|  |
| --- |
| **ETSU/Ballad Collaborative Research****Reciprocal Data Transfer and Use Agreement (“Agreement”)**Limited Data Set |
| Party 1: INSERT ORGANIZATION NAME | Party 2:INSERT ORGANIZATION NAME |
| Party 1 ScientistName: INSERT NAME Email: INSERT EMAIL  | Party 2 ScientistName: INSERT NAME Email: INSERT EMAIL |
| Party 1 Data Type: Limited Data Set[This template includes language and attachments for use when the data being shared is a Limited Data Set as defined under 45 CFR 164.514. Make sure you are using the appropriate template.] | Party 2 Data Type: Limited Data Set[This template includes language and attachments for use when the data being shared is a Limited Data Set as defined under 45 CFR 164.514. Make sure you are using the appropriate template.] |
| Agreement TermStart Date: INSERT START DATEEnd Date: INSERT END DATE[In general, ETSU is prohibited from entering into agreements that exceed a 5 (five) year term.]  | Project Title: INSERT PROJECT TITLE |
| **Terms and Conditions**1. The Parties shall provide the data set(s) described on Attachment 1 (the “Data”) to each other for the research purpose set forth in Attachment 1 (the “Project”). Each Party is a Providing Party when providing Data and a Receiving Party when receiving Data. Providing Party shall retain ownership of any rights it may have in the Data, and Receiving Party does not obtain any rights in the Data other than as set forth herein.
2. Receiving Party shall not use the Data except as authorized under this Agreement. The Data will be used solely to conduct the Project and solely by Receiving Party’s Scientist and Receiving Party’s faculty, employees, fellows, students, and agents (“Receiving Party Personnel”) and Third-Party 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”).
3. Except as authorized under this Agreement or otherwise required by law, Receiving Party 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 Providing Party. Receiving Party 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 the applicable Attachment 2.
4. Receiving Party agrees to use the Data in compliance with all applicable laws, rules, and regulations, as well as all professional standards applicable to such research.
5. The Parties are encouraged to make publicly available the results of the Project. Before either Party submits a paper or abstract for publication or otherwise intends to publicly disclose information about the results of the Project, the other Party 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. The non-publishing Party may request in writing that the proposed publication or other discloser be delayed for up to thirty (30) additional days as necessary to protect proprietary information. The Parties will together make decisions on jointly authored publications. Authorship will be in accordance with academic and/or scholarly standards.
6. Receiving Party agrees to recognize the contribution of the Providing Party as the source of the Data in all written, visual, or oral public disclosures concerning Receiving Party’s research using the Data, as appropriate in accordance with scholarly standards and any specific format that has been indicated in Attachment 1.
7. Unless terminated earlier in accordance with this section or extended via a modification in accordance with Section 12, 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, Receiving Party shall follow the disposition instructions provided in Attachment 1, provided; however, that Receiving Party 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.
8. EXCEPT AS PROVIDED BELOW OR PROHIBITED BY LAW, ANY DATA DELIVERED PURSUANT TO THIS AGREEMENT IS UNDERSTOOD TO BE PROVIDED “AS IS.” PROVIDING PARTY 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 THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Notwithstanding, Providing Party, to the best of its knowledge and belief, has the right and authority to provide the Data to Receiving Party for use in the Project.
9. Each Receiving Party shall be liable for damages, losses, claims, and demands which may arise from its use, storage, disclosure, or disposal of the Data except to the extent (a) prohibited by law and/or (b) caused by the negligence, willful misconduct, or violation of applicable privacy or security laws and regulations by the Providing Party.
10. 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 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.
11. 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:
12. Attachment 1: Project Specific Information
13. Attachment 2: Data-specific Terms and Conditions
14. Attachment 3: Identification of Permitted Third Parties (if any)
15. Attachment 4: Additional Terms and Conditions

In the event of any conflict between the obligations set forth in the applicable Attachment 2 and this Agreement, the obligations set forth in Attachment 2 shall prevail.1. No modification or waiver of this Agreement shall be valid unless in writing and executed by duly authorized representatives of both Parties.
2. The undersigned Authorized Officials of the Parties 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.
 |

|  |  |
| --- | --- |
| By an Authorized Official of Party 1: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_ Signature DatePrinted Name: INSERT NAMETitle: INSERT TITLEContact Information for Formal Notices:Name: INSERT NAME Address: INSERT ADDRESSEmail: INSERT EMAILPhone: INSERT PHONE | By an Authorized Official of Party 2:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_ Signature DatePrinted Name: INSERT NAMETitle: INSERT TITLEContact Information for Formal Notices:Name: INSERT NAME Address: INSERT ADDRESSEmail: INSERT EMAILPhone: INSERT PHONE |

|  |
| --- |
| **Attachment 1**Reciprocal Data Transfer and Use AgreementLimited Data SetProject-Specific Information |

1. Description of Project:

INSERT DESCRIPTION OF PROJECT

[This section of this attachment should provide sufficient information such that each Party understands the project that the Parties will perform using the Data. Content of this section will be very similar to the Statement of Work used in other types of Agreements. Examples of information that should be provided include:

* Objective or purpose of the Parties’ work.
* A general description of the actions to be performed by each Party using the Data and possibly the anticipated results.
* Whether or not the Parties are permitted to link the Data with other data sets (if yes, be sure to include any special disposition requirements related to the linked data sets in Section 6 and 7 of this attachment).]

