Human Subjects and Privacy Protections for SRAE Performance Measures Data

January 11, 2021
3:00 – 4:30 p.m. EST

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QUESTIONS AND ANSWERS

- Use the **chat box** to submit a question to the presenters
- Your questions will only be visible to our team, and not other attendees
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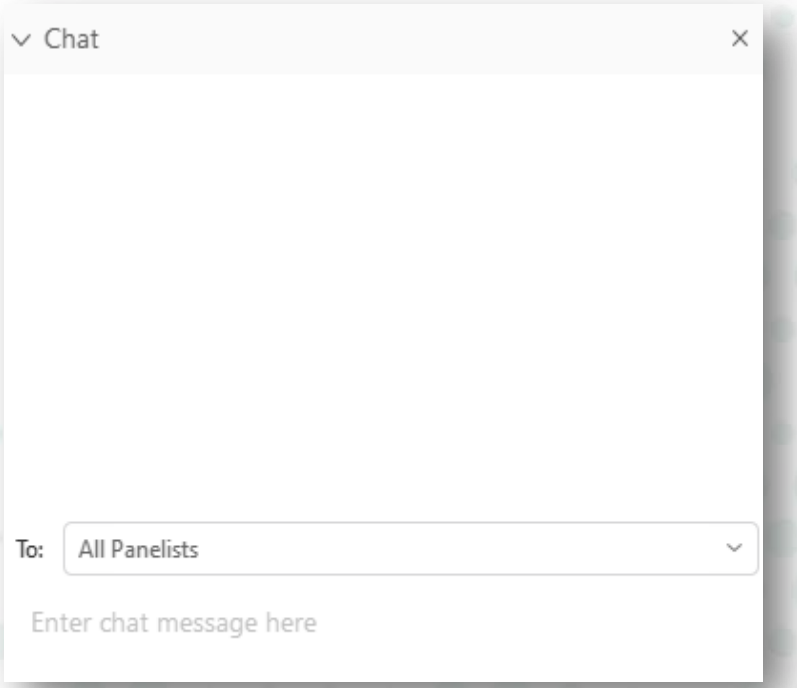

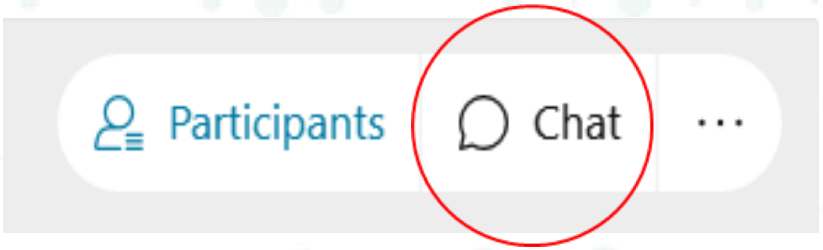

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WEBINAR MATERIALS AND RECORDING

- The webinar materials and recording will be available on the SRAE PAS website (www.sraepas.com) about a week and a half after the webcast.
- Handouts for this presentation will be available for download at the end of this webcast.

WEBINAR TECHNICAL ASSISTANCE

- If you experience technical difficulties, please call the Webex customer service number at 1-866-229-3239, Option 1.
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WELCOME

AGENDA

3:00 – 3:10	Welcome and introductions
3:10 – 3:15	Overview of the SRAE performance measurement timeline
3:15 – 3:50	Institutional Review Board (IRB) engagement
3:50 – 4:05	Required data privacy and security protocols
4:05 – 4:15	Review
4:15 – 4:30	Questions and answers

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WEBINAR OBJECTIVES

- Provide grantees with information to engage Institutional Review Boards (IRBs) for collection of the SRAE performance measures data
- Share and review written examples on the required data privacy and storage protocols for the SRAE performance measures

2021 PERFORMANCE MEASURES DATA COLLECTION AND SUBMISSION SCHEDULE

Measures to be Collected	Data Collection Period	Data Submission Period
Structure, cost, and support for program implementation	October 1, 2020 – September 30, 2021	July/August 2021
• Attendance, reach, and dosage • Participant characteristics, perceptions of program effects, and program experiences (entry and exit surveys)	January 1 – June 30, 2021	July/August 2021

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IRB ENGAGEMENT

POLL

Have you contacted an IRB to seek a letter of determination about whether IRB review/approval is needed for data collection of SRAE performance measures participant entry and exit surveys?

