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Intervention Research with Youths at Elevated Risk for Suicide: Meeting the Ethical and Regulatory Challenges of Informed Consent and Assent

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Abstract

Intervention research with youths at elevated risk for suicidal behavior and suicide—a vulnerable and high risk population—presents investigators with numerous ethical challenges. This report specifically addresses those challenges involving the informed consent and assent process with parents/guardians and youths. The challenges are delineated in the context of pertinent laws and regulatory requirements, and guidelines are suggested for their practical resolution. These are illustrated with case examples from NIMH-funded intervention trials. Through the sharing of such methodological information, intervention researchers can support each other in conducting ethical research in a manner that does not unduly compromise scientific rigor.

There is an urgent need for more research focused on preventing suicidal deaths and the morbidity related to suicide ideation and attempts among youth. Suicide is the third leading cause of death among adolescents and young adults ages 13 to 19 (Centers for Disease Control and Prevention [CDC], 2006), and suicidal behavior reaches a peak during the mid-adolescent years (Novick, Cibula, & Sutphen, 2003). In response to the gravity and significance of this public health problem, research on preventive interventions and treatments was established as a national priority in the U.S. Surgeon General's *Call to Action to Prevent Suicide* (U.S. Public Health Service, 1999).

As researchers strive to develop evidence-based preventive interventions and treatments for suicidal youth, it may not be possible to extrapolate all findings from intervention studies with suicidal adults because of important developmental considerations (Cicchetti, Rogosch, Toth, Reynolds, & Johnston, 1994; King, 1997). These include the substantially higher ratio of suicide attempts to suicide deaths in youth relative to older age groups and (CDC, 2006) the variable patterns of risk for completed suicide across the life span (Conwell & Brent, 1995). This issue of developmental specificity is not unique to the field of suicidology. It was recognized as a general concern by the National Institutes of Health in 1998 when they developed a policy requiring the appropriate inclusion of children and adolescents in federally funded research studies (National Institutes of Health, 1998). Because youths are, by definition, a “vulnerable” population (45CFR46.402), and because youths at elevated risk for suicide can be considered a “high risk” population, the recommended intervention research presents numerous ethical challenges.

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This report pertains to one set of these challenges—those involving the informed consent and assent process. Perhaps not surprisingly, the recruitment of youths at elevated risk for suicide presents substantial challenges in this arena. Extending upon earlier reports concerning intervention research with suicidal individuals (Fisher, Pearson, Kim, & Reynolds, 2002; Pearson, Stanley, King, & Fisher, 2001) and focusing specifically on issues concerning informed consent/assent that arise in research with children and adolescents, here we (1) review pertinent federal and state laws, regulations, and policies; (2) describe ethical issues or dilemmas, incorporating case illustrations; and (3) suggest guidelines for the practical resolution of these dilemmas. The case illustrations are from current NIMH-funded intervention studies with suicidal youths.

INVOLVING YOUTH AND PARENT/GUARDIAN IN CONSENT PROCESS

It is essential for intervention researchers working with suicidal youths to become familiar with the federal regulations pertinent to informed consent requirements with minors as well as the relevant state laws governing the consent process. As indicated in the "Guidelines for Adolescent Health Research" (Santelli et al., 2003), a general principle of "respect for the person" also requires attention to youths' emerging capacities to provide informed consent. "Respect for persons" was one of the three overarching ethical principles highlighted in the Belmont report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979), which guides many of the federal regulations for research with human subjects.

Pertinent Laws and Regulations

The *Code of Federal Regulations (CFR)* outlines the federal requirements for research involving human subjects, including the requirements for clinical investigations that require Food and Drug Administration involvement (i.e., psychoactive medications) (45CFR46). Investigators must obtain legal informed consent of the subject or the subject's legally authorized representative. A subsection of these regulations, *Additional Protections for Children Involved as Subjects in Research*, establishes the parameters or Internal Review Board (IRB) guidelines for conducting such research with children and adolescents (General research, 45CFR46; Clinical investigations, 21CFR50). These guidelines vary by the level of risk to the child or adolescent, and are similar whether or not the intervention research meets the specific definition of a "clinical investigation."

