Research Matters

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Outline

- Announcements
- Researcher and Study Team Training – AAHRPP Preparation

Announcements

Modifications

- All documents must be uploaded into the Modification SmartForm
  - New documents
  - Revised, tracked changes documents
- For documents finalized by the Investigator Relations Team (footer, renamed, locked to tracked changes)
  - Download document from “Documents” tab and make edits on this version

Approval Letters

- All documents uploaded into the new study, modification, or continuing review SmartForm will be pulled into the approval letter
  - Text will be based upon how the study team names document
  - These names are not revised during the approval process

Translated Consent Documents

- Modifications of studies with fully translated consent:
  - Consider whether a short form is required while pending a newly translated version
  - Upload a short form into the modification form to request it be stamped
  - Documents tab will have only one link for non-English consents (short form or fully translated)

Translated Consent Documents

- STU-2019-XXXX, PI Name, Form E.S2 – Spanish, NS, 01-01-19
- STU-2019-XXXX, PI Name, Form E2 – Spanish, Mod1, 01-15-19
- STU-2019-XXXX, PI Name, Form E.S2 – Spanish, Mod3, 03-01-19
- STU-2019-XXXX, PI Name, Form E2 – Spanish, Mod4, 03-15-19

Researcher and Study Team Training
AAHRPP Preparation

What are the 3 principles of the Belmont Report (select all that apply)?

Respect for Persons, Justice, Integrity

Respect for Persons, Beneficence Integrity

Integrity, Justice, Beneficence

Respect for Persons, Justice, Beneficence

Belmont Report

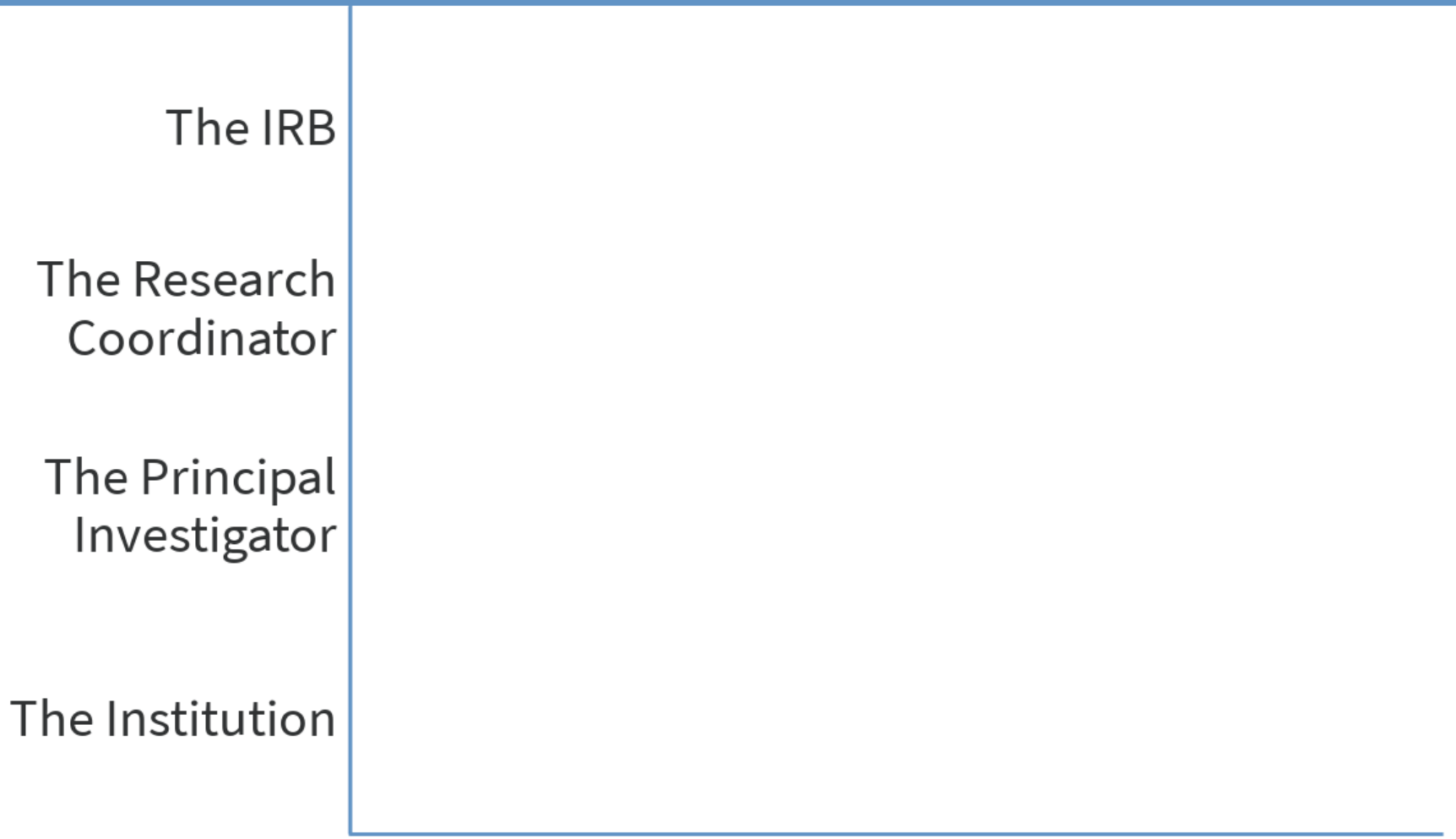
- Respect for Persons
  - Informed Consent, additional protections for vulnerable populations
- Justice
  - Share benefits and burden of research
- Beneficence
  - Protecting subjects from harm

