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Version: 2/2021

FDP Subaward Agreement Approval Form

- Subrecipient Name: _____ Subrecipient PI: _____
Subrecipient Contact: _____
Phone: _____ E-Mail: _____
- FAIN: _____ Federal Award #: _____ Federal Award Issue Date: _____
CFDA #: _____ CFDA Title: _____
- Amount this action: \$ _____ Incrementally Estimated Total: \$ _____
UIC Banner Index Code: -- ~~XXXXXXXXXXXXXXXXXXXX~~ Fund Code ~~XXX~~
- Are there sufficient funds in the banner account and banner line item number (15600) to meet this obligation? Yes No If No, submit a completed IPAS/OPAS form to Grants & Contracts with a copy to OSP.**
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- Was this Subrecipient specifically named in the original Prime Award?
Yes, If "Yes", **attach a copy of the budget page wherein the Gi VfYWjdYbhand dollar amount is identified.**
No, If "No", **please provide OSP with written authorization from the Prime Gdcbgcf allowing UIC to obligate these funds to the Gi VfYWjdYbh If unable to obtain written authorization** submit this document to purchasing for their bid process as explained in the Office of Business and Financial Services (OBFS) Policies section 7.2 (<https://www.obfs.uillinois.edu/bfpp/section-7-purchasing/section-7-2>).
- Effective Dates of this FDP Subaward Agreement: _____ through _____
- Effective Dates of Sponsor Prime Award: _____ through _____
- UIC PI: _____ Ext: _____ E-mail: _____
- UIC Contact: _____ Ext: _____ E-mail: _____

FDP Fixed Rate Clinical Research Subaward

Federal Awarding Agency:

Pass-Through Entity (PTE):

Subrecipient:

PTE PI:

Sub PI:

PTE Federal Award No:

Subaward No:

Project/
Study Title:

Subaward Budget Period:

Start:

End:

Estimated Period of Performance:

Start:

End:

Terms and Conditions

1. PTE hereby awards a fixed rate Subaward, (as determined by 2 CFR 200.331 and Chapter 8 – Administrative Requirements 8.1.2.11), to Subrecipient. The Statement of Work/protocol and budget for this Subaward are 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 the deliverable 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 shall be directed to the appropriate party's Contact, shown in Attachment 3A.
- 3.
4. Upon the receipt of proper invoices, the PTE agrees to process payments in accordance with this Subaward and 2 CFR 200.305. PTE reserves the right to reject an invoice.
5. Matters concerning the technical performance of this Subaward shall 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, and any changes requiring prior approval, shall be directed to the PTE' Contact and the Subrecipient's
Contact, as shown in Attachments 3A and 3B. Any such change made to this Subaward requires the
written approval of each party's Authorized Official, as shown in Attachments 3A and 3B.
7. The PTE may issue non-substantive changes to the Budget Period(s) and Budget . Unilateral modification
shall be considered valid 14 days after receipt unless otherwise indicated by Subrecipient when sent to Subrecipient's
Contact, as shown in Attachment 3B.
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 with 30 days written notice. Notwithstanding, if the Awarding Agency terminates the Federal Award, PTE will terminate in accordance with the Awarding Agency requirements. PTE notice shall be directed to the PTE's Contact and the Subrecipient's notice directed to the
Contact, as
shown in Attachments 3A and 3B. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix IX, as applicable.
10. By signing this Subaward including Attachments hereto which are hereby incorporated by reference, Subrecipient certifies that it will perform the Statement of Work in accordance with the terms and conditions of this Subaward and the applicable terms of the Federal Award, including the appropriate Research Terms and Conditions ("RTCs") of the Federal Awarding Agency, as referenced in Attachment 2. The parties further agree that they intend this Subaward to comply with all applicable laws, regulations and requirements.

By an Authorized Official of Pass-through Entity:

By an Authorized Official of Subrecipient:

Name:

Date

Title:

Name:

Date

Title:

Attachment 1

Certifications and Assurances

Subaward Number:

Certification Regarding Lobbying (2 CFR 200.450)

By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief, that 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 in accordance with 2 CFR 200.450.

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 PTE.

