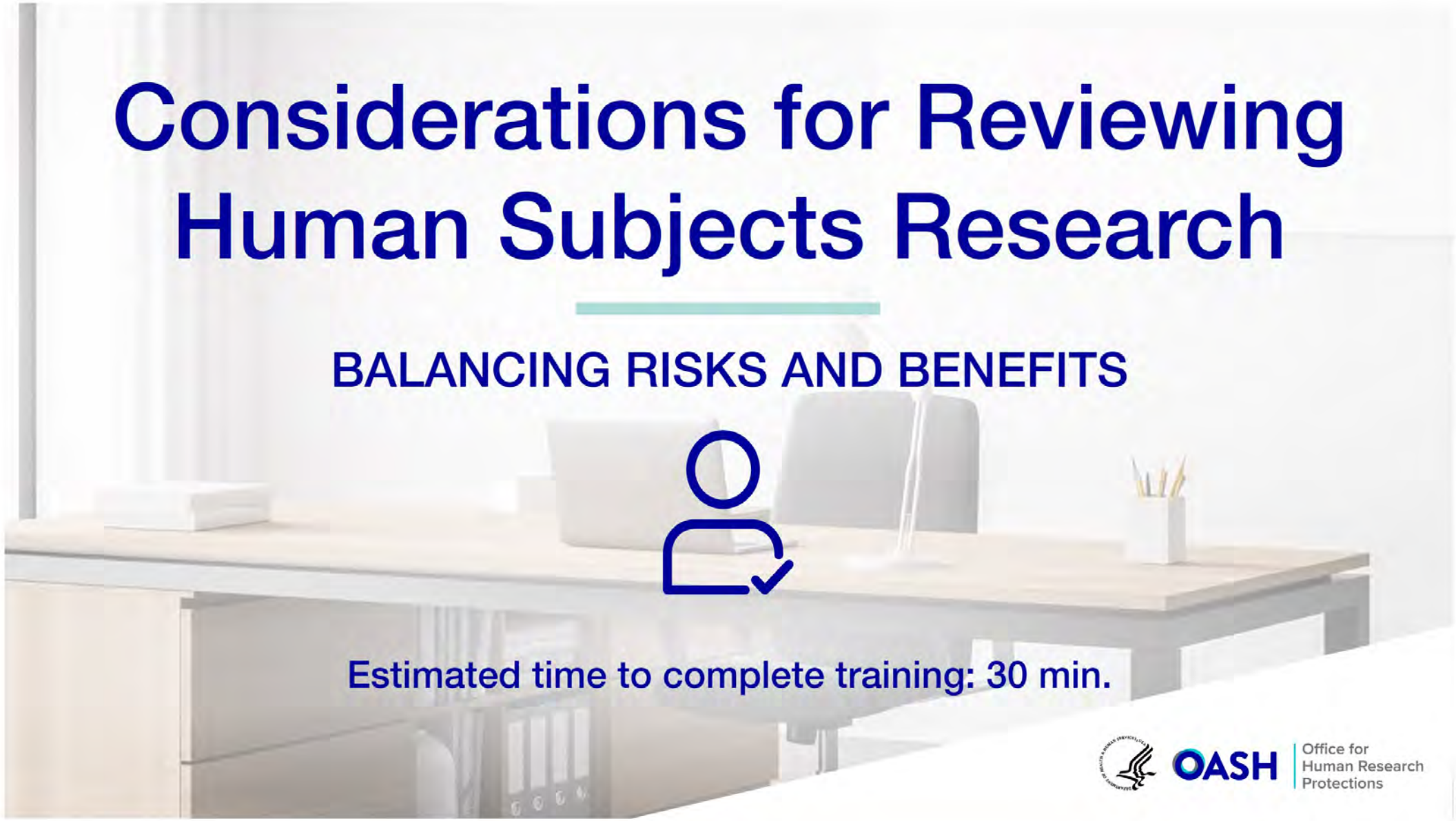