If the intervention research presents no greater than minimal risk, children and adolescents at elevated risk for suicide may participate if the IRB "finds and documents that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians." If it is determined that greater than minimal risk is involved but there is the prospect of direct benefit to the children or adolescents, the IRB must find and document that three conditions are met for the research to be approved. These conditions are defined by the regulations as follows: "(a) The risk is justified by the anticipated benefit to the subjects; (b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and (c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians" (45CFR46.404, 21CFR50.55). In both of these types of research, the permission of one parent/guardian is generally sufficient for research to be conducted (45CFR46.404, 46.405). A preventive intervention or treatment study should clearly be designed to meet the criteria for either "no greater than minimal risk" or "the prospect of direct benefit."

The principle of respecting youths' emerging capacities for providing assent is also reflected in these regulations (45CFR46.408). In determining the appropriateness of child assent,

federal regulations state that the "IRB shall take into account the ages, maturity, and psychological state of the children involved" (45CFR46.408). The FDA does not require the informed consent document to contain a designated space for the child or adolescent's signature and assent; however, many IRBs consider it standard practice to obtain the agreement of older children who can understand the essential elements of the study before enrolling them in research. Some IRBs require two documents, a fully detailed explanation for parents/guardians and older children to read and sign, and a shorter, simpler assent document for younger children (U.S. Food and Drug Administration [FDA], 1998).

Ethical Challenges and Suggested Guidelines

Youth Maturity and Psychological State—The investigator has the responsibility to determine whether or not a minor has the intellectual capacity and maturity to provide assent for participation in an intervention study. That is, the investigator must determine whether or not the youth understands the research and is able to make a balanced decision that takes into account risks and benefits. This generally requires an individualized approach and may be especially challenging with an adolescent who has recently made a suicide attempt, has a history of serious "errors in judgment" involving alcohol or drug use, or who has shown substantial recent deficits in problem-solving capabilities. The youth's capacity to make an important decision may be impaired, even if only for a period of time, due to an exacerbation of symptoms or worsening of a psychiatric illness. The investigator may need to obtain information about the youth's mental status by reviewing intake records, consulting with others (e.g., parent, clinical provider), or conducting a brief mental status exam. Because the investigator will often have a researcher-subject relationship with the youth, unless providing primary treatments, this step may require either IRB approval as part of the study protocol or specific parent/guardian permission.

Case example

Michael is a 15-year-old male who was admitted to the psychiatric hospital with suicidal ideation and recent psychotic symptoms. In an effort to evaluate Michael's capacity to give informed assent, project staff consulted with a member of his treatment team (in this case the psychiatric nurse) to determine the youth's mental status. The nurse confirmed that Michael was actively psychotic and unable to give informed assent. Despite the fact that parent/guardian informed consent had already been obtained, this youth could not be enrolled in the study as the IRB-approved protocol required parent/guardian consent and youth assent.

Parent/Guardian Authority Versus Youth Autonomy—The principle of "respect for the person" converges with the investigator's goal of developing a partnership or alliance with youth and parent/guardian research participants. The overall process involves respecting parent/guardian wishes and concerns about the vulnerability of the child and respecting youths' emerging capacities to make decisions about their participation. Researchers are advised to be sensitive to the dynamics between child and parent related to decision making and autonomy, particularly as the suicidal youth may be in a state of heightened emotional vulnerability or desirous of greater control. The investigator should first obtain permission from the parent/guardian to approach the youth, then independently approach the youth about potential participation. This process may involve several steps, including parent/guardian permission to contact their child, parent/guardian consent for child participation, then presentation of research to the child or adolescent. That is, in most instances, the parent/guardian has the initial veto power and the youth has the final veto power. It is recommended that research staff clarify that the youth's permission is key to the informed consent process.

Case example

The parents of a 13-year-old girl, April, gave their permission for her to participate in an intervention study. April had been hospitalized recently following an overdose of aspirin and prescription medication that was preceded by ambivalent suicidal intent. When approached by research staff, April declared she was not interested in participating in research. Her parents, however, were persistent with her and the research staff, explaining that it would be "good for (her)." The research staff explained the importance of the youth's own willingness to participate as essential to the process of being a study participant. The parents were able to accept their daughter's position and did not coerce her to become involved in research. Upon further consideration and on her own accord, April chose to participate.

OBTAINING YOUTH CONSENT WITHOUT PARENT/GUARDIAN CONSENT

Because some suicidal youth have experienced recent or longstanding psychosocial traumas such as abuse/neglect, significant parental drug dependence, or homelessness, investigators may encounter situations wherein parent/guardian consent is a formidable obstacle or perhaps even contraindicated. This may occur if the investigator's goal is to obtain the most representative sample possible (e.g., including emancipated minors) or if the goal is to develop an intervention for a special needs population (e.g., history of abuse, homeless, wards of state).

