Navigating the Institutional Review Board System to Conduct Suicide Research

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Abstract

Suicide is the 10th leading cause of death in the United States. In order to establish evidence-based best practices for suicide prevention, knowledge of suicide’s etiology and effective prevention measures is crucial. However, Institutional Review Board (IRB) approval for studies involving suicidal participants may be difficult to obtain for a study that involves participants who may be deemed vulnerable. Furthermore, the detailed process of compliance with federally mandated regulations may seem daunting to a first-time investigator when submitting a study for IRB approval. This article describes the process of obtaining Institutional Review Board (IRB) approval for a proposed study of Veterans who experienced either a non-fatal suicide attempt or serious suicidal ideations involving a firearm, as well as strategies for ensuring success. A collaborative process involving IRB administrators, IRB members and study investigators resulted in study approval of a protocol design that met the study’s objectives, educated the IRB on a subject population they were unfamiliar about, and safeguarded Veteran confidentiality and safety.

ABBREVIATIONS

VA: Veteran’s Administration; VHA: Veteran’s Health Administration; CAVHS: Central Arkansas Veteran’s Administration; IRB: Institutional Review Board; SAFIRE: Suicide Attempts Involving Firearms Study; NIH: National Institutes of Health

INTRODUCTION

Suicide ranks among the top five causes of death in 18-54 year olds [1], and is of particular concern to the Veterans Health Administration (VHA). An estimated 22 Veterans die from suicide daily [2] with 67% of those deaths occurring by firearms [3]. There are an additional 1,250 monthly suicide attempts by Veterans who receive care at VHA facilities; 15% of Veterans who survive an attempted suicide will repeat suicide attempts within 12 months [3]. In an effort to understand predisposing factors which prevent or facilitate a suicide attempt, research on suicide prevention needs to include individual experiences and thought processes of the Veteran population, including interviews of Veterans who have attempted suicide. However, Institutional Review Boards (IRBs), charged with ensuring the protection of human subjects in research, may deem recently suicidal research participants as a vulnerable population.

An IRB’s objective is to ensure that the benefits of the proposed research outweigh the risks and that the rights of all participants, particularly those belonging to vulnerable populations, are protected as delineated by the Belmont Report and Code of Federal Regulations in the United States [4-6] and various international regulatory agencies and International Conference of Harmonization [7-9]. A crucial aspect of ensuring participant rights is embedded in the informed consent process [4,5]. Consent rests on the respect for a person’s capacity for self-determination with special protections in place for those with limited capacity due to inherent or external factors (e.g. cognitive impairment or situations such as incarceration where subject participation might be coerced). IRBs have considered the emotional fragility of Veterans who have recently attempted suicide as a factor that could impact their capacity to give autonomous consent [10-12].
Research has shown that patients who have attempted suicide are as cognitively capable of choosing involvement in a research protocol as other patients and can autonomously give consent [10-12]. Yet the perception of reduced autonomy has limited inclusion of this patient cohort in studies investigating suicide and tends to demonstrate a lack of respect for individuals [10,13].

A carefully designed research protocol includes an evaluation of potential participants’ emotional state and cognitive ability by an independent evaluator as part of the screening and enrollment process as detailed in guidance documents [14]. When independent evaluators of participants’ mental capacity conduct the screening and enrollment, participants with a recent suicidal attempt or ideation can be included without negatively impacting autonomous consent.

IRB approval also rests on the Belmont Report’s principle of beneficence, which calls for balancing risks and benefits of research. However, undue concerns for risk may cause exclusion of important patient subpopulations, thus impacting a third principle in the Belmont Report--that of justice or equitable subject inclusion in a study. An IRB might be concerned that participants may find discussing the circumstances and thoughts leading to the recent suicide attempt emotionally distressful. Participants may also be concerned about confidentiality and inadvertent disclosure of their participation in the research study to outside parties. Several strategies to minimize these risks have been proposed including more stringent confidentiality, the need for the interviews to occur in a clinical setting with ancillary support staff, and having contingency plans if a participant becomes unduly distressed [13-15]. Although no empirical data suggests discussing a patient’s recent suicide attempt increases the risk for future attempts, this concern persists [16,17], potentially impeding critical suicide prevention research.