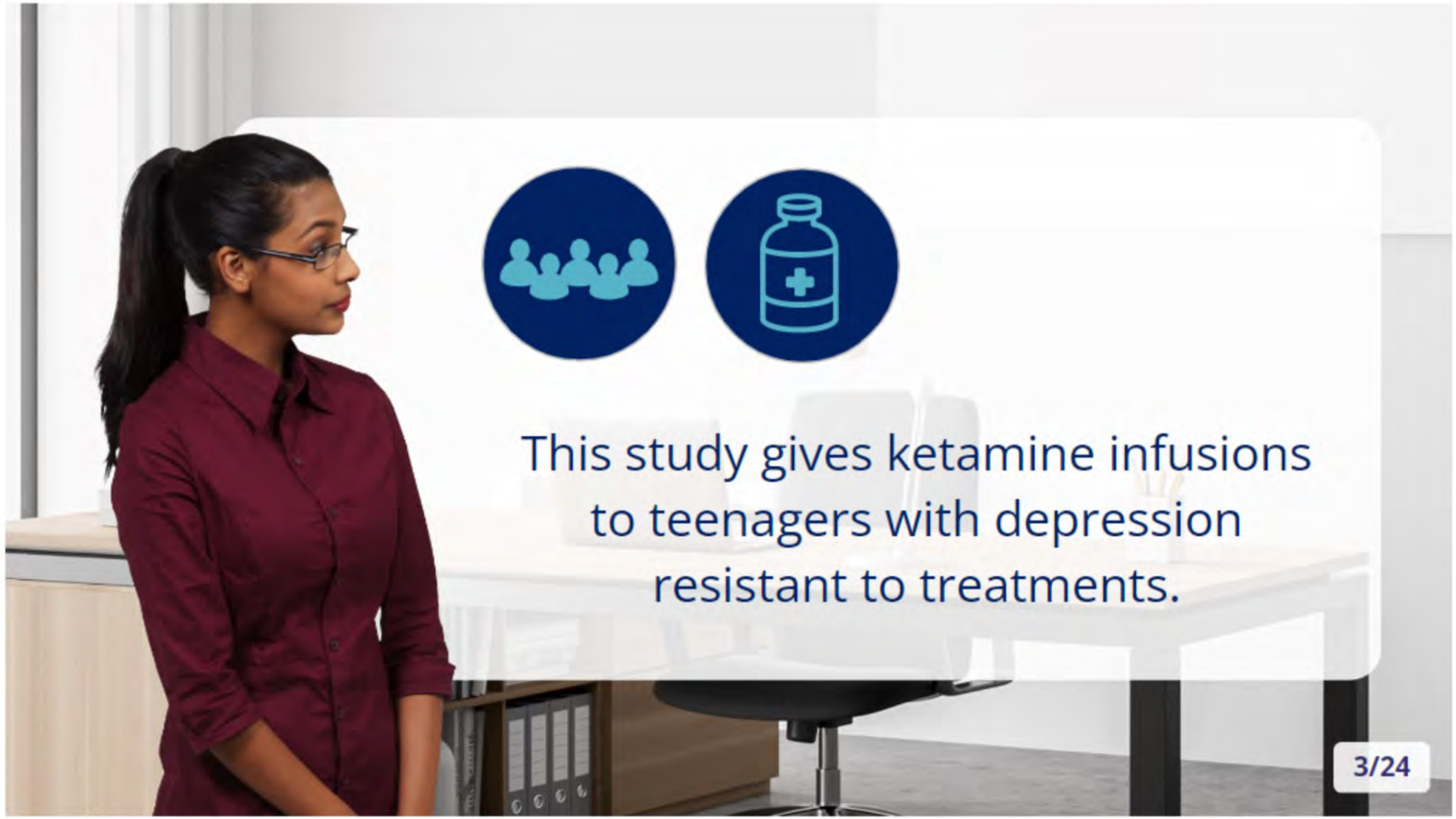
