient, return or destroy the Subject Material. PTE will also either destroy Modifications or remain bound by the terms of this Agreement as they apply to Modifications.

For the avoidance of doubt, PTE (or their subcontractors) shall not be entitled to use the Subject Material and/or Modifications thereof for commercial purposes without the prior written consent of the Subrecipient. For this Subaward Agreement, commercial purposes shall include the sale, lease, license, or other transfer of the Subject Material or Modifications to a for-profit organization or the use of the Subject Material or Modifications by any organization, including PTE, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, or license of the Subject Material or Modifications to a for-profit organization. PTE certifies that research with the Subject Material and/or Modifications will not be subject to the terms of any agreement or contract in which a third party, other than the federal government, gains rights to the Material and/or Modifications.

If the Study subject's informed consent form and/or pertinent institutional review board(s) does not allow for the disclosure of identifying information with the Subject Material, the Subject Material will be provided to the PTE de-identified and all Protected Health Information ("PHI"), as defined by the Federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191), as amended ("HIPAA", 45 C.F.R. 160 and 164), will have been removed and PTE will not be provided with any information that could be used to identify the subjects from whom the Subject Material was collected, although Subrecipient may retain a confidential link to the subjects' identities. Neither the PTE nor PTE's Investigator shall make any attempts to determine the identity of those subjects, or to contact the subjects.

Any Subject Material delivered pursuant to this Subaward Agreement is understood to be experimental in nature and may be hazardous. SUBRECIPIENT MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE SUBJECT MATERIAL AND/OR MODIFICATIONS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER RIGHTS, OR THAT THE SUBJECT MATERIAL AND/OR MODIFICATIONS WILL NOT POSE A SAFETY OR HEALTH RISK.

Subcontract/Assignment

Subrecipient may subcontract to other sites to conduct the Study in accordance with the Protocol with terms consistent with this Subaward Agreement with written approval of the PTE, which approval shall not be unreasonably withheld. Such subcontracts will be provided to the PTE upon written request.

Force Majeure

If either party hereto shall be delayed or hindered in, or prevented from, the performance of any act required hereunder for any reason beyond such party's direct control, including but not limited to, strike, lockouts, labor troubles, riots, insurrections, war, acts of God, inclement weather, or other reason beyond the party's control (a "Disability") then such party's performance shall be excused for the period of the Disability. Any Study timelines affected by a Disability shall be extended for a period equal to the delay and any affected Budget shall be adjusted to account for cost increases or decreases resulting from the Disability. The party affected by the Disability shall notify the other party of such Disability as provided for herein.

Counterparts

This Subaward Agreement may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document, and is binding on all Parties notwithstanding that each of the Parties may have signed different counterparts.

Entire Agreement

Section and clause headings are used herein solely for convenience of reference and are not intended as substantive parts of this Subaward Agreement. This Subaward Agreement incorporates the Attachments referenced herein. This written Subaward Agreement constitutes the entire agreement between the parties concerning the subject matter, and supersedes all other or prior agreements or understandings, whether written or oral, with respect to that subject matter. Any changes made to the terms, conditions or amounts cited in this Subaward Agreement require the written approval of each party's authorized representative. In the event of a conflict between the terms of this Subaward Agreement and the Protocol, the Protocol shall govern all medical and scientific matters, and this Subaward Agreement will govern all other matters.

Attachment 3A

Fixed Price Clinical Trial Subaward Agreement

Subaward Number:

Pass-through Entity Contacts

Pass-through Entity

Name:

Address:

City: State: Zip Code:

Pass-through Entity's Administrative Contact

Name:

Address:

City: State: Zip Code:

Telephone: Fax:

E-mail:

Pass-through Entity's Principal Investigator

Name:

Address:

City: State: Zip Code:

Telephone: Fax:

E-mail:

Pass-through Entity's Financial Contact

Name:

Address:

City: State: Zip Code:

Telephone: Fax:

E-mail:

Pass-through Entity's Authorized Official

Name:

Address:

City: State: Zip Code:

Telephone: Fax:

E-mail:

Attachment 3B

Subaward Number:

Fixed Price Clinical Trial Subaward Agreement

Subrecipient Contacts

DU? !

