

C.S. B1: Patient Data from Secondary Databases, Electronic Medical Records, and Questionnaires ($N=8000$)

Overview

This study abstracts data from VA electronic medical records and secondary data bases, including VISTA and other patient databases, and includes the collection of information on diagnoses, service utilization, and vaccination history as part of a project to assess and improve flu vaccination rates among spinal cord injury patients in the VA population. Patients will be sent letters reminding them to ask their physicians about annual flu vaccinations. A portion of these patients will also receive a follow-up survey.

Subjects & Sample Size

Subjects are 8000 VA patients with spinal cord injuries. 25% are to be followed up by mailed survey.

Data Collection

Electronic medical records are abstracted for data on diagnoses and vaccination history. VISTA and other patient databases (i.e., Pharmacy Benefits Management, Austin databases) are reviewed for data on service utilization.

The follow-up survey covers attitudes and knowledge regarding flu vaccination, and experiences with primary care physicians around vaccination issues.

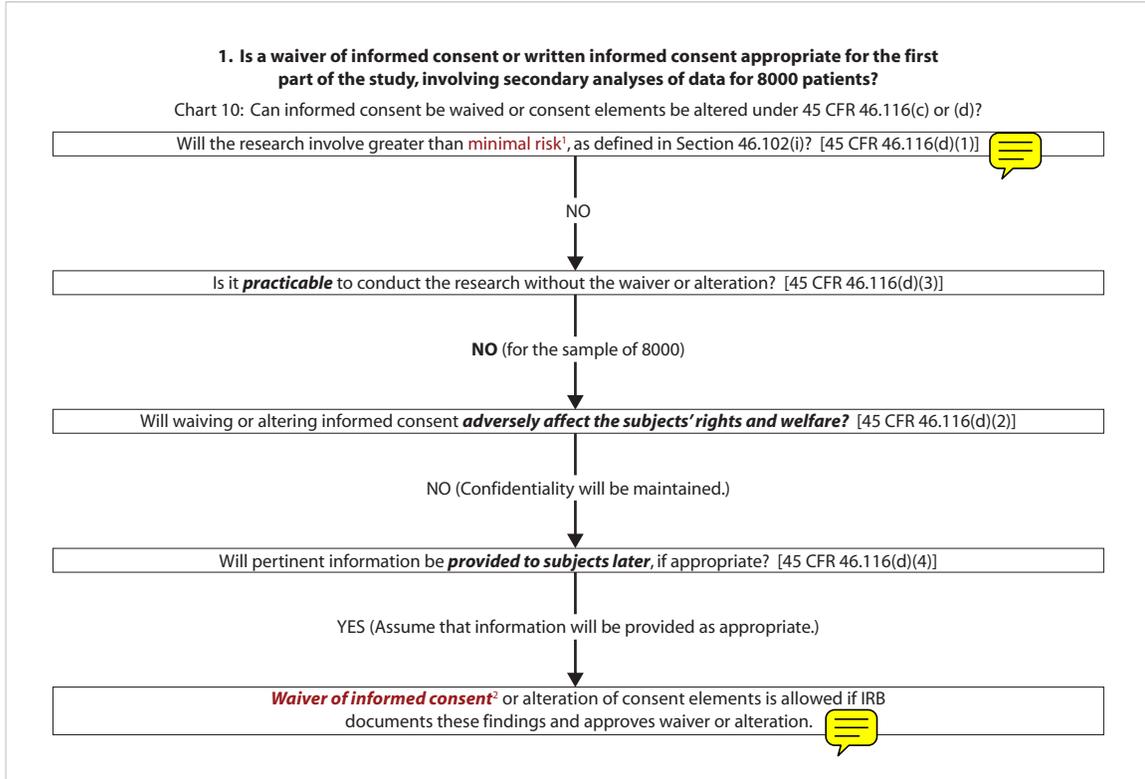
Subjects are assigned unique identifiers, and cross-walk files (files linking patient names/SSNs with study i.d. numbers) are stored separately and secured (via locked cabinet for hard copies and password protected files for electronic materials). Data for analysis does not include identifiers. Linkages will be destroyed after conclusion of the study.

