Status Active PolicyStat ID 17505855

Where the world comes for answers

Effective 3/1/2025
Next Review 2/29/2028

Owner Susan Kornetsky: Manager
Department Research
Applicability Boston Children's Hospital- Policies & Procedures

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

Internal Approval

SVP, Research Administration

EVP, Chief Scientific Officer

Scope

This policy applies to the Boston Children's Hospital (BCH) Research department and the respective staff.

Policy Statements

This policy specifies when a Mental Health Safety Plan (MHSP) in research protocols is required by the Institutional Review Board (IRB) and includes when an **"Immediate (24 hr)" MHSP** vs. a **"Timely (48 hr – 5 day)" MHSP** is required. This policy also provides guidance regarding what must be included within a research MHSP.

During the course of research, protocols may include administration of behavioral assessments and/or mental health screens, such as validated assessments to measure anxiety, depression, and/or suicidality, which could reveal clinically actionable information. As part of the IRB responsibility to assess risks and benefits of participating in research, the IRB must be assured that when research teams administer such assessments there is an established plan that will be followed by the Research Team to responsibly handle clinically actionable information, including predefined scores on a quantitative assessment, or responses on a qualitative assessment that reveal a specific concern or diagnosis (e.g. suicidal ideation, etc.).

Therefore, the IRB requires a MHSP when Research Teams administer such assessments. Research teams must develop a plan that includes which Research Team member will be responsible for prompt review of participant assessments and what scores or responses would trigger initiation of the MHSP.

The IRB recognizes that presence of anxiety or mood symptoms may be expected based on the characteristics of the eligible research population, and this can be acknowledged in the PI's submitted MHSP (e.g., all participants are already receiving mental health care, etc.). The IRB also acknowledges that administering certain assessments to vulnerable study populations (e.g., victims of childhood sexual abuse) may increase the risk of distress associated with completing some assessments, and this must be addressed in the PI's submitted MHSP. The IRB underscores the expectation that whenever possible, investigators should consider ways of maximizing the potential for benefit for subjects who agree to participate in research while not causing unnecessary distress. For this reason, we do not encourage providing feedback on behavioral screens that focus on quality of life or are otherwise are not considered tools to screen for specific mental health conditions or inquire about high-risk behaviors, unless they specifically ask about self harm or harm to/from others (abuse).

The IRB expects that, when necessary, PIs and Research Teams who are developing safety plans seek guidance from individuals experienced with standard clinical practice. PIs and Research Teams are encouraged to seek expertise within their own BCH department for developing MHSPs, particularly when administering "modified" assessments (e.g., questions on suicidality are removed, etc.) to ensure accurate scoring and assessment review.

Procedures

1. Immediate (24hr) MHSP

Immediate review/scoring within 24 hours is required for protocols administering validated, developmentally-appropriate questionnaires, assessments, surveys, or interviews in which participants are queried on abuse, violent actions, suicidality, and thoughts/plans of self-harm or harm to others, such as:

- Columbia Suicide Severity Rating Scale (C-SSRS)
- Ask Suicide Screening Questions (ASQ)

Immediate (24hr) MHSP are also required in research situations in which a single item asks about abuse, violent actions, suicidality, suicidal ideation, or thoughts/plans of self-harm or harm to others, such as:

- Children's Depression Inventory (CDI) and CDI-2
- Beck Depression Inventory (BDI)
- PHQ-9

The Research Team must include a qualified clinician with mental health expertise to review completed assessments within 24 hours and to initiate the MHSP when appropriate.

NOTE: Anonymous participation in assessments that include questions regarding abuse, violent actions, suicidality, active suicidal ideation, and/or thoughts/plans of self-harm or harm to others is prohibited by the IRB. If these questions are asked, there must be a way for the research team to identify individuals

with responses of concern and implement the Immediate MHSP.

Items to note:

a. The MHSP should align with standard clinical practice. If a plan deviates from standard practice, a rationale for the deviation must be provided.

b. A credentialed / licensed mental health clinical provider should be considered as a Research Team member and their role and scope of responsibility to review completed assessments and initiate the MHSP must be described in the protocol. Investigators should indicate in the MHSP who they consider to be their appropriately credentialed team member and include the rationale if not obvious. If it is not feasible to have a provider who is credentialed / licensed, the IRB **r**equires information in the submission regarding how the non-licensed provider will be trained appropriately for administering the assessments and immediately consulting with a licensed provider as needed.

c. The assessments MUST be reviewed immediately (in real time) when a subject is present in person, or within 24 hours if the information is collected remotely. The process used to review the assessments must be described (e.g., programmed into computer to notify PI, individual reviews assessment before participant leaves, etc.).

d. The MHSP must specify what scores or responses would prompt immediate referral to appropriate mental health personnel and services for further assessment and management. The plan should include procedures for when / how the research team will notify local law enforcement / police in situations where someone is actively describing current suicidality.