What education and training have you taken to conduct research?

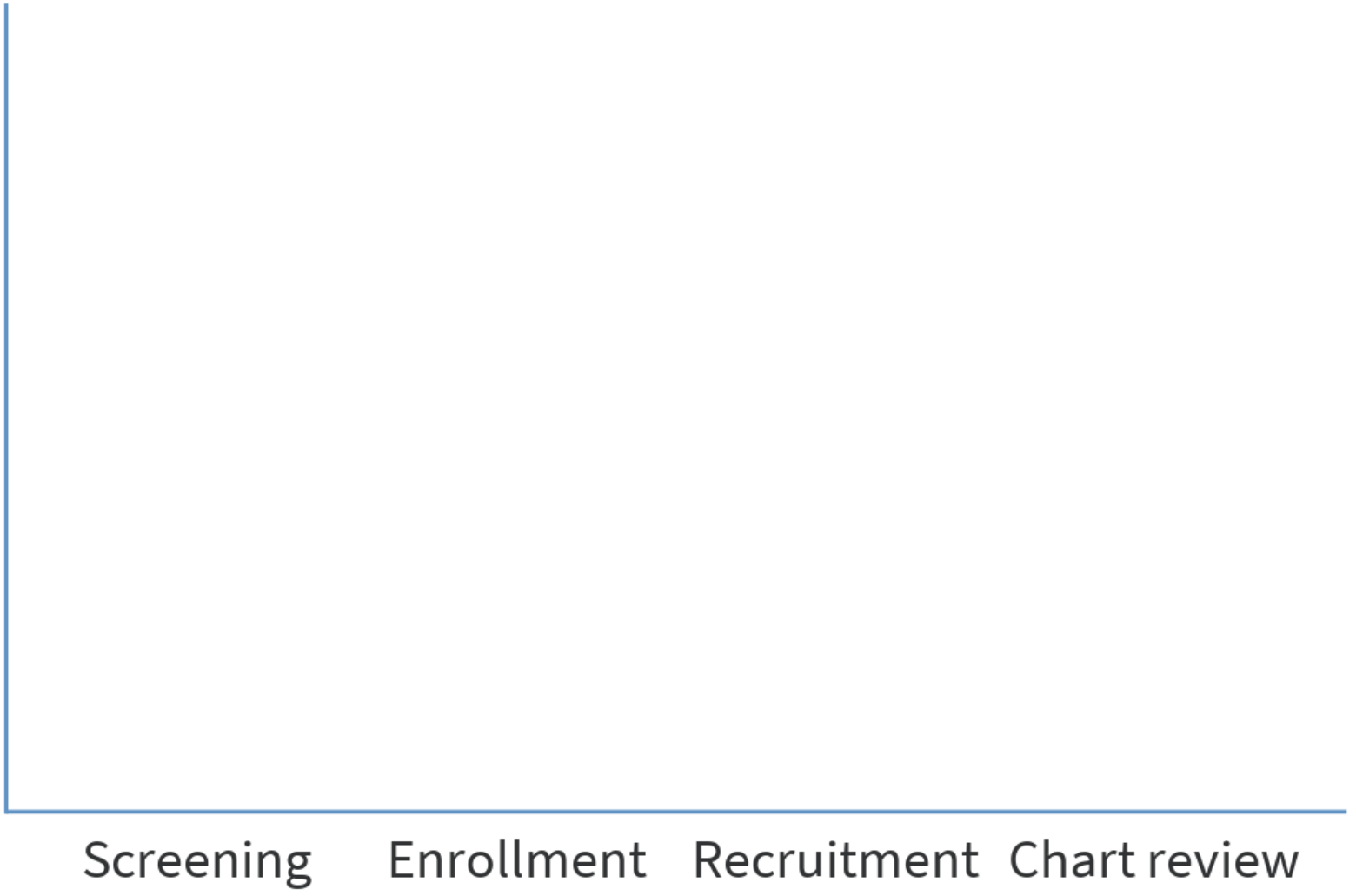
Training and Education

- CITI Training
  - HSP, GCP, Research HIPAA
- COI Training
  - Part of COI disclosure
- Personal education
  - Bachelors, Masters, Doctorate degrees
