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| **ETSU/Ballad Collaborative Research**  **One-Way Data Transfer and Use Agreement (“Agreement”)**  Personally Identifiable Information – HIPAA | |
| 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:  Personally Identifiable Information – HIPAA  [This template includes language and attachments for use when the data being shared is Personally Identifiable Information governed by HIPAA. 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  Personally Identifiable Information – HIPAA  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  Personally Identifiable Information – HIPAA  Data-specific Terms and Conditions |

**Additional Terms and Conditions:**

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 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.

1. 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.
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 or authorizations, if any, as Provider has obtained from individuals who are the subjects of the Data.
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 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.
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 implement reasonable safeguards, sufficient to meet 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.
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.
8. 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.
9. 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.

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| **Attachment 3**  One-Way Data Transfer and Use Agreement  Personally Identifiable Information – HIPAA  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  Personally Identifiable Information – HIPAA  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, Business Associate Agreement, etc. If no additional terms or conditions exist, None should be checked above.]