

GUIDANCE ON HIPAA AND IRB ISSUES FOR HUD OHHLHC GRANTEES

Note: The situations below are presented as examples only. Actual programs may differ in ways that make these examples not applicable to their particular programs. Grantees should consult their IRBs and their counsel for guidance.

1. Do “coalitions” have to comply with the Privacy Rule? In other words, are “coalitions” covered entities?

Coalitions, such as those funded by HUD for in-home asthma and lead remediation, are generally not “covered entities” under the HIPAA Privacy Rule. This is because covered entities include certain health care organizations (e.g., a hospital that bills for services electronically and health plans). Generally, coalitions funded by HUD are groups of organizations that band together to achieve a common goal and are not health care providers or health plans. As such, unless the coalition itself functioned as a health plan or health care provider that electronically transmits health information for billing or administrative purposes, it would not have to comply with the Privacy Rule because it is not a covered entity. However, if there is any doubt about whether your organization is a “covered entity,” you should consult the covered entity decision tool at www.hhs.gov/ocr/hipaa/.

2. An Asthma Coalition was funded by HUD to conduct in-home asthma remediations and community-based education and plans to publish its results. HUD considers this type of activity research, as it is a demonstration program designed to yield generalizable knowledge and publishable results. Does the Coalition need to seek IRB approval? Does HIPAA apply to the Coalition and the health information they collect?

Because the Coalition is performing HUD-funded research that involves interaction with human subjects (as defined by the Common Rule), IRB review and approval is needed. This project generally would not be considered exempt research because, for example, the research does involve existing data or records and subjects are probably identifiable. Before the research begins, an IRB will need to review and approve the project, as well as any informed consent document. If the Coalition does not have its own IRB, it may use the review services of a private or independent IRB, or perhaps the IRB of one of its collaborators.

HIPAA would probably not apply to the Coalition because it is not likely to meet the definition of a covered entity (e.g., a health plan or a health care provider that electronically performs billing or administrative functions). Therefore, the Privacy Rule would not apply to the Coalition’s collection of health information.

3 An Asthma Coalition was funded by HUD to implement a model program in 150 units. A second goal is capacity building, developing resources to continue their work after HUD funding is completed. They will collect data to demonstrate program effectiveness, performing an evaluation for internal reporting to HUD. Does this Coalition require IRB approval? Does HIPAA apply to the health information collected by the Coalition?

It is unlikely that IRB review and approval is required as long as the implementation effort and other objectives do not meet the definition of research (i.e., the study is not designed to develop or contribute to generalizable knowledge). Likewise, HIPAA is not likely to apply because the Asthma Coalition is probably not a covered entity.

4. A community health center is funded by HUD to conduct a multi-site study involving the Home City Asthma Coalition as a co-Principal Investigator. The community health center will invite asthma patients to participate in a clinical trial in which the Asthma Coalition will visit patients' homes to demonstrate proper cleaning techniques. Which sites need IRB approval and does HIPAA apply to either site?

IRB review and approval is needed for this activity because it is HUD-funded, human subjects research that is not likely to be exempt from the Common Rule. Both sites, the community health center and the Home City Asthma Coalition, need to comply with the Common Rule because both sites receive HUD funding (even if indirectly as a co-Principal Investigator) and both are conducting human subjects research.

The community health center is probably the only covered entity in this scenario (unless the Asthma Coalition functions as a covered health care provider, for example). Therefore, the community health center will need to obtain the patient's authorization for the research (unless an IRB has waived either or both requirements), in addition to any informed consent required by the Common Rule. On the other hand, even though the Asthma Coalition collects individually identifiable health information from the community health center, and perhaps from the patients they visit, the Asthma Coalition is not a covered entity under HIPAA because it probably is not a health plan, health care clearinghouse, or a covered health care provider.

5. A community health center obtains the patient's authorization to release the patients' name and address to the cleaning firm as part of their collaborative research project to reduce incidence of asthma attacks. Is a business associate agreement between the covered health center and the cleaning firm necessary for this research purpose?

No. Disclosures from a covered entity for research purposes do not require a business associate contract, even in those instances where the covered entity has hired an organization or individual to perform research on the covered entity's own behalf.

However, other provisions of the HIPAA Privacy Rule would apply (e.g., obtaining authorization for disclosing the protected health information).

6. A City Housing Agency receives HUD funding to perform lead hazard control remediation. The Agency receives limited identifiable information (e.g., names and addresses) from the City Health Department to remediate lead hazards in vacant and populated buildings. Does this activity require IRB review and approval? Does HIPAA apply?

No, IRB review or approval is not needed for this activity, because this type of activity is not research. As such, neither the City Housing Agency nor the City Health Department needs to follow the Common Rule for this activity. HIPAA, however, may apply to the City Health Department if it is a covered health care provider. Although the HIPAA Privacy Rule may apply to the Health Department's disclosure of names and addresses, such disclosures could be made for public health purposes or to avert a threat to health or safety. In addition, State or other laws may require such a disclosure – in which case the HIPAA Privacy Rule would permit the disclosure. The HIPAA Privacy Rule would probably not apply to the City Housing Agency because it is  likely to be a covered entity.

7. When a state public health department applies for HUD funding to support a large-scale lead remediation project in populated buildings, does the health department need to comply with the Common Rule or the HIPAA Privacy Rule?

If the HUD-funded project is not considered research, the Common Rule does not apply; therefore, IRB review is not required. However, the health department may be a covered entity. If this were the case, it would need to protect names, addresses, and other protected health information of individuals. For example, the health department would need to ensure that disclosures of such information are permitted by the HIPAA Privacy Rule (e.g., disclosures for public health purposes, to avert a serious health threat, or as required by law).

8. May covered entities send to HUD and local public health departments addresses requiring lead remediation and dates of blood lead level testing?

Yes, such disclosures may be made to a public health authority (e.g., HUD or a local public health department) for a public health purpose. For example, the HIPAA Privacy Rule permits covered entities to disclose to public health departments that dates of blood lead level testing and addresses requiring lead remediation for public health. In addition, the HIPAA Privacy Rule permits such a disclosure if such is required by State or federal laws. Other provisions of the HIPAA Privacy Rule may also permit this disclosure if, for example, the disclosure is made to avert a serious threat to an individual's health or safety.