DELETE INSTRUCTIONS PRIOR TO EACH USE

**INSTRUCTIONS FOR USE**

**HCSRN V3.1 SUBAWARD AGREEMENT TEMPLATE**

**Pre-negotiated Templates**

HCSRN sites have pre-negotiated a Sub-Award Agreement tempate to fast track study start up. All sites have had input into their development and agree to use these as a starting place for negotiations. Only project specific modifications are needed.

**HCSRN SITES ACCEPTING THIS SUBAWARD AGREEMENT TEMPLATE**

* Essentia Institute of Rural Health
* Geisinger Clinic
* Group Health Cooperative
* Harvard Pilgrim Health Care, Inc.
* HealthPartners Institute for Education and Research
* Henry Ford Health System
* Kaiser Foundation Research Institute (for all regions)
* Marshfield Clinic Research Foundation
* Palo Alto Medical Foundation Research Institute
* Scott and White Memorial Hospital
* University of Massachusetts Medical School/Meyers Primary Care Institute

**When to Use the HCSRN Subaward Agreement Template**

The HCSRN template is designed to be used for:

* Grant awards, not contracts
* Projects led by an HCSRN site
* Projects involving 2 or more HCSRN sites (where not all sites are KP)

HCSRN sites have also successfully used the template with non-HCSRN partners.

If the Subaward template is used, the HCSRN’s DUA template may also be used.

**General Template Layout**

In response to user feedback, the new Subaward template is similar to the format of FDP template.

* A summary table at the top captures most of the key information up front and in one place.
* Two Exhibit D options – one for NIH grant awards and another for grants from other HHS agencies.

**Communicating About the Template**

Inform subawardees that you are sending the pre-negotiated template when you send it for execution. Remind them that their site already accepted the terms. Only minimal/project specific edits should be made to retain the efficiency of the approach.

Inform staff at your center involved with DUAs that the Subaward template was used so they know that the DUA template is an option, when the time comes.

**General Instructions**

* Always **use track changes** when making edits to the document, so sites can quickly see how the pre-negotiated template was altered.

**Page 1**

Prime and subrecipients

Fill in the prime and sub recipient fields found both above and below the summary table.

Summary table

Enter the following information in the fields provided:

* Institution/Organization (“Pass Through Entity” or “PTE”) name
* Prime award number
* Awarding agency (“Prime Sponsor”)
* Institution/Organization (“Subrecipient”) name
* Subaward number
* Amount funded this budget period (i.e., current period of performance)
* Estimated total (if incrementally funded over the entire estimated project period)
* CFDA number
* CFDA title (If not on the award, look up at www.cfda.gov)
* Subaward Period of Performance – Budget period (from and to)
* Estimated Project Period (if incrementally funded) (from and to)
* Study Title (“Study”)
* Check any applicable reporting requirements (e.g., FFATA or specify other)

**Page 2**

Section 3. Estimated cost and payment

* Add any project specific requirements in paragraph 4 or delete if none.

**Page 9**

Section 21. Insurance

* Use alternative 1 or alternative 2 text as desired and delete alternative not used.
* Delete optional paragraph if not using.
* Delete red title and instruction text.

**Exhibit B**

* Add the budget to Exhibit B.

**Exhibit C**

* Fill in the contact fields for your site in the table

**Exhibit D**

* Include option 1 if the grant is from NIH. Include option 2 if the grant is from another HHS agency.
* Delete the Exhibit D option not used.
* Delete red text at the top of the option used.
* Check the appropriate box under Section 1.A. Conflict of Interest
* Specify to whom carry forward requests should be sent in section 2.C. General NIH Requirements
* Section 5. Check the box indicating automatic carry forward (Y/N). If no, indicate to which contact on Exhibit C carry forward requests should be sent.

**Exhibit E**

* Attach a copy of the notice of grant award as Exhibit E.



**HCSRN** **SUBAWARD AGREEMENT**

**BETWEEN**

**HCSRN PASS THROUGH ENTITY:**

AND

**HCSRN SUBAWARDEE:**

|  |
| --- |
| **HCSRN SUBAWARD AGREEMENT** |
| **Institution/Organization (“Pass-Through Entity”)****PTE:** **PTE Federal Award No.:** **FAIN:****Awarding Agency (“Prime Sponsor”):**  | **Institution/Organization (“Subawardee”)****Name:****Subaward No.:** **Amount funded this budget period:****Est. Total (if incrementally funded):**  |
| **CFDA #:** | **CFDA Title**  |
| **Subaward Period of Performance – Budget period:****From:** **To:**  | **Estimated Project Period (if Incrementally funded):****From:       To:** |
| **Study Title (“Study”):**  |
| **Reporting requirements (check if applicable):** **[ ]  FFATA [ ]  Other:** [Specify] |

This Subaward Agreement (“Agreement”) is entered into by and between HCSRN Pass Through Entity       (hereinafter referred to as "Awardee”) and HCSRN Subawardee site      . Awardee and Subawardee are sometimes referred to herein as “Parties” or individually as a “Party” in this Agreement.

WHEREAS, a principal mission of each Party is to provide health care and advance scientific knowledge to improve health and health care services. The Parties acknowledge that their participation in this Study will be in furtherance of that mission.

WHEREAS, Awardee desires Subawardee’s participation in the research activities under this Study, as described below;

WHEREAS, Subawardee would like to participate in the research activities in support of the Study, as described below; and,

WHEREAS, Awardee and Subawardee desire to enter into a Subaward Agreement under the Award on the following terms.

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, Awardee and Subawardee agree as follows:

**1. SCOPE OF WORK**

Subawardee shall perform those services described in Exhibit A, the Scope of Work, which is attached hereto and incorporated herein by reference. Any changes to the Scope of Work proposed by Subawardee shall require the prior written approval of Awardee and review and approval of both Parties’ IRBs, if required by such Parties’ human subjects protection programs. Any material changes in the performance of this Agreement as outlined in the Scope of Work set forth in Exhibit A shall not be made without the express written approval of both Awardee and Subawardee in an amendment to this Agreement.

**2. TERM AND PERFORMANCE PERIOD**

The term of this Agreement is specified as the “Subaward Period of Performance” on page 1.  This Agreement shall not extend beyond the termination date unless agreed to in writing by both Parties in an amendment to this Agreement.

It is the intention of the Awardee to continue this contracting relationship through the project period provided that ongoing funding from Sponsor is awarded at requested levels and that Subawardee meets project performance and reporting requirements including**,** but not limited to, 2 CFR Part 200..

If this is a multi-year study, as identified on page 1, then at the expiration of the term of this Agreement, if Subawardee has submitted a proposed budget to Awardee for the next annual budget period, within 30 days of confirmation of funding from the Sponsor via a Notice of Award, Awardee will issue a written confirmation of funding and will authorize Subawardee to begin performing the work for the next budget period for which Subawardee will be compensated under the terms of the new applicable Subaward. Subawardee will have no obligation to continue performing work until receipt of such authorization. If funding from the Sponsor is at the level requested by Awardee and there are no discrepancies between the submitted budgets and the award, Awardee will provide Subawardee with a new Subaward or modification to this Subaward within 90 days of receipt of notice of further funding.

