|  |  |
| --- | --- |
| **VCU IRB**  **APPENDIX A: HIPAA FOR RESEARCH** | |
|  | |
| **Principal Investigator:** |  |
| **Email:** |  |
| **Research Coordinator:** |  |
| **Email:** |  |
| **P.O. Box #:** |  |
| **Study Title:** |  |
|  | |
| **SECTION A: GENERAL INFORMATION** | |
|  | |
| **1.** **Describe the health information that will be obtained or used in this research.** | |
|  | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **2**. **Indicate the source(s) of the health information. (check all that apply)**  VCUHS medical records  Non-VCUHS health care provider medical records  PHI held by a component of the VCU ACE (other than VCUHS)  Directly from the research participant (e.g., physical exams, diagnostic results, interviews and questionnaires)  Records open to the public  Other (please specify): | | | | | | |
|  | | | | | | |
| **3. Explain how the PHI collected or used in this research is the minimum necessary to accomplish the research.** | | | | | | |
|  | | | | | | |
|  | | | | | | |
| **4. Select all of the identifiers that will be used in this research.** | | | | | | |
| Names | | Social security numbers | IP addresses | | | |
| Dates (e.g., birth, admission, death) | | Medical record numbers | License numbers | | | |
| Phone numbers | | Health plan beneficiary numbers | Internet URLs | | | |
| Fax numbers | | Device identifiers & serial numbers | Vehicle ID & serial numbers | | | |
| Ages ≥ 89 | | Full-face photos or comparable | Biometric identifiers | | | |
| Geographic subdivisions smaller than state (e.g., city, county, zip) | | Account numbers (e.g., bank, invoice#, credit card #) | Other unique identifying #, code, or characteristic | | | |
| None of the above | | | | | | |
|  | | | | | | |
| **5. Select all pathways this research will employ or use to access PHI.** | | | | | | |
| De-identified data [FINISHED WITH THIS FORM AFTER THIS QUESTION]  All identifiers removed (safe harbor)  Statistical analysis verifying no possibility of re-identification [SUBMIT ATTESTATION FROM STATISTICIAN WITH THIS FORM]  Limited Data Set (may ONLY include city, state, zip code, dates, and ages) [COMPLETE DATA USE AGREEMENT]  Waiver of Authorization [COMPLETE SECTION B]  Partial Waiver of Authorization for Recruitment (allows access to PHI to contact potential participants who will sign consent and authorization upon enrollment) [COMPLETE SECTION C]  Signed Authorization from participants in a combined Informed Consent and Authorization form [FINISHED WITH THIS FORM]  Signed Authorization from participants in a separate Authorization form [FINISHED WITH THIS FORM] | | | | | | |
|  | | | | | | |
| **SECTION B: WAIVER OF AUTHORIZATION** | | | | | | |
|  | | | | | | |
| **1. Describe how the use of PHI in this study poses no greater than minimal risk to participants’ privacy.** | | | | | | |
|  | | | | | | |
| **2. When will identifiers be destroyed? (Identifiers must be destroyed at earliest opportunity)**  End of the study        years after the end of the study (enter # of years)  Other (please specify): | | | | | | |
|  | | | | | | |
| **3. Other than the PI and research personnel, who else will have access to the health information?** | | | | | | |
|  | | | | | | |
| **4. Explain why this research cannot practicably be conducted without the use of PHI.** | | | | | | |
|  | | | | | | |
| **5. Explain why this research cannot practicably be conducted without a waiver of authorization.** | | | | | | |
|  | | | | | | |
| **Assurances**  In applying for a waiver of authorization, I agree to the following:   1. The identifiers used for this research study will not be used for any other purpose or disclosed to any other person or entity (aside from members of the research team identified in the research application), except as required by law. 2. If at any time I want to reuse this information for other purposes or disclose the information to other individuals, I will seek approval from the IRB. 3. I will comply with VCU HIPAA policies and procedures and with the use and disclosure restrictions described above. 4. I assume responsibility for all uses and disclosures of the PHI by members of the study team. | | | | | | |
| **signature of principal investigator or designee:** |  | | | **date of signature:** |  | |
|  | | | | | | |
| **SECTION C: PARTIAL WAIVER OF AUTHORIZATION** | | | | | | |
|  | | | | | | |
| **1. Describe how the use of PHI for recruitment poses no greater than minimal risk to participants’ privacy.** | | | | | | |
|  | | | | | | |
| **2. When will identifiers be destroyed? (Identifiers must be destroyed at earliest opportunity)**  Following participant contact  Following participant enrollment  Upon reaching study accrual objectives  Other (please specify): | | | | | | |
|  | | | | | | |
| **3. Other than the PI and research personnel, who else will have access to the health information?** | | | | | | |
|  | | | | | | |
| **4. Explain why this recruitment cannot practicably be conducted without the use of PHI.** | | | | | | |
|  | | | | | | |
| **5. Explain why the recruitment cannot practicably be conducted without the partial waiver of authorization.** | | | | | | |
| **Assurances**  In applying for a partial waiver of authorization, I agree to the following:   1. The identifiers used for this research study will not be used for any other purpose or disclosed to any other person or entity (aside from members of the research team identified in the research application), except as required by law. 2. If at any time I want to reuse this information for other purposes or disclose the information to other individuals, I will seek approval from the IRB. 3. I will comply with VCU HIPAA policies and procedures and with the use and disclosure restrictions described above. 4. I assume responsibility for all uses and disclosures of the PHI by members of the study team. | | | | | | |
| **signature of principal investigator:** |  | | | **date of signature:** |  | |