- Certifications
  - CCRP, CCRC, CIP, etc.

Who is ultimately responsible for the conduct of human subjects research?



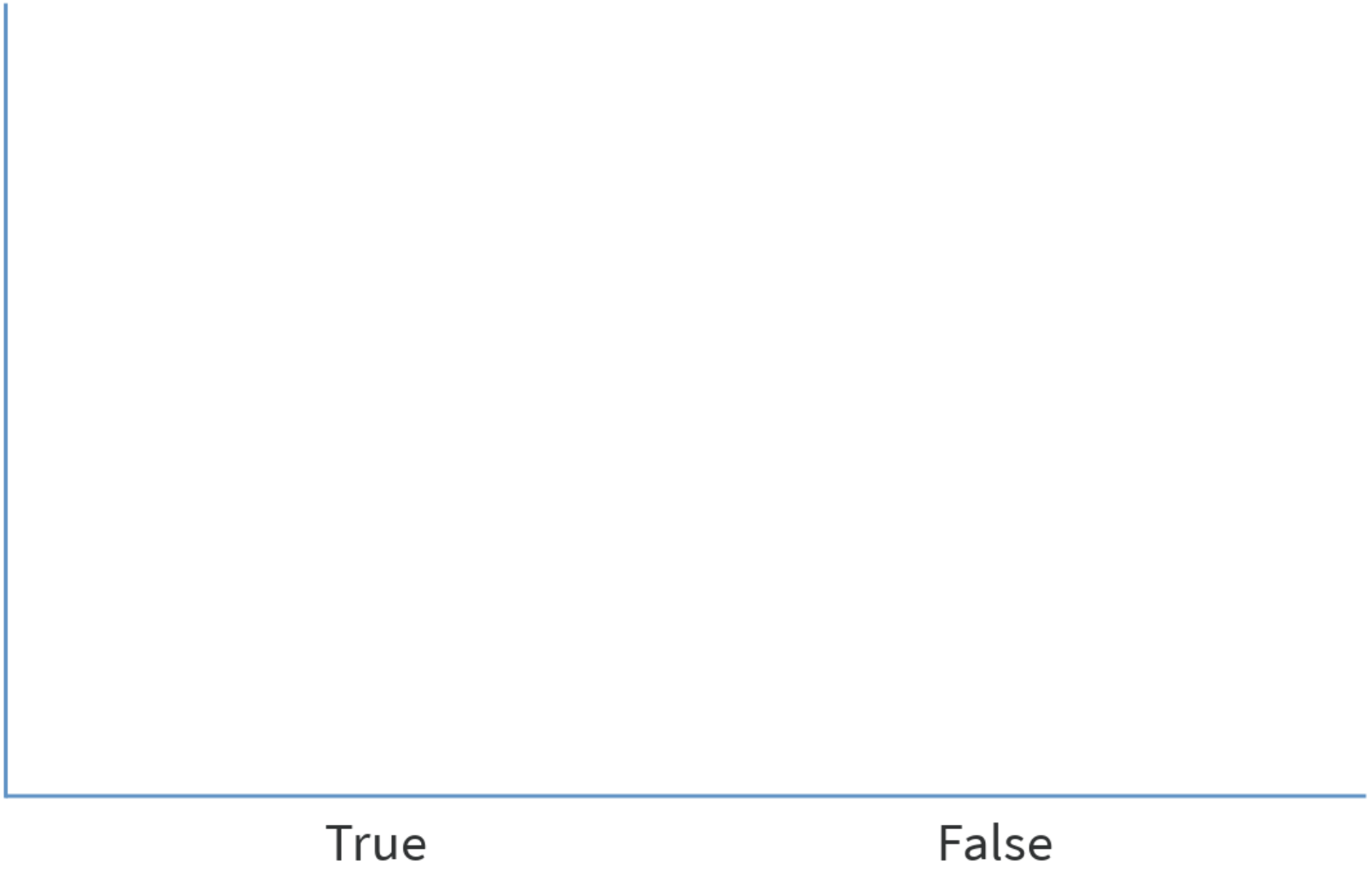
Federal regulations consider _____ to be the first step in the consent process.



