A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF RESEARCH ON END OF LIFE ISSUES

ADOLESCENT AND YOUNG ADULTS COPING WITH CANCER

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OVERVIEW

The social, behavioral, and educational research (SBER) case studies provide education and guidance on how to identify and mitigate risks associated with SBER. These studies may be used by both IRB administrators and investigators when reviewing and designing research studies that involved SBER components.

Case studies follow a standard format that includes: 1) a fact pattern, 2) regulatory, cultural, and ethical issues, and 3) a risk/benefit analysis and risk management options. This format was created to allow for flexibility in applying the case studies.

By identifying common themes, linking them directly to federal regulations and guidance, and outlining risk mitigation options, the case studies can be used in a variety of ways, which include: 1) as an education tool for training individuals in human subjects research, 2) as a basis for developing reviewer checklists/worksheets, and 3) as a tool in designing research projects.

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CASE STUDY

SCENARIO/FACT PATTERN:

A study team wants to compare psychological distress within the adolescent and young adult (AYA) population (defined as ages 29 to 40) with psychological distress described in an older cohort. The study seeks to identify risk and protective factors affecting the likelihood of psychosocial distress as well as to explore how medical-pharmacological factors and psychosocial factors influence the health and broader social and familial functioning of AYAs with cancer.

Potential participants would be cancer patients with advanced and incurable or metastatic cancer with a prognosis of less than 12 months to live. The institution’s recruitment policy requires approval and joint approach by the treating physician. The study team plans to identify potentially eligible participants by reviewing clinic lists from different disease groups as well as a vetting with oncologists and nurses at weekly care team meetings. If the oncology provider approves a request to approach his/her patient, the patient will be sent an introductory letter and the informed consent document. The consent form describes the research as follows:

This research study is evaluating Adolescents’ and Young Adults’ (AYAs) experience with cancer. The research study aims to look at the psychological, physical, social, and emotional aspects of a cancer diagnosis and treatment.

An opt-out card and phone number will be provided. Interested patients will be met in the clinic to discuss the study and to obtain their consent to participate. In an effort to enhance recruitment, several adult oncologists from various disease programs will participate as co-investigators.
Subjects will participate in a baseline interview and will then be asked to complete several instruments pertaining to:

- Socioeconomic and demographic factors
- Mental status
- Quality of life
- Prolonged grief
- Evaluation of suicidality
- Spirituality/religiousness
- Generalized self-efficacy
- Disability
- Human connection
- Emotional acceptance of terminal illness
- Preference for prognostic information
- End of life discussion
- Information-seeking experience
- Cognitive acceptance of terminal illness and patient’s evaluation of health
- Advance care planning
- Treatment preferences
- Social support
- Alcohol dependence
- Mental health service use
- Health status and medical factors
- Lifetime and current mood and anxiety disorders

Participants may choose to be interviewed in the clinic or at home. It is estimated that the interview will last 60 to 90 minutes. Subjects will be compensated for participating in the study. A psychiatrist whose expertise is psychosocial oncology and palliative care will be available in cases of participant distress. Participants who indicate a desire to speak with a mental health professional after the interview will be provided with a referral. In addition, participants whose responses indicate a risk for suicidality or are found to meet the DSM-IV criteria for major depressive disorder or an anxiety disorder will also be offered a referral to a mental health clinician.
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DISCUSSION

Questions/Comments for the researcher:

- What is the typical coping care provided to this population?
- Why is the age range so broad—29 to 40 encompass many stages of life?
- Are participants all from within the same institution, where all receive the same standard of care/support?
- What are the oncologists considering when they review their list of patients? Are they introducing any bias into the investigation by screening in – or out – certain types of patients?
- Consider adding exclusionary criteria such as someone with known suicide attempts, or other similar criteria/questions that will protect subjects, while maintaining scientific integrity.
- Is a letter the right way to make first contact?
- Discuss the question of researcher qualifications to carry out this kind of research.
- Address issues of coercion and willingness to participate (related to institutional policy of joint approach by treating physician)
- When are the responses on the instruments evaluated or reviewed?

REGULATORY, CULTURAL, & ETHICAL ISSUES:

The IRB’s major concerns are:

- The addition of oncologists to the study team
- Participant burden
- How the study team will handle emotional and mental distress issues that may arise

Of additional concern is the language in the consent form describing why these patients are being asked to participate in the study. The issue is two-pronged: how much do the participants need to know about the study’s objectives and how much do they need to understand about the reasons why they are being selected to participate in the study? The study team’s concern is that they should not disclose information about a participant’s prognosis to him/her if the participant’s oncologist has not yet done so.

RESOLUTION & DISCUSSIONS:

Risk/Benefit Analysis:

Of primary concern to the IRB is the ability of the study team to identify distress that must be addressed by a mental health professional outside of the study team. The sensitivity of a population with a difficult prognostic situation is of paramount importance in considering such risk.

Mitigation/Management of Risks:

In order to make inclusion criteria and characteristics of the target study population more clear, the IRB might suggest use of the term “advanced cancer” as opposed to just cancer, or adding “difficult to treat” or “has required multiple therapies.”

The study team should have procedures in place to identify situations of distress and to provide assistance and referrals. The study team must be prepared to discuss the meaning of a participant’s advanced cancer during the consenting and interview processes.
Alternate Details:

The study population was all adult participants. If pediatric participants were to be included, the additional risk considerations found under 45 CFR 46.401 et seq. (Subpart D) would apply as well as issues involving assent and the appropriate age group.

Other Events:

1. A surviving spouse requested the investigator to provide the decedent's questionnaire answers in order to understand what the decedent was feeling at the end of life. The IRB was advised by the General Counsel's office that as the executor of the estate, the surviving spouse had the legal authority to obtain certain records pertaining to the spouse. However, under HIPAA, the research records fall outside the definition of a Designated Record Set and therefore, the executor is not entitled to obtain the records under HIPAA.

   The IRB reviewed the consent form, which like most research informed consent documents, stated clearly that the data generated by the research would be seen only by the research staff. The IRB was sympathetic to the spouse but felt that the promise to the participant to keep responses confidential was of the highest importance and the request was denied.

2. Participant commits suicide.

REFERENCE(S)

45 CFR 46 (namely: 45 CFR 46.109(b) and 45 CFR 46.111).

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html