FDP Summary Overlay of DTUA and Subaward (with Attachment 7) Terms
Purpose: provide points of comparison between the FDP DTUA and the FDP Subaward (Cost Reimbursement) templates. The goal is to highlight where terms from the DTUA overlay into the FDP Subaward template, if Attachment 7 is included. If a term from the DTUA is not included in the Subaward, the rationale for not including the term is described. The goal is to help those reviewing specifically for data use terms to understand where related terms are located throughout the FDP Subaward. *Note:* Attachment 7 of the Subaward template is in the pilot phase and therefore FDP members are not required to utilize the Attachment.
Executive Summary: • Project relationship: Attachment 7 signifies the data is being transferred specifically as related to the project • Regulatory: Attachment 7 contains all regulatory requirements that attach to the data type; in addition, the sub and PTE are beholden to various federal regulations included in the prime award and flowed into the subaward that may include regulations around human subjects and data security • Liability: A subaward is collaborative, in contrast to a standard DUA scenario where the Provider is passively providing data to the Recipient for use in the Recipient's project. Therefore, the Provider has more standing in a DUA scenario to limit their liability for the Recipient's use of the data. • Different types of entities: Attachment 7 may be used by Covered and non-Covered Entities as both PTEs and Subrecipients may be either • Data Description: Attachment 7 contains room for the Provider to accurately describe the data that is being transmitted including any Protected Health Information • •

DTUA Facepage		
DTUA	**Subaward (Cost Reimbursement)**	**Explanation**
Provider & Recipient Information Blocks	**Attachment 7** identifies which institution is the Provider and which is the Recipient **Attachments 3A and 3B** provide contacts	The subaward template calls the parties PTE and subrecipient and does not necessarily align with the expectations of Provider / Recipient (i.e. in one case the PTE may be the Recipient and in another acting as the Provider). Thus, other than Attachment 7, the terms Provider and

		Recipient are not utilized in the FDP subaward template.
Agreement Term (usually three years after start date)	**Facepage, Period of Performance**	In a subaward, most frequently, the funds are authorized on an annual basis based on the most recent progress report. Most projects run 3-5 years. Attachment 1 also requires the subrecipient to maintain records in accordance with federal requirements for 3 years after the end of the project.
Project Title	**Facepage. Project Title**	
Attachment 2 Data Type Drop Down: *De-identified data about human subjects Limited Data Set* *Personally Identifiable Information-Common Rule Only* *Personally Identifiable Information-HIPAA* *Personally Identifiable Information-FERPA* *Other – See Attachment 2*	**Attachment 7** Drop Down: *Protected Health Information (PHI)* *Personally Identifiable Information (PII) (consolidated PII Common Rule and PII FERPA)* *Limited Data Set (LDS)* *De-identified* *Other (see description below)*	
1) Provider shall provide the data set described in Attachment 1 (the "Data") to Recipient for the research purpose set forth in Attachment 1 (the "Project"). Provider shall retain ownership of any rights it may have in the Data, and Recipient does not obtain any rights in the Data other than as set forth herein.	**Attachment 2, 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.	In a subaward scenario, the parties are collaborators and in order to complete the aims of the research project, may need to use the data to meet those objectives, however additional rights are not conferred to the other party.
2) If applicable, reimbursement of any costs associated with the preparation,	**Budget, Attachment 5**	In a subaward, the PTE is expecting to pay the subrecipient for the performance

