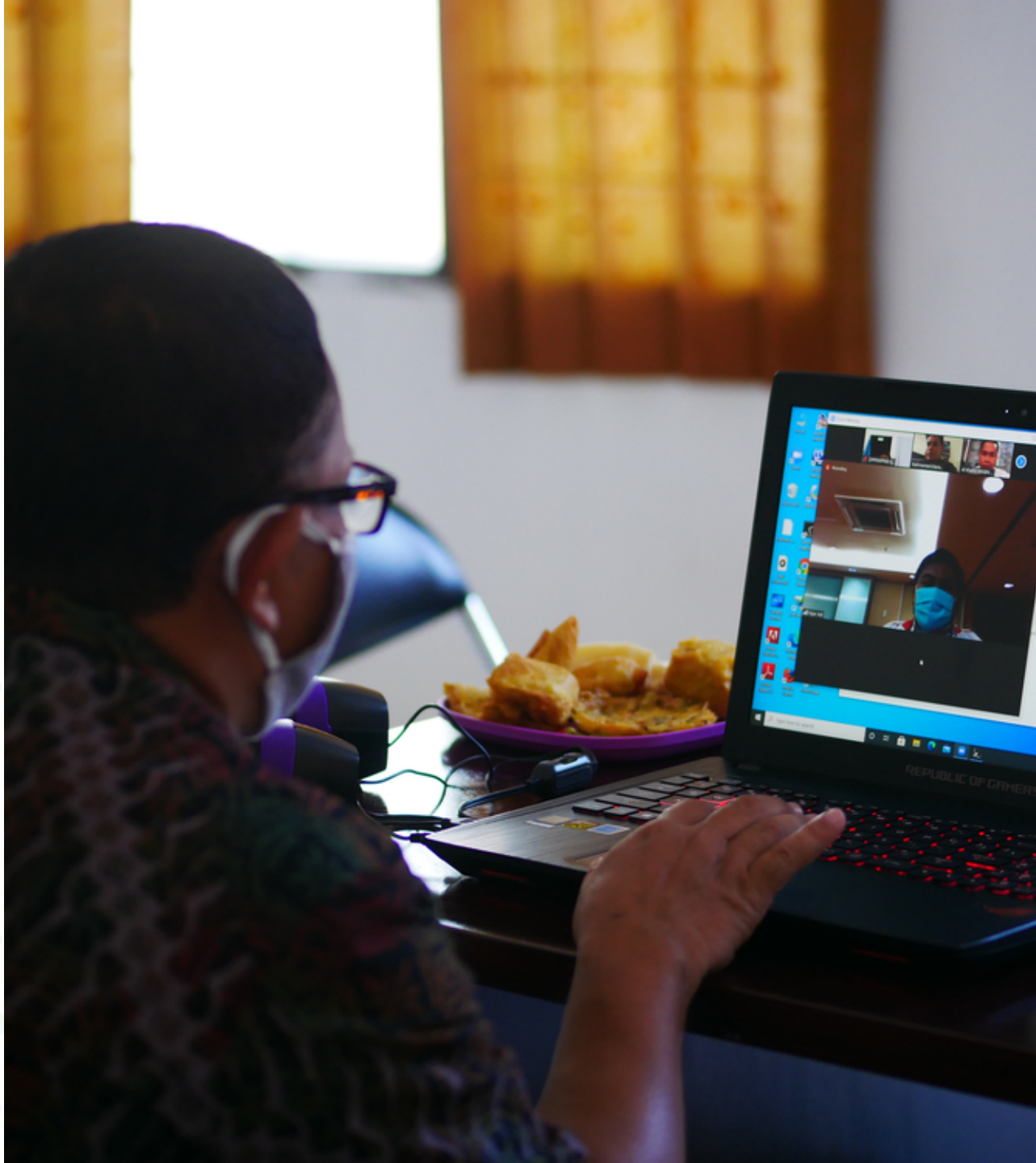
SRAEPAS
Sexual Risk Avoidance Education
Performance Analysis Study

WHAT IS AN INSTITUTIONAL REVIEW BOARD (IRB)?

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



PERFORMANCE MEASURES QUESTIONS

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- Each grantee is required to gather performance measures data as part of their grant responsibilities.
- Grantees should contact their Project Officer with any questions about the surveys for further instructions.

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CONTACTING AN IRB

Grantees must seek a ***Letter of Determination*** from an Institutional Review Board (IRB) about:

- Whether the performance measures must be reviewed by the IRB, and
- If so, what type of review will be needed

RESEARCH VS. PERFORMANCE MANAGEMENT

- Performance measures data collected by SRAE PAS grantees are used for performance management—rather than for research purposes—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 or not performance measures are exempt from IRB review/approval

HOW DO YOU KNOW WHETHER YOU NEED IRB APPROVAL?

- Grantees should contact an IRB now to request a Letter of Determination (if they do not already have one) about whether review/approval will be needed for data collection
- Individual-level participant data will now be submitted to ACF, so past approval decisions may no longer be relevant
- It is important to also 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?

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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 from surveys or focus groups
  - 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

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 much time 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 11

- **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

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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, the IRB will grant approval.
- The IRB will send you an approval form, which you should keep for your records.
- The IRB typically requires approval to be updated annually.

FINDING AN IRB

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