Recruitment

- All recruitment methods must be reviewed and approved by the IRB
  - No coercion
  - No undue influence
  - No claims of safety and/or effectiveness
  - No "FREE MEDICAL TREATMENT" incentivizing

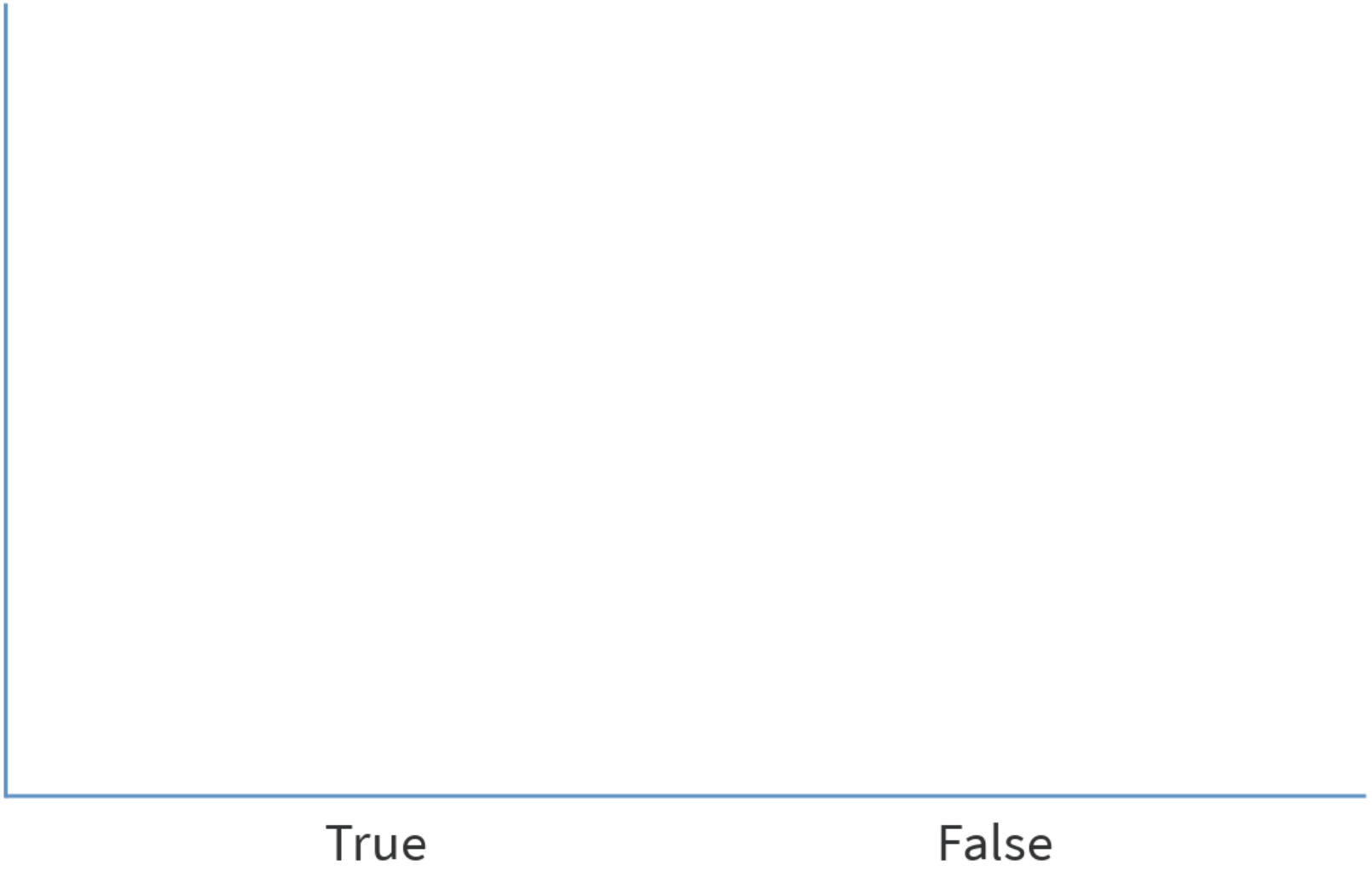
Minimal risk screening procedures can be conducted by participants before consent is obtained.