State laws and statutes are highly variable; however, an understanding of several of these laws is critical for intervention researchers interested in the possibility of youth consent without parent/guardian consent. In addition, federal regulations enable the IRB to waive the requirement of parent/guardian consent in appropriate circumstances when such a waiver is not inconsistent with federal, state, or local laws (45CFR46.408).

Laws and Regulations

Emancipated Minors—Some states have statutes that allow minors to become legally emancipated. As indicated in the *National Survey of State Laws*, this means that a minor will be treated as an adult for legal purposes (Leiter, 2004). For instance, some states provide for automatic emancipation if a minor enters a valid marriage, and many states have legislation that enables a court to declare a minor emancipated based on a petition from the minor and/or the minor's parents. These state statutes have commonalities such as a minimum age, and a situation wherein the minor lives independently from his or her parent and is economically self-sufficient. The range in age for emancipation across states is 14 to 18 years (Leiter, 2004). Information concerning emancipation can be found in the Juvenile Law Center publication, *Emancipation in the United States* (Juvenile Law Center, 1999–2006).

Mature Minor Rule—The mature minor rule enables minors to give consent to their own health care if they are able to understand the nature and consequences of the treatment and if they are mature enough to make a decision on their own. Only a small number of states have adopted this into statute or law, and it remains controversial (Boonstra & Has, 2000). Although it has been argued that this concept could reasonably be applied to research participants (Fisher, 2004; Society for Adolescent Medicine, 2003), the rule does not specifically address research. Furthermore, only some courts in states with a mature minor rule have applied it to research circumstances (Boonstra & Nash, 2000).

Ward of State—Special guidelines exist for instances in which a minor child is a ward of the state and has been appointed a guardian by the court for the responsibility of their care.

> Children who are wards of the state or any other agency, institution, or entity can be included in research approved under 46.406 or 46.407 only if such research is related to their status as wards; or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards. IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. (45CFR46.409)

Other Special Circumstances—The *CFR* allows IRBs to waive parent/guardian consent in select circumstances. The regulation states:

> if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements … provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. (45CFR46.408)

Investigators may be able to include suicidal adolescents who are homeless or possibly physically or sexually abused without parent/guardian consent when (a) involvement of parent/guardian would compromise the safety of the adolescent, and (b) the adolescent has the capacity to give informed consent. This would require IRB consideration and approval.

Ethical Challenges and Suggested Guidelines

Variation in Interpretation of Federal Regulations—When an investigator would like to seek permission to involve a child or adolescent without parent/guardian consent, the primary challenge may be variation in the interpretation of federal regulations and IRB policies (Society for Adolescent Health, 2003, p. 397). A decision to allow minors' to consent should involve the investigator's IRB, the data and safety monitoring board (DSMB) for the specific intervention study, and the National Institutes of Health (NIH). This network provides for optimal consideration of the complex issues involved in addition to a certain regulatory protection in terms of shared decision making.

Availability of Person to Go to in Crisis—Risk management protocols for intervention studies with youth generally specify that the parent/guardian is to be contacted if the youth is in crisis or shows signs of increasing suicide risk. With a mature or emancipated minor, there may not be a parent or guardian available to involve in the response plan. In circumstances in which a child is a ward of the state, this concern may be mitigated if the state has appointed an advocate for the child. Nevertheless, an advocate for consent purposes may or may not be available in a crisis. Although unavailability in a crisis can also be an issue with a parent or legally appointed guardian, it may be much more likely if one is involving a homeless adolescent or emancipated minor.

> **Case Example**
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> Todd is a 15-year-old male who assented to participate in an intervention study while residing with his uncle who had become his legal guardian several years earlier. The uncle provided informed consent for his participation. Todd had been admitted to the psychiatric hospital due to chronic, unrelenting suicidal ideation with a recent statement of suicidal intent. Prior to the first outcome assessment, Todd's uncle revoked his guardianship and Todd was placed in temporary foster care. At the 6-week assessment, Todd was identified as being at high risk and in need of an emergency psychiatric evaluation. Research staff notified Todd's foster

parents to provide them with these recommendations. However, they also had to contact the foster care worker who was the court appointed temporary guardian. This individual was able to provide consent for Todd's continuing participation in the study and authorize the emergency evaluation.