**3. ESTIMATED COST AND PAYMENT**

Payment for work performed by Subawardee will not exceed the “Amount funded this budget period”, as shown on Page1 unless amended by written mutual agreement.

Subawardee shall submit invoices monthly for the allowable costs incurred in the performance of this Agreement to the invoicing contact as specified on Exhibit C.

Subawardee will be paid by Awardee for services rendered in accordance with the terms of this Agreement, provided that such costs are allowable by terms of this Agreement and the applicable governmental cost principles were followed, including obtaining prior written approval from Awardee for all cost items requiring prior approval of the awarding agency as outlined in applicable governmental cost principles.

Invoices must clearly delineate expenditures by expense category as shown in the budget attachment(s) (Exhibit B – Budget). As defined by the Sponsor’s requirements, Subawardee may not deviate significantly from the major line items of the budget attachments (Exhibit B), unless specifically authorized by Awardee. Additionally, individual invoices must correctly reference: Subaward Agreement Number, Period of Performance covered by the invoice, specific Study Title, and [Add any project specific requirements here]. Invoices without such references will be returned to Subawardee.

The final invoice must be submitted within 60 calendar days after the end of the Subaward period of performance, as specified on page 1, or the effective date of any termination of this agreement, whichever occurs first. The final invoice must include a certification, signed by an official who is authorized to legally bind the entity, which reads as follows: “By signing this report, I certify to the best of my knowledge and belief that the report is true, complete, and accurate, and the expenditures, disbursements and cash receipts are for the purposes and objectives set forth in the terms and conditions of the Federal award. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims or otherwise. (U.S. Code Title 18, Section 1001 and Title 31, Sections 3729-3730 and 3801-3812).”, and must be marked "Final" by Subawardee. Failure to include the certification and sign the final invoice will not relieve Subawardee from this requirement. Final invoices may be sent via email in PDF format.

Subawardee may request extensions of time periods for submission of invoices, which approval will not be unreasonably withheld.

If during the record retention period of this Agreement, a finding or questioned cost is found related directly to this Agreement, then Subawardee will promptly notify Awardee in order to proceed with resolution of such matter, as may be required by Awardee’s prime sponsor or applicable Federal regulations.

Invoices and questions concerning invoice receipt or payments should be directed to the Awardee’s Administrative Contact as shown in Exhibit C.

Awardee shall make payments in accordance with Awardee’s accounts payable policies but in no event later than 45 days after receipt of an accurate invoice from Subawardee.

**4. REPORTS**

Subawardee will provide progress reports to Awardee as specified in the Statement of Work, or if not specified in the Statement of Work, within 30 days of receipt of Awardee’s written request.  Interim progress reports will be required from Subawardee to the extent required in the Award. All progress reports shall be directed to Awardee’s Principal Investigator and sent to Awardee’s Administrative Contact as identified in Exhibit C.

Subawardee shall timely provide financial status and other reports and data in the format reasonably requested by Awardee, and to the individual requested by the Awardee, in order to meet the Award’s reporting requirements.

**5. PRINCIPAL INVESTIGATOR/SITE PRINCIPAL INVESTIGATOR**

The Principal Investigator for Awardee and Site Principal Investigator for Subawardee are noted in Exhibit C. Subawardee’s Site Principal Investigator shall be responsible for the technical and administrative conduct of the Study covered by this Agreement. If a change in Subawardee's Site Principal Investigator or any other Key Personnel is necessary, Awardee must be notified in writing immediately. Awardee has the right to approve any Subawardee Site Principal Investigator, which approval shall not be unreasonably withheld.

**6. NOTICES**

For either Party, all notices required or permitted under this Agreement shall be effective only if given in writing and delivered by personal service, by express or registered mail, or via electronic mail with confirming receipt from recipient to the appropriate institutional officials identified in Exhibit C. All notices and requests for approvals from Awardee on financial or administrative matters shall be submitted to the Awardee’s Administrative Contact identified in Exhibit C.

**7. FEDERAL, STATE AND LOCAL TAXES**

Except as may be otherwise provided in this Agreement, the budget includes all applicable Federal, State and local taxes and duties.

**8. COMPLIANCE WITH LAW**

Each Party shall comply with any and all applicable State and Federal laws, regulations and policies applicable to its performance of this Agreement, and shall obligate any of its contractors and subcontractors to comply with such requirements.

**9. HIPAA COMPLIANCE**

A. The Parties may receive from or create on behalf of each other certain health or medical information in the performance of this Subaward ("Protected Health Information" or "PHI," including electronic PHI, as defined in 45 C.F.R. Section 164.501). Use or disclosure of PHI is subject to protection under State and Federal law, including the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191 ("HIPAA"), including the Standards for Security for the Protection of Electronic Protected Health Information (codified at 45 C.F.R. parts 160 and 164, Subpart C (“Security Rule”), and implementing regulations as amended by the "Final Omnibus Rule,” (78 Fed. Reg 5565, Jan 25, 2013) issued pursuant to HIPAA and the “HITECH Act,” P.L. 111-5, Sections 13001 et seq (“HIPAA Regulations”), and the terms of any data transfer, data sharing, data use, materials transfer, or other similar agreement executed by the Parties with respect to this Study. Each Party shall comply with such law and implementing regulations during the term of this Subaward and after termination.

B. Each Party shall maintain PHI securely in confidence and prevent any unauthorized access, use or disclosure of PHI, all in accordance with HIPAA, HIPAA Regulations and applicable State law. Except for disclosures to Federal, State or local public health authorities required by statute or other law for mandatory public health or other reporting requirements, each Party shall use and disclose PHI solely as necessary to perform its obligations under this Subaward in the conduct of the Study protocol and in accordance with the human subjects consent form (if any), all as approved by the applicable Institutional Review Board(s), and for no other purpose. Each Party shall permit access to and disclose PHI to its principals, directors, officers, employees, contractors and subcontractors only if and to the extent (i) it is necessary for the conduct of the Study, and (ii) such individuals and entities are informed of the confidential status of PHI and are contractually bound (or for a Party’s employees, are bound by applicable employment policies) by substantially equivalent restrictions on the use and disclosure of PHI set forth in this Subaward, HIPAA, HIPAA Regulations, applicable State law and any data transfer, data sharing, data use, materials transfer, or other similar agreement(s) entered into between the Parties with respect to the Study.

C. Patient-Identifiable Information under this Agreement shall be protected, used and disclosed solely for the purposes of the Study activity and in accordance with the provisions of this Agreement.

D. If a new law, regulation, or policy governing this subject matter is made at a future time that prevents the Receiving Party (as defined in Section 12) or Subawardee under this Agreement from being bound by obligation of nondisclosure, such Receiving Party or Subawardee may not continue to possess the Study Patient-Identifiable Information and shall return it to the Disclosing Party (as defined in Section 12) or destroy it. Upon the return or destruction of the Disclosing Party’s materials under this section, an authorized representative of the Receiving Party shall give the Disclosing Party written certification that all such material has either been returned to the Disclosing Party or destroyed.