- Yes
- No
- Not sure

POLL

Have you ever communicated with an IRB about whether approval is needed for data collection?

- Yes
- No
- Not sure

POLL

Have you ever received approval or exemption from an IRB for data collection involving minors?

- Yes
- No
- Not sure

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WHAT IS AN INSTITUTIONAL REVIEW BOARD (IRB)?

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

ETHICS OF DATA COLLECTION

IRBs make decisions about:

- Informed consent
- Risk and benefit of data collection
- Protection of special and vulnerable populations to ensure they benefit from research in which they participate

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WHY IS INFORMED CONSENT NEEDED?

Informed consent provides research participants with sufficiently detailed information on the study so that they can make an informed, voluntary, and rational decision to participate.

WHAT INFORMATION SHOULD BE PROVIDED TO PARTICIPANTS ABOUT THE INFORMED CONSENT PROCESS & IN THE CONSENT FORM?

- Purpose of the study
- Expected duration
- Data collection procedures
- Information on their right to decline or withdraw
- Foreseeable consequences of withdrawing or declining
- Potential risk, discomfort or adverse effects
- Prospective research benefits
- Incentives, such as payment or rewards
- Whom to contact for questions

HANDOUTS 1 AND 2

- Example parent consent form
- Example youth assent form

WHAT ARE THE RISK AND BENEFITS WEIGHED BY IRBS?

Risk: The probability and magnitude of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study

Benefit: A valued or desired outcome to be derived from the research, including

- Benefits (if any) to participants
- Importance of the knowledge to be gained

WHY DO WE WANT TO PROTECT INDIVIDUALS WITH LESS POWER?

- IRBs ensure that the populations bearing the burdens of research receive the benefits of research
- Protection from harm is of particular concern to an IRB when special or vulnerable populations are involved to ensure they are not being coerced
- Special or vulnerable populations include:
  - Minors (younger than age 17)
  - Persons with disabilities (physical, mental, or social)
  - Persons imprisoned or in institutions
  - Persons in the care of the state
  - Economically or educationally disadvantaged persons
  - Pregnant women

RESEARCH VS. PERFORMANCE MANAGEMENT

- Performance measures data collection is for the purpose of performance management—rather than research—and therefore may be considered exempt by some IRBs
- IRBs are established and governed by different institutions
- Each IRB sets its own standards for review and decisions
- Your local IRB will determine whether performance measures are exempt or not

HOW DO YOU KNOW WHETHER YOU NEED IRB APPROVAL?

- Grantees should contact an IRB now to request a letter of determination about whether review/approvals will be needed for data collection
- Individual-level data will be submitted to ACF, so past decisions about approvals may not be relevant now
- It is important also to learn and document the school/partner organization's requirements
  - Mutual understanding of requirements
  - Continuation of approval should there be a school administration change

WHEN IS IRB REVIEW NEEDED?

Typically, IRB review is required if at least one of the following is true:

- The data are collected through intervention or interaction with people.
- Personally identifiable information (PII) is collected from people (e.g., full name, date of birth).
- Sensitive personal questions are asked.
- Primary or secondary data will be analyzed for research reports.
  - Primary data are data grantees collect, such as surveys or focus group.
  - Secondary data are existing data, such as administrative or medical records.
- The results will be disseminated to a broader audience.

FYSB REQUIRES THAT GRANTEES OBTAIN A DETERMINATION LETTER FROM A LOCAL IRB

- Some IRBs have a short, easy application that grantees can submit to learn whether a data collection requires IRB review
- These IRBs will issue a determination letter that states whether the data collection requires IRB review

FOUR ACTIONS IRBS MAY TAKE

1. Determine 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

FINDING AN IRB

- Many organizations and school systems have internal or affiliated IRBs, so check with them first
  - Universities, state agencies, hospitals, research institutions
- External and commercial IRBs are also available
- You can search the DHHS Office of Human Research Protections database to learn whether the IRB you have in mind is registered: http://ohrp.cit.nih.gov/search

TWO OPTIONS FOR MULTI-SITE DATA COLLECTION

1. **One IRB reviews**
   - One IRB acts as the IRB of record
   - The IRB at each participating site will need to formally cede their IRB review to the reviewing IRB using a fully-executed authorization agreement, sometimes called a reliance agreement.
2. **Separate/multiple IRBs review:** Each participating organization obtains IRB approval from their own organization's IRB

HOW LONG DOES THE IRB PROCESS TAKE?