Intervention researchers are advised to proceed with caution when the written informed consent of a parent or legally appointed guardian of a suicidal youth is impossible to obtain or perhaps contraindicated. Nevertheless, it is understood that some research of substantial public health significance, such as research with suicidal homeless adolescents (or physically or sexually abused adolescents), may require going forward without the involvement of a parent/guardian. In these instances, it is recommended that investigators proactively consult with their IRB, DSMB, and the NIMH in determining how to best design the study and establish a risk management protocol that is feasible and guards the safety of participants.

It is also important to consider carefully the legal complexities posed by these extenuating circumstances. As one example, investigators are advised to consider their own state's laws concerning age of majority and emancipation in determining whether or not adolescent research subjects should be considered children, requiring parent/guardian consent under federal regulations (Santelli et al., 2003). Researchers are also advised to use caution in relying on state definitions of mature minors. As noted by Fisher (2004), most of these laws do not address whether or not the designations of emancipated minor or mature minor apply to research. Nevertheless, the mature minor rule may be extremely relevant in many intervention studies with suicidal youth as these youth may be in need of treatment for substance use or other mental disorders, which merges or blurs the boundaries of clinical care and research.

Youth Participant Is 18 Years or Older Prior to Study End—This change in status from a minor to an adult occurs commonly in intervention research with older adolescents who are suicidal. Intervention studies incorporate multiple assessments across a period of time that allow the investigator to examine outcomes and the stability of outcomes. When the participant turns 18, the investigator needs to re-consent the individual, seeking written informed consent from the participant. The parent's earlier provision of written informed consent will not apply at this time. One relatively easy strategy for managing this complication is to include the participants' birthday and "age at time of assessment" as columns on the assessment tracking log. If the subject will be 18 years or older at the time of the assessment, research staff can include a blank written informed consent document in the assessment materials folder.

LAWS AND REGULATIONS

Federal regulations require the inclusion of eight basic elements in each research consent document. As may be familiar to readers, these elements are as follows: (1) study purposes and procedures; (2) foreseeable risks or discomforts to the subject; (3) benefits to the subject; (4) appropriate alternative procedures or courses of treatment; (5) how confidentiality will be maintained; (6) compensation or available medical treatments and contact information if injury occurs for research involving more than minimal risk; (7) contact information for answers to questions about the research, rights of the research subject, and research-related injury to the subject; and (8) participation in research is voluntary, refusal to participate or subject discontinuation will involve no penalty or loss of benefits (45CFR46.116). Consistent with these required elements, youth and parents or guardians must understand that an intervention study is research and that the intervention or

treatment is not, in most instances (unless the intervention is characterized by a previous randomized controlled clinical trial demonstrating its efficacy), an evidence-based strategy.

ETHICAL CHALLENGE AND SUGGESTED GUIDELINES

Participants' Expectations and Assumptions

Youth participants and their parents/guardians may expect that participating in a treatment or intervention study will reduce the study subject's risk for suicide. Similarly, they may believe that they will get the optimal cutting-edge evidence-based treatment only by participating in such research. Although this may be true to the extent that the treatment or intervention being investigated is found to be efficacious in the study, an intervention may not be as effective as the investigators hypothesized it would be. Such parent or adolescent beliefs may be based partially on the youth's or family member's hope that the treatment will help to resolve unrelenting psychological distress and suicide risk.

There are clear parallels between this scenario and some individuals' motivations for involvement in cancer research. In a discussion of the challenges involved in obtaining parental permission for clinical trials for pediatric cancer patients, Fisher notes that recruitment generally occurs during a stressful period for the family, usually following a new diagnosis of cancer (Fisher, 2005). This context may facilitate a blurring of treatment and research goals (Fisher, 2005; Levi, Marsick, Drotar, & Kodish, 2000). Levi et al. discuss the possible positive and negative reactions that parents and youth may have to research recruitment efforts in clinical trials involving children with cancer. These include both a belief that providers may prioritize the research over clinical care and a positive sense of relief that they are getting the best or most advanced evaluation and treatment services (Levi et al., 2000). Parents and guardians of recently hospitalized suicidal patients are also in a state of crisis, especially if their child is being newly diagnosed with a psychiatric disorder or they are faced with the shock of a suicide attempt. They may feel desperate to put in place everything that is available and perceive participation in research as a way to obtain additional or specialized help.