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 31 U.S.C. 1352. 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 (2 CFR 200.214 and 2 CFR 180)

By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief that neither the Subrecipient nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this transaction by any federal department or agency, in accordance with 2 CFR 200.213 and 2 CFR 180.

Audit and Access to Records

Subrecipient certifies that it will provide PTE with notice of any adverse findings which impact this Subaward. Subrecipient certifies compliance with applicable provisions of 2 CFR 200.501-200.521. If Subrecipient is not required to have a Single Audit as defined by 200.501, Awarding Agency requirements, or the Single Audit Act, then Subrecipient will provide notice of the completion of any required audits and will provide access to such audits upon request. Subrecipient will provide access to records as required by parts 2 CFR 200.337 and 200.338 as applicable.

Program for Enhancement of Contractor Employee Protections (41 U.S.C 4712)

Subrecipient is hereby notified that they are required to: inform their employees working on any federal award that they are subject to the whistleblower rights and remedies of the program; inform their employees in writing of employee whistleblower protections under 41 U.S.C §4712 in the predominant native language of the workforce; and include such requirements in any agreement made with a subcontractor or subgrantee.

The Subrecipient shall require that the language of the certifications above in this Attachment 1 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.

Use of Name

Neither party shall use the other party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may use factual information regarding the existence and purpose of the relationship that is the subject of this Subaward for legitimate business purposes, to satisfy any reporting and funding obligations, or as required by applicable law or regulation without written permission from the other party. In any such statement, the relationship of the parties shall be accurately and appropriately described.

Prohibition on Certain Telecommunication and Video Surveillance Services or Equipment

Pursuant to 2 CFR 200.216, Subrecipient will not obligate or expend funds received under this Subaward to: (1) procure or obtain; (2) extend or renew a contract to procure or obtain; or (3) enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that uses covered telecommunications equipment or services (as described in Public Law 115-232, section 889) as a substantial or essential component of any system, or as a critical technology as part of any system.

Attachment 2A

Federal Award Terms and Conditions

Subaward Number

Required Data Elements

The data elements required by Uniform Guidance are incorporated

Awarding Agency Institute (If Applicable)

Federal Award Issue Date

FAIN

Assistance Listing No.

This Subaward Is:

Assistance Listing Program Title (ALPT)

Research & Development

Subject to FFATA

Key Personnel Per NOA

General Terms and Conditions

By signing this Subaward, Subrecipient agrees to the following:

1. To abide by the conditions on activities and restrictions on expenditure of federal funds in appropriations acts that are applicable to this Subaward to the extent those restrictions are pertinent. This includes any recent legislation noted on the Federal Awarding Agency's website:
2. 2 CFR 200 and 45 CFR Part 75.
3. The Federal Awarding Agency's grants policy guidance, including addenda in effect as of the beginning date of the period of performance or as amended found at:
4. Research Terms and Conditions, including any Federal Awarding Agency's Specific Requirements found at:
except for the following :
 - a. No-cost extensions require the written approval of the PTE. Any requests for a no-cost extension shall be directed to the Contact shown in Attachment 3A, not less than 30 days prior to the desired effective date of the requested change.
 - b. Any payment mechanisms and financial reporting requirements described in the applicable Federal Awarding Agency Terms and Conditions and Agency-Specific Requirements are replaced with Terms and Conditions (1) through (4) of this Subaward; and
 - c. Any prior approvals are to be sought from the PTE and not the Federal Awarding Agency.
 - d. Title to equipment as defined in 2 CFR 200.1 that is purchased or fabricated with research funds or Subrecipient cost sharing funds, as direct costs of the project or program, shall vest in the Subrecipient subject to the conditions specified in 2 CFR 200.313.
 - e. Prior approval must be sought for a change in Subrecipient PI or change in Key Personnel (defined as listed on the NOA).
5. Treatment of program income:

Special Terms and Conditions:

Data Sharing and Access:

Subrecipient agrees to comply with the Federal Awarding Agency's data sharing and/or access requirements as reflected in the NOA or the Federal Awarding Agency's standard terms and conditions as referenced in General Terms and Conditions 1-4 above.

