



To: Aspire IRB

From:

Date:

Re: Required Information for Phone Screening or Collection of Protected Health Information (PHI)

Protocol No.:

Name of PI and Site:

An IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects. This protection also extends to the protection of their privacy and confidentiality. In fulfilling these responsibilities, the IRB should review the methods and materials that investigators propose to use to recruit subjects. [21 CFR 56.107(a) and 56.111]

Please provide responses to the following questions:

1. What happens to the information if the individual who is contacted ends the interview or simply hangs up?
2. Will information be recorded or disclosed before the signing of a consent document or HIPAA authorization?
3. Are names of non-eligibles maintained in case they would qualify for another study?
4. Is permission asked to retain this information in the event they may qualify for another study?

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619.469.4108 (fax)

5. How is this information stored (computer, paper records)? How is it protected? Who has access?
6. Who will be obtaining the information (marketing company, staff members)?
7. Has this person (or persons) been trained on the requirement of subject confidentiality?
8. How long do you retain this information?
9. How is it destroyed?
10. Is your site a covered entity?*

*If your site is a covered entity, please also complete and submit a Request for Partial Waiver of Authorization form. This Partial Waiver of Authorization must be granted before your site is permitted to conduct phone screening and/or collect PHI.

The Privacy Rule applies only to covered entities. Covered entities are defined in the HIPAA rules as (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards. Generally, these transactions concern billing and payment for services or insurance coverage. For example, hospitals, academic medical centers, physicians, and other health care providers who electronically transmit claims transaction information directly or through an intermediary to a health plan are covered entities. Covered entities can be institutions, organizations, or persons. [45 CFR 160.103]

For further assistance in determining whether or not your site is a covered entity, please visit: <http://www.cms.hhs.gov/HIPAAGenInfo/Downloads/CoveredEntitycharts.pdf>

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