Investigators are responsible for clarifying that they are implementing a research protocol, which is usually extremely evident by the end of the written informed consent process. Investigators are, however, also responsible for informing participants about alternative available treatments. While maintaining a positive orientation, empathy, and hopefulness about the patient's future well-being, investigators are advised to be careful not to collude with what may be unrealistically high expectations for the treatment or intervention under investigation. That is, they must not allow the parent/guardian or child to enter the study with a false assumption that they are necessarily obtaining the fastest acting or most efficacious treatment through participation. This may be especially challenging when working with individuals from varying cultural backgrounds due to differing assumptions and implicit rules concerning appropriate responses to authority figures, including professional providers. At the same time, however, information and education about the implications of participation in research (including the possibility of enhanced monitoring of risk for suicide and completion of evaluations) should clarify the extent to which participation may have benefits. With the understanding that there are no strongly evidenced-based interventions for a youth's particular combination of problems resulting in elevated risk (even if alternative treatments are available), parents and guardians must make a carefully considered decision to participate in a study. They may do so with the hope that their youths may obtain better care than is available in the community due to the intensive monitoring that is characteristic of an intervention study or due to the involvement of university faculty with specialty expertise.

Case Example

The mother of a 16-year-old girl, Roseanne, admitted for a suicide attempt, was approached by recruitment staff about participating in an intervention study. After hearing about the study, the mother responded, “I would like her to do this. Roseanne can get all the help she needs for her depression.” The research staff took the time to review the purpose of the study and to clarify that the study was not an evidence-based clinical service and involvement did not guarantee improvement in her condition. The research staff also reiterated the differences between the research and clinical services that would be provided to her daughter. Once this issue was clarified, the research staff was able to proceed with the informed consent process.

Parental Concerns About Discussing Suicidality “After” the Crisis is Over

When approaching a suicidal youth’s parent about possible involvement in an intervention study that involves repeated assessments or any type of involvement following the index suicidal incident (i.e., emergency room visit, psychiatric hospitalization), it is not unusual for the parent to express a fear or concern about bringing up the incident or even mentioning “suicidal thoughts” or “suicide attempt” again. A parent may state that this “chapter is finished” or this “is history now.” This is inconsistent with participation in intervention research, which necessarily involves repeated assessments, including repeated questions concerning suicidal thoughts and hopelessness. Two recent studies provide a helpful foundation for the intervention researcher’s conversations with these parents. Recent empirical evidence indicates that asking questions about suicidality is not iatrogenic in school screening (Gould et al., 2005), and this is consistent with data on pre-post assessment changes in suicidality during randomized controlled trials (Reynolds, Lindenboim, Comtois, Murray, & Linehan, 2006). Reynolds et al. report that pre-post assessment changes in suicidality were modest and approximately evenly divided between decreases and increases in suicidality. It can be extremely helpful to share this scientifically based knowledge with parents or guardians when seeking written informed consent for their son or daughter’s participation in an intervention study.

Alternative Treatments and Safety Considerations

In discussing the treatment under investigation and alternative treatments, it has been recommended that investigators note limitations concerning what is known about treatment effectiveness in decreasing suicidality (Pearson et al., 2001). As a parallel to this, investigators have a responsibility to discuss possible safety concerns. A visible current example concerns safety considerations associated with selective serotonin reuptake inhibitors (SSRIs). Following a detailed examination of adverse events from clinical trials involving SSRIs, the FDA placed a cautionary “black box” warning on these medications (Leslie, Newman, Chesney, & Perrin, 2005), which received substantial coverage in the popular press. Recently this warning was revised to specify young adults in the warning (FDA, 2007). Investigators should be prepared to encounter sensitized consumers who are anxious about participating in a clinical trial involving medication and/or consumers who request much additional information prior to making a decision.

