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Boston Children's Hospital

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Department Research

Applicability Boston Children's Hospital- Policies & Procedures

Requirements for Mental Health Safety Plans in Research Protocols Policy/Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

This policy provides requirements and guidance to assess when an immediate safety plan is required.

Policy Statements

During the course of research, many protocols contain assessments such as quality of life questionnaires, behavioral assessments, and/or mental health screens. As part of the Intuitional Review Board's (IRB) responsibility to assess risks and benefits, the IRB must consider whether and how results of the assessments are communicated back to the subject and/or other health care providers as deemed necessary.

In all circumstances, there is an expectation that appropriate information learned about a subject during the course of research will be utilized to maximize the potential for direct benefit; however specific immediate safety plans are only required when a subject may be at risk for immediate harm to oneself or others. In some situations, information may be expected based on the characteristics of the eligible research population. In other situations, the information may be learned incidentally.

Procedures

The following questions and answers are intended to help researchers and the IRB determine when

immediate safety plans are required.

1. **What type of questionnaires or assessments would require an immediate safety action plan?**
   An immediate safety plan is required for questionnaires or assessments that either:
   a. Include individual items that indicate that someone is at real potential risk for harm – this would include single items that ask about suicidality, or child abuse, or plans to commit a violent act, etc. **or**
   b. Use tools that validly correspond to specific psychological conditions and have established "clinically-actionable" values or scores that suggest a potential diagnosis (e.g., Beck Depression Inventory)

   Participants who score in the clinical range on validated assessments or provide a concerning answer on individual items should trigger the safety action plan.

2. **Do quality of life assessments or questionnaires that may ask about sadness, feeling anxiousness, or levels of stress require a safety action plan?**

   These assessments are not typically developed to identify potential mental/psychological illnesses or actionable conditions such as depression and mood disorders. These scales **do not** require an immediate safety plan.
   a. However, when possible, investigators should consider ways of maximizing the potential for benefit for subjects who agree to participate in research.
   b. Depending on the type of information learned and the relationship with the subject, there may be ways to utilize the information from these questionnaires for the benefit of the subject.
      i. For example, responses may suggest that it may be helpful to offer a subject a referral to a social worker or provide additional resource information.
   c. Investigators also need to consider whether it may be beneficial to include results of validated assessments in the medical record so that other care providers may have access to the information and the ability to use the information for comparisons over time or if thought to be clinically relevant for planning care.
      i. These plans should be described in the potential benefit section of the research protocol and included in the informed consent document or process.

3. **What should an immediate safety plan include?**
   The following components must be included in a safety plan and specified in the protocol submitted to the IRB.

   In general, safety plans should align with standard clinical practice. If a safety plan deviates from standard practice, a rationale for the deviation should be provided.

   The IRB also expects that, when necessary, those who develop safety plans seek guidance from individuals experienced with standard clinical practice. This will help assure the plan

meets the standards required. Items to note:

a. The assessments should be reviewed immediately when a subject is present or within 24 hours if the information is collected remotely.
b. The individual performing/collecting and reviewing the assessments must be qualified to interpret the results or have plans to consult with qualified individuals within a specified time frame. Protocols should include these plans based on the acuity of the response.
c. Plans need to include immediate referral to appropriate mental health personnel and services for further assessment and management
d. Plans must also include appropriate notification of the concern to the subject and parents/legal guardians (if applicable).
e. Plans should include notification of relevant agencies (i.e., Dept. of Children and Families) or use of law enforcement personnel (e.g., police, security, etc.) to detain the individual for assessment and necessary services (if applicable).
f. The consent form should include information so that subjects/recognize the potential need to breach confidentiality and obtain necessary services.

Recommended steps, methods and guidance on how covered persons are to perform process, recognizing every case and patient are different.

Approval Signatures

Step Description	Approver	Date

Applicability

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