Data Rights:

Subrecipient grants to PTE the right to use data created in the performance of this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Copyrights:

to PTE 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 solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Subrecipient grants to PTE the right to use any written progress reports and deliverables created under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its Federal Award.

Promoting Objectivity in Research (COI):

Subrecipient must designate herein which entity's Financial Conflicts of Interest policy (COI) will apply:

If applying its own COI policy, by execution of this Subaward, Subrecipient certifies that its policy complies with the requirements of the relevant Federal Awarding Agency as identified herein:

Subrecipient shall report any financial conflict of interest to PTE's Administrative Representative or COI contact, as designated on Attachment 3A. Any financial conflicts of interest identified shall, when applicable, subsequently be reported to Federal Awarding Agency. Such report shall be made before expenditure of funds authorized in this Subaward and within 45 days of any subsequently identified COI.

Certificate of Confidentiality:

The Parties agree that this research funded in whole or in part by the National Institutes of Health ("NIH"), is subject to NIH Policy NOT-OD-17-109 (the "Policy") and therefore is deemed under the Policy to be issued a Certificate of Confidentiality ("Certificate") should the conditions outlined within the Policy apply. Accordingly, the subrecipients who collect or receive identifiable, sensitive information are required to adhere to the Policy and protect the privacy of individuals who are subjects of such research in accordance with the Policy and subsection 301(d) of the Public Health Service Act (the "PHS Act").

Additional Terms

<p style="text-align: center;">Attachment 2B FDP Fixed Rate Clinical Research Subaward Special Terms and Conditions</p>
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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 (“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’ 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 Form (“ICF”) and authorization form, applicable laws, and the terms of this Subaward Agreement. PTE may use Data for any purposes provided it is in accordance with the ICF, the authorization form and applicable laws.

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.

There is a separate Data Coordinating Center (“DCC”) ____ Yes ____ No.

Study Drug (if applicable)

The Study drug will be provided to Subrecipient ☐ at no cost to them/☐ at cost [PTE to choose]. Subrecipient asserts by signing this Subaward Agreement (i) that the drug provided will be used only for the Study identified on the Subaward Agreement face page; (ii) that the drug provided will be used only in accordance with the IRB approved Protocol; and (iii) that the drug is only dispensed to Study subjects who have signed the approved ICF. 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).

The drug provider ☐will/ ☐will not indemnify Subrecipient for third-party claims for injuries caused by defective design and manufacture of the Study Drug (if affirmative above, see attached letter from drug provider).

Monitoring and 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 Subrecipient's 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.

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.

Confidentiality

It is anticipated that in the performance of this Subaward 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; or
- 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 the 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.

The parties agree to use Confidential Information solely as allowed by this Subaward Agreement and for the purposes of conducting the Study. The 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; or
- 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.

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 the Federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191), as amended ("HIPAA", 45 C.F.R. 160 and 164) . Subrecipient further agrees to conduct all federally-funded human subjects research under their DHHS Federal Wide Assurance number and in accordance with all provisions contained therein.

HIPAA/PHI

Subrecipient ☐will ☐will not transmit protected health information ("PHI"), as defined by HIPAA, or personally identifiable information ("PII") to PTE in the performance of this Study.

PTE shall be provided with PHI or PII pursuant to the Protocol as allowed by law and the ICF and will take reasonable measures to safeguard PII and PHI consistent with applicable federal, state, local, and tribal laws regarding privacy and obligations of confidentiality, 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.

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 (42 U.S.C. 282). 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.

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. The 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 Study, 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.

Termination and Suspension

Either party may terminate this Subaward Agreement with thirty (30) business days' written notice. Upon expiration of this Subaward or early termination by either party, PTE shall pay Subrecipient on a pro rata basis for all Protocol milestones completed in accordance with the Payment Schedule. Upon receipt of a notice of termination, Subrecipient will use reasonable efforts to reduce or eliminate further costs and expenses and will cooperate with PTE to provide for an orderly wind-down of the Study at Subrecipient institution.

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 PTE 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, a 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 applicable IRB otherwise disapproves the Study in accordance with the terms of this Subaward 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 PTE Federal Award.

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

1. 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 Study; 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 to the Study) 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 to PTE.

