

RESEARCH

[45 CFR 164.501, 164.508, 164.512(i)]
[See also 45 CFR 164.514(e), 164.528, 164.532]

Background

The HIPAA Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. Research is defined in the Privacy Rule as, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” See 45 CFR 164.501. A covered entity may always use or disclose for research purposes health information which has been de-identified (in accordance with 45 CFR 164.502(d), and 164.514(a)-(c) of the Rule) without regard to the provisions below.

The Privacy Rule also defines the means by which individuals will be informed of uses and disclosures of their medical information for research purposes, and their rights to access information about them held by covered entities. Where research is concerned, the Privacy Rule protects the privacy of individually identifiable health information, while at the same time ensuring that researchers continue to have access to medical information necessary to conduct vital research. Currently, most research involving human subjects operates under the Common Rule (45 CFR Part 46, Subpart A) and/or the Food and Drug Administration’s (FDA) human subject protection regulations (21 CFR Parts 50 and 56), which have some provisions that are similar to, but separate from, the Privacy Rule’s provisions for research. These human subject protection regulations, which apply to most Federally-funded and to some privately funded research, include protections to help ensure the privacy of subjects and the confidentiality of information. The Privacy Rule builds upon these existing Federal protections. More importantly, the Privacy Rule creates equal standards of privacy protection for research governed by the existing Federal human subject regulations and research that is not.

How the Rule Works

In the course of conducting research, researchers may obtain, create, use, and/or disclose individually identifiable health information. Under the Privacy Rule, covered entities are permitted to use and disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances set forth in the Privacy Rule.

Research Use/Disclosure Without Authorization. To use or disclose protected health information without authorization by the research participant, a covered entity must obtain one of the following:

- Documented Institutional Review Board (IRB) or Privacy Board Approval. Documentation that an alteration or waiver of research participants' authorization for use/disclosure of information about them for research purposes has been approved by an IRB or a Privacy Board. See 45 CFR 164.512(i)(1)(i). This provision of the Privacy Rule might be used, for example, to conduct records research, when researchers are unable to use de-identified information, and the research could not practicably be conducted if research participants' authorization were required.

A covered entity may use or disclose protected health information for research purposes pursuant to a waiver of authorization by an IRB or Privacy Board, provided it has obtained documentation of *all* of the following:

- ▶ Identification of the IRB or Privacy Board and the date on which the alteration or waiver of authorization was approved;
- ▶ A statement that the IRB or Privacy Board has determined that the alteration or waiver of authorization, in whole or in part, satisfies the three criteria in the Rule;
- ▶ A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or Privacy Board;
- ▶ A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures; and
- ▶ The signature of the chair or other member, as designated by the chair, of the IRB or the Privacy Board, as applicable.

The following three criteria must be satisfied for an IRB or Privacy Board to approve a waiver of authorization under the Privacy Rule:

- ▶ The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
 - an adequate plan to protect the identifiers from improper use and disclosure;
 - an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
 - adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project,

- or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
- ▶ The research could not practicably be conducted without the waiver or alteration; and
 - ▶ The research could not practicably be conducted without access to and use of the protected health information.
- Preparatory to Research. Representations from the researcher, either in writing or orally, that the use or disclosure of the protected health information is solely to prepare a research protocol or for similar purposes preparatory to research, that the researcher will not remove any protected health information from the covered entity, *and* representation that protected health information for which access is sought is necessary for the research purpose. See 45 CFR 164.512(i)(1)(ii). This provision might be used, for example, to design a research study or to assess the feasibility of conducting a study.
 - Research on Protected Health Information of Decedents. Representations from the researcher, either in writing or orally, that the use or disclosure being sought is solely for research on the protected health information of decedents, that the protected health information being sought is necessary for the research, *and*, at the request of the covered entity, documentation of the death of the individuals about whom information is being sought. See 45 CFR 164.512(i)(1)(iii).
 - Limited Data Sets with a Data Use Agreement. A data use agreement entered into by both the covered entity and the researcher, pursuant to which the covered entity may disclose a limited data set to the researcher for research, public health, or health care operations. See 45 CFR 164.514(e). A limited data set excludes specified direct identifiers of the individual or of relatives, employers, or household members of the individual. The data use agreement must:
 - ▶ Establish the permitted uses and disclosures of the limited data set by the recipient, consistent with the purposes of the research, and which may not include any use or disclosure that would violate the Rule if done by the covered entity;
 - ▶ Limit who can use or receive the data; and
 - ▶ Require the recipient to agree to the following:
 - Not to use or disclose the information other than as permitted by the data use agreement or as otherwise required by law;
 - Use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the data use agreement;
 - Report to the covered entity any use or disclosure of the

