Research checklist

INSTRUCTIONS: The following is the text of 164.512 (i) (containing the requirements for using protected health information for research without an authorization or an opportunity to agree or object), excerpts from **Institutional Review Board (IRB) or Privacy Board Approval of a Waiver of Authorization** (containing changes effective as of October 15, 2002), and excerpts from **Uses and Disclosures Regarding FDA-Regulated Products and Activities** (containing changes effective as of October 15, 2002).

Check off each element if reviewing a Board waiver or trying to determine if you need an authorization for research, to make sure it contains the required elements.

§ 164.512 Uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required.

(i) Standard: uses and disclosures for research purposes.

1. ☐ Permitted uses and disclosures. A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that:
   - i. ☐ Board approval of a waiver of authorization. The covered entity obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by §164.508 for use or disclosure of protected health information has been approved by either:
     - A. ☐ An Institutional Review Board (IRB), established in accordance with 7 CFR 1c.107, 10 CFR 745.107, 14 CFR 1230.107, 15 CFR 27.107, 16 CFR 1028.107, 21 CFR 56.107, 22 CFR 225.107, 24 CFR 60.107, 28 CFR 46.107, 32 CFR 219.107, 34 CFR 97.107, 38 CFR 16.107, 40 CFR 26.107, 45 CFR 46.107, 45 CFR 690.107, or 49 CFR 11.107; or
     - B. ☐ A privacy board that:
       1. ☐ Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;
       2. ☐ Includes at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities; and
       3. ☐ Does not have any member participating in a review of any project in which the member has a conflict of interest.
   - ii. ☐ Reviews preparatory to research. The covered entity obtains from the researcher representations that:
     - A. ☐ Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;
     - B. ☐ No protected health information is to be removed from the covered entity by the researcher in the course of the review; and
     - C. ☐ The protected health information for which use or access is sought is necessary for the research purposes.
   - iii. ☐ Research on decedent's information. The covered entity obtains from the researcher:
     - A. ☐ Representation that the use or disclosure is sought is solely for research on the protected health information of decedents;

B. ☐ Documentation, at the request of the covered entity, of the death of such individuals; and

C. ☐ Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

2. ☐ Documentation of waiver approval. For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, under paragraph (i)(1)(i) of this section, the documentation must include all of the following:

i. ☐ Identification and date of action. A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved;

ii. ☐ Waiver criteria. A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

A. ☐ The use or disclosure of protected health information involves no more than minimal risk to the individuals;

B. ☐ The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;

C. ☐ The research could not practicably be conducted without the alteration or waiver;

D. ☐ The research could not practicably be conducted without access to and use of the protected health information;

E. ☐ The privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research;

F. ☐ There is an adequate plan to protect the identifiers from improper use and disclosure;

G. ☐ There is 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

H. ☐ There are 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.

iii. ☐ Protected health information needed. 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 has determined, pursuant to paragraph (i)(2)(ii)(D) of this section;

iv. ☐ Review and approval procedures. A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures, as follows:

A. ☐ An IRB must follow the requirements of the Common Rule, including the normal review procedures (7 CFR 1c.108(b), 10 CFR 745.108(b), 14 CFR 1230.108(b), 15 CFR 27.108(b), 16 CFR 1028.108(b), 21 CFR 56.108(b), 22 CFR 225.108(b), 24 CFR 60.108(b), 28 CFR 46.108(b), 32 CFR 219.108(b), 34 CFR 97.108(b), 38 CFR 16.108(b), 40 CFR 26.108(b), 45 CFR 46.108(b), 45 CFR 690.108(b), or 49 CFR 11.108(b)) or the expedited review procedures (7 CFR 1c.110, 10 CFR 745.110, 14 CFR 1230.110, 15 CFR 27.110, 16 CFR 1028.110, 21 CFR 56.110, 22 CFR 225.110, 24 CFR 60.110, 28 CFR 46.110, 32 CFR 219.110, 34 CFR 97.110, 38 CFR 16.110, 40 CFR 26.110, 45 CFR 46.110, 45 CFR 690.110, or 49 CFR 11.110);