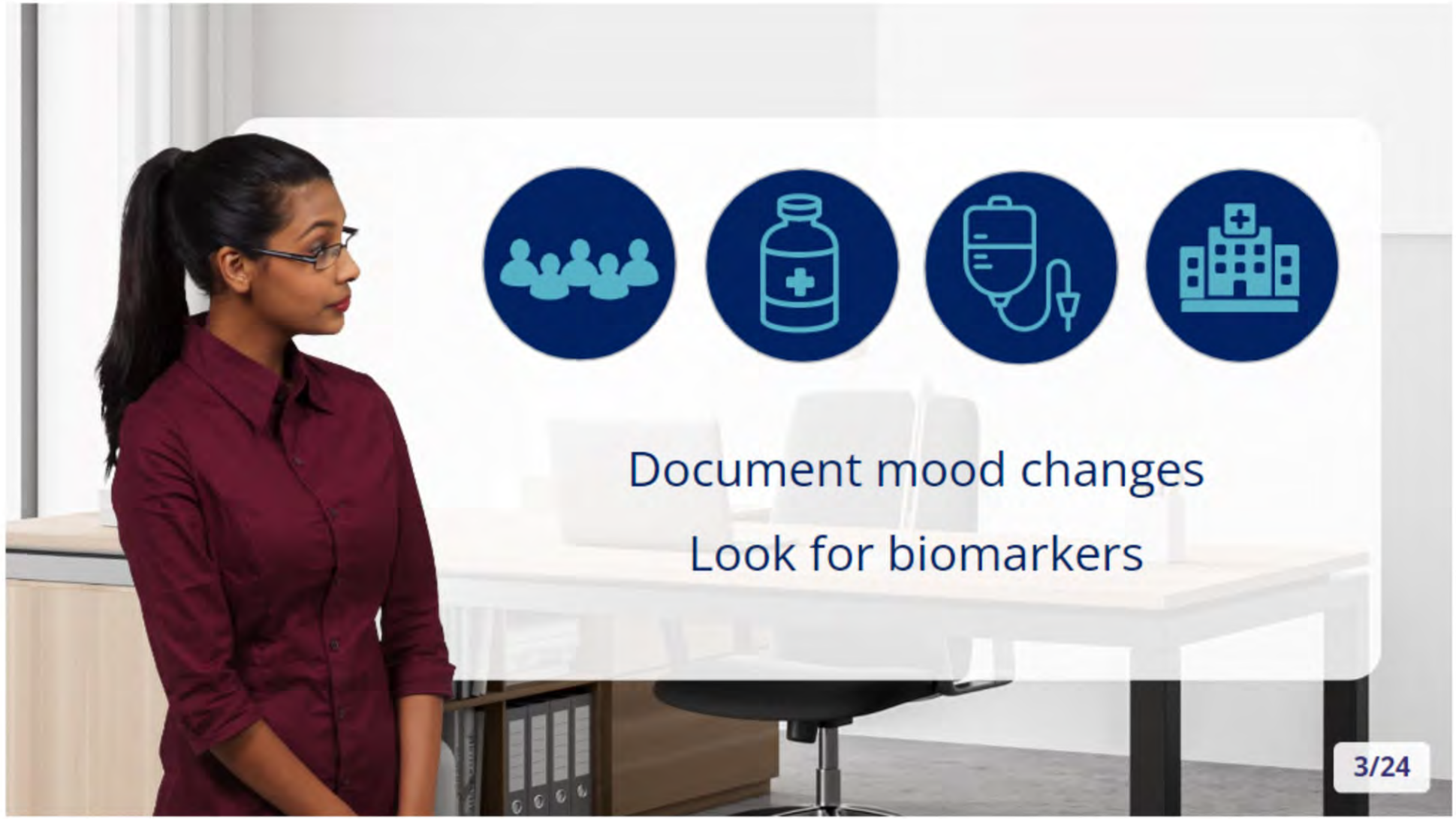