A discussion of alternative treatments and safety considerations can be challenging for investigators conducting intervention research with suicidal youth. Such investigators are usually clinically trained and highly experienced providers who want to establish positive or hopeful expectancies with patients. They also want to recruit youth for their clinical trials. Unfortunately, our toolbox of evidence-based treatments or interventions for suicidal youth is rather small and some of our tools are associated with possible harmfulness. Because of this, it is recommended that investigators (a) provide clear (concrete) data relevant to safety

concerns (which is reassuring to many youth and parents who may have exaggerated concerns based on perceptions of media reports), and (b) focus on evidence-based treatments for suicide risk factors (e.g., depression, alcohol abuse). If relevant efficacy or effectiveness data are available for the intervention being investigated or an alternative available treatment, it is recommended that the investigator share with the participant and parent/guardian the (a) the numbers of patients that need to be treated to benefit one additional child or adolescent, and (b) the numbers of patients that need to be treated to cause harm to one additional child or adolescent (Sackett, Richardson, Rosemberg, & Haynes, 2000; Whittington, Kendall, Fonagy, Cottrell, Cotgrove, & Boddington, 2004). These numbers provide more information and perspective than a simple safety warning.

CLARIFYING THE LIMITS OF CONFIDENTIALITY

Laws and Regulations

Subjects are protected from disclosure of personal identifying and other sensitive information without their written permission (45CFR Part 160 and Subpart A and E of Part 164). Moreover, among the criteria required for IRB approval is the assurance of "adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data" (45CFR46.111). Both DHHS and FDA regulations identify the requirement for informed consent to include statements, "describing the extent, if any, to which confidentiality of records identifying the subject will be maintained" (21CFR50.25, 45CFR46.116). Whereas these regulations are concerned with the risks associated with research participation, including confidentiality risks, the privacy rule addresses the risk to the subjects' privacy that is associated with the use and disclosure of the subject's protected health information (PHI) (DHHS, 2004). Exceptions to confidentiality in research with high risk youth include the presence of risk of self-harm, threat of harm to others, and report of abuse or neglect. The pertinent regulations are described below.

Child Abuse Reporting—According to the U.S. code on child abuse reporting, a person engaged in professional activities (as identified in the code), who learns of facts that give reason to suspect that a child has suffered an incident of child abuse, is required to make a report of the suspected abuse as soon as possible (U.S. Code collection, Title 42, Chapter 132, Subchapter IV, 13031. Child Abuse Reporting, p. 1, retrieved August 9, 2006, from www.law.cornell.edu).

Duty to Warn—The duty to protect third parties from harm requires disclosure of threats of harm to others when the provider has a reasonable basis to believe the threat is real and harm could result. In the leading case, *Tarasoff v. Regents of the University of California* (1976), the California Supreme Court ruled, "that psychotherapists who determine, or reasonably should determine, that their patients are likely to be dangerous to identifiable third parties have a duty to take whatever steps are reasonably necessary to protect the potential victims" (Applebaum & Rosenbaum, 1989, p. 886). Since then, other states have passed specific statutes of protective disclosure (Kachigian & Felthous, 2004). These laws attempt to avoid injury to a third party by making duty to warn an exception to the need for professional confidentiality.

Because of the variable interpretations of these statutes, it is recommended that researchers obtain ethical and legal consultation on the duty to report the threat of harm to a third party for their particular state or jurisdiction. The duty to warn is supported within the HIPAA privacy regulations at section 164.512 (j), which states that a covered entity may disclose protected health information if necessary to "prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat, or is necessary for law

enforcement authorities to identify or apprehend an individual." Thus, the duty to warn and maintain safety is an exception to state and federal regulations concerning confidentiality.

Self-Harm—In *Privacy and Confidentiality in Mental Health Care*, Gates and Arons (2000) provide an index of state mental health confidentiality law provisions, which include those concerning reporting requirements related to danger to self. "The question of whether confidentiality may be breached to prevent the suicide of a client is a discrete question. In most jurisdictions, it has been assumed that such a breach is warranted" (Gates & Arons, 2000, p. 103). Furthermore, as discussed in the duty to warn section above, HIPAA regulations allow for the disclosure of protected health information if necessary for patient safety.

Certificate of Confidentiality—Investigators engaged in biomedical, behavioral, clinical, or other research may obtain additional confidentiality protections for research subjects with a Certificate of Confidentiality from the Department of Health and Human Services. Such a certificate is recommended for most intervention research with suicidal youth as sensitive information must usually be obtained to achieve research objectives. Certificates are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. "They allow the investigator and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level" (National Institutes of Health, 2006). When an investigator becomes aware of a suicidal threat or imminent suicide risk, however, the importance of taking action to ensure the participant's safety takes precedence over these protections. According to documentation provided by the NIH Office of Extramural Research (National Institutes of Health, 2006), researchers may choose to disclose matters such as child abuse or the subject's threat of violence to self or others. The written informed consent/assent documents must specify any such disclosures.

