Appendix H: Use of Protected Health Information (PHI)

This application form is based on the University of Minnesota IRB's *Appendix H* form and has been adapted with their permission.  
Version 1.1  
Updated September 2013

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| Principal Investigator: |  |
| Project Title: |  |

To use PHI in research you must have approval through one of the following methods:

1. An authorization signed by the research participant which meets HIPAA requirements;
2. An IRB waiver of the HIPAA authorization requirement;
3. An IRB alteration of the HIPAA authorization requirement; or
4. Use of a limited data set under a data use agreement.

Check below to indicate which method of approval you will to use:

*Note: An authorization is required for studies where you obtain a signed consent document from the subjects. The waiver or alteration options normally are only available for studies where there is no signed consent document and you meet the criteria on page 2.*

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|  | Research participants in this study will sign an Authorization to Use or Disclose Protected Health Information for Research Purposes. You may use HIPAA authorization form available on the IRB website, fill in the required information, and attach the authorization form to this application. |
|  | I wish to obtain an IRB waiver of the authorization requirement. *Complete parts 2 & 3 of this appendix.* |
|  | I wish to obtain an IRB alteration of the authorization requirement. *Complete parts 2& 3 of this appendix.* |
|  | I will access a limited data set by signing a data use agreement with the party that releases the PHI. A limited data set must have all the identifiers listed below removed from the data. It is the responsibility of the researcher and the party releasing the PHI to have in place and maintain a copy of a data use agreement which meets HIPAA requirements. .  The following identifiers for the individual and the individual’s relatives, employer or household members must be removed to create a limited data set:   |  |  | | --- | --- | | 1. Names 2. Postal address information other than town/city, state and zip 3. Telephone number 4. Fax number 5. Email address 6. Social security number 7. Medical record number 8. Health plan number | 1. Account numbers 2. Certificate or license numbers 3. Vehicle identification/serial numbers, including license plate numbers 4. Device identification/serial numbers 5. Universal resource locators (URLs) 6. Internet protocol addresses (IPs) 7. Biometric identifiers 8. Full face photographs and comparable images | |

Appendix H: Part 2  
Request for IRB Waiver or Alteration of HIPAA Authorization

*Do not complete this page if you are obtaining a HIPAA authorization from the study subjects.*

1. Check below to indicate which IRB action you are requesting:  
   *Note: Under Minnesota law, the waiver option is not available to researchers external to the party releasing the PHI. External researchers may request the alteration option for IRB approval to use a research authorization that meets Minnesota law requirements.*  
     
    Waiver of Authorization  
    Alteration of Authorization. *Include proposed altered authorization form.*
2. The use or disclosure of Protected Health Information (PHI) involves no more than a minimal risk to the privacy of individuals. Explain why. *Include a detailed list of the PHI to be collected and a list of the source(s) of the PHI.*

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* 1. Describe the plan to protect identifiers and indicate where PHI will be stored and who will have access:

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* 1. All identifiers collected during the study must be destroyed at the earliest opportunity consistent with the conduct of research.

Please describe when and how the identifiers (electronic, paper, audio/video, photography, other) will be destroyed; OR

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Alternatively, the identifiers collected during the study will not be destroyed because (explain below)

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* 1. By signing my initials below, I assure that the protected health information used in this study will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research which meets IRB and HIPAA requirements.

1. The research could not practicably be conducted without the alteration or waiver because (explain below):

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1. The research could not practicably be conducted without access to, and use of, the PHI because (explain below):

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Appendix H: Part 3  
Documentation of IRB Approval for Waiver or Alteration of Individual Authorization

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| Principal Investigator: |  |
| Project Title: |  |

Description of PHI that may be obtained under this waiver or alteration:   
(please copy your answer from Part 2 question #2)

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*Investigator section ends – Investigators can stop here.*

*IRB section begins*

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| IRB Use |
| **Waiver Approval**  **Alteration Approval**  Following the requirements of the Common Rule, including the typical review procedures at **21 CFR 56.108(b),** **45 CFR 46.108(b).**  **Full convened IRB review**  **Expedited review procedures** **21 CFR 56.110**, **45 CFR 46.110**  Signature of IRB officer\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of IRB action\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| Waiver and Alteration Criteria: | | |  | |
|  | A. The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on at least the presence of the following elements; | |  | |
|  |  | 1. An adequate plan to protect the identifiers from improper use and disclosure; |  |  |
|  |  | 2. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and |  |  |
|  |  | 3. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research where the use or disclosure of protected health information meets IRB and HIPAA requirements; |  |  |
|  | B. The research could not practicably be conducted without the alteration or waiver or alteration; and | |  | |
|  | C. The research could not practicably be conducted without access to and use of the protected health information. | |  | |