- The IRB review process varies depending on the IRB and the type of approval required
- Full reviews take longer than exempt and expedited reviews
- Contact your IRB to ask about
  - How frequently the IRB meets to review studies
  - When materials need to be submitted prior to a meeting
  - How long to allow for approval

WHAT INFORMATION DO I NEED TO PREPARE AN IRB APPLICATION?

Examples of the types of information typically required include the following:

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

HANDOUT 3

- **Example IRB application**

WHAT DOCUMENTS DO I NEED TO PREPARE FOR THE IRB PACKAGE?

Examples of the types of documents typically required include the following:

- Recruitment materials for partner organizations
- MOUs for partner organizations
- Recruitment or notification letters to parents
- Consent and assent forms
- Data collection instruments
- Protocol for identifying and responding to distress and disclosures
- Referral list
- Survey administration script
- Staff confidentiality agreement
- Any IRB-specific submission forms

SOME IRBS REQUIRE ADDITIONAL DOCUMENTS

- Resumes or CVs of staff involved in data collection activities
- Conflict of interest forms disclosing potential conflicts of interest among staff
- A data security plan detailing how the study will protect any PII gathered
- Proof of training in protection of research participants for all of those involved in collecting and analyzing the data

HOW TO OBTAIN TRAINING IN PROTECTION OF RESEARCH PARTICIPANTS

- Training may be available through your organization or through the IRB
- Your institution might be a part of the Collaborative Institutional Training Initiative, which provides online training materials for a fee (see https://www.citiprogram.org/)
- OHRP offers free training (see https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/index.html)

WHAT CAN I EXPECT FROM AN IRB?

- After the IRB reviews your application, it might ask questions to clarify procedures, request changes to your data collection forms, or request additional information.
- If no additional clarification or changes are required, it will grant approval.
- The IRB will send you an approval form, which you should keep for your records.
- The IRB typically requires approval annually.

Required Data Privacy and Security Protocols

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GOAL

Secure all data

- Personally identifiable information
- Participant data
- Sensitive organizational performance measures data

PERSONALLY IDENTIFIABLE INFORMATION (PII)

- Any data that could potentially be used to identify a particular person, such as
  - Full name
  - Date of birth
  - E-mail address
  - Drivers license number
- Any unauthorized access or release of such information could result in severe consequences for the individuals whose data have been compromised.

ACCESS TO DATA

- Identify who will have access to the data, based on a need to know
  - For example, facilitators may collect attendance data but may not need access to entry and exit survey response data
  - Staff responsible for data collection, data entry or scanning, and submission through the portal will need access to the data
- Require signed staff confidentiality agreements

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HARD COPY DATA STORAGE

- Use a locked filing cabinet
- Separate survey responses from any PII. This can be done by:
  - Not collecting PII on surveys
  - Collecting and recording PII separately (e.g., a roster) and use identification numbers on surveys
  - Keeping completed surveys in a separate filing cabinet from rosters, consent/assent forms, and attendance sheets

ELECTRONIC DATA STORAGE

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- Use password-protected shared drives
- Grant access only to authorized staff with signed confidentiality agreements
- Store in the cloud as long as data are encrypted, password-protected, and accessed only on authorized computers with password protection
- Keep survey response data separate from any PII. For example, this can be done by
  - Storing PII in a separate dataset from survey responses, in a different folder that can be accessed only by staff who need access to the PII
  - Locking hard copy consent/assent forms, rosters, and attendance sheets in a filing cabinet and using identification numbers in the electronic survey dataset

LOCAL HARD COPY DATA TRANSMISSION

- When data collectors send completed surveys to the grantee organization and/or local evaluator:
  - Ship PII separately from survey responses
  - Send in packages marked confidential via U.S. Postal Service or Federal Express
  - Require an authorized signature and show of picture identification before receipt
  - Obtain tracking number to follow up if data are not received
- Data submission to FYSB will not involve hard copies

