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| State Health Plan Data Request |
| **Civil Money Penalties.** Office of Civil Rights may impose a penalty on a covered entity for a failure to comply with a requirement of the Privacy Rule. Penalties will vary significantly depending on factors such as the date of the violation, whether the covered entity knew or should have known of the failure to comply, or whether the covered entity’s failure to comply was due to willful neglect. Penalties may not exceed a calendar year cap for multiple violations of the same requirement.   |  |  |  | | --- | --- | --- | |  | **For violations occurring prior to 2/18/2009** | **For violations occurring on or after 2/18/2009** | | **Penalty Amount** | Up to $100  per violation | $100 to $50,000 or more  per violation | | **Calendar Year Cap** | $25,000 | $1,500,000 |   **Criminal Penalties.** A person who knowingly obtains or discloses individually identifiable health information in violation of the Privacy Rule may face a criminal penalty of up to $50,000 and up to one-year imprisonment. The criminal penalties increase to $100,000 and up to five years imprisonment if the wrongful conduct involves false pretenses, and to $250,000 and up to 10 years imprisonment if the wrongful conduct involves the intent to sell, transfer, or use identifiable health information for commercial advantage, personal gain or malicious harm. The Department of Justice is responsible for criminal prosecutions under the Privacy Rule. |
| Organization |
| 1. Name of Organization: 2. Research Affiliation: (Sheps, Lineberger, etc.): 3. Funding Source: 4. Primary Contact Name/Role/Phone/E-mail: 5. Alternate Contact Name/Role/Phone/E-mail: 6. HIPAA Compliance Contact Name/Phone/E-mail: 7. Date of Request: |
| Project Title |
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| Project Description |
| Describe the request for Data. Identify the intended use of the Data and outcomes. Attach any documentation that may assist in the understanding the project for which you are requesting the Data. |
| **Data Elements Requested** |
| Indicate with an “X” on a copy of Schedule A.2 Master Data Set Elements which data elements are being requested in the Limited Data Set or De-Identified Data Set for this project. |
| **Institutional Review Board (IRB) Status** |
| Attach (1) a letter documenting that this project does not require IRB approval; or (2) a statement by the investigator of IRB waiver of authorization and a letter from the IRB documenting that waiver of informed consent for research and waiver of HIPAA authorization has been issued. |
| **Organizational Data Use Agreement (DUA)** |
| Attach an executed DUA between the Organization and the Investigator, which includes the data dictionary for the data elements requested for the project. |
| **Project Benefit to State Health Plan and/or its Members** |
| Describe the project’s benefit to the State Health Plan and/or its Members. |
| **Project Duration** |
| List the requested duration that the Data will need to be used for the project. Include the anticipated start and end dates for the project. |
| Complete the Following Section ONLY if You Are Requesting PHI |
| Security Measures |
| 1. Describe why PHI is necessary for this project. 2. Explain how the minimum necessary rule has been applied. 3. Provide the names of any individuals and their roles associated with this project, who will have access to PHI, including those who will be creating the limited data set. (If necessary, please complete and attach an additional page.) 4. Will you be utilizing a subcontractor(s) for this project? If so, provide the name(s) of the subcontractor(s) and attach a copy of your Business Associate Agreement(s) (BAA) with the subcontractor(s). |
| Signature |
| Your signature below indicates your understanding of your responsibilities for safeguarding this Data. It also confirms your understanding that this Data cannot be shared with anyone without explicit approval of the Department of State Treasurer and North Carolina State Health Plan. In addition, by signing this document, you acknowledge that if you receive PHI as defined under HIPAA, you have the necessary and appropriate safeguards in place to protect such information, that anyone using the information has been properly trained in the use and protection of PHI, and that policies and procedures exist surrounding the creation, receipt, maintenance, and transmission of the PHI.  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| State Health Plan Use Only |
| Executed Data Use Agreement, including Business Associate Agreement, with Organization: \_\_\_\_  Request Reviewed and Approved by Information Governance Committee: \_\_\_\_ Date of Approval: \_\_\_\_\_\_  Cost to the Plan Evaluated and Estimated to be $\_\_\_\_\_\_.  IGC Chair Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_  HIPAA Privacy Officer Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_  Executive Director Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_ |