Consent

- No research procedure may be initiated before consent is obtained
- Informed consent must be sought from each subject or the subject's LAR
- Informed consent must be appropriately documented (signatures and notes)

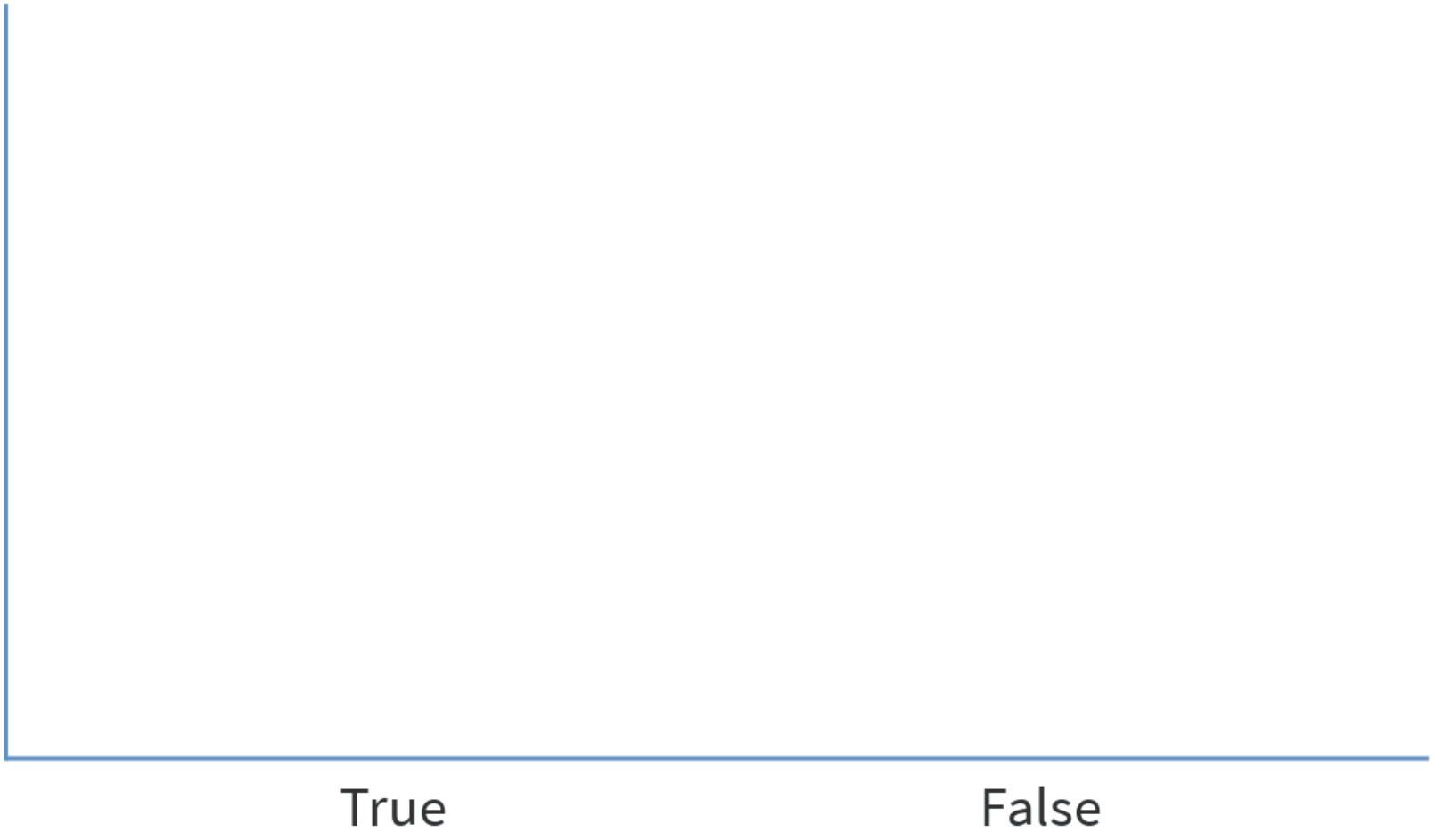
Federal regulations require informed consent documents to be written at 6-8th grade reading level.