This paper describes the authors’ successful development of a research protocol and its subsequent IRB approval at the Central Arkansas Veterans Healthcare System (CAVHS) to conduct key informant interviews with participants who had recently either attempted suicide using a firearm expressed serious suicidal ideation of using a firearm for the Suicide Attempts involving Firearms (SAFIRE) study [18-20]. In describing the protocol development and IRB approval process, the authors identify proactive steps taken to protect human subjects, allay IRB concerns, and discuss the common ethical issues considered throughout the process. The paucity of suicide research from the participant’s perspective makes qualitative research with individuals who have attempted or seriously threatened suicide critical. Our description of a successful IRB process may help others initiate and conduct more of this important research, including obtaining IRB approval within a manageable timeframe.

**Developing the Study Protocol and Getting Support from Key Stakeholders**

To avert barriers to IRB approval, support was obtained from essential stakeholders and involved the IRB early in the development of the research protocol and informed consent documents. A team of stakeholders including VA mental health care professionals and researchers, members of the CAVHS Suicide Prevention Team, IRB representatives, and suicide prevention experts were recruited for guidance in protocol development. Specifically, the original protocol involved outpatient home visits to participants who had attempted suicide within the past 30 days. Suicide and mental health experts advised that data relying on participant recall of a traumatic experience was most reliable within the first 72 hours after the event and that those participants within an in-patient unit were not any more emotionally liable than those in out-patient settings. This change in protocol to recruit in-patient participants greatly served to appease IRB concerns for participant safety.

Clinical staff was also recruited to inform the protocol design.

<table>
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<tr>
<th>Risk Categories</th>
<th>Challenge(s):</th>
<th>Approach(s)</th>
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<tbody>
<tr>
<td>Confidentiality Risk(s)</td>
<td>Recruitment: The need to protect confidentiality of in-patients during screening for study.</td>
<td>Approach: Screening of potential candidates will be performed by the clinical in-patient staff. Willing candidates will then be referred to the study team for recruitment and consent.</td>
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<tr>
<td>Participant confidentiality:</td>
<td>Challenge: Assuring that sensitive information disclosed during interviews is kept confidential and cannot be subpoenaed by third parties or divulged without the participant’s consent.</td>
<td>Approach: A Certificate of Confidentiality was obtained from the NIH to protect participants’ information.</td>
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<tr>
<td>Participant Harm</td>
<td>Challenge: Talking about suicide attempts/ideation may bring back thoughts of self-harm and anxiety</td>
<td>Approach: Evidence presented to IRB that discussing a suicidal event does not mean participant will repeat suicidal event.</td>
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<td>Study Team Risks</td>
<td>Approach: Implement risk assessment plan that includes Pre-interview risk assessment by clinical staff Post-interview assessment by clinical staff Safety plan for emergencies during the interview process</td>
<td>4. Participant follow-up by the VA’s Suicide Prevention Team</td>
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<td>Abbreviations: NIH: National Institutes of Medicine; VA: Veterans Administration</td>
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by advising on clinical logistics and processes. Clinical staff members were indispensable stakeholders in that they would identify and screen potential participants, including assessing willingness to participate in the study. Thus the clinical team provided a warm-hand off of the potential study participant to the research team. The researchers would then describe the study in detail, answer any questions, and if the patient was willing, proceed with consent and enrollment into the study. IRB approval required clear role definition and separation of clinical staff from research staff roles. Involvement of clinical stakeholders was essential in obtaining IRB approval because it provided mechanisms by which risks would be minimized.