compilation, and transfer of the Data to the Recipient will be addressed in Attachment 1.		of their work, including data preparation. Those costs may not be specifically enumerated/called out in the budget.
3) Recipient shall not use the Data except as authorized under this Agreement. The Data will be used solely to conduct the Project and solely by Recipient Scientist and Recipient's faculty, employees, fellows, students, and agents ("Recipient Personnel") and Collaborator Personnel (as defined in Attachment 3) that have a need to use, or provide a service in respect of, the Data in connection with the Project and whose obligations of use are consistent with the terms of this Agreement (collectively, "Authorized Persons").	**Attachment 2 and 7**: Human Subjects Data ("Data") will be exchanged *under this Subaward* Attachment 7 includes an obligation to return or destroy data at Budget or Project Period end of Subaward	Attachment 2 is where the parties indicated whether data exchange will be a part of this Subaward and the terms of Attachment 7 set forth the terms of exchange. Both are intricately linked to the project itself.
4) Except as authorized under this Agreement or otherwise required by law, Recipient agrees to retain control over the Data and shall not disclose, release, sell, rent, lease, loan, or otherwise grant access to the Data to any third party, except Authorized Persons, without the prior written consent of Provider. Recipient agrees to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized use of or access to the Data and comply with any other special requirements relating to safeguarding of the Data as may be set forth in Attachment 2.	**Attachment 7** Authorized Persons are not included **Attachment 2, Federal Award Terms and Conditions**	The Subaward and Attachment 7 is only between the PTE and Subrecipient unless specifically noted and agreed. Thus, Authorized Persons only include applicable study staff from PTE or Subrecipient who are working on the Project. We would recommend that parties only use Attachment 7 when no outside entities are included in Authorized Persons. If there will be additional collaborators handling the data, a separate DTUA may be necessary.

		Federal Award Terms and Conditions includes provisions regarding the safety and privacy around human subjects used in federally funded research.
5) Recipient agrees to use the Data in compliance with all applicable laws, rules, and regulations, as well as all professional standards applicable to such research.	**Attachment 2, Federal Award Terms and Conditions**	Federal Award Terms and Conditions includes provisions regarding the safety and privacy around human subjects used in federally funded research.
6) Recipient is encouraged to make publicly available the results of the Project. Before Recipient submits a paper or abstract for publication or otherwise intends to publicly disclose information about the results of the Project, the Provider will have thirty (30) days from receipt to review proposed manuscripts and ten (10) days from receipt to review proposed abstracts to ensure that the Data is appropriately protected. Provider may request in writing that the proposed publication or other disclosure be delayed for up to thirty (30) additional days as necessary to protect proprietary information.	**Attachment 2, Copyrights** Subrecipient grants/shall grant 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.	Publication should be joint in a collaborative subaward setting. Furthermore, all federally funded research grants and cooperative agreements require the free, unfettered dissemination of results. Typically prior review/approval is not included in the FDP subaward template for that reason.
7) Recipient agrees to recognize the contribution of the Provider as the source of the Data in all written, visual, or oral public disclosures concerning Recipient's		Publication should be joint in a collaborative subaward setting and each party should follow academic rules of authorship, thereby automatically

research using the Data, as appropriate in accordance with scholarly standards and any specific format that has been indicated in Attachment 1.		acknowledging the other. This is in contrast to a standard DUA scenario where the contribution of the Provider may not rise to the level of authorship.
8) Unless terminated earlier in accordance with this section or extended via a modification in accordance with Section 13, this Agreement shall expire as of the End Date set forth above. Either party may terminate this Agreement with thirty (30) days written notice to the other party's Authorized Official as set forth below. Upon expiration or early termination of this Agreement, Recipient shall follow the disposition instructions provided in Attachment 1, provided, however, that Recipient may retain one (1) copy of the Data to the extent necessary to comply with the records retention requirements under any law, and for the purposes of research integrity and verification.	**Facepage Article 9** 9. Either party may terminate this Subaward with 30 days written notice. PTE notice shall be directed to the Contact, and Subrecipient notice shall be 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.	Termination is tailored to the specific circumstances of data exchange versus collaboration. Furthermore, in a collaboration, the parties may have different expectations as to continued use of the data (as long as it comports with all approved protocols) and thus return/destruction of the data may not be contemplated by the parties.
9) Except as provided below or prohibited by law, any Data delivered pursuant to this Agreement is understood to be provided "AS IS." PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR	None	A subaward is collaborative, in contrast to a standard DUA scenario where the Provider is passively providing data to the Recipient for use in the Recipient's project. Therefore, the Provider has more standing in a DUA scenario to limit their liability for the Recipient's use of the data. Moreover, in a Subaward context the Subrecipient is being paid for their efforts; therefore the PTE expects that data is being exchanged for a particular purpose

THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Notwithstanding, Provider, to the best of its knowledge and belief, has the right and authority to provide the Data to Recipient for use in the Project.		that the PTE has a stake in and that the Subrecipient's results will be useful to them in the performance of the Project.
10) Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its use, storage, disclosure, or disposal of the Data. The Provider will not be liable to the Recipient for any loss, claim, or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Data by the Recipient, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider. No indemnification for any loss, claim, damage, or liability is intended or provided by either party under this Agreement.	**Facepage Article 8** 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.	The liability clause is broader in the subaward template because of the nature of the collaboration. Both parties may be reasonably using the data in the course of their work, rather than in a more narrow circumstance where data is merely being provided. Further, neither clause contemplates or allows for indemnification because many FDP members, as state entities are not able to accept indemnification provisions. If you need an indemnification, neither FDP vehicle is appropriate.
11) 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 disclose factual information regarding the existence and purpose of the relationship that is the subject of this	**Attachment 1** 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	Minor differences in the text should be attributed to the different nature of the relationship between the parties, as well as the applicability of reporting requirements relative to subaward relationships.

Agreement for other purposes without written permission from the other party provided that any such statement shall accurately and appropriately describe the relationship of the parties and shall not in any manner imply endorsement by the other party whose name is being used.	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.*	
12) Unless otherwise specified, this Agreement and the below listed Attachments embody the entire understanding between Provider and Recipient regarding the transfer of the Data to Recipient for the Project: I. Attachment 1: Project Specific Information II. Attachment 2: Data-specific Terms and Conditions III. Attachment 3: Identification of Permitted Collaborators (if any).	**Facepage** 10. By signing this Subaward, including the 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.	
13) No modification or waiver of this Agreement shall be valid unless in writing and executed by duly authorized representatives of both parties.	**Facepage Article 6.** 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's Contact and the Subrecipient’s	

	Contact 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.	
14) The undersigned Authorized Officials of Provider and Recipient expressly represent and affirm that the contents of any statements made herein are truthful and accurate and that they are duly authorized to sign this Agreement on behalf of their institution.	**Facepage** Authorized Official signature is required	The intent of the FDP is that the Authorized Official is equilvant to the NIH -deinfed. Authorized Organization Representative (AOR) AOR is the individual, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards. This individual is equivalent to the signing official in the eRA Commons, i.e., holds the SO Role. AOR signature is required at various stages in the federal award process, including signatures from Subrecipients. FDP members are entrusted to have robust processes and policies in place to ensure that AORs are signing off on Subawards and related documents.
Address for formal notifications	**Attachment 3A and 3B** Typically the Authorized Official	Throughout the FDP template, specific actions need to be routed to specific actors within the organization, who will not always be the same person. In a DTUA scenario, the process is simplified to only the scientists and authorized officials.

Attachment 1: DTUA Project Specific Information		
1. Description of Data	**Attachment 7**	
2. Description of Project	**Attachment 5, Statement of Work**	
3. Provider Support & Data Transmission	Attachment 3A and 3B	PI information is included in Attachment 3. PIs in a collaboration are in touch regarding a number of items and are expected to discuss data transmission procedures. Data transmission may also be covered by the applicable IRB Protocol referenced in Attachment 2.
4. Reimbursement of Costs: *None* *As governed by a separate written agreement between the parties Reimbursement Agreement Reference # (if required):* *As described below*	**Attachment 5, Budget**	Note that in the budget of a subaward, the preparation of the data for exchange may not be separately enumerated, but it may be accounted for in the amount of time and effort of a project team member.
5. Disposition Requirements upon the termination or expiration of the Agreement:	**Attachment 7** Upon completion of the Recipient shall retain or destroy the Data as instructed by the Provider; provided, however, that Recipient may retain one (1) archival copy of the Data	If more complex destruction terms are required, a separate DTUA may be necessary.
Attachment 3: Identification of Permitted Collaborators		
For all purposes of this Agreement, the definition of "Collaborator Personnel" checked below will pertain: *"Collaborator Personnel" means: None. No collaborators are permitted on the Project.* -OR-		This is not covered in the FDP subaward. We would recommend that parties only use Attachment 7 when the None applies. If there will be additional collaborators handling the data, a separate DTUA may be necessary.