e. Applicability of mandatory reporting: for assessments or questions regarding presence of sexual or physical abuse, the MHSP should include how the team would fulfill the obligation to notify relevant entities (i.e., BCH Child Protection Team, or Mass. Dept. of Children and Families) and/or engage law enforcement personnel (e.g., police, security, etc.) to detain the individual for assessment and necessary services (if applicable). This requirement pertains to all assessments / questions, whether they are performed in person, remotely, or electronically (e.g., Zoom). Referral to local Emergency Departments may be appropriate.

f. The Consent Form must include how the Research Team will respect the participant's autonomy while minimizing risk to themselves and others. This includes disclosing to participants the potential need to breach confidentiality in order for the Research Team to carry out the necessary actions to obtain services and/or protect the participant and others. There is suggested language in the informed consent template found on the IRB website.

g. For participants <18 years of age, the Consent Form must include plans for notification of the concern to the participant and parents/legal guardians that are age-appropriate and respect the child's autonomy while protecting their safety. See #3 below for additional considerations re: communication plans.

2. Timely (48 hour – 5 days) Mental Health Safety Plans (MHSP)

When research involves validated tools or assessments that correspond to specific psychological conditions, such as anxiety and depression, and/or have established "**clinically actionable**" values or scores that suggest risk for a potential diagnosis, the IRB requires a "Timely (48hr – 5 day) MHSP. These are assessments that indicate mental health concerns but not self-harm or harm to others. The safety action plan should be triggered when a participant scores in the clinically

actionable range on a validated assessment or provides a concerning answer on individual items (e.g. passive suicidal ideation; thoughts of self-harm without plan to act). The IRB requires that assessment responses are reviewed by a qualified mental health clinician (or other appropriately trained individual) listed on the Research Team within 48 hours, and no later than 5 days. This MHSP must also include age-appropriate notification of the clinically actionable validated findings to the participant and parents/legal guardians (if applicable). (See #3 below for additional considerations).

The IRB recognizes that details in the Timely (48hr – 5 days) MHSP (including defined cut-off scores or responses of concern) may depend on the research population. For example, it has been established that illnesses can increase anxiety, so for certain protocols it may be justifiable to propose a cutoff score consistent with "severe" anxiety/depression vs. "moderate." Another consideration for developing MHSP is whether all eligible participants are existing BCH patients who are followed clinically and monitored for mental health at BCH. In those cases, it may be appropriate to request participants' permission to connect directly with BCH providers.

The following validated assessments are (non-exhaustive) examples of measures requiring a Timely (48hr – 5day) MHSP:

- PROMIS Anxiety or PROMIS Anxiety Short Form
- PROMIS Depression or PROMIS Depression Short Form
- PROMISE Pediatric - 25 (both anxiety and depression)
- Generalized Anxiety Disorder Assessment (GAD-7)
- Beck Depression Inventory (BDI)
- Children's Depression Inventory (CDI) and CDI-2
- Item level responses such as "I think about killing myself but I would not do it."

3. Communication of Research Mental Health Results to Participants/Families and Care Providers (Immediate and Timely MHSPs):

The IRB requires all MHSPs address how communication to participants and families will be handled. Research Teams must obtain permission from the participant/family PRIOR to contacting the participants treating physician (or provider) with information regarding clinically actionable results or responses of concern.

Items to note:

a. Consent Form MUST include disclosure that Research Team will be reviewing assessments within [X] days and that participants/family members may be contacted if referrals to mental health resources (or contacting their own treating doctor) is appropriate

b. Consider age-appropriate communication to adolescent participants, and contemplate how responses of concern will be handled for younger children (i.e. plan to contact parents, etc.)

c. MHSP must specify what mental health resources will be provided to participant (i.e., referral to BCH providers, etc.). For example, if Research Team identifies clinically actionable depression, then referral may be to BCH Social Work or back to the individual's provider. It is

also acceptable to provide referral-finder resources such as psychologytoday.com website, with guidance on how to use these resources.

d. MHSP communication plans to participants should be tailored to the specific study population.

e. When a MHSP is utilized, investigators and research team members should document their actions in the participant's research record.

Approval Signatures

Step Description	Approver	Date
Co-chair Approval	David Davis	3/1/2025
Site Administrator: Education/ Training Requirement	Dwight Mayfield	2/25/2025
Steering Committee	Dwight Mayfield	2/25/2025
Required Departmental Review/Approval	August Cervini	2/2/2025
Committee Chair(s)	Susan Kornetsky: Manager	2/1/2025
Contributor(s)	Susan Kornetsky: Manager	2/1/2025
Document Owner	Susan Kornetsky: Manager	2/1/2025

Applicability

Boston Children's Hospital- Policies & Procedures