Consent

- Informed consent must be sought from each subject or the subject's LAR
  - Understandable (level of language)
  - Native Language

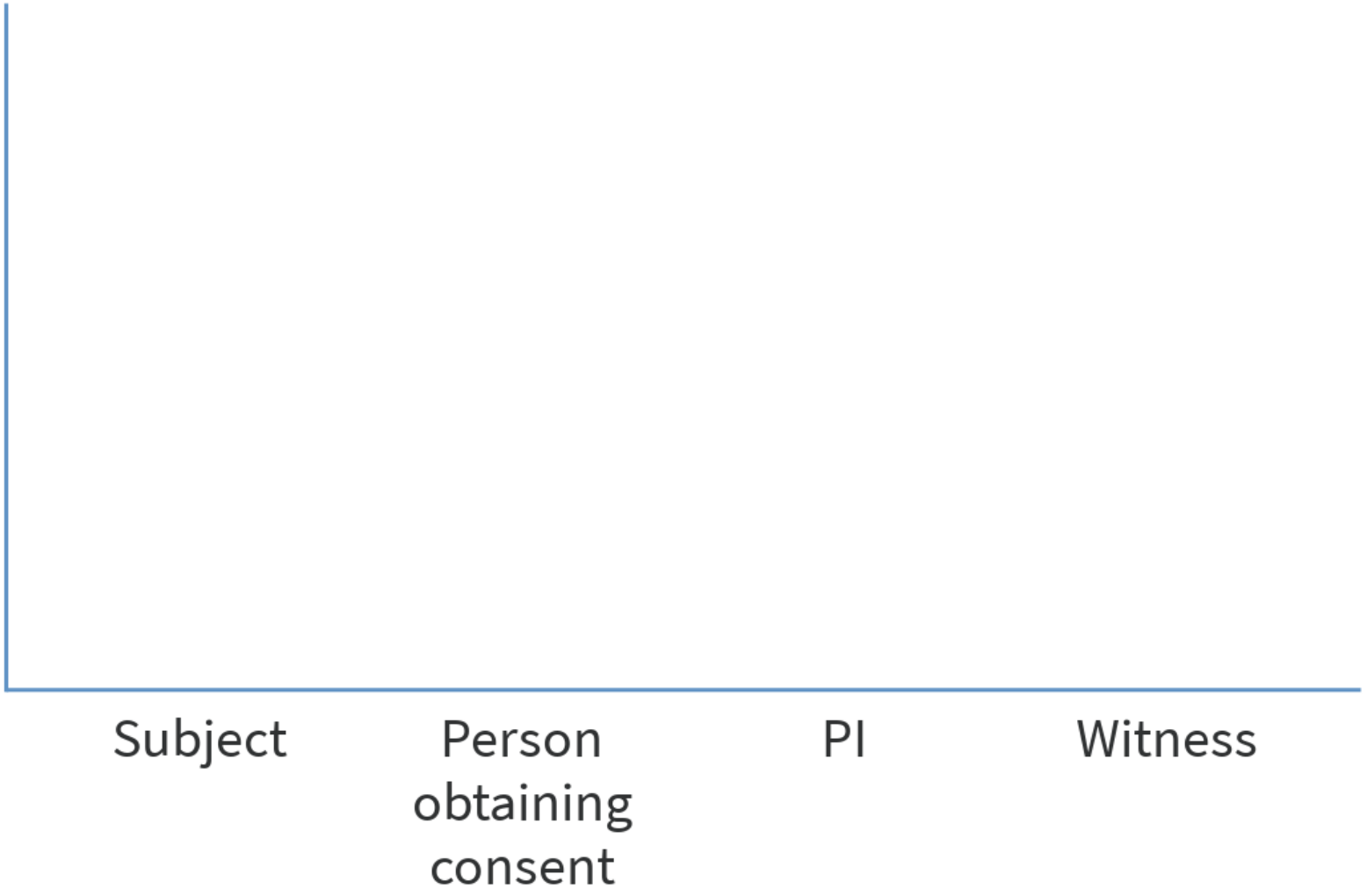
A subject, enrolled by her LAR, regains decision-making capacity during study participation. The subject must be re-consented.