- information not provided for by the data use agreement of which the recipient becomes aware;
- Ensure that any agents, including a subcontractor, to whom the recipient provides the limited data set agrees to the same restrictions and conditions that apply to the recipient with respect to the limited data set; and
 - Not to identify the information or contact the individual.

Research Use/Disclosure With Individual Authorization. The Privacy Rule also permits covered entities to use or disclose protected health information for research purposes when a research participant authorizes the use or disclosure of information about him or herself. Today, for example, a research participant's authorization will typically be sought for most clinical trials and some records research. In this case, documentation of IRB or Privacy Board approval of a waiver of authorization is not required for the use or disclosure of protected health information.

To use or disclose protected health information with authorization by the research participant, the covered entity must obtain an authorization that satisfies the requirements of 45 CFR 164.508. The Privacy Rule has a general set of authorization requirements that apply to all uses and disclosures, including those for research purposes. However, several special provisions apply to research authorizations:

- Unlike other authorizations, an authorization for a research purpose may state that the authorization does not expire, that there is no expiration date or event, or that the authorization continues until the "end of the research study;" and
- An authorization for the use or disclosure of protected health information for research may be combined with a consent to participate in the research, or with any other legal permission related to the research study.

Accounting for Research Disclosures. In general, the Privacy Rule gives individuals the right to receive an accounting of certain disclosures of protected health information made by a covered entity. See 45 CFR 164.528. This accounting must include disclosures of protected health information that occurred during the six years prior to the individual's request for an accounting, or since the applicable compliance date (whichever is sooner), and must include specified information regarding each disclosure. A more general accounting is permitted for subsequent multiple disclosures to the same person or entity for a single purpose. See 45 CFR 164.528(b)(3). Among the types of disclosures that are exempt from this accounting requirement are:

- Research disclosures made pursuant to an individual's authorization;

- Disclosures of the limited data set to researchers with a data use agreement under 45 CFR 164.514(e).

In addition, for disclosures of protected health information for research purposes without the individual's authorization pursuant to 45 CFR 164.512(i), and that involve at least 50 records, the Privacy Rule allows for a simplified accounting of such disclosures by covered entities. Under this simplified accounting provision, covered entities may provide individuals with a list of all protocols for which the patient's protected health information may have been disclosed under 45 CFR 164.512(i), as well as the researcher's name and contact information. Other requirements related to this simplified accounting provision are found in 45 CFR 164.528(b)(4).

Transition Provisions. Under the Privacy Rule, a covered entity may use and disclose protected health information that was created or received for research, either before or after the compliance date, if the covered entity obtained any one of the following prior to the compliance date:

- An authorization or other express legal permission from an individual to use or disclose protected health information for the research;
- The informed consent of the individual to participate in the research; or
- A waiver of informed consent by an IRB in accordance with the Common Rule or an exception under FDA's human subject protection regulations at 21 CFR 50.24.

However, if a waiver of informed consent was obtained prior to the compliance date, but informed consent is subsequently sought after the compliance date, the covered entity must obtain the individual's authorization as required at 45 CFR 164.508. For example, if there was a temporary waiver of informed consent for emergency research under the FDA's human subject protection regulations, and informed consent was later sought after the compliance date, individual authorization would be required before the covered entity could use or disclose protected health information for the research after the waiver of informed consent was no longer valid.

The Privacy Rule allows covered entities to rely on such express legal permission, informed consent, or IRB-approved waiver of informed consent, which they create or receive before the applicable compliance date, to use and disclose protected health information for specific research studies, as well as for future unspecified research that may be included in such permission.

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Frequently Asked Questions

Q: Will the HIPAA Privacy Rule hinder medical research by making doctors and others less willing and/or able to share with researchers information about individual patients?