Questions:

- 1. Is a waiver of informed consent or written informed consent appropriate for the first part of the study, involving secondary analyses of data for 8000 patients?** [[Link](#)]
- 2. Is a waiver of HIPAA authorization appropriate for the first part of the study, involving secondary analyses of data for 8000 patients?** [[Link](#)]
- 3. Is a waiver of informed consent or written informed consent appropriate for the second part of the study, involving the distribution of surveys to 2000 patients?** [[Link](#)]
- 4. Is a waiver of HIPAA authorization appropriate for the second part of the study, involving the distribution of surveys to 2000 patients?** [[Link](#)]

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[From OHRP Web site: www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm]



Notes for C.S. B1: Q1

¹**Definition:** “Minimal risk means that the *probability* and *magnitude* of harm or discomfort anticipated in the research are not greater in and of themselves than those *ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests*” (CFR 46.102(1)).

Discussion: Panel members considered this study to be minimal risk. The risk to the patient of participating in this study is potential loss of confidentiality. The *probability and magnitude* of harm from loss of confidentiality, given the safeguards described, are no greater than *that which is encountered in daily life*—e.g., the probability of loss of confidentiality of non-research-related health data collected and maintained within VA medical centers and clinics, or by non-VA healthcare providers. The small probability of loss of confidentiality is based on the assumption that the safeguards for

maintaining data confidentiality by the investigators are sufficient and are as good as those used elsewhere in the health care facility for ensuring the confidentiality of health-related data. Therefore, sufficient information must be provided by investigators to the IRB committee for them to determine that the procedures for maintaining data confidentiality are acceptable.

Several panel members emphasized that the magnitude of harm from loss of confidentiality must be carefully considered. Could a breach in confidentiality result in loss of a job? Loss of insurance? If so, then this research could be considered greater than minimal risk.

²**Discussion:** Panel members felt that waiver of informed consent is appropriate, given that the study poses no more than minimal risk, and it would not be practicable to contact the 8000 subjects.

Notes for C.S. B1: Q2**2. Is a waiver of HIPAA authorization appropriate for the first part of the study, involving secondary analyses of data for 8000 patients?**

Yes, the study meets all of the following HIPAA waiver criteria:

(1) The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals based on at least the presence of:

- an adequate plan presented to the IRB to protect PHI identifiers from improper use and disclosure;*
- an adequate plan to destroy those identifiers at the earliest opportunity consistent with the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law;*

- adequate written assurances that the PHI 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 PHI is permitted by the Privacy Rule.*