Consent

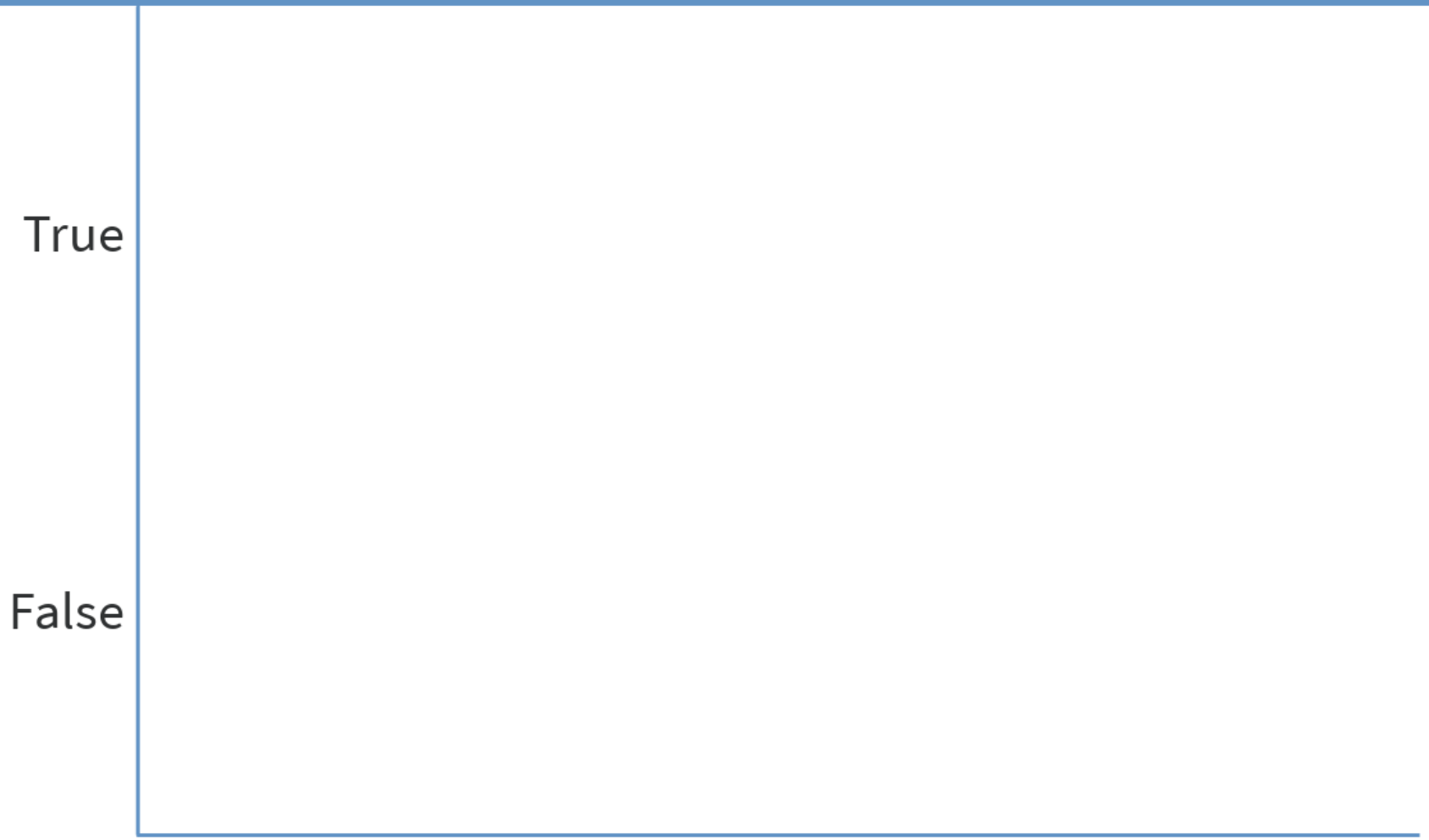
- For subjects whose decision-making capacity may fluctuate and either regain capacity to consent or those with decreasing capacity to give consent, a re-consenting plan may be necessary.
  - (HRPP Policy and Procedure Manual 3.2)

Who must sign both the consent document and the short form document?



	Non-English Speaking Subject	Interpreter	Person Obtaining Consent
Fully Translated Consent (w/ English Consent)	Fully Translated Consent	No signature (document in consent note)	English Consent
	Non-English Speaking Subject	**Witness**	**Person Obtaining Consent**
Short Form and English Summary	Short Form	Short Form AND English Summary	English Summary

New conflicts of interest or changes to prior conflicts must be reported to the COI office within 30 days.