A. We do not believe that the Privacy Rule will hinder medical research. Indeed, patients and health plan members should be more willing to authorize disclosures of their information for research and to participate in research when they know their information is protected. For example, in genetic studies conducted at the National Institutes of Health, nearly 32 percent of eligible people offered a test for breast cancer risk declined to take it. The overwhelming majority of those who refuse cite concerns about health insurance discrimination and loss of privacy as the reason. The Privacy Rule both permits important research and, at the same time, encourages patients to participate in research by providing much needed assurances about the privacy of their health information.

The Privacy Rule will require some covered health care providers and health plans to change their current practices related to documenting research uses and disclosures. It is possible that some covered health care providers and health plans may conclude that the Rule's requirements for research uses and disclosures are too burdensome and will choose to limit researchers' access to protected health information. We believe few providers will take this route, however, because the Common Rule includes similar, and more rigorous requirements, that have not impaired the willingness of researchers to undertake Federally-funded research. For example, unlike the Privacy Rule, the Common Rule requires an Institutional Review Board (IRB) review for all research proposals under its purview, even if informed consent is to be sought. The Privacy Rule requires documentation of IRB or Privacy Board approval only if patient authorization for the use or disclosure of protected health information for research purposes is to be altered or waived. See the fact sheet and frequently asked questions about the research provisions on this web site for more information about the Common Rule and Institutional Review and Privacy Boards.

Q: Are some of the criteria so subjective that inconsistent determinations may be made by Institutional Review Boards (IRB) and Privacy Boards reviewing similar or identical research projects?

A: Under the HIPAA Privacy Rule, IRBs and Privacy Boards need to use their judgment as to whether the waiver criteria have been satisfied. Several of the waiver criteria are

closely modeled on the Common Rule's criteria for the waiver of informed consent and for the approval of a research study. Thus, it is anticipated that IRBs already have experience in making the necessarily subjective assessments of risks. While IRBs or Privacy Boards may reach different determinations, the assessment of the waiver criteria through this deliberative process is a crucial element in the current system of safeguarding research participants' privacy. The entire system of local IRBs is, in fact, predicated on a deliberative process that permits local IRB autonomy. The Privacy Rule builds upon this principle; it does not change it. Nonetheless, the Department will consider issuing guidance as necessary and appropriate to address concerns that may arise during implementation of these provisions. See the fact sheet and frequently asked questions about the research provisions on this web site for more information about the Common Rule and Institutional Review and Privacy Boards.

Q: Does the HIPAA Privacy Rule prohibit researchers from conditioning participation in a clinical trial on an authorization to use/disclose existing protected health information?

A: No. The Privacy Rule does not address conditions for enrollment in a research study. Therefore, the Privacy Rule in no way prohibits researchers from conditioning enrollment in a research study on the execution of an authorization for the use of pre-existing health information.

Q: Does the HIPAA Privacy Rule permit the creation of a database for research purposes through an Institutional Review Board (IRB) or Privacy Board waiver of individual authorization?

A: Yes. A covered entity may use or disclose protected health information without individuals' authorizations for the creation of a research database, provided the covered entity obtains documentation that an IRB or Privacy Board has determined that the specified waiver criteria were satisfied. Protected health information maintained by a covered entity in such a research database could be used or disclosed for future research studies as permitted by the Privacy Rule – that is, for future studies in which individual authorization has been obtained or where the Rule would permit research without an authorization, such as pursuant to an IRB or Privacy Board waiver. See the fact sheet and frequently asked questions about the research provisions on this web site for more information about Institutional Review and Privacy Boards.

Q: Can researchers continue to access existing databanks or repositories that are maintained by covered entities, even if those databases were created prior to the compliance date without patient permission or without a waiver of informed consent by an Institutional Review Board (IRB)?

A: Yes. Under the HIPAA Privacy Rule, covered entities may use or disclose protected health information from existing databases or repositories for research purposes either with individual authorization as required at 45 CFR 164.508, or with a waiver of individual authorization as permitted at 45 CFR 164.512(i). See the fact sheet and frequently asked questions about the research provisions on this web site for more information about Institutional Review Boards.

Q: How does the Rule help Institutional Review Boards (IRB) handle the additional responsibilities imposed by the HIPAA Privacy Rule?

A: Recognizing that some institutions may not have IRBs, or that some IRBs may not have the expertise needed to review research that requires consideration of risks to privacy, the Privacy Rule permits the covered entity to accept documentation of waiver of authorization from an alternative body called a Privacy Board—which could have fewer members, and members with different expertise than IRBs. See the fact sheet and frequently asked questions about the research provisions on this web site for more information about Institutional Review and Privacy Boards.