**10. REVIEW OF HUMAN SUBJECTS IN RESEARCH PROJECTS**

If IRB approval is required for the Study, Subawardee shall comply with all conditions of approval as documented in the approval process by the IRB of record. If Subawardee is the IRB of record or is conducting its own site-specific IRB review for the Study, upon request, Subawardee will provide to Awardee documentation of IRB approval. In all other circumstances, upon request, Awardee will confirm approval by an IRB of record for the Study.

As applicable, Subawardee shall comply with Department of Health and Human Services (DHHS) policies and regulations regarding the Protection of Human Subjects (Title 45 Code of Federal Regulations, Part 46, Subpart A, as amended) and with 21 CFR 50 and 21 CFR 56.

Subawardee represents and certifies that:

1. Subawardee or its designated IRB holds a current Assurance of Protection for Human Subjects (Multiple Project Assurance or Federal-wide Assurance) with the Office for Human Research Protections (OHRP);
2. Any human subjects research to be conducted under this Subaward shall be reviewed and approved by an Institutional Review Board (IRB) operating under a Federal-wide Assurance prior to the commencement of any work under this Subaward.

**11. OWNERSHIP AND USE OF DATA AND STUDY MATERIALS**

“Data” means all data, whether in identifiable, anonymized, de-identified or aggregate format, provided by or on behalf of Subawardee from its patients’ or members’ medical records or patient-specific data derived from a Participating Site’s Study Materials (defined below) and other information provided by Subawardee, including but not limited to Subawardee’s health care delivery practices, utilization data, pharmacy data, membership or other clinical or health plan information.

“Participating Site” means Awardee and the Subawardees that have entered into a Subaward with Awardee for participation in the Study.

“Study Materials” means tangible biological, chemical, or physical materials that are furnished or collected by or on behalf of a Participating Site or its patients in connection with the performance of the Study, including without limitation, blood, saliva, and tissue samples (including, for example, genetic assays and serum or other biospecimen analysis results), and any Study Materials generated therefrom.

A. All Data and Study Materials are and shall remain exclusively owned by the Participating Sites that originally contributed such Data and Study Materials and its use by other Participating Sites is governed by this Agreement, and any executed data transfer, data sharing, data use, materials transfer, or other similar agreement(s) executed by the Parties.

B. Each Participating Site may use Data and Study Materials provided by other Participating Sites solely as necessary to perform their obligations in connection with the Study for which such Data and Study Materials are provided under this Agreement. Such use shall also be in compliance with applicable laws and regulations, protocols, consent forms, if any, IRB approvals and HIPAA regulations. No other use, disclosure, or transfer of or access to Data and Study Materials by a Participating Site or any third party is permitted without the prior written approval of the Participating Site’s Institution that originally provided the Data and Study Materials, and in accordance with any applicable data transfer, data sharing, data use, materials transfer, or other similar agreement(s) with such Participating Site, respectively.

C. De-identified Data that are received by Subawardee or Awardee for specific work preparatory to research, including the development of new research proposals, shall not be used, disclosed, or accessed for any other purpose or transferred to any other Participating Site or third party without the prior written approval of the Principal Investigator of the Participating Site that originally provided (and owns) the Data and only in compliance with any data transfer, data sharing, data use, materials transfer, or other similar agreements, if applicable, and IRB approval, if required.

D. Warranty Disclaimer: All Data, Confidential Information and Study Materials furnished to either Party by the other pursuant to this Agreement are provided on an “AS IS” basis for experimental purposes only. THE PROVIDING PARTY MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES, OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO ANY DATA, CONFIDENTIAL INFORMATION AND STUDY MATERIALS, AND EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND WITH RESPECT THERETO, INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

**12. RETURN OF STUDY MATERIALS AND DATA**

Upon the termination or expiration of this Agreement, Awardee and Subawardee receiving Study Material or Data pursuant to this Subaward ("Receiving Party") shall return, and Awardee shall direct every other Participating Site which has received Study Material or Data to return, all Study Materials and Data provided to Awardee or such other Participating Sites which have provided Study Material or Data ("Disclosing Party") as part of the Study; provided however, Awardee and any Receiving Party may retain copies of data sets (stripped of all patient and provider identifiers): (i) to the extent required to complete all pending and approved study activities in accordance with IRB approval and HIPAA regulations, or (ii) as may be mutually agreed in writing (including email) by Disclosing Party and Receiving Party and in accordance with IRB approval and HIPAA regulations.

The Parties may agree to the destruction of Study Materials and Data instead of their return, in which case such destruction shall be carried out in compliance with appropriate IRB approvals and HIPAA regulations. Subawardee and each Participating Site shall be subject to these same provisions with respect to Data and Study Materials obtained from Awardee and other Participating Sites.

Upon request, each Receiving Party shall give each Disclosing Party written certification that all such Study Materials and Data have been either returned to the Disclosing Party or destroyed. Subawardee shall incorporate the requirements of this section in lower tier Subawards and other contractual agreements.

**13. CONFIDENTIALITY**

A. Each Party shall keep confidential that information received from the other Party that is confidential or proprietary in nature, whether received directly or indirectly, during or otherwise in connection with projects governed by this Agreement. "Confidential Information" includes but is not limited to the following:

1. Data or Study Materials provided under Section 11 (Ownership and Use of Data and Study Materials) above or study participant medical records, research data, and other identifiable personal health information;
2. any other member- or patient-identifiable information;
3. provider-identifiable information;
4. any nonpublic Information about the business operations of each Party;
5. any other nonpublic information of each Party including but not limited to health care delivery practices, utilization data, pharmacy data, membership or other health plan information; and
6. Confidential Information of other participating Subawardees.

B. Each Party shall make reasonable efforts to mark Confidential Information clearly, or so identify Confidential Information that is disclosed orally provided however, that items described in Section 13(a) (i), (ii) and (iii) above shall be automatically deemed Confidential Information without further identification. If a Party determines it has made an oral disclosure of Confidential Information, the Party making the disclosure shall be responsible for clearly informing the other Party, in writing within 30 days that the information disclosed is confidential. Except for items described in Section13(a) (i), (ii) and (iii), which confidentiality shall be maintained as required by law, the Parties shall use reasonable efforts to maintain the confidentiality of the items described in Section 13(a) (iv) and (v) for a period of 5 years after termination of the Agreement.

C. The obligation to keep information confidential shall not apply to:

1. information that is shown to have been rightfully in the possession of the receiving Party before being disclosed by the Disclosing Party (defined below);
2. information which is now, or later becomes, generally available to the public through no fault of any Party to this Agreement;
3. information which is received from a third party who is not under an obligation of confidentiality;
4. information which is independently developed by the Receiving Party (defined below) without access to the confidential information of the Disclosing Party; or
5. information required to be released by law by order of a court of competent jurisdiction, administrative agency or governmental body; subpoena, summons or other legal process rule or regulation; or applicable regulatory or professional standards, provided that the other Party whose information required to be released is notified promptly in writing of any such law, order, subpoena, summons or other legal process to making such release of information and has the opportunity, if it chooses, to contest such release.

