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| **Institutional Review Board (IRB)** |  | **IRB Form 6.1**  HIPPA Data Use Agreement for  Research Purposes |

**Note:** To acquire a limited data set from a HIPAA covered entity, investigators must complete both the limited data set form as well as a data use agreement. The data use agreement specifies how the limited data set can be used and shared with others, and gives the covered entity the authority to terminate the investigator’s right to the data if the agreement is not followed. The data use agreement must be signed by the P.I. and a responsible representative of the information holder (“covered entity”).

This agreement is made by and between \_\_\_\_\_\_ *(NAME OF HOSPITAL/CLINIC WHO HOLDS THE HEALTH INFORMATION)* ("Covered Entity”) and \_\_\_\_\_\_\_*(NAME OF P.I.)* (“Data Recipient").

Both parties are committed to complying with the standards for privacy of individually identifiable health information (“Privacy Rule”) under HIPAA. This Agreement sets forth the terms and conditions under which Protected Health Information (PHI) that is provided by or received by the data recipient from or on behalf of the covered entity (PHI), will be handled between the data recipient and the covered entity and with third parties during the term of the agreement and after its termination.

The parties agree to the following terms:

1. **DEFINITIONS**
   1. Protected Health Information shall have the same meaning as the term “protected health information” in 45 C.F.R. §164.501, limited to the information created or received by data recipient from or on behalf of covered entity.
   2. Privacy Rule shall mean the standards for privacy of individually identifiable health information at 45 C.F.R. part 160 and part 164, subparts A and E.
   3. Limited Data Set shall have the same meaning as the term “limited data set” in 45 C.F.R. §164.514(e)(2).
   4. Secretary shall mean the secretary of the Department of Health and Human Services (DHSS) or his/her designee.
   5. Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in the Privacy Rule.
2. **PURPOSE**

Data recipient represents that s/he will use health information for RESEARCH purposes only.

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|  | Research (Protocol) Title: |  | |
|  | IRB Number: |  |  |

1. **OBLIGATIONS OF COVERED ENTITY**

Covered entity shall disclose to data recipient a limited data set of protected health information (PHI).

1. **OBLIGATIONS AND ACTIVITIES OF DATA RECIPIENT**
   1. Data recipient agrees to not use or disclose the limited data set other than as permitted or required by the agreement or as required by law.
   2. Data recipient agrees to use appropriate safeguards to prevent use or disclosure of the limited data set other than as provided for by this agreement.
   3. Data recipient agrees to report to covered entity any use or disclosure of the limited data set not provided for by this agreement of which it becomes aware.
   4. Data recipient agrees to ensure that any agent, including a subcontractor, to whom it provides the limited data set received from covered entity agrees to the same restrictions and conditions that apply through this agreement to data recipient with respect to such information.
   5. Data recipient agrees not to identify the information or contact the individuals
2. **WHO MAY RECEIVE LIMITED DATA SET**

Data recipient, and any of his/her agents, including a subcontractor, to whom they provide limited data set information received from covered entity, provided they agree to the restrictions and conditions that apply through this agreement with respect to such information.

1. **Permitted Uses and Disclosures by Data Recipient**
   1. Except as otherwise limited in this agreement, data recipient may use or disclose limited data set to perform research functions, activities, or servicesprovided that such use or disclosure would not violate the Privacy Rule if done by covered entity.
   2. With permission of the UNG Institutional Review Board, data recipient may de-identify any and all PHI received by data recipient under this agreement; provided, however, that the de-identification conforms to the requirements of the Privacy Rule. Such resulting de-identified information would not be subject to the terms of this agreement.
2. **PERMISSIBLE REQUESTS BY COVERED ENTITY**

Covered entity shall not request data recipient to use or disclose limited data set in any manner that would not be permissible under the Privacy Rule if done by covered entity.

1. **Term and TERMINATION**
   1. **Term**. The term of this agreement shall be effective upon execution, and shall be effective permanently, except as in section 8(b) below.
   2. **Termination for Cause**. Upon covered entity's knowledge of a material breach of this agreement by data recipient, covered entity shall either:
   3. Provide an opportunity for data recipient to cure the breach or end the violation OR terminate this agreement if data recipient does not cure the breach or end the violation within the time specified by covered entity; or
   4. Immediately terminate this agreement,if cure is not possible, and report the violation to the secretary.
   5. **Effect of Termination**

Data recipient shall extend the protections of this agreement to any limited data set information that it does not destroy or return to covered entity and limit further uses and disclosures of such limited data set for so long as data recipient and its agents and contractors retain limited data set information.

1. **MISCELLANEOUS**
   1. **Regulatory References**. A reference in this agreement to a section in the Privacy Rule means the section as in effect or as amended.
   2. **Amendment**. The parties agree to take such action as is necessary to amend this agreement from time to time as is necessary for either party or both parties to comply with the requirements of the Privacy Rule and the Health Insurance Portability and Accountability Act (HIPPA) of 1996, Pub. L. No. 104-191.
   3. **Survival**. The respective rights and obligations of data recipient under sections 4, 5, and 6 of this agreement shall survive the termination of this agreement.
   4. **Interpretation**. Any ambiguity in this agreement shall be resolved to permit covered entity to comply with the Privacy Rule.
   5. **Construction of Terms**. The terms of this agreement shall be construed in light of any applicable interpretation or guidance on HIPAA or the Privacy Rule issued by the Department of Health and Human Service or its Office of Civil Rights from time to time.
   6. **No Third Party Beneficiaries**. Nothing in this agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.

*By signing the agreement, both parties agree to the terms outlined above. The agreement goes into effect on \_\_\_\_\_\_\_\_\_\_\_ (specify date).*

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|  | **Data Recipient:** |  | **Covered Entity:** |  |
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|  | **Print Name:** |  | **Print Name:** |  |
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|  | **Print Title:** |  | **Print Title:** |  |
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|  | **Date:** |  | **Date:** |  |