The IRB Review Process to Reduce Risk

Study investigators coordinated protocol development and IRB review through a six-step process: (1) Contacting the IRB administrator, (2) Requesting an administrative pre-review by IRB staff, (3) Presenting a study overview of purpose and proposed methods to the IRB, (4) Undergoing a second pre-review by IRB staff when the protocol significantly changed, (5) Contacting the IRB member assigned as primary reviewer for the protocol, and (6) Undergoing a full review by the IRB.

1. Contacting the IRB Administrator. An initial meeting with the IRB administrators included a discussion of required review concerns that the IRB might have for this first time submittal. This was essential because this was the first time that the IRB members and administrators had dealt with a protocol involving suicide. Discussion informed the protocol submission by delineating: (a) participant identification and recruitment; (b) the consent process, including determining a participant’s ability to consent; (c) assessment of risk and safety before, during, and after the interview; (d) safety measures in the event of a crisis; (e) follow-up safety measures; (f) data collection, storage and dissemination, (g) waivers of consent for screening purposes by clinical staff, and (h) participant confidentiality specifically as relating to participants at risk for suicide.

2. Administrative Pre-Review. The pre-review identified that submitted paperwork was complete and accurate, including all elements required by regulations [21,22].

3. IRB Presentation. The investigators presented an in-person overview to the convened IRB of the purpose and study design which included out-patient interviews at 30 days after the attempt. IRB members received clarification to questions from study investigators and, as a result, the application was moved from a greater-than-minimal-risk to a minimal-risk category. Input from IRB members who were mental health professionals was instrumental in helping the entire IRB membership understand participant characteristics and the effectiveness of possible risk reduction strategies. The presentation also led to discussion of potential risks to study team members in terms of physical safety for off-site interviews and for mental distress to investigators following interviews. As a result, investigators added safety parameters for study team members to the 30-day protocol and the opportunity for them to de-brief with a mental health specialist.

4. Second pre-review. When expert suicide research consultants advised that the qualitative interviews with participants needed to be conducted within 72 hours for interview integrity of the study's objectives, the protocol's enrollment criteria was revised to inpatient participants. A revised application was presented to the IRB administrative staff for a second pre-review. Early involvement of IRB administration as a key stakeholder allowed each pre-review to be seen as a collaborative endeavor by both investigators and IRB in the protocol development process.

5. Contact with primary reviewer: Although the in-patient status of participants in the revised protocol minimized risk of immediate self-harm, the ability to consent and the risk of inflicting greater distress due to the interview was an area of potential concern to the convened IRB. Disclosure of the identity of the study’s primary reviewer prior to full committee review allowed the investigators to be available for further clarifications that might be needed.

6. Full IRB review and subsequent approval: During the full review the convened IRB approved the protocol contingent on attaining a NIH Certificate of Confidentiality to protect the identity of research participants from compelled disclosure in legal proceedings [15,23].

RESULTS AND DISCUSSION

This was the first protocol our institution reviewed that dealt with suicide and participants who had attempted suicide. Because of the sensitive nature of the research topic and unfamiliarity of the IRB members with this patient population, specific care was undertaken to ensure that steps normally taken to ensure participants right and to mitigate risks were also adequate for this patient population and that extra precautionary steps were added when warranted. Each of the outlined steps allowed for collaborative problem-solving to allay concerns on both sides and determine the best approach to the research question. The main areas of IRB concern were: 1) confidentiality and data security, 2) potential participant harm, and 3) study team risk. Table 1 shows the risk categories, the challenges concerning these categories, and the IRB-approved approaches to reduce those risks.