Considerations for Reviewing Human Subjects Research
BALANCING RISKS AND BENEFITS
Estimated time to complete training: 30 min.
OASH
Office for Human Research Protections

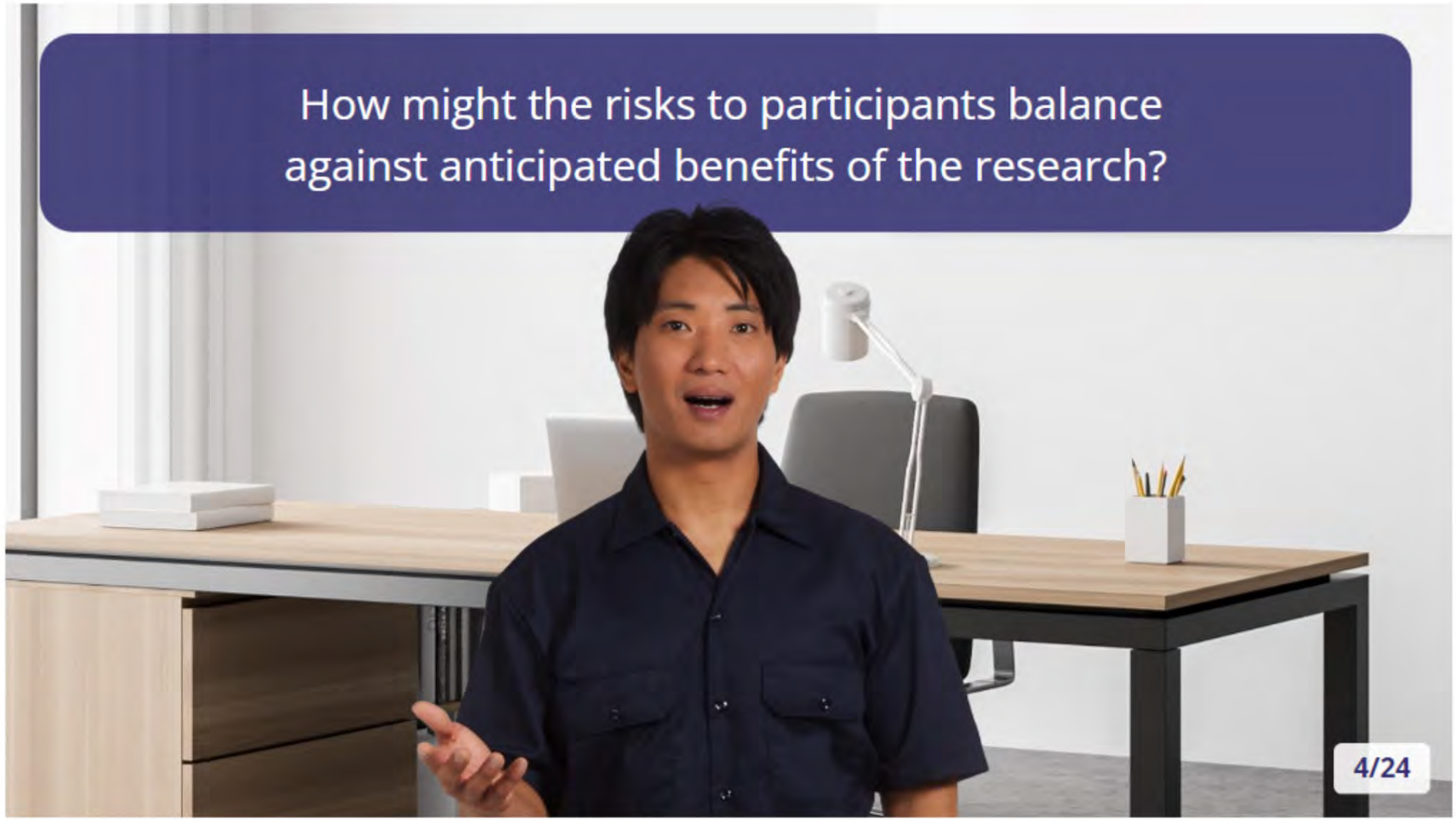

The IRB office can help researchers prepare submissions for IRB reviews
C.K. Li, PhD
IRB Office
Zara Bazzi, MD
2/24


The IRB office can help researchers prepare submissions for IRB reviews
C.K. Li, PhD
IRB Office
Zara Bazzi, MD
2/24

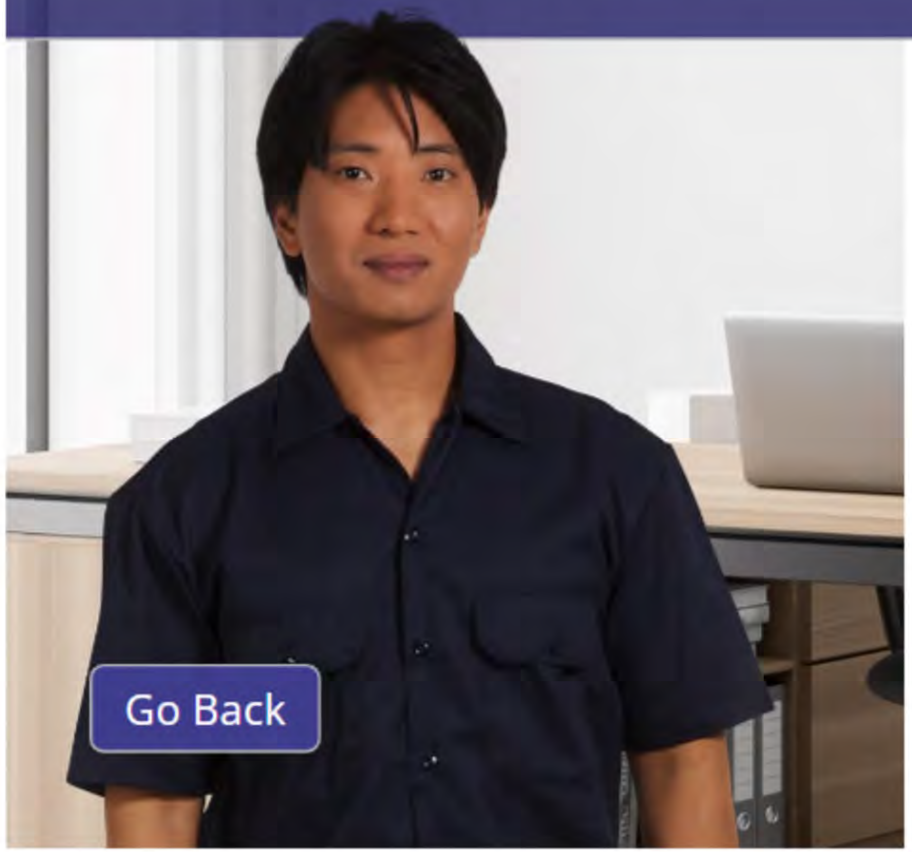

This study gives ketamine infusions to teenagers with depression resistant to treatments.
3/24