"Collaborator Personnel" means as set forth below and agreed upon between the Parties:		
Attachment 2: De-identified Data		
1. The Data will not include personally identifiable information as defined in NIST Special Publication 800-122. If the Data being provided is coded, the Provider will not release, and the Recipient will not request, the key to the code.	**Attachment 7** same	
2. If Provider is a Covered Entity, the Data will be de-identified data, as defined by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").	**Attachment 7** same	
3. Recipient will not use the Data, either alone or in concert with any other information, to make any effort to identify or contact individuals who are or may be the sources of Data without specific written approval from Provider and appropriate Institutional Review Board (IRB) approval, if required pursuant to 45 CFR 46. Should Recipient inadvertently receive identifiable information or otherwise identify a subject, Recipient shall promptly notify Provider and follow Provider's reasonable written instructions, which may include return or destruction of the identifiable information.	**Attachment 7** same	
4. By signing this Agreement, Recipient provides assurance that relevant institutional policies and applicable	**Facepage, Attachment1 and Attachment 2**	On the facepage the Federal Award applies to the Subrecipient, various federal-wide regulations are included in

federal, state, or local laws and regulations (if any) have been followed, including the completion of any IRB or ethics review or approval that may be required.		Attachment 1 and the Federal Agency specific conditions are included in Attachment 2. IRB compliance is also addressed in Attachment 2.
5. Recipient shall promptly report to the Provider any use or disclosure of the Data not provided for by this Agreement of which it becomes aware.	**Attachment 7** same	
Attachment 2: Limited Data Set		
1. Nothing herein shall authorize the Recipient to use or further disclose the Data in a manner that would violate the requirements of Provider under 45 CFR 164.514.	**Facepage, Attachment1 and Attachment 2**	Compliance with applicable regulations is embedded in various places in the subaward. On the facepage the Federal Award applies to the Subrecipient, various federal-wide regulations are included in Attachment 1 and the Federal Agency specific conditions are included in Attachment 2. Whether the Provider or Recipient is the PTE or Subrecipient, both must comply with all applicable regulations when receiving federal funding.
2. Recipient shall not use or further disclose the Data other than as permitted by this Agreement or as otherwise required by law.	**Facepage, Attachment 1 and Attachment 2**	Compliance with applicable regulations is embedded in various places in the subaward. On the facepage the Federal Award applies to the Subrecipient, various federal-wide regulations are included in Attachment 1 and the Federal Agency specific conditions are included in Attachment 2. Whether the Provider or Recipient is the PTE or Subrecipient, both must comply with all applicable

		regulations when receiving federal funding.
3. Recipient shall report to the Provider any use or disclosure of the Data not provided for by this Agreement within 5 business days of when it becomes aware of such use or disclosure.	**Attachment 7** same	
4. Provider is a HIPAA Covered Entity, and the Data will be a Limited Data Set as defined by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). In accordance with Section 164.514(e)(2) of the HIPAA Privacy Rule, the Data shall exclude the following direct identifiers of the individual or of relatives, employers, or household members of the individual: (i) Names; (ii) Postal address information, other than town or city, State, and zip code; (iii) Telephone numbers; (iv) Fax numbers; (v) Electronic mail addresses; (vi) Social security numbers; (vii) Medical record numbers; (viii) Health plan beneficiary numbers; (ix) Account numbers; (x) Certificate/license numbers; (xi) Vehicle identifiers and serial numbers, including license plate numbers; (xii) Device identifiers and serial numbers; (xiii) Web Universal Resource Locators (URLs); (xiv) Internet Protocol (IP) address numbers; (xv) Biometric identifiers, including finger and voice prints; and (xvi) Full face photographic	**Attachment 7** Data transferred under this Agreement contains identifiable data elements derived from human subjects and constitutes a Limited Data Set ("LDS Data"), defined in the Health Insurance and Portability Act of 1996 at 45 C.F.R. § 164.514(e)(2) ("HIPAA").	Attachment 7 may be used by Covered and non-Covered Entities as both PTEs and Subrecipients may be either. It is incumbent upon the Provider to accurately understand and describe the data that is being transmitted and, if the data is a Limited Data Set and the Provider is a Covered Entity, that all HIPAA requirements are included in the Subaward or other contractual mechanism used to transfer the data. The specific data elements that make up a Limited Data Set are included by reference to the CFR.