Conflict of Interest

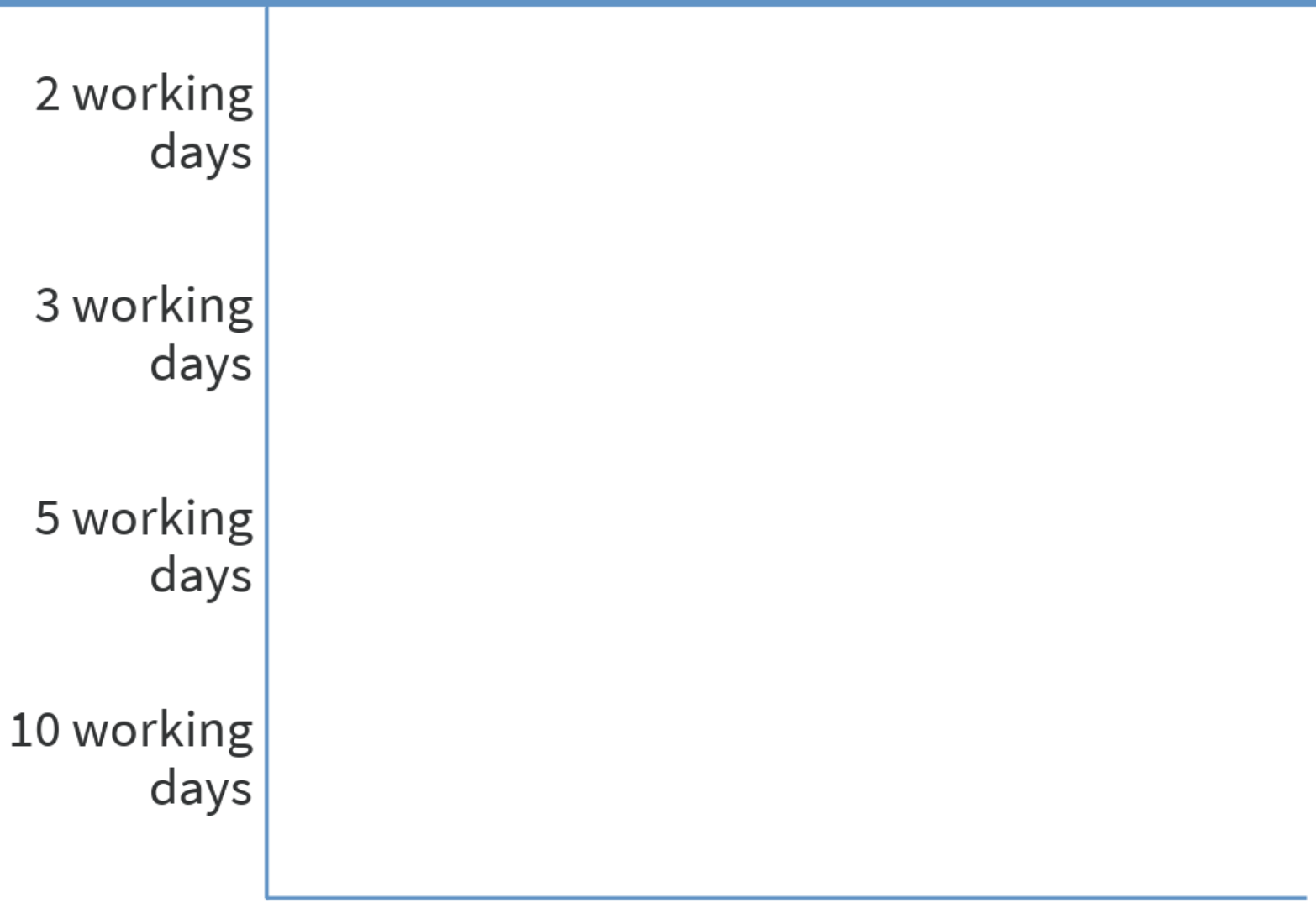
- ETH-104 Conflicts of Interest, Conflicts of Commitment, and Outside Activities
  - No later than the 30th day of initial employment
  - Annually, between January 1 and March 1
  - No later than the 30th day after acquiring a new financial interest or outside activity that requires disclosure
  - Prior to engaging in research or submitting research proposals

UPIRSOs must be reported when meeting what 3 criteria?

Unanticipated Problems Involving Risks to Subjects or Others

- Unexpected in nature, frequency, or severity (i.e., generally not expected in a subject's underlying condition or not expected as a risk of the study; therefore, not included in the investigator's brochure, protocol, or informed consent document)
- Definitely or probably related to participation in the research
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized

Reportable events must be reported to the UTSW IRB within:



Reportable Events

- Reporting requirement:
  - Emergency deviations must be promptly reported to the IRB within 5 working days of occurrence
  - Major deviations must be promptly reported to the IRB within 5 working days of PI awareness
  - UPIRSOs must be promptly reported to the IRB within 5 working days of PI awareness
  - Complaints must be promptly reported to the IRB within 5 working days of PI awareness

Reportable Events

- Reporting requirement when relying:
  - The local events must be promptly reported to the UT Southwestern IRB within 5 working days of PI awareness.
  - In addition, the external IRB's responses or determinations on these local events must be submitted to the UT Southwestern IRB within 10 working days of receipt
- Reporting requirement when IRB of Record:
  - Notify UTSW HRPP Director of terminations, suspensions, or modifications of clinical privileges of persons participating in studies approved by the UTSW IRB
  - UPIRSOs, serious or continuing non-compliance with federal regulations or determinations of UTSW IRB

Questions?