Subrecipient Place of Performance

Name:

Address:

City: State: **Zip Code + 4:**

EIN No.: Institution Type:

Is Subrecipient currently registered in SAM? ☐ Yes ☐ No

Is Subrecipient exempt from reporting compensation? ☐ Yes ☐ No

If no , please complete 3B page 2

DUNS No.: Parent DUNS No.: FWA No.: Congressional District: Congressional District:

d

Subrecipient Administrative Contact

Name:

Address:

City: State: Zip Code:

Telephone: Fax:

E-mail:

Subrecipient Principal Investigator (PI)

Name:

Address:

City: State: **Zip Code + 4:**

Telephone: Fax:

E-mail:

Subrecipient Financial Contact

Name:

Address:

City: State: Zip Code:

Telephone: Fax:

E-mail:

Subrecipient Authorized Official

Name:

Address:

City: State: Zip Code:

Telephone: Fax:

E-mail:

Subrecipient

Name:

PI:

Highest Compensated Officers

The names and total compensation of the five most highly compensated officers of the entity(ies) must be listed if the entity in the preceding fiscal year received 80 percent or more of its annual gross revenues in Federal awards; and $25,000,000 or more in annual gross revenues from Federal awards; and the public does not have access to this information about the compensation of the senior executives of the entity through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. See FFATA § 2(b)(1) Internal Revenue Code of 1986.

Officer 1 Name

Officer 1 Compensation

Officer 2 Name

Officer 2 Compensation

Officer 3 Name

Officer 3 Compensation

Officer 4 Name

Officer 4 Compensation

Officer 5 Name

Officer 5 Compensation

Attachment 4

Fixed Price Clinical Trial Subaward Agreement

Reporting Requirements

Pass-through Entity will check all that apply that the Subrecipient will agree to:

☐ A Final technical/progress report will be submitted to the Pass-through Entity's Principal Investigator identified in Attachment 3 within 90 days after the end of the period of performance.

☐ Monthly technical/progress reports will be submitted to the Pass-through Entity's Financial Contact identified in Attachment 3, within 90 days of the end of the month.

☐ Quarterly technical/progress reports will be submitted within thirty (30) days after the end of each project quarter to the Pass-through Entity's Administrative Contact identified in Attachment 3.

☐ Technical/progress reports on the project as may be required by Pass-through Entity's Administrative Contact in order that Pass-through Entity may be able to satisfy its reporting obligations to the Federal Awarding Agency.

☐ Annual technical /progress reports will be submitted within 90 days prior to the end of each project period to the Pass-through Entity's Administrative Contact identified in Attachment 3. Such report shall also include an updated Other Support for key personnel, certification of appropriate education in the conduct of human subject research of any new key personnel, and annual IRB or IACUC approval, if applicable.

☐ In accordance with 37 CFR 401.14, Subrecipient agrees to notify PTE's Financial Contact identified in Attachment 3A within 90 days after Subrecipient's inventor discloses invention(s) in writing to Subrecipient's personnel responsible for patent matters. The Subrecipient will submit a final invention report using Awarding Agency specific forms to the PTE's Principal Investigator identified in Attachment 3A within 60 days of the end of the period of performance so that it may be included with the PTE's final invention report to the Awarding Agency. A negative report ☐ is ☐ is not required.

☐ A Certification of Completion, in accordance with 2 CFR 200.201(b)(3), will be submitted within 90 days after the end of the project period to the Pass Through Entity 's Administrative Contact identified in Attachment 3 (for Fixed Price subawards only.)

☐ Property Inventory Report; frequency, type, and submission instructions listed here and only to be used when required by PTE Federal Award

Other Special Reporting Requirements

Attachment 5

Fixed Price Clinical Trial Subaward Agreement

Statement of Work	Indirects	Payment Schedule

Statement of Work

Below ☐ or ☐ Attached pages

If award is FFATA eligible and SOW exceeds 4000 characters, include a *Subrecipient Federal Award Project Description*

Indirect Information

Indirect Cost Rate (IDC) Applied % on ☐ TDC, or ☐ MTDC, or ☐ OTHER

Payment Schedule

Attachment 6

Fixed Price Clinical Trial Subaward Agreement

Prime Award

Attachment 7

Fixed Price Clinical Trial Subaward Agreement Prime Award

Form of Transfer Record

This Record is to document shipment of Subject Material from Subrecipient to PTE, under the terms of a Fixed Price Clinical Trials Subaward Agreement entered by and between the parties effective . The Subject Material is provided as part of the Study defined in that Subaward Agreement, and all use of these Subject Material shall be subject to the provisions of that Subaward Agreement.

List and Description of Subject Material included in this shipment:

Human-derived materials, such as this Subject Material, may pose known, or unknown, health or safety risks and must be handled accordingly, and in compliance with all applicable laws and regulations, including, but not limited to current EPA, FDA, USDA and NIH guidelines.

Date Shipped: _____	_____	_____
Shipping Authorization (to be completed at time of shipment)	Signature	Printed Name

Date Received: _____	_____	_____
Receipt Acknowledgement (to be completed upon receipt)	Signature	Printed Name