images and any comparable images. If the Data being provided is coded, the Provider will not release, and the Recipient will not request, the key to the code.		
5. Recipient will not use the Data, either alone or in concert with any other information, to make any effort to identify or contact individuals who are or may be the sources of Data without specific written approval from Provider and appropriate Institutional Review Board approval, if required pursuant to 45 CFR 46. Should Recipient inadvertently receive identifiable information or otherwise identify a subject, Recipient shall promptly notify Provider and follow Provider's reasonable written instructions, which may include return or destruction of the identifiable information.	**Attachment 7** same	
6. By signing this Agreement, Recipient provides assurance that relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including the completion of any IRB or ethics review or approval that may be required.	**Facepage, Attachment1 and Attachment 2**	On the facepage the Federal Award applies to the Subrecipient, various federal-wide regulations are included in Attachment 1 and the Federal Agency specific conditions are included in Attachment 2. IRB compliance is also addressed in Attachment 2.
7. The parties agree to take such action as is necessary to amend this Agreement, from time to time, in order for the Provider to remain in compliance with the requirements of HIPAA.	**Facepage Article 6 and Attachment 2 Federal Award Terms and Conditions** 6. Matters concerning the request or negotiation of any changes in the terms,	Amendments are addressed in the facepage. Attachment 2 includes federal regulations that apply to both the PTE and Subrecipient, so any changes that need to be made to comply with federal law

	conditions, or amounts cited in this Subaward, and any changes requiring prior approval, shall be directed to the PTE's Contact and the Subrecipient's Contact 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.	(including HIPAA) would necessarily be made and be made via an amendment to the Subaward.
Attachment 2: Personally Identifiable Data – Common Rule Only		
1. The Data is Personally Identifiable Information, as that is defined in OMB Memorandum M-07-16, and not covered under HIPAA, FERPA, or similar laws or regulations governing personal information that require the addition of special terms beyond those included in this Attachment 2. ☐ If checked, the Data is subject to the Federal Privacy Act of 1974, as amended, at 5 U.S.C. § 552a. ☐ If checked, the Data is covered under a Certificate of Confidentiality, which must be asserted against compulsory legal demands, such as court orders and subpoenas for identifying information or characteristics of a research participant. See https://grants.nih.gov/grants/guide/notice-files/NOT-OD17-109.html for further information.	**Attachment 7- Personally Identifiable Information** Data transferred under this Agreement contains identifiable data elements derived from human subjects and constitutes Personally Identifiable Information ("PII Data"), as that is defined in OMB Memorandum M-17-12, and is not covered under HIPAA, FERPA, or similar laws or regulations governing personal information that require the addition of special terms beyond those included herein. **Attachment 2, Certificate of Confidentiality (if NIH is Federal Awarding Agency)** 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	CoC may apply to other Federal Awarding Agencies. FDP has only developed language to comply with NIH policy. For other agencies applying a CoC, the PTE must include tailored CoC language in Special Terms and Conditions in Attachment 2.

	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").	
2. Notwithstanding any statement herein to the contrary, Provider represents that it has full authority to share the Data with the Recipient and has confirmed that the Project is consistent with such consents as Provider may have obtained from individuals who are the subjects of the Data.	**Attachment 7** Provider certifies that it will only provide PII Data to Recipient after the transfer has been authorized by Provider's IRB. In accessing PII Data, Recipient may only use and disclose data as permitted by: this Agreement, the Informed Consent ("ICF"), the IRB-approved protocol ("Protocol"), or as required by law.	
3. Unless otherwise required by law or legal process, Recipient shall not use or further disclose the Data other than as permitted by this Agreement. If Recipient believes it is required by law or legal process to use or disclose the Data, it will promptly notify Provider, to the extent allowed by law, prior to such use or disclosure and will disclose the least possible amount of Data necessary to fulfill its legal obligations.	**Attachment 7** In accessing PII Data, Recipient must use appropriate technical and physical safeguards to prevent use or disclosure of PII Data other than as allowed by this Agreement.	Any applicable CoC policy will include requirements regarding compelled disclosure by law or legal process.