2. Description of Party 1 Data:

INSERT DESCRIPTION OF PARTY 1 DATA

[This section of this attachment should provide sufficient information such that each Party understands the information that will be transmitted by Party 1 under this Agreement. If Party 1 will not be sharing any Data under this Agreement, simply indicate “None” in this section and insert “None” in the Party 1 Data Type section on the face page. Examples of information that should be provided include:

* If the Party 1 Data is obtained from human subjects, a description of the population included in the Party 1 Data.
* If the Party 1 Data is from animal subjects, the species of animal the Party 1 Data was obtained using
* If not from human or animal subjects, a description of the focus of the Party 1 Data.
* The number of subjects and/or experiments included.
* Name of the study that the Party 1 Data was obtained under - If there is a particular study that needs to be acknowledged/cited as the source of the Party 1 Data, this information should be included here.]

3. Party 1 Disposition Requirements upon the termination of expiration of the Agreement:

INSERT DISPOSITION REQUIREMENTS

[This section of this attachment should provide sufficient information such that each Party understands the Receiving Party’s obligations with regards to the Party 1 Data upon the expiration or early termination of this Agreement. If the Receiving Party is permitted to link the Data with other data sets, be sure to include any special disposition requirements related to the linked data sets in this attachment.]

4. For Party 1, send Data INSERT METHOD OF TRANSMISSION to:

 Name: INSERT NAME

Address: INSERT ADDRESS

Email: INSERT EMAIL

Phone: INSERT PHONE

5. Description of Party 2 Data:

INSERT DESCRIPTION OF PARTY 2 DATA

[This section of this attachment should provide sufficient information such that each Party understands the information that will be transmitted by Party 2 under this Agreement. If Party 2 will not be sharing any Data under this Agreement, simply indicate “None” in this section and select “None” from the Party 2 Data Type drop-down menu on the face page. Examples of information that should be provided include:

* If the Party 2 Data is obtained from human subjects, a description of the population included in the Party 2 Data
* If the Party 2 Data is from animal subjects, the species of animal the Party 2 Data was obtained using
* If not from human or animal subjects, a description of the focus of the Party 2 Data
* The number of subjects and/or experiments included
* Name of the study that the Party 2 Data was obtained under - If there is a particular study that needs to be acknowledged/cited as the source of the Party 2 Data, this information should be included here.]

6. Party 2 Disposition Requirements upon the termination or expiration of the Agreement.

INSERT DISPOSITION REQUIREMENTS

[This section of this attachment should provide sufficient information such that each party understands the Receiving Party’s obligations with regards to the Party 2 Data upon the expiration or early termination of this Agreement. If the Receiving Party is permitted to link the Data with other data sets, be sure to include any special disposition requirements related to the linked data sets in this attachment.]

7. For Party 2, send Data INSERT METHOD OF TRANSMISSION to:

 Name: INSERT NAME

Address: INSERT ADDRESS

Email: INSERT EMAIL

Phone: INSERT PHONE

|  |
| --- |
| **Attachment 2**Data Transfer and Use AgreementLimited Data Set Data-specific Terms and Conditions |

**Additional Terms and Conditions:**

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.
2. Recipient shall not use or further disclose the Data other than as permitted by this Agreement or as otherwise required by law.
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.
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:
	1. Names;
	2. Postal address information, other than town or city, state, and zip code;
	3. Telephone numbers;
	4. Fax numbers;
	5. Electronic mail addresses;
	6. Social security numbers;
	7. Medical record numbers;
	8. Health plan beneficiary numbers;
	9. Account numbers;
	10. Certificate/license numbers;
	11. Vehicle identifiers and serial numbers, including license plate numbers;
	12. Device identifiers and serial numbers;
	13. Web Universal Resource Locators (URLs);
	14. Internet Protocol (IP) addresses;
	15. Biometric identifiers, including finger and voice prints; and
	16. Full face photographic 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.

1. 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.
2. Recipient will use appropriate safeguards to prevent use or disclosure that is not permitted by this Agreement.
3. 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.
4. 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.

|  |
| --- |
| **Attachment 3**One-Way Data Transfer and Use AgreementLimited Data SetIdentification of Permitted Third Parties (if any) |

For all purposes of this Agreement, the definition of “Third Party Personnel” checked below will pertain:

[ ]  “Third Party Personnel” means: None. No collaborators are permitted on the Project.

 -OR-

[ ]  “Third Party Personnel” means as set forth below and agreed upon between the Parties:

[Sample definition language for the drafter; delete if the first option is checked or after a final definition has been agreed between the Parties:

“Third Party Personnel” means: faculty, employees, fellows, or students of INSERT NAME OF THIRD PARTY INSTITUTION, an academic institution, which institution (i) has agreed to collaborate in the Project, (ii) has faculty, employees, fellows, or students who have a need to use or provide a service in respect of the Data in connection with its collaboration in the Project, and (iii) has been made aware of the terms of this Agreement and agreed to comply, and to cause it personnel to comply, with such terms.

An alternative option for (iii): “has executed an agreement that is substantially similar to this Agreement.”]

|  |
| --- |
| **Attachment 4**Data Transfer and Use AgreementLimited Data SetAdditional Terms and Conditions |

**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.

[This section should be completed if the research being conducted includes a grant or other contract. For example: Material Transfer Agreement, Sponsor Agreement, Confidentiality Agreement (e.g. NDA), MOU, etc. If no additional terms or conditions exist, None should be checked above.]