Ethical Challenges and Recommended Guidelines

Clarifying Exceptions to Confidentiality—Informed consent documents emphasize confidentiality and the protection of privacy to the extent possible. It is important to provide the youth and parents with information about exceptions to this confidentiality, despite the fact that concerns about these exceptions may dissuade someone from participating. Balancing the issues of confidentiality and privacy with issues of safety, the investigator has a professional responsibility to respond to reports of abuse and neglect, homicidal threats, and statements or behaviors suggesting imminent risk for suicide.

Case Example

Victor is a 14-year-old male intervention study participant who was diagnosed with major depressive disorder. He had a history of impulsive behavior and two previous psychiatric hospitalizations for suicidal thoughts with intent. During a study outcome assessment, Victor reported drinking rubbing alcohol earlier in the day. He also reported recent suicidal ideation. The independent evaluator notified Victor of the need to inform his parents and to consult with either the Project Psychiatrist or Project Director, which was in keeping with information in the IRB-approved consent/assent document. The recommendation was made for the youth to go the emergency department of a nearby psychiatric hospital for evaluation. The independent evaluator (a) shared this information with the youth and parent, and (b) assisted the parent with plans for accessing the emergency evaluation and safely transporting the youth to the facility.

The informed consent and assent documents (and the discussion of these during the consent process) should include explicit information about the level of confidentiality upheld by the study and exceptions to this confidentiality. In areas where confidentiality may need to be breached in order to comply with legal or ethical obligations, this information should be included in the research consent. As one example, the statement below is included in the IRB-approved informed consent document for the NIMH-funded intervention study, Youth-Nominated Support Team for Suicidal Adolescents.

> There are some exceptions to this confidentiality. If we have any concerns about your safety or the safety of others, we will notify the appropriate people and authorities to obtain help. This would occur if we had urgent concerns about serious self-harm, violence, child abuse, or about severe substance abuse that greatly impaired your current health. For instance, if we obtain information to suggest that you are at high risk for suicidal behavior such that urgent care is needed, this would be shared with your parent/guardian, your mental health care provider, and a legal authority (if needed to maintain safety). The information would be shared to obtain needed help or services.

CONCLUSIONS

No one questions the importance of learning how to best intervene and prevent suicidal behavior and suicidal deaths among youths. Yet the research required to accomplish such learning confronts the investigator with numerous ethical challenges. This report addresses those challenges associated with the informed consent and assent process, providing intervention researchers with information about each challenge, the associated regulatory requirements, and suggested guidelines for its practical resolution. Through the sharing of such methodological information, intervention researchers can support each other in conducting highly ethical research in a manner that does not unduly compromise scientific rigor.

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REFERENCES

Applebaum P, Rosenbaum A. Tarasoff and the researcher. American Psychologist. 1989; 44:885–894. [PubMed: 11644381]

Boonstra H, Nash E. Minors and the right to consent to health care. The Gunttmacher Report on Public Policy. 2000:4–8.

Centers for Disease Control and Prevention. Web-based injury statistics query and reporting system (WISQARS). 2006 [Retrieved January 1, 2006]. from www.cdc.gov/ncipc/wisqars

Cicchetti, D.; Rogosch, FA.; Toth, SL.; Reynolds, WM.; Johnston, HF. Handbook of depression in children and adolescents. New York: Plenum; 1994. A developmental psychopathology perspective on depression in children and adolescents; p. 123-141.

Conwell Y, Brent D. Suicide and aging. I: Patterns of psychiatric diagnosis. International Psychogeriatrics. 1995; 7:149–164. [PubMed: 8829424]

DHHS. Clinical research and the HIPPA privacy rule. 2004 [Retrieved August 11, 2006]. from http://privacyruleandresearch.nih.gov

DHHS Protection of Human Subjects, 45 Code of Federal Regulations Part 46. 2007 [Retrieved August 28, 2006]. from http://www.gpoaccess.gov/index.html

FDA Protection of Human Subjects 21 Code of Federal Regulations DHHS, Part 50. 2007 [Retrieved August 28, 2006]. from http://www.gpoaccess.gov/index.html

Fisher CB. Informed consent and clinical research involving children and adolescents: Implications of the revised APA ethics code and HIPAA. Journal of Clinical Child & Adolescent Psychology. 2004; 33:832–839. [PubMed: 15498750]

Fisher CB. Commentary: SES, ethnicity and goodness-of-fit in clinician-parent communication during pediatric cancer trials [Comment]. Journal of Pediatric Psychology. 2005; 30:231–234. [PubMed: 15784919]

Fisher CB, Pearson JL, Kim S, Reynolds CF. Ethical issues in including suicidal individuals in clinical research. Irb: A Review of Human Subjects Research. 2002; 24(5):9–14.