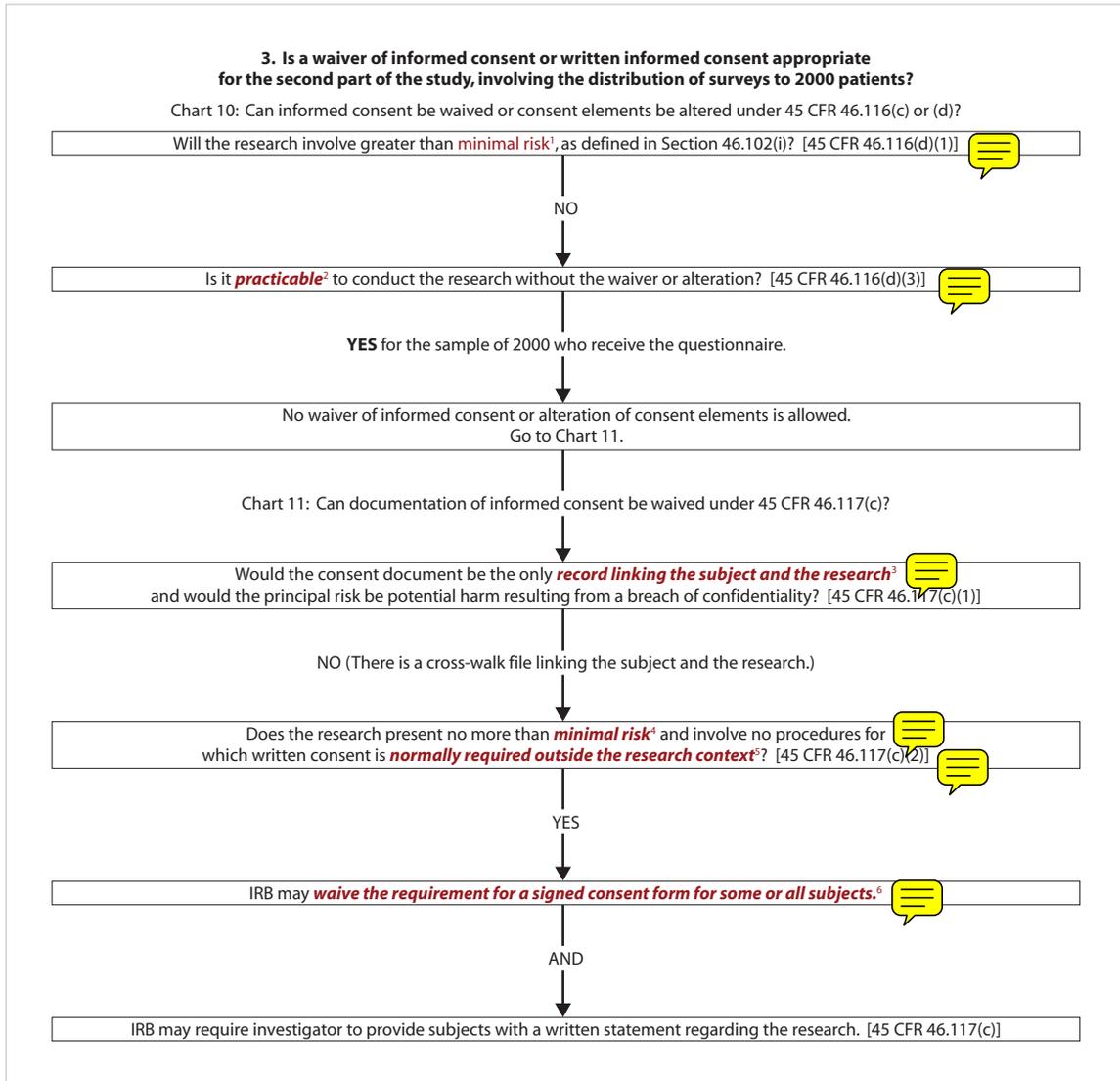
(2) The research could not practicably be conducted without the alteration or waiver; and

(3) The research could not practicably be conducted without access to and use of the PHI.

**The investigator would need to provide an adequate plan/assurances in the proposal.*

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[From OHRP Web site: www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm]



Notes for C.S. B1: Q3

¹**Definition:** “Minimal risk means that the *probability* and *magnitude* of harm or discomfort anticipated in the research are not greater in and of themselves than those *ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests*” (CFR 46.102(1)).

Discussion: Panel members considered this study to be minimal risk. The risk to the patient of participating in this study is potential loss of confidentiality. The *probability and magnitude* of harm from loss of confidentiality, given the safeguards described, are no greater than *that which is encountered in daily life*—e.g., the probability of loss of confidentiality of non-research-related health data collected and maintained within VA medical centers and clinics, or by non-VA healthcare providers. The small probability of loss of confidentiality is based on the assumption that the safeguards for maintaining data confidentiality by the investigators are sufficient and are as good as those used elsewhere in the health care facility for ensuring the confidentiality of health-related data. Therefore, sufficient information must be provided by investigators to the IRB committee for them to determine that the procedures for maintaining data confidentiality are acceptable. In addition, it is unlikely that a survey of immunization behavior would contain sensitive questions or that a breach in the confidentiality of these data could result in social, psychological, or economic harm to the subjects. The IRB would need to review the survey questions to ensure these criteria are met.

