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| **Section I: Instructions** | | | | | | | |
| **1.** Use this form to determine whether protected health information (PHI) being used or disclosed for research purposes constitutes a \*limited data set under the [HIPAA Privacy Rule](https://privacyruleandresearch.nih.gov/pr_08.asp), which requires a \*\*Data Use Agreement. | | | | | | | |
| *\*Limited Data Set* refers to PHI that excludes specific categories of direct identifiers and may be used or disclosed, for purposes of research, public health, or health care operations, without obtaining either an individual's Authorization or a waiver or an alteration of Authorization for its use and disclosure, with a data use agreement. | | | | | | | |
| *\*\*Data Use Agreement* is an agreement into which the covered entity enters with the intended recipient of a limited data set that establishes the ways in which the information may be used and how it will be protected. | | | | | | | |
| **2.** A Data Use Agreement is the means by which covered entities obtain satisfactory assurances that the recipient of a limited data set will use or disclose PHI in the data set only for specified purposes. Even if the person requesting a limited data set from a covered entity is an employee or otherwise a member of the covered entity's workforce, a written Data Use Agreement must be in place between the covered entity and the limited data set recipient. | | | | | | | |
| **Section II: General Information** | | | | | | | |
| **1. Principal Investigator Name:** | | | | | | | |
| **2. Project/Protocol Title:** | | | | | | | |
| **Section III: Limited Data Set** | | | | | | | |
| **1. Does the PHI being used or disclosed exclude all of the following 16 direct identifiers?** | | | | | | | |
|  | * Names | | * Street addresses | | * Telephone numbers | * Fax numbers |  |
|  | * Email addresses | | * Social Security numbers | | * Medical record numbers | * Account numbers |  |
|  | * Health plan beneficiary numbers | | * Certificate/license numbers | | * Device identifiers and serial numbers | * Web universal resource locators (URLs) |  |
|  | * Internet protocol (IP) address numbers | | * Vehicle identifiers and serial numbers, including license plate numbers | | * Biometric identifiers, including fingerprints and voiceprints | * Full-face photographic images and any comparable images |  |
| Yes | | | | | | | |
| No | | | | | | | |
| **2. Is the PHI being used or disclosed limited to no more than the following identifiers?** | | | | | | | |
|  | * Race | * Gender | | * Age, stated in hours, days, months or years | | |  |
|  | * State, county, city, town, 5-digit zip code, precinct and any other geographic subdivision | | | | | |  |
|  | * Elements of date: birth date; date of death; service dates; admission dates; and discharge dates | | | | | |  |
|  | * Other unique characteristics not already excluded (and not able to identify an individual directly) | | | | | |  |
| Yes | | | | | | | |
| No | | | | | | | |
| **Section IV: Final Determination** | | | | | | | |
| **1. If the responses to both questions in Section III are “Yes”, the PHI being used or disclosed for the research constitutes a limited data set necessitating a Data Use Agreement. If the responses to either question in Section III is “No”, the PHI being used or disclosed for the research is more than a limited data set necessitating compliance with the HIPAA Privacy Rule.** | | | | | | | |
| **a. The final determination for this research is (choose one):** | | | | | | | |
| Data Use Agreement Required **>** Complete and include a [Data Use Agreement](https://www.osfhealthcare.org/media/filer_public/5e/9b/5e9bb9c7-5569-4549-ac0b-4146722fe826/data_use_agreement_template.doc) in the OSF Research Application | | | | | | | |
| Data Use Agreement Not Required **>** Include either a request for IRB waiver of HIPAA Authorization or a HIPAA Authorization for IRB review in the OSF Research Application | | | | | | | |