B. ☐ A privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who satisfies the criterion stated in paragraph (i)(1)(i)(B)(2) of this section, and the alteration or waiver of authorization must be approved by the majority of the privacy board members present at the meeting, unless the privacy board elects to use an expedited review procedure in accordance with paragraph (i)(2)(iv)(C) of this section;

C. ☐ A privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the protected health information for which use or disclosure is being sought. If the privacy board elects to use an expedited review procedure, the review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board, or by one or more members of the privacy board as designated by the chair; and

v. ☐ Required signature. The documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the IRB or the privacy board, as applicable.

F. Section 164.512--Uses and Disclosures for Which Authorization or Opportunity To Agree or Object Is Not Required

2. Institutional Review Board (IRB) or Privacy Board Approval of a Waiver of Authorization

March 2002 NPRM

A number of commenters informed the Department that the eight waiver criteria in the December 2000 Privacy Rule were confusing, redundant, and internally inconsistent. These commenters urged the Department to simplify these provisions, noting that they would be especially burdensome and duplicative for research that was currently governed by the Common Rule. In response to these comments, the Department proposed the following modifications to the waiver criteria for all research uses and disclosures of protected health information, regardless of whether or not the research is subject to the Common Rule:

- The Department proposed to delete the criterion that "the alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals," because it may conflict with the criterion regarding the assessment of minimal privacy risk.
- In response to commenters' concerns about the overlap and potential inconsistency among several of the Privacy Rule's criteria, the Department proposed to turn the following three criteria into factors that must be considered as part of the IRB's or Privacy Board's assessment of minimal risk to privacy:
    - ☐ There is an adequate plan to protect the identifiers from improper use and disclosure;
    - ☐ There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with the 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
    - ☐ There are 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.

- ☐ In response to concerns that the following waiver criterion was unnecessarily duplicative of other provisions to protect patients' confidentiality interests, the Department proposed to eliminate the criterion that: "the privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to the anticipated benefits, if any, to the individual, and the importance of the knowledge that may reasonably be expected to result from the research."

In sum, the NPRM proposed that the following waiver criteria replace the waiver criteria in the December 2000 Privacy Rule at Sec. 164.512(i)(2)(ii):

1. 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:
    - ☐ (a) An adequate plan to protect the identifiers from improper use and disclosure;
    - ☐ (b) 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
    - ☐ (c) 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;
2. ☐ The research could not practicably be conducted without the waiver or alteration; and
3. ☐ The research could not practicably be conducted without access to and use of the protected health information.

Final Modifications

The Department agrees with the majority of commenters that supported the proposed waiver criteria, and adopts the modifications as proposed in the NPRM. The criteria safeguard patient privacy, require attention to issues sometimes currently overlooked by IRBs, and are compatible with the Common Rule. Though IRBs and Privacy Boards may initially struggle to interpret the criteria, as a few commenters mentioned, the Department intends to issue guidance documents to address this concern. Furthermore, the Department notes that experience and guidance have enabled IRBs to successfully implement the Common Rule's waiver criteria, which also require subjective determinations.

This final Rule also contains a conforming modification in Sec. 164.512(i)(2)(iii) to replace "(i)(2)(ii)(D)" with "(i)(2)(ii)(C)."

F. Section 164.512--Uses and Disclosures for Which Authorization or Opportunity To Agree or Object Is Not Required

1. Uses and Disclosures Regarding FDA-Regulated Products and Activities

Final Modifications

In the final modifications, the Department adopts the language proposed in the NPRM. Section 164.512(b)(1)(iii), as modified, permits covered entities to disclose protected health information, without authorization, to a person subject to the jurisdiction of the FDA with

respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety, or effectiveness of such FDA-regulated product or activity. Such purposes include, but are not limited to, the following activities and purposes listed in subparagraphs (A) through (D): (1) To collect or report adverse events (or similar activities regarding food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations, (2) to track FDA-regulated products, (3) to enable product recalls, repairs, or replacement, or for lookback (including locating and notifying persons who have received products that have been withdrawn, recalled, or are the subject of lookback), and (4) to conduct post-marketing surveillance.

