|  |  |  |  |
| --- | --- | --- | --- |
| HIPAA Waiver Request FormThe purpose of this form is to provide information to justify a waiver of HIPAA.

|  |  |
| --- | --- |
| Instructions: | Complete the required sections.Sections marked with an asterisk ( \* ) are required. Sections marked with a double asterisk ( \*\* ) are required if applicable. |

 | C:\Users\cbcholka\AppData\Local\Microsoft\Windows\INetCache\Content.Word\UNM_OfficeInstitutionalReviewBoard_Horizontal_RGB.PNG1805 Sigma Chi NE | Tel: (505) 277-2644 Website: irb.unm.edu | Email: IRBMainCampus@unm.edu |

|  |
| --- |
| Project Identification |
| *\* IRB reference number:* |  | *\* Project title:* |  |

|  |
| --- |
| Principal Investigator of Record |
| \* The Principal Investigator of record is: *(select one)* | [ ]  Principal Investigator | [ ]  Responsible Faculty |
| \* Name: |  | \* Phone: |  | \* Email: |  |
| Additional Contact Person |
| \*\* The contact person for this project is: *(select one)* | [ ]  Student Investigator | [ ]  Project Coordinator |
| \*\* Name: |  | \*\* Phone: |  | \*\* Email: |  |

|  |
| --- |
| Certification |
| \* The information listed in the waiver application is accurate and all research staff will comply with the HIPAA regulations and the waiver criteria. I assure that [Protected Health Information (PHI)](http://www.hhs.gov/hipaa/) obtained as part of this research will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law. If, at any time, I want to reuse this information for other purposes or disclose the information to other individuals or entity I will seek approval by the IRB. HIPAA regulation requires reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. Please note that researchers are also accountable for any PHI released under a waiver. |

|  |  |
| --- | --- |
| Principal Investigator/Responsible Faculty | Student Investigator |
|  |  |  |  |
| \* Signature | Date | \*\* Signature | Date |

|  |
| --- |
| HIPAA Waiver Justification |
| *\* The researcher is requesting:* | [ ]  Waiver of HIPAA for entire project | [ ]  Waiver of HIPAA for Recruitment ONLY |
| *\* Explain how the use or disclosure of Protected Health Information (PHI)\* involves no more than minimal risk to the privacy of individuals.* |  |
| *\* Provide a detailed list of the PHI to be collected and a list of the source(s) of the PHI.* |  |
| *\* Describe the plan to protect and store PHI.* |  |
| *\* List everyone who will have access to the PHI. (Note: researchers must list all of the entities that are able access to the project’s PHI such as Institutional Review Board, UNM Privacy Officer, sponsors, FDA, data safety monitoring boards and any others given authority by law).* |  |
| *Specify and justify the earliest opportunity (consistent with the research plan) that all PHI collected during the project will be destroyed. Or, justify why PHI will not be destroyed.* |  |
| *\* Describe the process to destroy PHI (address electronic, paper, audio, etc. as appropriate).* |  |
| *\* Explain why the research could not be practicably conducted without the waiver.* |  |
| *\* Explain why the research could not be practicably conducted without access to and use of the PHI.* |  |
| *\* Explain why PHI obtained for this research are the minimum information needed to meet the research objectives.* |  |

|  |
| --- |
| UNM IRB Determination |
| Upon review of the HIPAA waiver request, I authorize that the request meets all required criteria under CFR 164.512(i)(2) and a waiver of HIPAA is approved. |
|  |  |  |
| Name of IRB Member | Signature of IRB Member | Date |