D. Confidential Information provided from one Party (“Disclosing Party”) to the other (“Receiving Party”) under this Agreement shall be maintained by the Receiving Party in a secure and confidential manner, and used by the Receiving Party solely in the conduct of the Study and in accordance with this Agreement, the consent documents, if any, and the Study as approved by the applicable IRBs. Any other use or disclosure is prohibited except as expressly authorized by applicable law or elsewhere in this Agreement. A Receiving Party shall disclose Confidential Information only to such persons (employees, agents, contractors, and vendors) having a need to know such information necessary for the Receiving Party to conduct the Study.

E. The Parties to this Agreement agree that any Confidential Information received from the other Party and retained by either Party must be recorded in such a manner that it cannot be directly or indirectly linked through identifiers to any patient, enrollee, employee, provider, or other individual related to the Party from whom the information was received, except as authorized in the IRB-approved Study protocol or in a Data Use Agreement executed by the Parties for the Study.

F. The Parties shall advise each of their investigators, subcontractors, employees and agents who have access to Confidential Information received from the other Party of the confidentiality obligations under the terms of this Agreement.

G. The Disclosing Party may require the other Party’s Subawardees, agents, contractors and vendors to sign confidentiality agreements acceptable to the Disclosing Party before providing such individuals access to its Confidential Information.

**14. PUBLICATIONS AND PRESENTATIONS**

A. Awardee’s Principal Investigator and Subawardee’s Site Principal Investigator shall confer in good faith during the course of the project as to authorship of any research report or other publication resulting from the work performed under this Agreement. Authorship shall be determined in accordance with International Committee of Medical Journal Editors *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, (“Uniform Requirements”) <http://www.icmje.org/urm_main.html>, and any written publication guidelines created and agreed upon for the Study by the investigators.

Each Party shall have the right to publish (consistent with academic standards) and disseminate information (including multimedia scientific presentations) derived from the performance of its work under this Agreement. All manuscripts for publication and other materials prepared for public dissemination shall be provided to the other Party 30 days prior to publication or dissemination for review and comment regarding confidential or proprietary information, and further provided that at the reviewing Party’s request, such submission shall be deferred for an additional period not to exceed 60 days to enable such Party to protect its rights in such confidential or proprietary information and/or data.

Publications, journal articles, presentations and other publicly disseminated materials must bear an acknowledgement and disclaimer, as appropriate, such as: “This publication was supported by Grant Number XXX from the [prime sponsor]. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Awardee, Subawardee, or the [prime sponsor].”

B. Notwithstanding anything to the contrary in this Agreement, no publication or public disclosure related to the work under this Agreement shall contain any Party’s Confidential Information as described in Section 13 (Confidentiality) of this Agreement.

**15. TERMINATION**

Notwithstanding the provisions of Section 2 (Term and Performance Period) above, either Party may terminate this Agreement for any reason upon 30 days prior written notification to the other Party, effective on the date the other Party receives such notice, and with cause 30 days after an uncured material breach described in a written notification to the breaching Party.

In the event of early termination, Subawardee shall take all reasonable steps to minimize further costs, and shall be entitled to reimbursement for costs and non-cancelable obligations incurred prior to the effective date of such early termination, except in no event shall such reimbursement exceed the amount set forth in Section 3 (Estimated Cost and Payment). If this Agreement is terminated early, then Subawardee shall deliver such information and items completed up to the early termination date to the Awardee.

The following Sections shall survive the expiration or termination of this Agreement: Section 9 (HIPAA Compliance), 10 (Review of Human Subjects in Research Projects), 11 (Ownership and Use of Data and Study Materials), 12 (Return of Study Materials and Data), 13 (Confidentiality), 14 (Publications and Presentations), 15 (Termination), 16 (Dispute Resolution), 18 (Patents and Inventions), 19 (Copyrights and Data Rights), 20 (Indemnification), 26 (Assignment and Transfer), and 29 (Order of Precedence).

**16. DISPUTE RESOLUTION**

A. Equitable Relief. Nothing in this Agreement shall prevent either Party from seeking equitable relief.

B. Meet and Confer. No Party shall initiate legal action under or in relation to this Agreement unless it has first complied with the process described in this Subsection, excluding actions for which equitable relief is sought. Should a dispute arise under or in relation to this Agreement or to a specific Study Agreement governed by this Agreement and equitable relief is not sought, a Party shall issue a written notice to the other Party describing the dispute and the remedy sought. The disputing Parties shall meet and confer in person or by telephone within 5 business days of receipt of such notice, or such other time period as the Parties may mutually agree in writing. If such dispute is not resolved through such conference within 5 business days, the matter shall be immediately referred to the persons to whom each such individual reports within its organization who shall attempt to resolve the dispute. If the dispute is not resolved within 20 business days after receipt of the notice, or such other time period as the Parties may mutually agree in writing, either Party may seek any remedy available under this Agreement or the law including, without limitation, immediate termination of this Agreement.

**17. FORCE MAJEURE**

No Party shall be liable for any delays or failures in performance resulting from circumstances or causes beyond its reasonable control, including, without limitation, fire or other casualty, act of God, war or other violence, or any law, order or requirement of any governmental agency or authority, provided that the Party claiming the Force Majeure event shall use reasonable efforts to continue to perform on any specific study governed by this Agreement.

**18. PATENTS AND INVENTIONS**

Subawardee shall promptly and fully report directly to Awardee all inventions made and reduced to practice in the course of performing the Study under this Agreement in order that Awardee may carry out the conditions of the prime award with regard to the filing of patent applications and disposition of patent rights. 37 CFR Part 401, “Rights to Inventions made by Nonprofit Organizations and Small Business Firms under Government Grants, Contracts, and Cooperative Agreements” and any further implementing regulations issued by DHHS are made a part hereof by reference and Subawardee shall comply with the applicable provisions thereof.

It is recognized and understood that the inventions, technologies and other tangible or intangible property created, conceived, reduced to practice or developed by Awardee or Subawardee prior to or independent of this Agreement are each such Party’s separate property, respectively, and are not affected by this Agreement, and neither Party shall have any claims to or rights in such inventions and technologies of the other Party, except as expressly provided in this Agreement.

Title to any inventions or discoveries conceived and reduced to practice solely by Subawardee employees, as determined in accordance with United States patent law, in the course of performing this Study and not from Awardee’s Confidential Information provided to Subawardee in connection with this Study shall be exclusively owned by Subawardee.

Title to any inventions or discoveries conceived and reduced to practice solely by Awardee employees, as determined in accordance with United States patent law, in the course of performing this Study and not from Subawardee’s Confidential Information provided to Awardee in connection with this Study shall be exclusively owned by Awardee.

Inventions and discoveries conceived and reduced to practice jointly by Awardee and Subawardee, as determined under United States patent law, shall be owned jointly by Awardee and Subawardee. Awardee and Subawardee shall promptly disclose joint inventions and discoveries to the other and both shall keep such information confidential. Subawardee shall incorporate the requirements of this Section in lower tier Subawards.

If either Awardee or Subawardee desires to make commercial use of a joint invention, or desires to license to a third party to make a commercial use of a joint invention, prior to such use or license the Parties shall negotiate in good faith a written inter-institutional agreement for the management and disposition of any joint inventions including reasonable and customary terms on control of patent prosecution and related expenses, and sharing of revenue for commercial use or licensing of such joint invention.