☐ This clinical trial includes the transfer of Subject Material to PTE. 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 ICF or pertinent IRB(s). PTE agrees that any use of Subject Materials, other than as allowed by the Study subject’s ICF, 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 Subaward Agreement as they apply to Modifications.

For the avoidance of doubt, PTE (or its 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 ICF and/or pertinent IRB(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 PHI, as defined by HIPAA, 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

With written approval of the PTE, Subrecipient may subcontract to other sites to conduct the Study in accordance with the Protocol with terms consistent with this Subaward Agreement. PTE's approval shall not be unreasonably withheld. Copies of 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.

Conflicts

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
Pass-Through Entity (PTE) Contacts

Subaward Number:

PTE Information

Entity Name:

Legal Address:

Website:

PTE Contacts

Central Email:

Principal Investigator Name:

Email:

Telephone Number:

Administrative Contact Name:

Email:

Telephone Number:

COI Contact email (if different to above):

Financial Contact Name:

Email:

Telephone Number:

Email invoices? Yes No Invoice email (if different):

Authorized Official Name:

Email:

Telephone Number:

PI Address:

Administrative Address:

Invoice Address:

Attachment 3B

Subrecipient Contacts

Subaward Number:

Subrecipient Information for [FFATA](#) reporting

Entity's DUNS Name:

EIN No.:

Institution Type:

DUNS:

Currently registered in SAM.gov: Yes No

Exempt from reporting executive compensation: Yes No *(if no, complete 3Bpg2)*

Parent DUNS:

This section for U.S. Entities:

Zip Code [Look-up](#)

Place of Performance Address

Congressional District:

Zip Code+4:

Subrecipient Contacts

Central Email:

Website:

Principal Investigator Name:

Email:

Telephone Number:

Administrative Contact Name:

Email:

Telephone Number:

Financial Contact Name:

Email:

Telephone Number:

Invoice/Payment Email:

Authorized Official Name:

Email:

Telephone Number:

Legal Address:

Administrative Address:

Payment Address:

Attachment 3B-2
Highest Compensated Officers

Subaward Number:

Subrecipient:

Institution Name:

PI Name:

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
Reporting and Prior Approval Terms

Subaward Number:

Subrecipient agrees to submit the following reports (PTE contacts are identified in Attachment 3A):

Technical Reports:

Monthly technical/progress reports will be submitted to the PTE's _____ within _____ days of the end of the month.

Quarterly technical/progress reports will be submitted within 30 days after the end of each project quarter to the PTE's _____.

Annual technical / progress reports will be submitted within _____ days prior to the end of each budget period to the PTE's _____. Such report shall also include a detailed budget for the next Budget Period, 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.

A Final technical/progress report will be submitted to the PTE's _____ within _____ days of the end of the Project Period or after termination of this award, whichever comes first.

Technical/progress reports on the project as may be required by PTE's _____ in order for the PTE to satisfy its reporting obligations to the Federal Awarding Agency.

Prior Approvals:

Carryover is not applicable for fixed rate Subawards

Other Reports:

In accordance with 37 CFR 401.14, Subrecipient agrees to notify both the Federal Awarding Agency via iEdison and PTE's _____ within 60 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 Federal Awarding Agency specific forms to the PTE's _____ within 60 days of the end of the Project Period to be included as part of the PTE's final invention report to the Federal Awarding Agency.

A negative report is required:

Property Inventory Report (only when required by Federal Awarding Agency), specific requirements below.

Other Special Reporting Requirements:

Subaward Number:

Attachment 5
Statement of Work & Payment Schedule

Statement of Work/Protocol

Under separate cover Below Attached, pages

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

Payment Schedule Information

Below Attached, pages

Attachment 6

Notice of Award (NOA) and any additional documents

The following pages include the NOA and if applicable any additional documentation referenced throughout this Subaward.

Not incorporating the NOA or any additional documentation to this Subaward.

<p style="text-align: center;">Attachment 7 Fixed-Rate Clinical Trial Subaward Agreement Prime Award Form of Transfer Record</p>

This Record is to document shipment of Subject Material from Subrecipient to PTE, under the terms of a Fixed-Rate 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