LOCAL ELECTRONIC DATA TRANSMISSION

- When data collectors send completed surveys to the grantee organization and/or local evaluator:
  - Use encrypted e-mail, CDs, or flash drives
  - Follow same protocols for shipping hard copy data when shipping CDs or flash drives
  - Transmit passwords separately from data
- Data submission to FYSB will be through the SRAE Performance Measures Portal

SUBMISSION OF DE-IDENTIFIED DATA TO THE SRAE PERFORMANCE MEASURES PORTAL

Detailed guidance for submitting entry and exit survey data to the Portal will be provided in June 2021, prior to the July-August 2021 data submission window

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DESTROY PII AFTER THREE YEARS

QUIZ

To learn whether IRB approval is needed for performance measures data collection, grantees only need to ask schools and other partner organizations.

- True
- False
- Not sure

ANSWER

False.

FYSB requires that grantees contact a local IRB to obtain a determination letter to learn whether IRB review/approval is required. Grantees also need to contact schools and other partner organizations to learn what approvals will be needed for performance measures data collection. Grantees should discuss with schools and other partner organizations that individual-level data will be submitted to ACF, so past decisions about IRB exemptions or not needing approvals may not be relevant now.

QUIZ

To find an IRB, grantees should:

- **Check with their organization and/or school system to learn whether they have internal or affiliated IRBs**
- **Consider external and commercial IRBs**
- **Search the DHHS Office of Human Research Protections database to learn whether the IRB they have in mind is registered: http://ohrp.cit.nih.gov/search**
- **All of the above**

ANSWER

To find an IRB, grantees should:

- **Check with their organization and/or school system to learn whether they have internal or affiliated IRBs**
- **Consider external and commercial IRBs**
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- **All of the above**

QUIZ

Only staff who need to know the contents of data should have access to the data after they sign a staff confidentiality agreement.

- True
- False
- Not sure

ANSWER

True.

This means that only certain staff should have access to the data. Staff who need access to SRAE performance measures data must sign a staff confidentiality agreement.

QUIZ

Completed hard copy entry questionnaires must be stored in a separate locked filing cabinet from completed hard copy exit questionnaires.

- True
- False
- Not sure

ANSWER

False.

Completed hard copy entry and exit questionnaires must be stored in a locked filing cabinet separate from any identifying information.

UPCOMING TA EVENT

Webinar	Timeline	Content
Office Hours: Survey Performance Measures, Human Subjects and Data Privacy Protections	January 14, 2021 (3 – 4:30 p.m. EST)	• Q&A on obtaining a required letter of determination from an IRB • Q&A on following required data privacy and security procedures • Q&A on collecting participant entry and exit survey performance measures • Q&A on conducting online data collection • Q&A on using the optional Excel data recording tools developed for participant entry and exit survey data

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QUESTIONS AND COMMENTS

FOR QUESTIONS AND ADDITIONAL INFORMATION ABOUT SRAE PERFORMANCE MEASURES

- Additional information about the SRAE performance measures is available at www.sraepas.com.

- For further support, contact Public Strategies at SRAEperformancemeasures@publicstrategies.com or call toll-free 833-797-0166.

RESOURCES

Martin, S. L., Ashley, O. S., White, L., Axelson, S., Clark, M., & Burrus, B. (2017). Incorporating trauma-informed care into school-based programs. *Journal of School Health, 87*(12), 958-967.

Office of the Secretary. (1979). *The Belmont Report*. Available at: https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf

Public Strategies and Mathematica. (2019). *Institutional review boards (IRBs): Frequently asked questions*. Available at: https://sraene.com/sites/default/files/pdfs/Frequently_asked_questions_about_working_with_IRBs.pdf

U.S. Department of Health and Human Services. (n.d.). *Office for Human Research Protections (OHRP) database for registered IORGs & IRBs, approved FWAs, and documents received in last 60 days.* Available at: http://ohrp.cit.nih.gov/search

POLL

How prepared do you feel to train your staff in data privacy and security protocols required for SRAE performance measures?

- Very prepared
- Somewhat prepared
- Somewhat unprepared
- Very unprepared

Additional questions, comments?

Thanks for participating!

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