**19. COPYRIGHTS AND DATA RIGHTS**

Subawardee hereby grants to Awardee 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 Agreement solely for the purpose of and only to the extent required to meet Awardee’s obligations to the Federal Government under its Prime Award. Subawardee further grants to Awardee the right to use data created in the performance of this Agreement solely for the purpose of and only to the extent required to meet Awardee’s obligations to the Federal Government under its Prime Award.

**20. INDEMNIFICATION**

A. Each Party shall defend, indemnify, and hold the other Party , its officers, employees, and agents harmless from and against any and all liability, damage, loss or expense (including reasonable attorneys' fees), incurred in connection with any third party claims, suits, actions, demands or judgments arising from any cause of action or theory of liability for injury or damages arising out of or relating to the performance of this Agreement (or any data transfer, data sharing, data use, materials transfer, or other similar Agreement(s) executed by the Parties) but only in proportion to and to the extent such liability, loss, expense, attorneys' fees, or claims for injury or damages are caused by or result from the negligent or intentionally wrongful acts or omissions or any breach of this Agreement (or any data transfer, data sharing, data use, materials transfer, or other similar Agreement(s) executed by the Parties) of the indemnifying Party, its officers, employees, or agents.

B. The indemnified Party shall give the indemnifying Party prompt notice in writing of any claim, action, or suit for which the indemnified Party seeks indemnification, and shall cooperate fully with the indemnifying Party in the investigation and defense thereof. Upon written acknowledgement of its assumption of responsibility for the results of the action or claim as provided in this Section 20, the indemnifying Party will have the right to assume and control the defense and settlement of such action or claim, and in such case the indemnified Party may employ its own counsel if it wishes to do so, at its own expense. Regardless, the indemnifying Party shall not settle or compromise any claim or suit in a manner that admits wrongdoing by the indemnified Party or that imposes any expense, liability, obligation or restriction on the indemnified Party, without prior written consent of the indemnified Party. The Parties’ obligations under this Section shall survive termination of this Agreement until all claims involving any of the indemnified matters are fully and finally resolved or barred by applicable statutes of limitation.

C. Notwithstanding the foregoing, if Awardee or Subawardee is a State governmental agency and as such is prohibited by law from contractually obligating itself to provide indemnification, then this Section 20 shall not be given effect to the extent prohibited by law; provided however, that in such cases each Party shall be responsible for the negligent or willful acts or omission of itself and its agents to the extent allowed by law. If the indemnification and other obligations of one Party under this Section 20 are modified in accordance with this Section 20(c), then the indemnification and other obligations of the other Party under this Section 20 shall also be modified to maintain the mutuality and reciprocity of these obligations.

**21. INSURANCE**

**Alternative #1**

**(INSTRUCTIONS: Use Alternative #1 when Awardee will not impose specific requirements as to the levels of insurance to be maintained during the Research).**

The Parties agree that Subawardee shall maintain those amounts of insurance or self-insurance in effect as it may consider appropriate during its activities related to this Subaward.

**Alternative #2**

**(INSTRUCTIONS: Use Alternative #2 when Awardee wishes to impose specific requirements on the levels of insurance to be maintained during the Research. Insurance amounts herein can be negotiated between the Parties).**

At its sole expense, Subawardee shall maintain in effect the following policies of insurance or self-insurance covering claims and liabilities arising from this Subaward: (i) all insurance coverages required by federal and state law, including workers’ compensation and employer’s liability insurance all with statutory minimum limits, (ii) employer’s liability insurance with no less than a $1,000,000 limit; (iii) commercial general liability insurance with limits of not less than $3,000,000 per occurrence and aggregate, providing coverage for personal injury, or death of any persons and injury to or destruction of property, including loss of use resulting therefrom, and also including contractual liability covering Subawardee’s liability under this Agreement; and (iv) professional liability or errors and omissions insurance with limits of at least $3,000,000, which provides coverage on an occurrence basis or, if on a claims-made basis, then Subawardee shall maintain continuous coverage for 5 years after the termination or expiration of this Agreement; and (v) automobile (or other motor vehicle) liability insurance with not less than a $1,000,000 limit covering the use of any auto (or other motor vehicle) in the rendering of services to be provided under this Agreement. The insurance required under this Section must be carried by companies rated “A, X” or better by [A.M. Best](http://www.ambest.com/).

**INSTRUCTION: This paragraph can be added when the Parties agree that the Subawardee may meet the insurance requirements above by maintaining a program of self-insurance.** Notwithstanding any other provision of this Agreement and in lieu of any insurance requirements contained herein, Subawardee may fulfill such insurance obligations under this Agreement through its alternative risk management programs, including self-insurance, and Awardee hereby consents to such self-insurance and agrees that, in such case, Subawardee will not be required to provide endorsements or report deductibles, or self-insured retentions, or other requirements that are inconsistent with a program of self-insurance.

**22. AUDIT AND RECORDS**

A. All financial records, supporting documents and other records generated in or relating to Subawardee’s performance of this Agreement shall be retained by Subawardee for a period of three (3) years from the date of submission of the final expenditure report, except that records pertaining to audits, appeals, litigation or settlement of claims arising out of performance of this Agreement shall be retained for such time as until such audits, appeals, litigation, or claims have been fully resolved and are not subject to appeal or other challenge as provided under law.

B. Upon a reasonable prior request and mutually agreeable time, in any event, no more than 10 business days after receipt of a written request from Awardee, Subawardee shall provide Awardee’s representatives and auditors or agents with access to Subawardee’s financial records, supporting documents and other records generated in or relating to Subawardee’s performance of this Agreement as reasonably requested by Awardee. Subawardee shall reasonably and promptly cooperate with any such request. Subawardee shall refund to Awardee all overcharges not in compliance with this Agreement that are identified as a result of the review.

C. All research records, including but not limited to original data and primary data**‑**yielding materials, secondarily derived tables and figures, and statistical tabulations and other summaries, pertinent to this Agreement shall be made available to Awardee at Subawardee’s premises upon its reasonable written request during normal business hours and shall be retained by Subawardee for a period of 3 years from the termination date of this Agreement, except (i) to the extent a Party has requested the return of such records, or (ii) that records pertaining to any allegation of scientific misconduct or investigation, appeal, administrative proceeding or litigation relating to any charge arising out of the scientific performance of this Agreement shall be retained until 3 years after the later of the conclusion of the allegation, investigation, appeal, administrative proceeding, litigation or acceptance by PHS of a final report pertaining thereto. Subawardee shall be provided at least 10 business days to prepare for Awardee’s review.

D. Administration of this Agreement shall be in accordance with generally accepted accounting principles. Subawardee acknowledges and agrees that in the event of incomplete performance, Awardee may require Subawardee to obtain, at Subawardee's sole expense, an independent audit of costs claimed under this Agreement.

**23. INDEPENDENT CONTRACTOR**

Subawardee is deemed at all times to be an independent contractor and shall be wholly responsible for the manner in which it performs the services required of it by the terms of this Agreement. Nothing contained herein shall be construed as creating the relationship of employer and employee between Awardee and Subawardee or its officers, agents, and employees.