In addition, the Rule allows an IRB to use expedited review procedures as permitted by the Common Rule to review and approve requests for waiver of authorizations. Similarly, the Rule permits Privacy Boards to use an expedited review process when the research involves no more than a minimal privacy risk to the individuals. An expedited review process permits covered entities to accept documentation of waiver of authorization when only one or more members of the IRB or Privacy Board have conducted the review. See the fact sheet and frequently asked questions about the research provisions on this web site for more information about the Common Rule.

Q: By establishing new waiver criteria and authorization requirements, hasn't the HIPAA Privacy Rule, in effect, modified the Common Rule?

A: No. Where both the Privacy Rule and the Common Rule apply, both regulations must be followed. The Privacy Rule regulates only the content and conditions of the documentation that covered entities must obtain before using or disclosing protected health information for research purposes. See the fact sheet and frequently asked questions about the research provisions on this web site for more information about the Common Rule.

Q: Is documentation of Institutional Review Board (IRB) and Privacy Board approval required by the HIPAA Privacy Rule before a covered entity would be permitted to disclose protected health information for research purposes without an individual's authorization?

A: No. The HIPAA Privacy Rule requires documentation of waiver approval by either an IRB *or* a Privacy Board, not both. See the fact sheet and frequently asked questions about the research provisions on this web site for more information about Institutional Review and Privacy Boards.

Q: **Does the HIPAA Privacy Rule require a covered entity to create an Institutional Review Board (IRB) or Privacy Board before using or disclosing protected health information for research?**

A: No. The IRB or Privacy Board could be created by the covered entity or the recipient researcher, or it could be an independent board. See the fact sheet and frequently asked questions about the research provisions on this web site for more information about Institutional Review and Privacy Boards.

Q: **What does the HIPAA Privacy Rule say about a research participant's right of access to research records or results?**

A: With few exceptions, the Privacy Rule gives patients the right to inspect and obtain a copy of health information about themselves that is maintained by a covered entity or its business associate in a "designated record set." A designated record set is basically a group of records which a covered entity uses to make decisions about individuals, and includes a health care provider's medical records and billing records, and a health plan's enrollment, payment, claims adjudication, and case or medical management record systems. While it may be unlikely that a researcher would be maintaining a designated record set, any research records or results that are actually maintained by the covered entity as part of a designated record set would be accessible to research participants unless one of the Privacy Rule's permitted exceptions applies.

One of the permitted exceptions applies to protected health information created or obtained by a covered health care provider/researcher for a clinical trial. The Privacy Rule permits the individual's access rights in these cases to be suspended *while the clinical trial is in progress*, provided the research participant agreed to this denial of access when consenting to participate in the clinical trial. In addition, the health care provider/researcher must inform the research participant that the right to access protected health information will be reinstated at the conclusion of the clinical trial.

Q: **Are the HIPAA Privacy Rule's requirements regarding patient access in harmony with the Clinical Laboratory Improvements Amendments of 1988 (CLIA)?**

A: Yes. The Privacy Rule does not require clinical laboratories that are also covered health care providers to provide an individual access to information if CLIA prohibits them from

doing so. CLIA permits clinical laboratories to provide clinical laboratory test records and reports only to “authorized persons,” as defined primarily by State law. The individual who is the subject of the information is not always included as an authorized person. Therefore, the Privacy Rule includes an exception to individuals’ general right to access protected health information about themselves if providing an individual such access would be in conflict with CLIA.

In addition, for certain research laboratories that are exempt from the CLIA regulations, the Privacy Rule does not require such research laboratories, if they are also a covered health care provider, to provide individuals with access to protected health information because doing so may result in the research laboratory losing its CLIA exemption.

Q: Do the HIPAA Privacy Rule’s requirements for authorization and the Common Rule’s requirements for informed consent differ?