Although the list of permissible disclosures is no longer exclusive, the Department disagrees with commenters that asserted the modifications permit virtually unlimited disclosures for FDA purposes. As modified, such disclosures must still be made to a person subject to the jurisdiction of the FDA. The disclosure also must relate to FDA- regulated products or activities for which the person using or receiving the information has responsibility, and be made only for activities related to the safety, effectiveness, or quality of such FDA-regulated product or activity. These terms are terms of art with commonly accepted and understood meanings in the FDA context, meanings of which providers making such reports are aware. This limits the possibility that FDA-regulated manufacturers and entities will able to abuse this provision to obtain information to which they would otherwise not be entitled.

Moreover, Sec. 164.512(b)(1) specifically limits permissible disclosures to those made for public health activities and purposes. While a disclosure related to the safety, quality or effectiveness of an FDA-regulated product is a permissible disclosure, the disclosure also must be for a "public health" activity or purpose. For example, it is not permissible under Sec. 164.512(b)(1)(iii) for a covered entity to disclose protected health information to a manufacturer to allow the manufacturer to evaluate the effectiveness of a marketing campaign for a prescription drug. In this example, although the disclosure may be related to the effectiveness of an FDA-regulated activity (the advertising of a prescription drug), the disclosure is made for the commercial purposes of the manufacturer rather than for a public health purpose.

A disclosure related to a "quality" defect of an FDA-regulated product is also permitted. For instance, the public health exception permits a covered entity to contact the manufacturer of a product to report drug packaging quality defects. However, this section does not permit all possible reports from a covered entity to a person subject to FDA jurisdiction about product quality. It would not be permissible for a provider to furnish a manufacturer with a list of patients who prefer a different flavored cough syrup over the flavor of the manufacturer's product. Such a disclosure generally would not be for a public health purpose. However, a disclosure related to the flavor of a product would be permitted under this section if the covered entity believed that a difference in the product's flavor indicated, for example, a possible manufacturing problem or suggested that the product had been tampered with in a way that could affect the product's safety.

The Department clarifies that the types of disclosures that covered entities are permitted to make to persons subject to FDA jurisdiction are those of the type that have been traditionally made over the years. These reports include, but are not limited to, those made for the purposes identified in paragraphs (A)-(D) of Sec. 164.512(b)(1)(iii) of this final Rule.

Also, the minimum necessary standard applies to public health disclosures, including those made to persons subject to the jurisdiction of the FDA. There are many instances where a report about the quality, safety, or effectiveness of an FDA-regulated product can be made without disclosing protected health information. Such may be the case with many adverse drug events where it is important to know what happened but it may not be important to know to whom. However, in other circumstances, such as device tracking or blood lookback, it

is essential for the manufacturer to have identifying patient information in order to carry out its responsibilities under the Food, Drug, and Cosmetic Act. Therefore, identifiable health information can be disclosed for these purposes, consistent with the minimum necessary standard.

☐ As the Department stated in the preamble of the NPRM, "a person" subject to the jurisdiction of the FDA does not mean that the disclosure must be made to a specific individual. The Food, Drug, and Cosmetic Act defines "person" to include an individual, partnership, corporation, and association. Therefore, covered entities may continue to disclose protected health information to the companies subject to FDA's jurisdiction that have responsibility for the product or activity. Covered entities may identify responsible companies by using information obtained from product labels or product labeling (written material about the product that accompanies the product) including sources of labeling, such as the Physician's Desk Reference.