**Access to PHI Preparatory to Research**

For activities involved in preparing for research, covered entities may use or disclose protected health information (PHI) to a researcher without an individual’s Authorization, a waiver or an alteration of Authorization, or a data use agreement (DUA) if:

1. The use or disclosure is requested solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research,
2. The PHI will not be removed from the covered entity in the course of review\*\*, and
3. The PHI requested is necessary for the research

Preparatory to research activities include, but are not limited to, the following:

* Determination of study feasibility (available number and eligibility of potential subjects) and aid study recruitment;
* Development of research questions;
* Development of eligibility criteria (inclusion/exclusion); or
* Determination of eligibility for individual potential subjects.

\*\*A covered entity may permit a researcher who works for that covered entity to use PHI for purposes preparatory to research. It may also permit a researcher who is not a workforce member to review PHI within that covered entity for purposes preparatory to research. However, this provision does not permit the researcher to remove PHI from the covered entity’s site.

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| Project Title: |       |
| Principal Investigator: |       | Institution |       |
| Address/City/State/Zip: |       |
| Email address: |       | Phone: |       |
|  |
| **Complete the following:** |
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| Identify research staff needing access to the PHI: |
|  |       |       |
|  |       |       |
|  |       |       |
| Describe why access to PHI is needed: |
|       |
|  |
| Time frame needed to access PHI: | From:       | To:       |
|  |
| Describe the PHI elements needed for this activity: |
|       |
|  |
| Describe how information will be protected from improper use or disclosure: |
|       |
|  |
| The research could not practicably be conducted without access to and use of the PHI  |
| because: |
|       |

As the principal investigator for this research study, I certify that:

* The use and/or disclosure of protected health information (PHI) is solely to prepare a research protocol for grant preparation or IRB review, or for those preparatory to research activities described at the top of this form;
* No PHI will be removed from the covered entity during the course of the review;
* The PHI that is being used is the minimum necessary for research preparation purposes.

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Signature Date