A: Yes. Under the Privacy Rule, a patient’s authorization is for the use and disclosure of protected health information for research purposes. In contrast, an individual’s informed consent, as required by the Common Rule and the Food and Drug Administration’s (FDA) human subjects regulations, is a consent to participate in the research study as a whole, not simply a consent for the research use or disclosure of protected health information. See the fact sheet and frequently asked questions about the research provisions on this web site for more information about the Common Rule. For this reason, there are important differences between the Privacy Rule’s requirements for individual authorization, and the Common Rule’s and FDA’s requirements for informed consent. However, the Privacy Rule’s authorization elements are compatible with the Common Rule’s informed consent elements. Thus, both sets of requirements can be met by use of a single, combined form, which is permitted by the Privacy Rule. For example, the Privacy Rule allows the research authorization to state that the authorization will be valid until the conclusion of the research study, or to state that the authorization will not have an expiration date or event. This is compatible with the Common Rule’s requirement for an explanation of the expected duration of the research subject’s participation in the study. It should be noted that where the Privacy Rule, the Common Rule, and/or FDA’s human subjects regulations are applicable, each of the applicable regulations will need to be followed.

Q: When is a researcher a covered health care provider under HIPAA?

A: A researcher is a covered health care provider if he or she furnishes health care services to individuals, including the subjects of research, and transmits any health information in electronic form in connection with a transaction covered by the Transactions Rule. See 45 CFR 160.102, 160.103. For example, a researcher who conducts a clinical trial that

involves the delivery of routine health care, such as an MRI or liver function test, and transmits health information in electronic form to a third party payer for payment, would be a covered health care provider under the Privacy Rule. Researchers who provide health care to the subjects of research or other individuals would be covered health care providers even if they do not themselves electronically transmit information in connection with a HIPAA transaction, but have other entities, such as a hospital or billing service, conduct such electronic transactions on their behalf. For further assistance in determining covered entity status, see the “decision tool” at www.hhs.gov/ocr/hipaa/.

Q: When does a covered entity have discretion to determine whether a research component of the entity is part of their covered functions, and therefore, subject to the HIPAA Privacy Rule?

A: A covered entity that qualifies as a hybrid entity, meaning that the entity is a single legal entity that performs both covered and non-covered functions, may choose whether it wants to be a hybrid entity. If such a covered entity decides not to be a hybrid entity then it, and all of its components, are subject to the Privacy Rule in its entirety. Therefore, if a researcher is an employee or workforce member of a covered entity that has decided not to be a hybrid entity, the researcher is part of the covered entity and is, therefore, subject to the Privacy Rule.

If a covered entity decides to be a hybrid entity, it must define and designate as its health care component(s) those parts of the entity that engage in covered functions. “Covered functions” are those functions of a covered entity that make the entity a health plan, a health care provider, or a health care clearinghouse. Thus, research components of a hybrid entity that function as health care providers and engage in standard electronic transactions must be included in the hybrid entity's health care component(s), and be subject to the Privacy Rule.

However, research components that function as health care providers, but do not engage in standard electronic transactions may, but are not required to, be included in the health care component(s) of the hybrid entity. For example, a hybrid entity, such as a university, has the option to include or exclude a research laboratory, that functions as a health care provider but does not engage in electronic transactions, as part of the hybrid entity's health care component. If such a research laboratory is included in the hybrid entity's health care component, then the employees or workforce members of the laboratory must comply with the Privacy Rule. But if the research laboratory is excluded from the hybrid entity's health care component, the employees or workforce members of the laboratory are not subject to the Privacy Rule.

Q: If a research subject revokes his or her authorization to have protected health

information used or disclosed for research, does the HIPAA Privacy Rule permit a researcher/covered health care provider to continue using the protected health information already obtained prior to the time the individual revoked his or her authorization?

A: Covered entities may continue to use and disclose protected health information that was obtained prior to the time the individual revoked his or her authorization, as necessary to maintain the integrity of the research study. An individual may not revoke an authorization to the extent the covered entity has acted in reliance on the authorization. For research uses and disclosures, this reliance exception at 45 CFR 164.508(b)(5)(i) permits the continued use and disclosure of protected health information already obtained pursuant to a valid authorization to the extent necessary to preserve the integrity of the research study. For example, the reliance exception would permit the continued use and disclosure of protected health information to account for a subject's withdrawal from the research study, as necessary to incorporate the information as part of a marketing application submitted to the Food and Drug Administration, to conduct investigations of scientific misconduct, or to report adverse events.

However, the reliance exception would not permit a covered entity to continue disclosing additional protected health information to a researcher or to use for its own research purposes information not already gathered at the time an individual withdraws his or her authorization.

