Working with Institutional Review Boards (IRBs)
Community of Practice Meeting

November 14, 2024
3:00 – 4:30 p.m. EST

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OPRE
Sexual Risk Avoidance Education
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FYSB Family & Youth Services Bureau

Mat

AGENDA

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3:00 to 3:10	Welcome and introductions
3:10 to 3:20	Working with Institutional Review Boards (IRB)
3:20 to 4:10	Breakout discussions
4:10 to 4:25	Wrap up discussion and reflection
4:25 to 4:30	Next steps

PARTICIPATION AND TECHNICAL ASSISTANCE

- Change your name to include your state and grantee by clicking the “participants” tab, hover over your name and click the blue “rename” button
- Participants can control mute and camera functions
- Use the **chat box** to submit a question or make a comment.
- If you experience technical difficulties:
  - Call Zoom customer service at 1-888-799-9666
  - Ask for help in the chat box

POLL

Do you have experience working with an IRB to obtain a Letter of Determination about the SRAE performance measures?

1. Yes, and the IRB determined the measures were not in their purview *or* exempt from review
2. Yes, and the IRB required an expedited *or* full review
3. Currently in the process of doing so
4. No
5. Not sure

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INSTITUTIONAL REVIEW BOARD (IRB)

THE IRB'S ROLE

- An IRB is an administrative group that:
  - Protects the rights and welfare of human subjects recruited to participate in research studies or activities
  - Ensures that risks to research participants are minimal and are offset by potential gains in knowledge for the benefit of communities
  - IRBs are established and governed by different institutions, and each sets its own standards for review

FACTORS IN DETERMINING IF IRB REVIEW IS NEEDED

Typically, IRB review is required for research projects for which:

- Data are collected through intervention or interaction with people
- Personally identifiable information (PII) is collected from people (e.g., full name, date of birth) or sensitive personal questions are asked
- Data will be analyzed for research reports that contribute to generalizable knowledge
- The purpose of the performance measures data collected by SRAE grant recipients is performance management, not research
- Therefore, some IRBs may consider the performance measures surveys exempt from review

INITIAL STEPS

- Identify local IRB
  - Check with your partner organizations
  - Search the HHS Office of Human Research Protections database: http://ohrp.cit.nih.gov/search
  - Learn about IRBs with which other SRAE grantees have worked
- Seek a Letter of Determination from IRB about:
  - Whether the performance measures must be reviewed by the IRB, and
  - If yes, what type of review will be needed

FOUR ACTIONS IRBs MIGHT TAKE

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1. Determine that performance measures are not in their purview because the measures focus on program improvement and not research
2. Determine that performance measures data collection is research but that it is exempt from review (e.g., if youth responses are anonymous)
3. Require an expedited review (by a subset of the IRB committee)
4. Require a full review

IRB PROCESS TIMELINES

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- The IRB review process varies depending on the IRB and the type of approval required
  - Full reviews take longer than exempt and expedited reviews
- Ask your IRB
  - How frequently the IRB meets to review studies
  - When materials need to be submitted
  - How much time to allow for approval

INFORMATION TYPICALLY INCLUDED IN IRB APPLICATIONS

- Rationale and purpose of the data collection
- Number of participants to be recruited and their characteristics
- How prospective participants will be contacted and selected
- What will be expected of participants
- Procedures for obtaining informed consent
- How data will be collected and maintained securely
- Risks and benefits of data collection
- Safeguards to minimize risks

DOCUMENTS THAT MIGHT BE REQUIRED AS ATTACHMENTS TO THE IRB PACKAGE

- Data collection instruments
- Recruitment materials
- MOUs for partner organizations
- Consent and assent forms
- Protocol for identifying and responding to distress and disclosures
- List of resources to refer youth who may experience distress
- Survey administration script
- Staff confidentiality agreement
- Any IRB-specific submission forms

WHAT TO EXPECT AFTER SUBMITTING AN IRB APPLICATION

- After the IRB reviews your application:
  - It might ask for more information or request changes to your data collection forms
  - If no additional clarification or changes are required, the IRB will grant approval
    - Keep the IRB approval form for your records
- IRBs typically requires approval to be updated annually

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Breakout Discussions

BREAKOUT DISCUSSION PROTOCOL

- Directions [5 min]
- Individual write [5 min]
- Read through others' responses [5 min]
- Discuss [30 min]
  - What insights or advice can you offer related to your colleagues' hopes and fears?
  - What answers to specific questions posed by your colleagues can you provide?
  - What insights or advice provided by others do you feel is helpful, or would you like to know more about?
  - What outstanding questions remain?
- Wrap up [5 min]

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Wrap up Discussion and Reflection

BREAKOUTS SHARE OUT

- Facilitators share 2-3 big takeaways from their breakout group discussions.

INDIVIDUAL REFLECTION

- What did you learn today that was helpful for you in thinking about IRBs?
- What outstanding questions do you have, or additional information would be helpful for you?

FOR ADDITIONAL IRB SUPPORT

- Additional training and technical assistance (T&TA) tools and guidance are available at https://www.sraepas.com/tta-resources/
  - IRB/Human Subjects Protections and Data Privacy

- Contact the Help Desk with IRB related questions or to request 1-1 technical assistance
  - Visit www.sraepas.com/contact/
  - Call toll-free (833) 797-0166

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