Gates, J.; Arons, B. Privacy and confidentiality in mental health care. New York: Health Professions Press; 2000.

Gould MS, Marrocco FA, Kleinman M, Thomas JG, Mostkoff K, Cote J, et al. Evaluating iatrogenic risk of youth suicide screening programs: A randomized controlled trial. JAMA. 2005; 293:1635–1643. [PubMed: 15811983]

Juvenile Law Center. Emancipation in the United States. 1999–2006 [Retrieved June 2, 2006]. from http://www.jlc.org/home/mediacenter/factsheets/emancipUSA.html

Kachigian C, Felthous AR. Court responses to Tarasoff statutes. Journal of the American Academy of Psychiatry & the Law. 2004; 32:263–273. [PubMed: 15515914]

King, CA. Suicidal behavior in adolescence. In: Maris, R.; Silverman, M.; Canetto, S., editors. Review of suicidology. New York: Guilford; 1997. p. 61-95.

Leiter, RA., editor. National survey of state laws. 5th ed.. Michigan: Thomas Gale; 2004. p. 501-512.

Leslie LK, Newman TB, Chesney PJ, Perrin JM. The Food and Drug Administration's deliberations on antidepressant use in pediatric patients [Comment]. Pediatrics. 2005; 116:195–204. [PubMed: 15995053]

Levi RB, Marsick R, Drotar D, Kodish ED. Diagnosis, disclosure, and informed consent: Learning from parents of children with cancer. Journal of Pediatric Hematology/Oncology. 2000; 22:3–12. [PubMed: 10695815]

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research. 1979 [Retrieved July 20, 2007]. from http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm

National Institutes of Health. NIH policy and guidelines on the inclusion of children as participants in research involving human subjects. 1998 [Retrieved July 15, 2007]. from http://grants.nih.gov/grants/guide/notice-files/not98-024.html

National Institute of Health. Certificates of Confidentiality: Background information. 2006 [Retrieved September 9, 2006]. from http://grants.nih.gov/grants/policy/coc/background.htm

Novick LF, Cibula DA, Sutphen SM. Adolescent suicide prevention. American Journal of Preventive Medicine. 2003; 24:150–156. [PubMed: 12744997]

Pearson JL, Stanley B, King CA, Fisher CB. Intervention research with persons at high risk for suicidality: Safety and ethical considerations. Journal of Clinical Psychiatry. 2001; 62 Suppl 25:17–26. [PubMed: 11765091]

Reynolds SK, Lindenboim N, Comtois KA, Murray A, Linehan MM. Risky assessments: Participant suicidality and distress associated with research assessments in a treatment study of suicidal behavior. Suicide and Life-Threatening Behavior. 2006; 36:19–34. [PubMed: 16676622]

Sackett, D.; Richardson, W.; Rosemberg, W.; Haynes, B. Evidence-based medicine. 2nd ed.. London, England: Churchill Livingstone; 2000.

Santelli J, Smith Rogers A, Rosenfeld W, Durant R, Dubler N, et al. Guidelines for adolescent health research: A position paper of the society for adolescent medicine. Journal of Adolescent Health. 2003; 33:396–409. [PubMed: 14596961]

U.S. Food and Drug Administration. FDA information sheets [Electronic version]. 1998 [Retrieved September 15, 2006]. from http://www.fda.gov/oc/ohrt/irbs/default.htm

U.S. Food and Drug Administration. Antidepressant use in children, adolescents, and adults. 2007 [Retrieved May 8, 2007]. from www.fda.gov/cder/drug/antidepressants/labelTemplate.pdf

U.S. Public Health Service. Washington, DC: Author; 1999. The surgeon general's call to action to prevent suicide.

Whittington CJ, Kendall T, Fonagy P, Cottrell D, Cotgrove A, Boddington E. Selective serotonin reuptake inhibitors in childhood depression: Systematic review of published versus unpublished data. Lancet. 2004; 363:1341–1345. [PubMed: 15110490]