

# C.S. B4: Implementation and Evaluation of a Depression Care Model with Patient Telephone Interviews and Review of Patient Information from VA Databases

## Overview

This study assesses the impact of a depression care management model in primary care settings at seven VAMCs.

## Subjects & Sample Size

Subjects for this arm of the project are drawn from patients diagnosed with depression at the participating VAMCs. Total projected sample size is 855.

## Data Collection

Subjects will be interviewed over the telephone about their depressive symptoms, depression care, medications, quality of life, and demographic information. An outside telephone survey firm will conduct the interviews. Appointment data, cost/utilization data, and other health care information will be collected about these subjects from VA databases. Identifying information is stored separately from study data,

which are entered into a database without identifying information. All electronic data sets are maintained in password protected files. Study documents are stored in a locked cabinet. Identifying data will be destroyed at the conclusion of analysis.

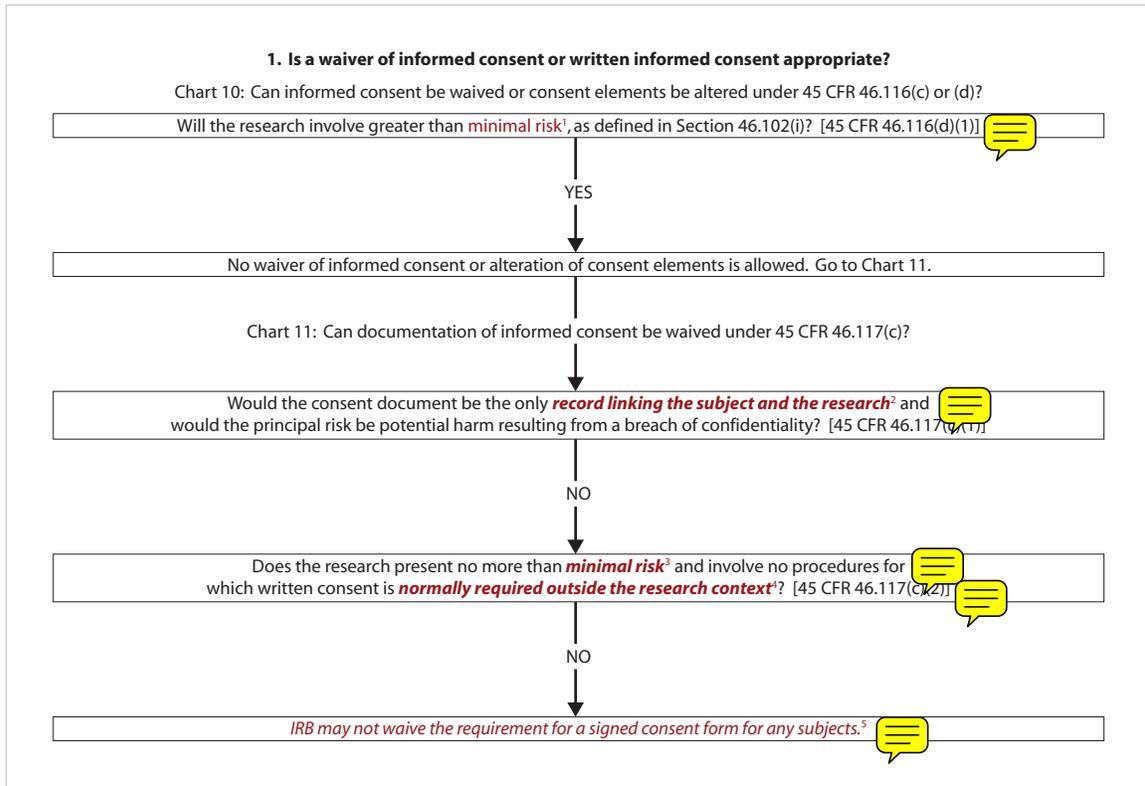
[Note: This case study does not include a description of the means by which patients are contacted regarding the study. For purposes of focusing the discussion on informed consent and HIPAA authorization, it should be assumed that potential subjects are identified and contacted in accordance with all regulations.]

## Questions:

- 1. Is a waiver of informed consent or written informed consent appropriate?** [[Link](#)]
- 2. Is a waiver of HIPAA authorization appropriate?** [[Link](#)]

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



**Notes for C.S. B4.1**

**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:** The majority of panel members felt that this study is greater than minimal risk, because patients with mental illness are frequently stigmatized. Therefore, the magnitude of harm that might result from loss of confidentiality of their healthcare data is greater than minimal. In addition, the study may be greater than minimal risk if the interview questions could upset the subjects (e.g., if subjects are asked to recall anxious or unpleasant experiences) and could contribute to suicidal feelings.

One panel member considered this study to be minimal risk. The risk to the patient of participating in this study is potential loss of confidentiality. The panel member felt that the *probability and magnitude* of harm from loss of confidentiality are no greater than *that which is encountered in daily life or during the performance of routine physical or psychological examinations or tests*. It is likely that the questions included in the interviews are no more upsetting than questions routinely asked of depressed patients as part of a psychological examination. In addition, 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 con-

fidentiality 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.

Regarding the magnitude of harm that could result from a breach in confidentiality, the panel member who felt this study was minimal risk assessed the probability and magnitude of harm in the context of daily life for this particular group of subjects—not for the population in general. That is, patients with depression are routinely subjected to potentially upsetting questions as part of their psychological exams, and are subjected to the risk that information on their health status could be revealed; so, this study does not represent a risk greater than that which they encounter daily. (Those who argue that the study is greater than minimal risk say that the standard should be the daily risks of the general population. For example, the risk of social stigmatization, which could come to a person whose depression status is revealed, is a risk greater than that experienced by the average person on a daily basis. In addition, the types of questions that the average, healthy person is asked during a routine psychological examination may be less sensitive than those asked of a person with depression.)

For further discussion of the relativistic vs. absolute interpretation of daily life risks, see Resnik DB. Eliminating the daily life risks standard from the definition of minimal risk. *J Med Ethics* 2005;31:35-38. [*A link to this article is included on the home page.*]

**Notes for C.S. B4.1 (cont.)**

<sup>2</sup>**Definition:** The investigators are maintaining a file of identifiers that can be linked to the subjects.

<sup>3</sup>**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:** The majority of panel members considered this study to be greater than minimal risk. However, one member disagreed, and considered the study to be minimal risk. See discussion for note #1.

<sup>4</sup>**Discussion:** The panel members who considered the study to be minimal risk also felt that written consent is not usually required by the VA when patients answer questions or are interviewed about these topics. In this case, informed consent could be provided verbally over the telephone (via an IRB-approved script), including explicit instructions that participants can refuse to answer any question.

<sup>5</sup>**Other comments from the panel:** The protocol must include explicit plans for immediate action in the event that a participant indicates s/he is in crisis or suicidal, including assurances that the interviewers can make this determination and can take the appropriate action.

**Notes for C.S. B4: Q2****2. Is a waiver of HIPAA authorization appropriate?**

The majority of the panel felt that the study does not meet HIPAA waiver criteria #2 below.

(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;\*
- and

- 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.*