The IRB concerns regarding confidentiality of patients undergoing psychiatric treatment and minimizing research personnel access to sensitive health information were alleviated by involving mental health clinical staff in the participant screening process. Involvement of clinical care providers in identifying potential participants and referring those interested to the research team for further information and consent is a common practice in clinical studies; however, this approach protects sensitive health information of all potential participants regardless of their decision to enroll in a research trial. Thus, the study team would have access only to the names and contact information of eligible patients willing to be contacted to participate in the study. Means by which established VHA Regulations regarding secure storage of electronic and hard data files (i.e., consent, HIPPA documents, and authorization for audio recording of interviews) were scrutinized due to the sensitive nature of information given by study participants [22,24] to ensure that confidentiality of sensitive material was maintained at all steps of the study data acquisition and storage. The IRB also required investigators to obtain a Certificate of Confidentiality...
The IRB expressed concern that talking about a suicide attempt or ideation could cause a study participant to experience additional anxiety and increase the potential for self-harm. Investigators presented evidence that discussing a suicidal event does not increase the likelihood that a participant will re-attempt suicide or have recurring ideations [24,25]. IRB members who were mental health professionals and had experience treating suicidal patients corroborated these studies. The study protocol modification to the 72-hour window and a monitored in-hospital setting required a change in the safety plan that included ensuring that all members of the clinical psychiatry unit staff were aware of the study protocol. In the event of participant distress, study team members would immediately notify clinical staff and discontinue the research interview [14,26]. The IRB required an additional emphasis throughout the entire screening, consent, and enrollment process that in-patient participants are made aware of the voluntary nature of participation and their rights as research subjects. The IRB also required that an independent data safety and monitoring board (DSMB) review study progress, any adverse events, and concerns that might arise in the research process. Study investigators recruited DSMB members from the VA psychiatric staff, national VA experts in suicide prevention, and the health services clinical team [13-27]. Risk mitigation was also considered by the IRB in terms of study team members. Thus consultants for the study who were either part of the clinical staff or were mental health professional colleagues were recruited to debrief study team researchers in the event of an emotionally difficult interview, severe adverse event, or participant distress leading to interview cessation or participant withdrawal [27,28].

Although this manuscript details the experience of one investigator with an IRB, the approaches detailed within have applicability to other protocols of similar sensitive natures, particularly if those protocols are the first-in-kind that a particular IRB has considered. Institutional Review Boards are governed by a set of regulatory standards [6,28], yet their internal composition and operational timelines depend on the size of the institution’s research and individual environment of each particular institution [6,27,28]. The mechanisms by which IRBs form decisions have been addressed in an effort to increase transparency and provide standard frameworks for mechanisms for IRB review while maintaining individuality of each board [27-29]. However, policies and procedures for protocol submittals and required timelines may have nuances that are particular to each institution. The first step of meeting with IRB administrators is thus an important step when dealing with a unique patient population, vulnerable patients, a protocol that may have significant perceived risks, or when an investigator is new to the particular institution. Investigator meetings with the convened board are an option when a board is faced with aspects of a protocol that pose ethical questions or ambiguities. Thus involving the IRB members and administrative staff as stakeholders or partners in a review process results in a cooperative process that ensures participant’s rights and research integrity.

CONCLUSION

A multi-step process to ensure IRB approval and mitigated risk to participants was obtained:

Early identification of key stakeholders including members of clinical staff, IRB administration staff, and IRB members in addition to experts in suicide prevention is instrumental in protocol development and revisions.

Initial meeting with IRB administrators to inform study team of IRB approval process and additional IRB requirements regarding suicide research early in the study protocol development process.

- Recognition that members of the IRB may not be experts in suicide prevention; an in-person presentation can help both investigators and IRB members recognize strengths and weaknesses in the protocol design prior to submission. A mental health professional (as a permanent part or as an ad-hoc IRB reviewer) can be instrumental in the final review process.

- Early engagement of the IRB administration as an important stakeholder for ensuring human subjects rights and safety allows for willing subsequent pre-reviews of material.

The authors experienced that the IRB members were willing to learn about suicide and suicide prevention research and have been willing to support future research on this topic. The established stakeholder relationships allowed for a final protocol that assured participant safety and confidentiality while maintaining research integrity; and enabled an efficient approval process that has continued in subsequent proposals.

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Human Subjects Approval: The Central Arkansas Veterans Healthcare System Institutional Review Board approved this study.

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REFERENCES


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