SOM SOP 401.1

Obtaining and Documenting Informed Consent from Adult Research Participants

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Session Outline

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Attesting in PaTS

SOP Overview

Questions

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Attesting in PaTS

Personnel and Training System

Who is Required to Attest in PaTS?

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All personnel who select the responsibility of “obtain informed consent from research participants” are required to attest to the SOP in PaTS.

If you did not select the responsibility, you can still view and attest to the SOP.

When Is the Attestation Due?

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30 Days from Issue Date

June 14, 2022

How to Attest

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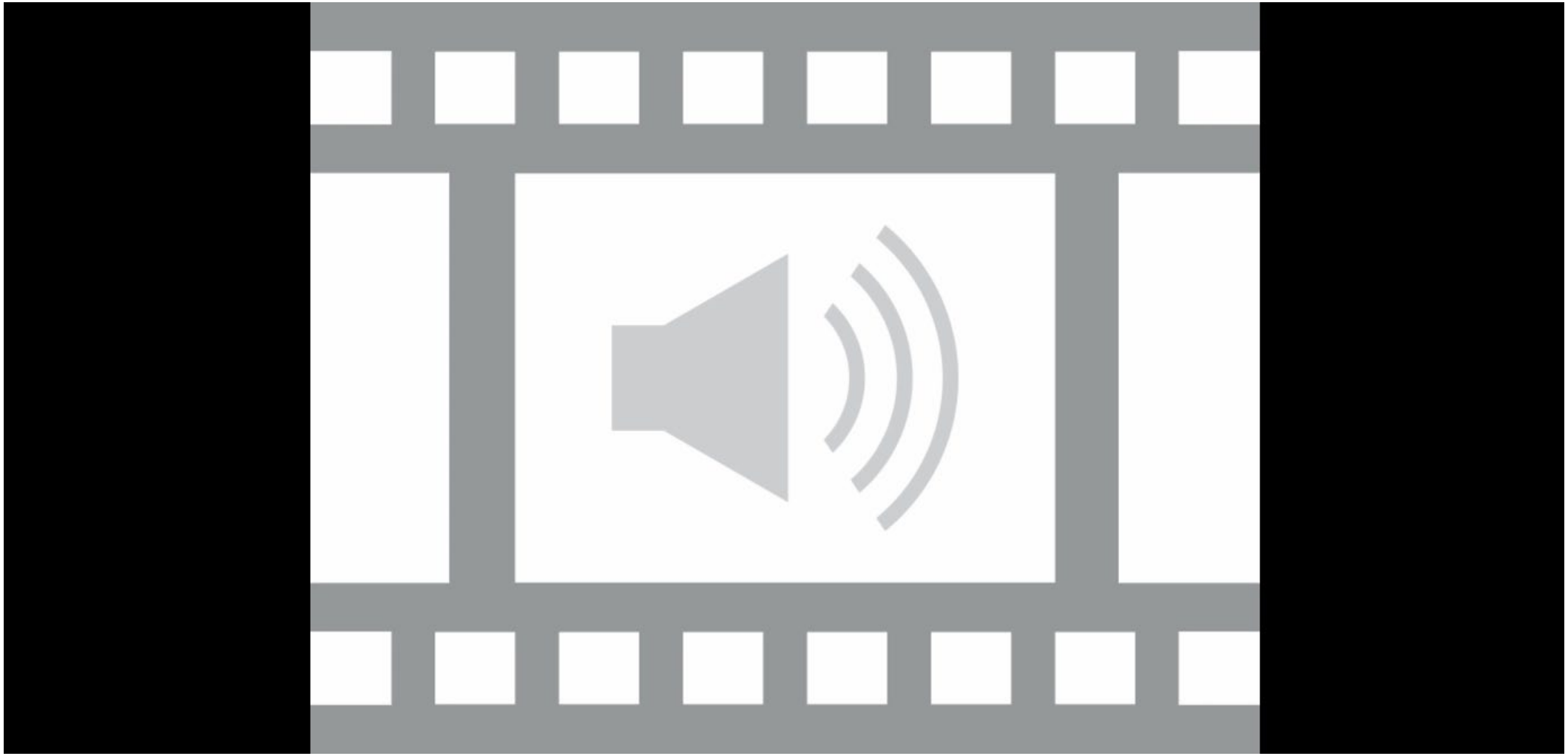

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SOP Overview

Obtaining and Documenting Informed Consent from Adult Research Participants

SOP Sections

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- Prepare for the Informed Consent Discussion
- Conduct the Informed Consent Discussion
- Document Informed Consent
- Maintain Informed Consent
- Provide Participants with New Information, as Applicable
- Document Withdrawal of Consent, as Applicable
- Prepare for Other Circumstances

SOP Sections

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Prepare for the Informed Consent Discussion

- Prepare the appropriate consent form
- Do not cross out or write in information on the form
- You may want to provide the form to the potential participant prior to the initial discussion

SOP Sections

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Conduct the Informed Consent Discussion

- Provide the ICF to the participant during the discussion so they can follow along
- Address each section of the ICF and ensure adequate time for the discussion
- Ask for and answer questions
- Ensure participants understand the information presented

SOP Sections

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Document Informed Consent

- If the potential participant decides to participate, have them sign and print their name, and date the form.
- The study team member obtaining consent should also sign, print, and date the form.
- Document the process of obtaining informed consent
- Keep a signed copy in study records and give a copy of the form to the participant.

SOP Sections

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Maintain Informed Consent

- The consent process does not end at consent signature- ensure the participant understands the study and still wants to participate throughout their participation.

SOP Sections

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Provide Participants with New Information, as Applicable

- New information should be communicated to participants via an IRB-approved method (e.g., re-consent using an updated consent form).
- Document the outcome of the discussion- if re-consent is necessary, document informed consent per the SOP section “document informed consent”.

SOP Sections

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Document Withdrawal of Consent, as Applicable

- If a participant withdraws consent, document details.

SOP Sections

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Prepare for Other Circumstances

- If other consent methods are necessary (e.g., short form consent, verbal consent, remote consent, electronic consent, consent waivers, etc.), ensure the methods are adequately detailed in the IRB application and approved prior to use.

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Questions


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