4. In the event Recipient becomes aware of any use or disclosure of the Data not provided for by this Agreement, Recipient shall take any appropriate steps to minimize the impact of such unauthorized use or disclosure as soon as practicable and shall notify Provider of such use or disclosure as soon as possible, but no later than 5 business days after discovery of the unauthorized use or disclosure. Recipient shall cooperate with Provider to investigate, correct, and/or mitigate such unauthorized use or disclosure. Recipient acknowledges that Provider may have an obligation to make further notifications under applicable state law and shall cooperate with the Provider to the extent necessary to enable Provider to meet all such obligations.	**Attachment 7** same	
5. Recipient will not use the Data, either alone or in concert with any other information, to make any effort to contact individuals who are the subjects of the Data without appropriate Institutional Review Board (IRB) approval, specific written approval from Provider, and informed consent from the individual, if required.	**Attachment 7** Recipient will not use PII Data to contact any individuals who are or may be the sources of PII Data without specific written approval from Provider and appropriate IRB approval.	
6. Recipient agrees to store Data with security controls adequate to protect Personally Identifiable Information, to ensure that only Authorized Persons have access to the Data, and to maintain	**Attachment 7** In accessing PII Data, Recipient must use appropriate technical and physical safeguards to prevent use or disclosure of	Authorized persons are not referenced.

appropriate control over the Data at all times.	PII Data other than as allowed by this Agreement.	
7. Recipient agrees to remove and securely destroy or return, as directed by the Provider in Attachment 1, the part or parts of the Data that identifies the individual who is the subject of the Data at the earliest time at which removal and destruction or return can be accomplished, consistent with the purpose of the Project.	**Attachment 7** Recipient will remove and securely destroy or return, as directed by the Provider, the part or parts of the PII Data that identifies the individual who is the subject of the PII Data at the earliest time at which removal and destruction or return can be accomplished, consistent with the purpose of the Project.	
8. By signing this Agreement, Recipient provides assurance that its relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including the completion of any IRB review or approval that may be required prior to Recipient's use of the Data. Upon Provider's written request to the Recipient's Contact for Formal Notices identified in the signature block, Recipient shall provide documentation of its IRB-Approved Protocol.	**Facepage, Attachments 1 and 2** **Attachment 7** Recipient will remain in compliance with all applicable U.S. federal, state, and local laws and regulations regarding handling or storing PII Data and record retention requirements.	Compliance with federal regulations and human subjects specific regulations is included in the Facepage and Attachments 1 and 2.
Attachment 2: Personally Identifiable Data – HIPAA		
1. The Data is Protected Health Information ("PHI") as that term is defined in the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), at 45 C.F.R. §160.103 (and not a Limited Data Set). ☐ *If checked, the Data is covered under a Certificate of*	**Attachment 7** Data transferred under this Agreement contains identifiable data elements derived from human subjects and constitutes Protected Health Information ("PHI Data") as defined in the Health	CoC may apply to other Federal Awarding Agencies. FDP has only developed language to comply with NIH policy. For other agencies applying a CoC, the PTE must include tailored CoC language in Special Terms and Conditions in Attachment 2.

Confidentiality, which must be asserted against compulsory legal demands, such as court orders and subpoenas for identifying information or characteristics of a research participant. See https://grants.nih.gov/grants/guide/notice-files/NOT-OD17-109.html for further information.	Insurance Portability and Accountability Act of 1996 ("HIPAA"), at 45 C.F.R. §160.103. **Attachment 2, Certificate of Confidentiality (if NIH is Federal Awarding Agency)** 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").	
2. Nothing herein shall authorize the Recipient to use or further disclose the Data in a manner that would violate the requirements applicable to Provider under 45 CFR §164.514.		

