

C.S. A2: Observational Study Using Patient Interviews and Questionnaires

Overview

This study examines health related quality-of-life for individuals in the VA health care system with a specific, non-sensitive chronic illness. Investigators propose to administer two quality-of-life measures to patients at baseline and a follow-up structured interview every month for a 1-year study period. They will use a written informed consent form, which will include a HIPAA authorization form (“Request for Patient Authorization for Access to Protected Health Information”).

Subjects and Sample Size

The subjects are 500 patients at 8 VAMCs. They are identified via VA databases and initially contacted and invited by letter to participate in the project. Interested patients are scheduled to meet with project staff at an upcoming clinic appointment to go over requirements for participation and sign the consent form.

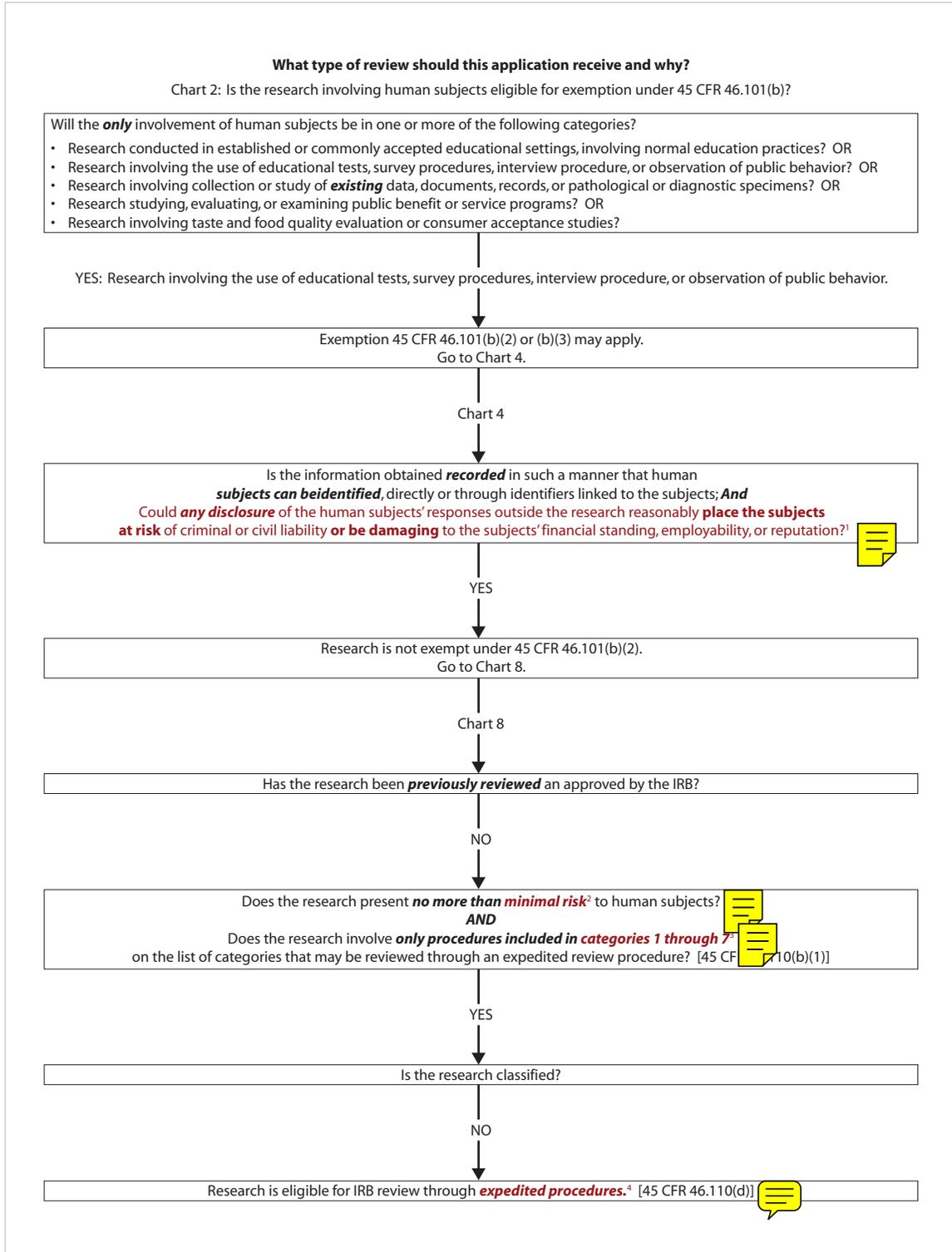
Data Collection and Confidentiality

Baseline interviews are conducted in person at a regularly scheduled clinic appointment, and follow-up interviews are conducted over the telephone. Data collected from patients include demographics/SES, general health information, and quality-of-life data. Data are confidential but not anonymous—linkages are maintained in a crosswalk file to facilitate the monthly follow-up. The crosswalk file linking patient identifying data to study identification numbers will be maintained as a separate file, in a password-protected drive that is separate from the drive containing the study data. No study data will be maintained with the patient identifying data.

What type of review should this application receive and why?

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



Notes for C.S. A2

¹**Definition:** There are identifiers in the study data set that can be linked to the subject. In addition, disclosure of the data, which would necessarily identify participating patients as having a chronic illness of some kind, could potentially damage the subject's employability, to the extent that an employer might not want to hire someone who may need to take a lot of sick leave or may eventually incur an illness-associated disability that may adversely affect their productivity. Disclosure of the data could also affect the patient's insurability.

²**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 the panel felt that the *probability and magnitude* of 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 other, 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 adequate—or, at a minimum, that the procedures are as good as those used elsewhere in the health care facility for ensuring the confidentiality of health-related data. If there has been a history

of problems with maintaining the confidentiality of research data at a particular institution, or if the investigators do not have much experience with the collection and use of interview and survey data, then the local IRB may choose full review as a means to more carefully review the procedures and ensure that they are adequate.

Several panel members expressed concern that if any of the questions in the interviews and surveys asked for sensitive data, the study would require full review. In addition, in the event that the illness being studied was of a sensitive nature (e.g., substance abuse, mental illness, HIV/AIDS), then the study would require full review.

Other comments by panel members:

- In addition to the risk of loss of confidentiality, there may also be a risk of burden associated with completing the questionnaire. If the burden could be considered excessive for a patient in poor health, then the risk to the patient is increased. However (noted by another panel member), making it clear to patients that they do not need to complete the questionnaire in the event they find it too burdensome should keep the risk at a minimal level.
- There may be a risk of psychological harm to the patient if potentially upsetting questions are asked about their health. If there is any reason to think that the questions might cause distress, then the IRB must consider the adequacy of provisions for responding to that distress. However (noted by another panel member), most questions in quality-of-life questionnaires are not any more upsetting than those posed by a patient's physician or by friends and family members on a day-to-day basis.

Notes for C.S. A2 (cont.)

³**Definition:** The research involves procedures included in category 7: Research on individual or group characteristics (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. [Return to home page for full list of categories eligible for expedited review under 45 CFR 46.110(b)(1).]

⁴**Discussion:** The research is potentially eligible for expedited review under the assumptions described in the above notes from the panel discussion. A member of the IRB who understands these issues would need to review carefully the proposed research and make this determination.