**24. SEVERABILITY**

If any provision of this Agreement or any provision of any document incorporated by reference shall be held invalid, the Parties will attempt to construe the provision in a manner that eliminates the offending language but maintains the overall intent of the Agreement. If that is not possible, the provision will be excised from this Agreement. The remainder of the Agreement will remain in full force and effect only if the excised provision does not relate to payment or obligations and enforcing this Agreement would not result in substantial unfairness to a Party. Otherwise, either Party may terminate this Agreement upon 30 days advance written notice.

**25. MODIFICATIONS**

No modification, amendment, supplement to, or waiver of this Agreement shall be binding upon the Parties unless made in writing and duly signed by the authorized institutional officials of both Awardee and Subawardee as identified in Exhibit C.

**26. ASSIGNMENT/TRANSFER**

Except for subcontracting or delegation as provided for in the Scope of Work (Exhibit A), Subawardee may not assign, subcontract, delegate, cede or otherwise transfer any of its rights or obligations under this Agreement without the prior written consent of the Awardee, which consent will not be unreasonably withheld; provided, however, without the Awardee’s consent Subawardee may assign this Agreement to a successor in interest in connection with the transfer or sale of all or substantially all of its assets or business or its merger or consolidation with another company but in such event, the assigning Party shall provide the other Party with no less than 30 days prior written notice of the assignment, and the other Party may terminate this agreement  pursuant to Section 15 (Termination), herein. This Agreement shall inure to the benefit of and be binding upon each Party hereto, its successors and permitted assigns. No assignment shall relieve either Party of the performance of any accrued obligation which such Party may then have under this Agreement.

**27. USE OF NAME**

Neither Party shall use the names, logos, symbols or trademarks of the other Participating Sites, the other Party or affiliates or related entities, or refer to the existence of this Agreement in any press release, promotional materials, internet sites, or products, without the express written permission of the other Party, except that the Awardee and Subawardee may identify each other and the Sponsor in: (i) annual reports and like documents that generally describe or refer to the Study; and (ii) public websites supported and provided by the Sponsor.

**28. SPECIAL CONDITIONS FOR THE AWARD**

Subawardee shall comply with the conditions as identified in Exhibit D, attached hereto and incorporated herein by reference.

**29. ORDER OF PRECEDENCE**

This Agreement is subject to the terms and conditions of the Award, which is attached hereto as Exhibit E and incorporated herein by reference. If there is a conflict between the terms and conditions of this Agreement and the Award, the terms and conditions of this Agreement shall control.

**30. ENTIRE AGREEMENT**

This Agreement, including exhibits and attachments, constitutes the entire agreement between the Parties regarding the subject matter herein and supersedes all prior agreements between the Parties.

**31. APPROVALS**

Any written approvals required under this Agreement may be made via email.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement on the month, day and year specified below.

**Awardee Subawardee**

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Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**EXHIBIT A**

**SCOPE OF WOR[[1]](#footnote-2)K**

The Scope of Work (SOW) is the definition of what the Subawardee agrees to perform in order to be paid (SOW is also known as Statement of Work).

Areas to consider addressing in the SOW are:

Purpose or objective(s) of the work to be performed by the Subawardee.

An explanation of the work to be performed.

Specify general types of data to be used (PHI, etc.) and if any biological specimens will be collected and stored.

Timetable or schedule of the work to be performed, if applicable.

Any expected deliverables, outcomes or products.

Outline of how the work’s progress or results are measured (e.g. patients enrolled, patients completed, etc.).

Identification of Key Personnel

Any special requirements or considerations – these could be related to specific program requirements, compliance requirements, additional subrecipient monitoring requirements, specific invoicing/payment terms, or any other special requirements of the subawardee.

Clearly specify any required documentation that you need from the Subawardee to fulfill your requirements to your sponsor, either under Subawardee Responsibilities or Subawardee deliverables/milestones.

Remember to allow sufficient time for you to review these documents when specifying a due date.

**EXHIBIT B**

**BUDGET**

**INSTRUCTIONS: Add budget here.**

Salary $

Fringe Benefits $

Equipment $

Supplies $

Travel $

Other $

Direct Costs $

F & A Costs @ ***(rate plus MTDC if app)*** $

**Total Costs $**

**EXHIBIT C**

**PASS THROUGH ENTITY (PTE) AND SUBAWARDEE CONTACTS**

|  |  |
| --- | --- |
| **PTE CONTACTS**  | **SUBAWARDEE CONTACTS**  |
| **Administrative Contact (Study PI Office):** Name:       Address:      Telephone:      Fax:      Email:       | **Administrative Contact:** Name:       Address:      Telephone:      Fax:      Email:       |
| **Principal Investigator**: ame:       Address:      Telephone:      Fax:      Email:       | **Site Principal Investigator:** Name:       Address:      Telephone:      Fax:      Email:       |
| **Financial Contact:** Name:       Address:      Telephone:      Fax:      Email:       | **Financial Contact:** Name:       Address:      Telephone:      Fax:      Email:       |
| **Send Invoices to:**Name:       Address:      Telephone:      Fax:      Email:       | **Direct Questions Regarding Submitted Invoices to:**Name:       Address:      Telephone:      Fax:      Email:       |
| **Authorized Institutional Official:** Name:       Address:      Telephone:      Fax:      Email:       | **Authorized Institutional Official:** Name:       Address:      Telephone:      Fax:      Email:       |

**EXHIBIT D, OPTION 1**

**INSTRUCTIONS: Use Exhibit D, Option 1 for NIH grants. Use Exhibit D, Option 2 for non-NIH funded HHS grants.**

**EXHIBIT D**

**RESEARCH SUBAWARD AGREEMENT - PRIME AWARD TERMS AND CONDITIONS**

**NIH GRANTS**

**1. CONFLICT OF INTEREST**

Subawardee must comply with the requirements of 42 CFR Part 50, Subpart F, “Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought.”

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 Institution (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 the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.”*

**Subawardee must designate herein whether the financial conflicts of interest policy of [ ]  Awardee Institution, or [ ]  Subawardee Institution (check one) will apply. If applying its own financial conflicts of interest policy, by execution of this Subaward Agreement, Subawardee Institution certifies that its policy complies with 42 CFR Part 50.**

B. **Subawardee shall report any financial conflict of interest to Awardee’s Administrative Representative, as designated on Exhibit C**. Any financial conflicts of interest identified shall subsequently be reported to Sponsoring Agency. Such report shall be made before expenditure of funds authorized in this Subaward Agreement and within 45 days of any subsequently identified financial conflict of interest.

**2. GENERAL NIH REQUIREMENTS:**

A. Restrictions on the expenditure of federal funds in appropriations acts are applicable to this Subaward Agreement as specified in the Notice of Award (Exhibit E).

B. The NIH Grants Policy Statement, including addenda, in effect as of the beginning date of the period of performance and found at <http://grants.nih.gov/grants/policy/policy.htm>, except for the payment mechanism and final reporting requirements are replaced with Reporting Requirements and Terms and Conditions incorporated in this agreement.

C. Expanded Authorities apply, except for the right to carry forward an unobligated balance from one budget period to the next, and the right to initiate an automatic one-time extension of the end date, which are both replaced by the need to obtain prior written approval from the Awardee. Carry forward requests must be sent to Awardee’s [Specify] Contact listed in Exhibit C unless automatic carry forward is allowed as indicated in Section 5 of this Exhibit.

