** IRB Administration Office**

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HIPAA Documents Review

|  |  |  |  |
| --- | --- | --- | --- |
| **Principal Investigator** |  | **IRB#** |  |
| **HIPAA Reviewer** |  | **Date** |  |

**HIPAA Documents Reviewer Recommendation**

|  |
| --- |
| **Accept**  **Not Accepted**  **Comments:** |
| **HIPAA Reviewer’s Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**HIPAA Summary Form**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section** | **Correct** | **Incorrect** | **N/A** | **Comments** |
| Section A: PI, Location, Documentation |  |  |  |  |
| Section B: Recruitment and Use of PHI |  |  |  |  |
| Section C: Disclosure of PHI |  |  |  |  |
| Section D: Waiver of Authorization |  |  |  |  |

**HIPAA Authorization & Informed Consent Documents**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section** | **Correct** | **Incorrect** | **N/A** | **Comments** |
| HIPAA Authorization |  |  |  |  |
| HIPAA Information in  Consent Documents |  |  |  |  |

**Is a Waiver of HIPAA Authorization requested?**  **Yes**  **No**  **Other:**      **Waiver of HIPAA Authorization**

*Complete only if the Principal Investigator requests a Waiver of HIPAA Authorization*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Principal Investigator** |  | **HIC#** |  | | |
| The research could not practicably be conducted without the waiver or alteration. | | | | True | False |
| The research could not practicably be conducted without access to and use of the PHI. | | | | True | False |
| There is an adequate plan to protect health information identifiers from improper use and disclosure. | | | | True | False |
| There is an adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so). | | | | True | False |
| There are adequate written assurances that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule. | | | | True | False |
| **Is a Waiver of HIPAA Authorization granted?**  **Yes**  **No**  **Other:** | | | | | |
| **Protocol-specific justification for a Waiver of HIPAA Authorization:** | | | | | |