3. Notwithstanding any statement herein to the contrary, Provider represents that it has full authority to share the Data with the Recipient and has confirmed that the Project is consistent with such consents or authorizations, if any, as Provider has obtained from individuals who are the subjects of the Data.	**Attachment 7** Provider certifies that it will only provide PHI Data to Recipient after the transfer has been authorized by Provider's IRB.	
4. Unless otherwise required by law or legal process, Recipient shall not use or further disclose the Data other than as permitted by this Agreement. If Recipient believes it is required by law or legal process to use or disclose the Data, it will promptly notify Provider, to the extent allowed by law, prior to such use or disclosure and will disclose the least possible amount of Data necessary to fulfill its legal obligations.	**Attachment 7** In accessing PHI Data, Recipient may only use and disclose data as permitted by: this Agreement, the Informed Consent ("ICF") or HIPAA Waiver of Authorization ("Waiver of Authorization"), the IRB-approved protocol ("Protocol"), or as required by law. If Recipient becomes aware of any use or disclosure of PHI Data not allowed by this Agreement, including if disclosure of PHI Data is required by law or court order, Recipient will notify Provider as soon as possible, and in no event later than five (5) business days after its discovery. Recipient will reasonably cooperate with Provider in taking all appropriate or required steps to minimize the impact of any disclosure of PHI Data. Provider may have an obligation to make further notifications as set forth in Subpart D of 45 CFR §164 or under applicable state law and shall cooperate with the	Any applicable CoC policy will also include requirements regarding compelled disclosure by law or legal process.

	Provider to the extent necessary to enable Provider to meet all such obligations.	
5. In the event Recipient becomes aware of any use or disclosure of the Data not provided for by this Agreement, Recipient shall take any appropriate steps to minimize the impact of such unauthorized use or disclosure as soon as practicable and shall notify Provider of such use or disclosure as soon as possible, but no later than 5 business days after discovery of the unauthorized use or disclosure. Recipient shall cooperate with Provider to investigate, correct, and/or mitigate such unauthorized use or disclosure. Recipient acknowledges that Provider may have an obligation to make further notifications as set forth in Subpart D of 45 CFR §164 or under applicable state law and shall cooperate with the Provider to the extent necessary to enable Provider to meet all such obligations.	**Attachment 7** If Recipient becomes aware of any use or disclosure of PHI Data not allowed by this Agreement, including if disclosure of PHI Data is required by law or court order, Recipient will notify Provider as soon as possible, and in no event later than five (5) business days after its discovery. Recipient will reasonably cooperate with Provider in taking all appropriate or required steps to minimize the impact of any disclosure of PHI Data. Provider may have an obligation to make further notifications as set forth in Subpart D of 45 CFR §164 or under applicable state law and shall cooperate with the Provider to the extent necessary to enable Provider to meet all such obligations.	
6. Recipient will not use the Data, either alone or in concert with any other information, to make any effort to contact individuals who are the subjects of the Data without appropriate Institutional Review Board (IRB) approval, specific written approval from Provider, and informed consent and authorization from the individual or a waiver, if required.	**Attachment 7** Recipient will not use PHI Data to contact any individuals who are or may be the sources of PHI Data without specific written approval from Provider and appropriate IRB approval.	
7. Recipient agrees to implement reasonable safeguards, sufficient to meet	**Attachment 7**	

the standards of 45 CFR §164.530(c), to limit incidental, and avoid prohibited, uses and disclosures of the Data, and to ensure that only Authorized Persons have access to the Data.	In accessing PHI Data, Recipient must use appropriate technical and physical safeguards to prevent use or disclosure of PHI Data other than as allowed by this Agreement.	
8. Recipient agrees to remove and securely destroy or return, as directed by the Provider in Attachment 1, the part or parts of the Data that identifies the individual who is the subject of the Data at the earliest time at which removal and destruction or return can be accomplished, consistent with the purpose of the Project.	**Attachment 7** Recipient will remove and securely destroy or return, as directed by the Provider, the part or parts of the PHI Data that identifies the individual who is the subject of the PHI Data at the earliest time at which removal and destruction or return can be accomplished, consistent with the purpose of the Project.	
9. The parties agree to take such action as is necessary to amend this Agreement, from time to time, in order for the Provider to remain in compliance with the requirements of the HIPAA Privacy Regulations.	**Facepage Article 6 and Attachment 2 Federal Award Terms and Conditions** 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's Contact and the Subrecipient's Contact 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.	Amendments are addressed in the facepage. Attachment 2 includes federal regulations that apply to both the PTE and Subrecipient, so any changes that need to be made to comply with federal law (including HIPAA) would necessarily be made and be made via an amendment to the Subaward.
10. By signing this Agreement, Recipient provides assurance that its relevant institutional policies and applicable federal, state, or local laws and	**Attachment 2** Subrecipient agrees that any non-exempt human and/or vertebrate animal research protocol conducted under this Subaward	