Q: Can the preparatory research provision of the HIPAA Privacy Rule at 45 CFR 164.512(i)(1)(ii) be used to recruit individuals into a research study?

A: The preparatory research provision permits covered entities to use or disclose protected health information for purposes preparatory to research, such as to aid study recruitment. However, the provision at 45 CFR 164.512(i)(1)(ii) does not permit the researcher to remove protected health information from the covered entity's site. As such, a researcher who is an employee or a member of the covered entity's workforce could use protected health information to contact prospective research subjects. The preparatory research provision would allow such a researcher to identify prospective research participants for purposes of seeking their authorization to use or disclose protected health information for a research study. In addition, the Rule permits a covered entity to disclose protected health information to the individual who is the subject of the information. See 45 CFR 164.502(a)(1)(i). Therefore, covered health care providers and patients may continue to discuss the option of enrolling in a clinical trial without patient authorization, and without an Institutional Review Board (IRB) or Privacy Board waiver of the authorization. See the fact sheet and frequently asked questions about the research provisions on this web site for more information about Institutional Review and Privacy Boards.

However, a researcher who is not a part of the covered entity may not use the preparatory research provision to contact prospective research subjects. Rather, the outside researcher could obtain contact information through a partial waiver of individual authorization by an IRB or Privacy Board as permitted at 45 CFR 164.512(i)(1)(i). The IRB or Privacy Board waiver of authorization permits the partial waiver of authorization for the purposes of allowing a researcher to obtain protected health information as necessary to recruit potential research subjects. For example, even if an IRB does not waive informed consent and individual authorization for the study itself, it may waive such authorization to permit the disclosure of protected health information as necessary for the researcher to be able to contact and recruit individuals into the study.

Q: Does the HIPAA Privacy Rule require documentation of Institutional Review Board (IRB) or Privacy Board approval of an alteration or waiver of individual authorization before a covered entity may use or disclose protected health information for any of the following provisions: (1) for preparatory research at 45 CFR 164.512(i)(1)(ii), (2) for research on the protected health information of decedents at 45 CFR 164.512(i)(1)(iii), or (3) a limited data set with a data use agreement as stipulated at 45 CFR 164.514(e)?

A: No. Documentation of IRB or Privacy Board approval of an alteration or waiver of individual authorization is only needed before a covered entity may use or disclose protected health information under 45 CFR 164.512(i)(1)(i). See the fact sheet and frequently asked questions about the research provisions on this web site for more information about Institutional Review and Privacy Boards.

Q: If research subjects' consent was obtained before the compliance date, but the Institutional Review Board (IRB) subsequently modifies the informed consent document after the compliance date and requires that subjects be reconsented, is authorization now required from these previously enrolled research subjects under the HIPAA Privacy Rule?

A: Yes. If informed consent or reconsent (ie., asked to sign a revised consent or another informed consent) is obtained from research subjects after the compliance date, the covered entity must obtain individual authorization as required at 45 CFR 164.508 for the use or disclosure of protected health information once the consent obtained before the compliance date is no longer valid for the research. The revised informed consent document may be combined with the authorization elements required by 45 CFR 164.508. See the fact sheet and frequently asked questions about the research provisions on this web site for more information about Institutional Review Boards.

Q: Can covered entities continue to disclose adverse event reports that contain

protected health information to the Department of Health and Human Services (HHS) Office for Human Research Protections?

A: Yes. The Office for Human Research Protections is a public health authority under the HIPAA Privacy Rule. Therefore, covered entities can continue to disclose protected health information to report adverse events to the Office for Human Research Protections either with patient authorization as provided at 45 CFR 164.508, or without patient authorization for public health activities as permitted at 45 CFR 164.512(b).

Q: **Can covered entities continue to disclose protected health information to the HHS Office for Human Research Protections for purposes of determining compliance with the HHS regulations for the protection of human subjects (45 CFR Part 46)?**

A.: Yes. The Office for Human Research Protections is a health oversight agency under the HIPAA Privacy Rule. Therefore, covered entities can continue to disclose protected health information to the Office for Human Research Protections for such compliance investigations either with patient authorization as provided at 45 CFR 164.508, or without patient authorization for health oversight activities as permitted at 45 CFR 164.512(d).