Two panel members noted that if any of the questions in the survey asked for sensitive data, or if responding to the questions might

cause psychological distress, then the study could no longer be considered minimal risk. One panel member strongly disagreed with this concern, arguing that people are exposed to highly sensitive questions during the performance of routine physical or psychological examinations or tests. It is very unlikely that the survey questions would be more sensitive.

²**Discussion:** The majority of the panel felt that it is practicable to conduct the research without the waiver or alteration. The potential participants can be informed of the study via a cover letter at the time they receive the questionnaire. However, one panel member suggested the possibility that it might not be practicable to conduct the research without the waiver, if the elements of informed consent in the cover letter were at all confusing or daunting for potential subjects to read and understand. To the extent that this confusion might dissuade patients from participating, then this could jeopardize the representativeness of the study sample. The IRB should weigh the benefits of obtaining a representative sample against the minimal risks of the study.

³**Definition:** There are identifiers in the study data set that can be linked to the subjects.

⁴**Definition:** “Minimal risk means that the *probability* and *magnitude* of harm or discomfort anticipated in the research are not greater in and of themselves than those *ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests*” (CFR 46.102(1)).

Discussion: Panel members considered this study to be minimal risk. See discussion for note #1.

Notes for C.S. B1: Q3 (cont.)

⁵**Discussion:** The questionnaire asks patients about their attitudes and knowledge regarding flu vaccination, and experiences with primary care physicians around vaccination issues. The majority of panel members felt that these are questions which may be asked of patients by providers outside the research context.

⁶**Discussion:** The majority of the panel members felt that obtaining signed informed consent is not necessary. Informed consent can be obtained via a cover letter containing all of the elements required for informed consent. Subjects who complete and return the questionnaire are indicating their agreement to participate.

What if the investigators were going to collect additional data from the patients' medical

records, for linking to the questionnaire data? The majority of panel members felt that if the data to be obtained from the medical record included PHI, then written consent should be obtained, because HIPAA authorization would be required and written informed consent could be obtained at the same time. If PHI were not being collected from the medical record, then written informed consent would not be necessary. The informed consent document for the survey (e.g., the cover letter) should mention which data from the medical record will be collected.

However, two panel members felt that a waiver of HIPAA authorization could be granted in this case even if PHI were being collected, because it would not be practicable to conduct the research without a waiver of HIPAA authorization. See discussion below for question #4.

Notes for C.S. B1: Q4**4. Is a waiver of HIPAA authorization appropriate for the second part of the study, involving the distribution of surveys to 2000 patients?**

The study involves the collection of PHI, because the questions about immunizations relate to the past, present, or future physical or mental health or condition of an individual, or the provision of health care to an individual.

The majority of panel members felt that the research could be practicably carried out without the waiver, because patients can get a copy of the authorization at the time they receive the questionnaire. Therefore, HIPAA authorization is required. Some panel members felt that because HIPAA authorization is required, then the investigator might as well go ahead and get a signed consent form at the same time (even though it is not be required, per the panel's response to question #3 above). A signed consent form (theoretically) provides added protection to the subject and the investigator.

This is an example where the human subjects protection regulations and HIPAA regulations have different requirements. Written authorization is required for HIPAA, because there are PHI and the research could be practicably carried out without the waiver. However, written consent is not required, because the study is minimal risk. In the case of the human subjects regulations, the minimal risk nature of the study has greater weight in determining the need for written consent; in the case of the HIPAA regulations, the practicability issue has greater weight.

Two panel members felt there was a possibility that the research could not be practicably carried out without the waiver—that there may be a number of respondents who would forget to sign and return the form with the survey (thus precluding use of the survey) or who would not sign the HIPAA authorization because of a lack of understanding. These sorts of responses could significantly limit the number of usable surveys received, thereby jeopardizing the research. Assuming that appropriate precautions for protecting the data were taken, then, a waiver of HIPAA authorization could be granted in this case.