regulations (if any) have been followed, including the completion of any IRB review or approval that may be required prior to Recipient's use of the Data. Upon Provider's written request to the Recipient's Contact for Formal Notices identified in the signature block, Recipient shall provide documentation of its IRB-Approved Protocol.	shall be reviewed and approved by the appropriate Institutional Review Board (IRB) and/or its Institutional Animal Care and Use Committee (IACUC), as applicable and that it will follow current and duly approved research protocols for all periods of the Subaward involving human and/or vertebrate animal research. If Subrecipient is using its own IRB and/or IACUC, Subrecipient certifies that its IRB and/or IACUC are in full compliance with applicable state and federal laws and regulations. The Subrecipient certifies that any submitted IRB/IACUC approval represents a valid, approved protocol that is entirely consistent with the Project associated with this Subaward. In no event shall Subrecipient invoice or be reimbursed for any human or vertebrate animals related expenses incurred in a period where any applicable IRB/IACUC approval is not properly in place. **Attachment 7** In accessing PHI Data, Recipient may only use and disclose data as permitted by: this Agreement, the Informed Consent ("ICF") or HIPAA Waiver of Authorization ("Waiver of Authorization"), the IRB-approved	

	protocol ("Protocol"), or as required by law.	
Attachment 2: Personally Identifiable Data - FERPA		
1. The Data is Personally Identifiable Information, as that is defined in the Family Education Rights and Privacy Act of 1974 at 20 U.S.C. §1232(g) and regulations at 34 C.F.R. §99.3 (collectively, "FERPA") and is further categorized as Education Records and/or Treatment Records as those terms are defined in FERPA. ☐ *If checked, the Data is covered under a Certificate of Confidentiality, which must be asserted against compulsory legal demands, such as court orders and subpoenas for identifying information or characteristics of a research participant. See https://grants.nih.gov/grants/guide/notice-files/NOT-OD17-109.html for further information.*		
2. Notwithstanding any statement herein to the contrary and pursuant to 34 CFR §99.31(a)(6), Provider represents that it has full authority to share the Data with the Recipient for the Project.		
3. Unless otherwise required by law or legal process, Recipient shall not use or further disclose the Data other than as permitted by this Agreement. If Recipient believes it is required by law or legal process to use or disclose the Data, it will promptly notify Provider, to the extent		

allowed by law, prior to such use or disclosure and will disclose the least possible amount of Data necessary to fulfill its legal obligations.		
4. In the event Recipient becomes aware of any use or disclosure of the Data not provided for by this Agreement, Recipient shall take any appropriate steps to minimize the impact of such unauthorized use or disclosure as soon as practicable and shall notify Provider of such use or disclosure as soon as possible, but no later than 5 business days after discovery of the unauthorized use or disclosure. Recipient shall cooperate with Provider to investigate, correct, and/or mitigate such unauthorized use or disclosure. Recipient acknowledges that Provider may have an obligation to make further notifications under applicable state law and shall cooperate with the Provider to the extent necessary to enable Provider to meet all such obligations.		
5. Recipient will not use the Data, either alone or in concert with any other information, to make any effort to contact individuals who are the subjects of the Data without appropriate Institutional Review Board (IRB) approval, specific written approval from Provider, and informed consent and authorization from the individual or a waiver, if required.		

6. Recipient agrees to store Data with security controls adequate to protect Personally Identifiable Information, to ensure that only Authorized Persons have access to the Data, and to maintain appropriate control over the Data at all times.		
7. Pursuant to 34 CFR §99, Recipient agrees to remove and securely destroy, as directed by the Provider in Attachment 1, the Personally Identifiable Information at the earliest time at which removal and destruction can be accomplished consistent with the Project.		
8. By signing this Agreement, Recipient provides assurance that its relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including the completion of any IRB review or approval that may be required prior to Recipient's use of the Data. Upon Provider's written request to the Recipient's Contact for Formal Notices identified in the signature block, Recipient shall provide documentation of its IRB-Approved Protocol.		
Attachment 2: Other		
Additional Terms and Conditions: *None. No additional terms and conditions are required*. -OR-		

The additional terms and conditions are as set forth below and agreed upon between the Parties:		