D. Subawardee assures, by signing this Subaward Agreement, that all of Subawardee’s personnel who are responsible for the design and conduct of projects involving human research participants have successfully completed their institutional training in accordance with the NIH Guide, Notice OD-00-039.

E. Whistleblower Protection. Subawardee is hereby given notice that 48 CFR section 3.908, implementing section 828, entitled "Pilot Program for Enhancement of Contractor Employee Whistleblower Protections," of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2013 (Pub. L. 112-239, enacted January 2, 2013), applies to all NIH grants and subaward agreements issued beginning July 1, 2013 through January 1, 2017. Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights (Sep 2013) include the following:

1. This Agreement and employees working on this Agreement will be subject to the whistleblower rights and remedies in the pilot program on Subawardee employee whistleblower protections established at 41 U.S.C. 4712 by section 828 of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L.112-239) and FAR 3.908.
2. The Subawardee shall inform its employees in writing, in the predominant language of the workforce, of employee whistleblower rights and protections under 41 U.S.C. 4712, as described in section 3.908 of the Federal Acquisition Regulation.
3. The Subawardee shall insert the substance of this clause, including this paragraph, in all subawards over the simplified acquisition threshold.

F. All approvals requested by Subawardee for any matter relating to performance of this Agreement must be directed to Awardee and not the Federal Awarding Agency.

**3. PHS CERTIFICATIONS/ASSURANCES**

By executing this Agreement, the following assurances/certifications are made and verified by Subawardee’s Authorized Official Signature, as specified on Exhibit C to this Agreement. Descriptions of individual assurances/certifications are provided in, Application for a Public Health Service Grant Supplemental Instructions, Instructions for PHS 398, SF424 (R&R), PHS 416-1, PHS 2590, RPRR and PHS 416-0, Rev. 09/12,. Updated 11/2013, Part III – 2.

|  |  |
| --- | --- |
| 1. Human Subjects Research2. Research on Transplantation of Human Fetal Tissue3. Research Using Human Embryonic Stem Cells4. Women and Minority Inclusion Policy5. Race and Ethnicity Data Policy6. Inclusion of Children Policy7. Clinical Trials.gov Requirements8. Vertebrate Animals9. Debarment and Suspension10. Drug-Free Workplace11. Lobbying12. Non-Delinquency on Federal Debt13. Research Misconduct | 14. Civil Rights, Handicapped Individuals, Sex Discrimination, Age Discrimination, (Form HHS690)15. Recombinant or Synthetic DNA and Human Gene Transfer Research 16. Financial Conflict of Interest17. Smoke Free Workplace18. Prohibited Research19. Select Agent Research20. Program Director/PI Assurance, Fellow and Sponsor Assurance21. Impact of Grant Activities on the Environment and Historic Properties22. Institutions Receiving Awards for Training of Graduate Students for Doctoral Degrees |

**4. FINANCIAL COMPLIANCE, AUDIT AND RECORDS**

A. Administration of this Agreement shall be in accordance with generally accepted accounting principles, with 2 CFR 200, and with applicable provisions of the NIH Grants Policy Statement (NIHGPS). Subawardee acknowledges and agrees that, as part of Awardee’s implementation of 2 CFR 200Awardee will monitor Subawardee's performance under this Agreement and, in the event of incomplete performance, Awardee may require Subawardee to obtain, at Subawardee's sole expense, an independent audit of costs claimed under this Agreement.

If Subawardee expends $750,000 or more in federal funds in any one year, Subawardee will arrange for an annual examination by an independent accountant in order to ascertain the effectiveness of the Subawardee's financial management systems and internal procedures established to meet the terms of this Agreement.

Title to equipment costing $5,000 or more that is purchased or fabricated with research funds or Subawardee cost sharing funds, as direct costs of the project or program, shall unconditionally vest in Subawardee upon acquisition without further obligation to the Federal Awarding Agency, subject to the conditions specified in the NIH Grants Policy Statement.

B. If Subawardee is subject to the uniform administrative requirements of 2 CFR 200and arranges for audits that comply with 2 CFR 200 or equivalent guidelines, Subawardee shall provide its independent accountant's or firm's written report to Awardee upon execution of this Agreement. Any subsequent audit report shall be sent to the Awardee within thirty (30) days of receipt by the Subawardee. The report(s) shall be sent to the Awardee’s Financial Contact address referenced in Exhibit C.

Subawardee shall monitor other entities that receive funding through Subawardee as a result of this Agreement and shall adhere to all applicable regulations outlined in 2 CFR 200, including requirements of Subpart D, Section 200.330 et seq. -Subrecipient Monitoring and Management.

Subawardee shall comply with the reporting requirements on executive compensation on the Federal Subaward Reporting System (FSRS) that includes reports required by the Federal Funding Accountability and Transparency Act of 2006 (FFATA) at [www.FSRS.gov](http://www.FSRS.gov). For additional information regarding Subaward and executive compensation reporting requirements, please see [NIH Guide Notice NOT-OD-11-005](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-005.html_).

If any audit report or other significant accounting errors in invoicing or budgeting reflect major shortcomings in Subawardee's internal control systems, Awardee may seek to impose more stringent prior approval requirements for certain types of expenditures and/or rebudgeting and may require detailed supporting documentation for all claims for reimbursement until Subawardee has reasonably demonstrated that necessary corrective action has been, or will be taken.

Within six months of receipt of a report or statement identifying an instance of noncompliance with Federal laws and regulations, Subawardee shall provide to Awardee its plan for corrective action and shall cooperate with Awardee in resolving questions Awardee may have. All such records and reports or statements prepared in accordance with the requirements of 2 CFR 200, as applicable, shall be available for inspection by representatives of Awardee or the government during normal business hours. Subawardee shall ensure that other Subawardees who receive funding or perform work pursuant to a contract with Subawardee as a result of this Agreement adhere to the terms of this Section.

Failure to comply with the terms of this paragraph may lead to Agreement termination in accordance with Section 15 (Termination).

C. The Comptroller General of the United States, the U.S. Department of Health and Human Services, Awardee and any of their duly authorized representatives shall have access at any reasonable time after prior written notification to pertinent books, documents, papers and records of Subawardee at Subawardee’s premises in order to make audits, examinations, excerpts and transcripts. If any payment made to Subawardee is determined on the basis of such audits to be unallowable, Subawardee shall promptly refund the unallowable amount to Awardee upon demand. Subawardee shall be provided at least seven (7) business days to prepare for such audit.

**5. SPECIAL TERMS AND CONDITIONS**

Automatic Carry Forward:

[ ]  Yes [ ]  No.

If No, Carry Forward requests must be sent to Awardee’s [Specify] contact, as shown in Exhibit C.

**EXHIBIT D, OPTION 2**

**INSTRUCTIONS: Use Exhibit D, Option 2 for non-NIH funded HHS grants. Use Exhibit D, Option 1 for NIH grants.**

**EXHIBIT D**

**RESEARCH SUBAWARD AGREEMENT - PRIME AWARD TERMS AND CONDITIONS**

**HHS GRANTS**

**1. CONFLICT OF INTEREST**

Subawardee must comply with the requirements of 42 CFR Part 50, Subpart F, “Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought.”

