# Self-Certification of HIPAA Compliance for Review Preparatory to Research

HIPAA Privacy Rule imposes restrictions on the use of protected health information (PHI) in activities preparatory to research.

These data elements are each considered PHI:

* + Names
  + Account #s
  + Geographic info. (city, state, and zip)
  + Certificate/License #s
  + VIN and Serial #s, license plate #s
  + Elements of Dates. (except years)
  + Device identifiers,
  + Telephone #s
  + Serial #s
  + Fax #s
  + Web URLs
  + E-mail address
  + IP address #s
  + Social Security #s
  + Biometric identifiers (finger prints)
  + Medical Record #s
  + Prescription #s
  + Full face photo images
  + Health Plan Beneficiary #s
  + Unique identifying #s

## Submission Instructions

Self-certification forms should be kept in your study binder. You should not submit this study to the IRB; call the IRB if you have questions regarding how you are using, storing or sending out PHI. You should not submit this study to the Conflict of Interest Review Committee.

## Administrative Information

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Study# |  | | Date of this certification |  | | |
| Study Title |  | | | | | |
| Department |  | | Division |  | | |
| Role\* | Name | | Email | | Phone | Fax |
| Principal Investigator |  | |  | |  |  |
| Contact Person |  | |  | |  |  |
| Co-Investigators |  | |  | |  |  |
|  |  | |  | |  |  |
| \* PI and Contact Person are required; list all other study personnel as well, one line per person. Principal Investigators and Co-Investigators must be NYU SoM faculty. | | | | | | |
| All personnel listed above have completed the CITI Tutorial  <http://www.citiprogram.org> | | Yes  No | | | | |

## Acceptable Use of PHI for Review Preparatory to Research

|  |  |
| --- | --- |
| PI is accessing PHI exclusively for  check all that apply | the development of research questions  the determination of study feasibility (in terms of the available number and eligibility of potential study participants)  the development of eligibility (inclusion and exclusion) criteria  the determination of eligibility for study participation of individual potential subjects  Note: if you are using PHI for any other purpose, your study is probably not exclusively review preparatory to research. In this case, you must contact the IRB for submission instructions. |
| PI attests that  check all that apply | The use or disclosure is requested solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research  The PHI will not be removed from the covered entity in the course of review  The PHI for which use or access is requested is necessary for the research  The PHI will be removed from the data collected from the retrospective chart review before giving it to the sponsor to prepare to conduct research  Note: if you did not check off all of the four boxes above, your study is probably not exclusively review preparatory to research. In this case, you must contact the IRB for submission instructions. |

## PI’s Signature

|  |  |
| --- | --- |
| Date |  |
| Print Name |  |
| Signature | I ATTEST THAT THE INFORMATION CONTAINED HEREIN IS A TRUE AND ACCURATE REPRESENTATION OF MY STUDY |