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| **ETSU/Ballad Collaborative Research**  **One-Way Data Transfer and Use Agreement (“Agreement”)**  Limited Data Set | |
| Provider:  INSERT ORGANIZATION NAME | Recipient:  INSERT ORGANIZATION NAME |
| Provider Scientist  Name: INSERT NAME  Email: INSERT EMAIL | Recipient Scientist  Name: INSERT NAME  Email: INSERT EMAIL |
| Agreement Term  Start Date: INSERT START DATE  End 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 |
| Attachment 2 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.] | |
| **Terms and Conditions**   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. 2. If applicable, reimbursement of any costs associated with the preparation, compilation, and transfer of the Data to the Recipient will be addressed in Attachment 1. 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 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”). 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. 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. 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. 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 research using the Data, as appropriate in accordance with scholarly standards and any specific format that has been indicated in Attachment 1. 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. 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 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. 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. 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 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. 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: 13. Attachment 1: Project Specific Information 14. Attachment 2: Data-specific Terms and Conditions 15. Attachment 3: Identification of Permitted Third Parties (if any) 16. Attachment 4: Additional Terms and Conditions 17. No modification or waiver of this Agreement shall be valid unless in writing and executed by duly authorized representatives of both parties. 18. 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. | |
| By an Authorized Official of Provider:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_  Signature Date  Printed Name: INSERT NAME  Title: INSERT TITLE  Contact Information for Formal Notices:  Name: INSERT NAME  Address: INSERT ADDRESS  Email: INSERT EMAIL  Phone: INSERT PHONE | By an Authorized Official of Recipient:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_  Signature Date  Printed Name: INSERT NAME  Title: INSERT TITLE  Contact Information for Formal Notices:  Name: INSERT NAME  Address: INSERT ADDRESS  Email: INSERT EMAIL  Phone: INSERT PHONE |

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| **Attachment 1**  One-Way Data Transfer and Use Agreement  Limited Data Set  Project-Specific Information |

1. Description of Data:

INSERT DESCRIPTION OF DATA

[This section of this attachment should provide sufficient information such that each party understands the information that will be transmitted under this Agreement. Examples of information that should be provided include:

* Whether the data is obtained from human subjects and, if so, a description of the population included in the data.
* If the data is from animal subjects, the species of animal the data was obtained using.
* If not from human or animal subjects, a description of the focus of the data.
* The number of subjects and/or experiments included
* Name of the study that the data was obtained under

If there is a particular study that needs to be acknowledged/cited as the source of the data, this information should be included here.]

2. 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 Recipient 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 Recipient’s work
* A general description of the actions to be performed by the Recipient using the Data and possibly the anticipated results
* Include whether or not the Recipient is 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 5 of this attachment).]

3. Provider Support and Data Transmission:

Provider shall transmit the Data to Recipient INSERT METHOD OF TRANSMISSION to:

Name: INSERT NAME

Address: INSERT ADDRESS

Email: INSERT EMAIL

Phone: INSERT PHONE

Upon execution of this Agreement, Provider shall send any specific instructions necessary to complete the transfer of the Data to the contact person listed above, if not already included below in this section of Attachment 1.

[This section of this attachment should also provide sufficient information such that each party understands the level of support the Provider will supply to the Recipient. Examples of information that may be appropriate to include in this section are:

* Format of Data
* Provision of Data dictionary
* Availability of Provider to assist Recipient in understanding the Data structure (e.g. variables, code lists, etc.)
* If/how Data will be revised and resent if errors are found by the Recipient
* Specific instructions necessary to complete the transfer of the Data, if available/appropriate, and any support supplied by the Provider for the transfer.]

4. Reimbursement of Costs:

None

As governed by a separate written agreement between the parties

Reimbursement Agreement Reference # (if required): [Insert if required.]

As set forth herein: [Insert if required.]

5. 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 Recipient’s obligations with regards to the Data upon the expiration or early termination of this Agreement. If the Recipient 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.]

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| **Attachment 2**  Data Transfer and Use Agreement  Limited 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.

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| **Attachment 3**  One-Way Data Transfer and Use Agreement  Limited Data Set  Identification 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.”]

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| **Attachment 4**  Data Transfer and Use Agreement  Limited Data Set  Additional 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.]