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 Institution (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 the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.”*

**Subawardee must designate herein whether the financial conflicts of interest policy of [ ]  Awardee Institution, or [ ]  Subawardee Institution (check one) will apply. If applying its own financial conflicts of interest policy, by execution of this Subaward Agreement, Subawardee Institution certifies that its policy complies with 42 CFR Part 50.**

B. **Subawardee shall report any financial conflict of interest to Awardee’s Administrative Representative, as designated on Exhibit C**. Any financial conflicts of interest identified shall subsequently be reported to Sponsoring Agency. Such report shall be made before expenditure of funds authorized in this Subaward Agreement and within 45 days of any subsequently identified financial conflict of interest.

**2. GENERAL HHS TERMS AND CONDITIONS:**

A. Restrictions on the expenditure of federal funds in appropriations acts are applicable to this Subaward Agreement as specified in the Notice of Award (Exhibit E).

B. The Health and Human Services Grants Policy Statement (HHS GPS) , including appendices, in effect as of the beginning date of the period of performance and found at <http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>, except for the payment mechanism and final reporting requirements are replaced with Reporting Requirements and Terms and Conditions incorporated in this agreement.

C. Expanded Authorities apply, except for the right to carry forward an unobligated balance from one budget period to the next, and the right to initiate an automatic one-time extension of the end date, which are both replaced by the need to obtain prior written approval from the Awardee. Carry forward requests must be sent to Awardee’s [Specify] Contact listed in Exhibit C unless automatic carry forward is allowed as indicated in Section 5 of this Exhibit.

D. Subawardee assures, by signing this Subaward Agreement, that all of Subawardee’s personnel who are responsible for the design and conduct of projects involving human research have successfully completed any required institutional training.

E. All approvals requested by Subawardee for any matter relating to performance of this Agreement must be directed to Awardee and not the Federal Awarding Agency.

**3. PHS CERTIFICATIONS/ASSURANCES**

By executing this Agreement, the following assurances/certifications are made and verified by Subawardee’s Authorized Official Signature, as specified on Exhibit C to this Agreement. Descriptions of individual assurances/certifications are provided in, Application for a Public Health Service Grant Supplemental Instructions, Instructions for PHS 398, SF424 (R&R), PHS 416-1, PHS 2590, RPRR and PHS 416-0, Rev. 09/12,. Updated 11/2013, Part III – 2.

|  |  |
| --- | --- |
| 1. Human Subjects Research2. Research on Transplantation of Human Fetal Tissue3. Research Using Human Embryonic Stem Cells4. Women and Minority Inclusion Policy5. Race and Ethnicity Data Policy6. Inclusion of Children Policy7. Clinical Trials.gov Requirements8. Vertebrate Animals9. Debarment and Suspension10. Drug-Free Workplace11. Lobbying12. Non-Delinquency on Federal Debt13. Research Misconduct | 14. Civil Rights, Handicapped Individuals, Sex Discrimination, Age Discrimination, (Form HHS690)15. Recombinant or Synthetic DNA and Human Gene Transfer Research 16. Financial Conflict of Interest17. Smoke Free Workplace18. Prohibited Research19. Select Agent Research20. Program Director/PI Assurance, Fellow and Sponsor Assurance21. Impact of Grant Activities on the Environment and Historic Properties22. Institutions Receiving Awards for Training of Graduate Students for Doctoral Degrees |

**4. FINANCIAL COMPLIANCE, AUDIT AND RECORDS**

A. Administration of this Agreement shall be in accordance with generally accepted accounting principles, 2 CFR 200 and with applicable provisions of the Health and Human Services Grants Policy Statement (HHS GPS). Subawardee acknowledges and agrees that, as part of Awardee’s implementation of 2 CFR 200 Awardee will monitor Subawardee's performance under this Agreement and, in the event of incomplete performance, Awardee may require Subawardee to obtain, at Subawardee's sole expense, an independent audit of costs claimed under this Agreement.

If Subawardee expends $750,000 or more in federal funds in any one year, Subawardee will arrange for an annual examination by an independent accountant in order to ascertain the effectiveness of the Subawardee's financial management systems and internal procedures established to meet the terms of this Agreement.

Title to equipment costing $5,000 or more that is purchased or fabricated with research funds or Subawardee cost sharing funds, as direct costs of the project or program, shall unconditionally vest in Subawardee upon acquisition without further obligation to the Federal Awarding Agency, subject to the conditions specified in the HHS Grants Policy Statement.

B. If Subawardee is subject to the uniform administrative requirements of 2 CFR 200 and arranges for audits that comply with 2 CFR 200 or equivalent guidelines, Subawardee shall provide its independent accountant's or firm's written report to Awardee upon execution of this Agreement. Any subsequent audit report shall be sent to the Awardee within thirty (30) days of receipt by the Subawardee. The report(s) shall be sent to the Awardee’s Financial Contact address referenced in Exhibit C.

Subawardee shall monitor other entities that receive funding through Subawardee as a result of this Agreement and shall adhere to all applicable regulations outlined in 2 CFR 200, including requirements of Subpart D--Post Federal Award Requirements.

Subawardee shall comply with the reporting requirements on executive compensation on the Federal Subaward Reporting System (FSRS) that includes reports required by the Federal Funding Accountability and Transparency Act of 2006 (FFATA) at [www.FSRS.gov](http://www.FSRS.gov).

If any audit report or other significant accounting errors in invoicing or budgeting reflect major shortcomings in Subawardee's internal control systems, Awardee may seek to impose more stringent prior approval requirements for certain types of expenditures and/or rebudgeting and may require detailed supporting documentation for all claims for reimbursement until Subawardee has reasonably demonstrated that necessary corrective action has been, or will be taken.

Within six months of receipt of a report or statement identifying an instance of noncompliance with Federal laws and regulations, Subawardee shall provide to Awardee its plan for corrective action and shall cooperate with Awardee in resolving questions Awardee may have. All such records and reports or statements prepared in accordance with the requirements of 2 CFR 200, as applicable, shall be available for inspection by representatives of Awardee or the government during normal business hours. Subawardee shall ensure that other Subawardees who receive funding or perform work pursuant to a contract with Subawardee as a result of this Agreement adhere to the terms of this Section.

Failure to comply with the terms of this paragraph may lead to Agreement termination in accordance with Section 15 (Termination).

C. The Comptroller General of the United States, the U.S. Department of Health and Human Services, Awardee and any of their duly authorized representatives shall have access at any reasonable time after prior written notification to pertinent books, documents, papers and records of Subawardee at Subawardee’s premises in order to make audits, examinations, excerpts and transcripts. If any payment made to Subawardee is determined on the basis of such audits to be unallowable, Subawardee shall promptly refund the unallowable amount to Awardee upon demand. Subawardee shall be provided at least seven (7) business days to prepare for such audit.

**5. SPECIAL TERMS AND CONDITIONS**

Automatic Carry Forward:

[ ]  Yes [ ]  No.

If No, Carry Forward requests must be sent to Awardee’s [Specify] contact, as shown in Exhibit C.

**EXHIBIT E**

**NOTICE OF GRANT AWARD**

1. [↑](#footnote-ref-2)