**Jefferson-Rowan Determination Form**

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| --- | --- |
| **Study Title:** |  |
| **PI:** |  |
| **Site Investigator(s)**  |  |
| **Reviewing IRB:** |  |
| **Reviewing IRB’s IRB Study ID** |  |
| **Relying Institution:** |  |
| **Relying Institution’s IRB Study ID** |  |
| **Reviewing IRB** |
| 1. **Acceptance of Review**
 | [ ]  **OPTION 1** – **Rowan University has agreed to serve as IRB of Record**[ ]  **OPTION 2** – **Thomas Jefferson University has agreed to serve as IRB of Record** |
| 1. **HIPAA determinations and actions**
 | [ ]  **Not applicable** – **Ceded study does not fall under HIPAA Privacy Rule regulations**[ ]  **OPTION 1** – **Reviewing IRB will make certain HIPAA determinations and perform certain HIPAA actions required for Relying Institution to use/disclose PHI** The Reviewing IRB will make determinations as to what pathway under the HIPAA Privacy Rule (authorization / alteration or waiver of authorization / Limited Data Set) is applicable and required for the Relying Institution to use/disclose PHI for the identified study. * If an authorization is required, the Reviewing IRB will determine the form of the authorization (e.g., incorporated into a consent form vs. freestanding) in collaboration with the Relying Institution.
* If alteration or waiver of authorization is requested the Reviewing IRB will perform the alteration/waiver analysis and be responsible for granting waivers or alterations of authorization
* If the Limited Data Set pathway is applicable, the Reviewing IRB will confirm that the PHI constitute a Limited Data Set and that appropriate language be included in the Data Use Agreement.

[ ]  **OPTION 2** – **Relying Institution will make any local HIPAA determinations or perform any HIPAA actions**The Reviewing IRB will not make HIPAA determinations or perform any HIPAA actions on behalf of the relying institution. The Relying Institution will make determinations for themselves as to what pathway under the HIPAA Privacy Rule (authorization / alteration or waiver of authorization / Limited Data Set) is applicable and required for them to use/disclose PHI for the identified study. * If an authorization is required, the Relying IRB will determine the form of the authorization (e.g., incorporated into a consent form vs. freestanding) in collaboration with the Reviewing Institution.
* If alteration or waiver of authorization is requested the Relying IRB will perform the alteration/waiver analysis and be responsible for granting waivers or alterations of authorization
* If the Limited Data Set pathway is applicable, the Reviewing IRB will confirm that the PHI constitute a Limited Data Set and that appropriate language be included in the Data Use Agreement.
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**Jefferson-Rowan IRB Reliance Determination Form**

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Printed Name of Reviewing IRB Designee

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Signature of Reviewing IRB Designee Date

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Printed Name of Relying IRB Designee

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Signature of Relying IRB Designee Date