PREV NEXT


Document mood changes
Look for biomarkers
3/24

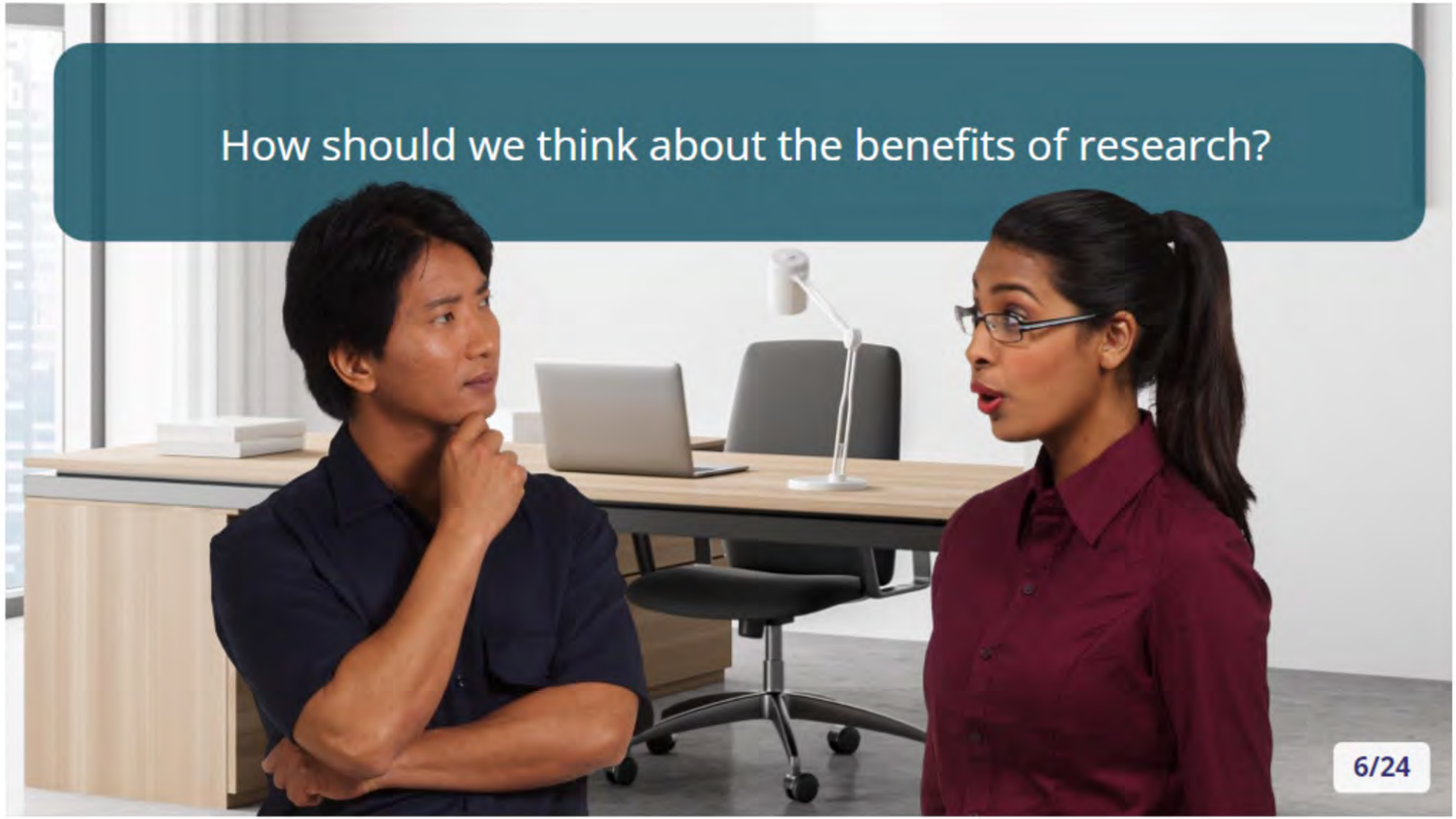

How might the risks to participants balance against anticipated benefits of the research?
4/24

As a reminder, what are some of the criteria for IRB approval of research under the Common Rule? (select all that apply)

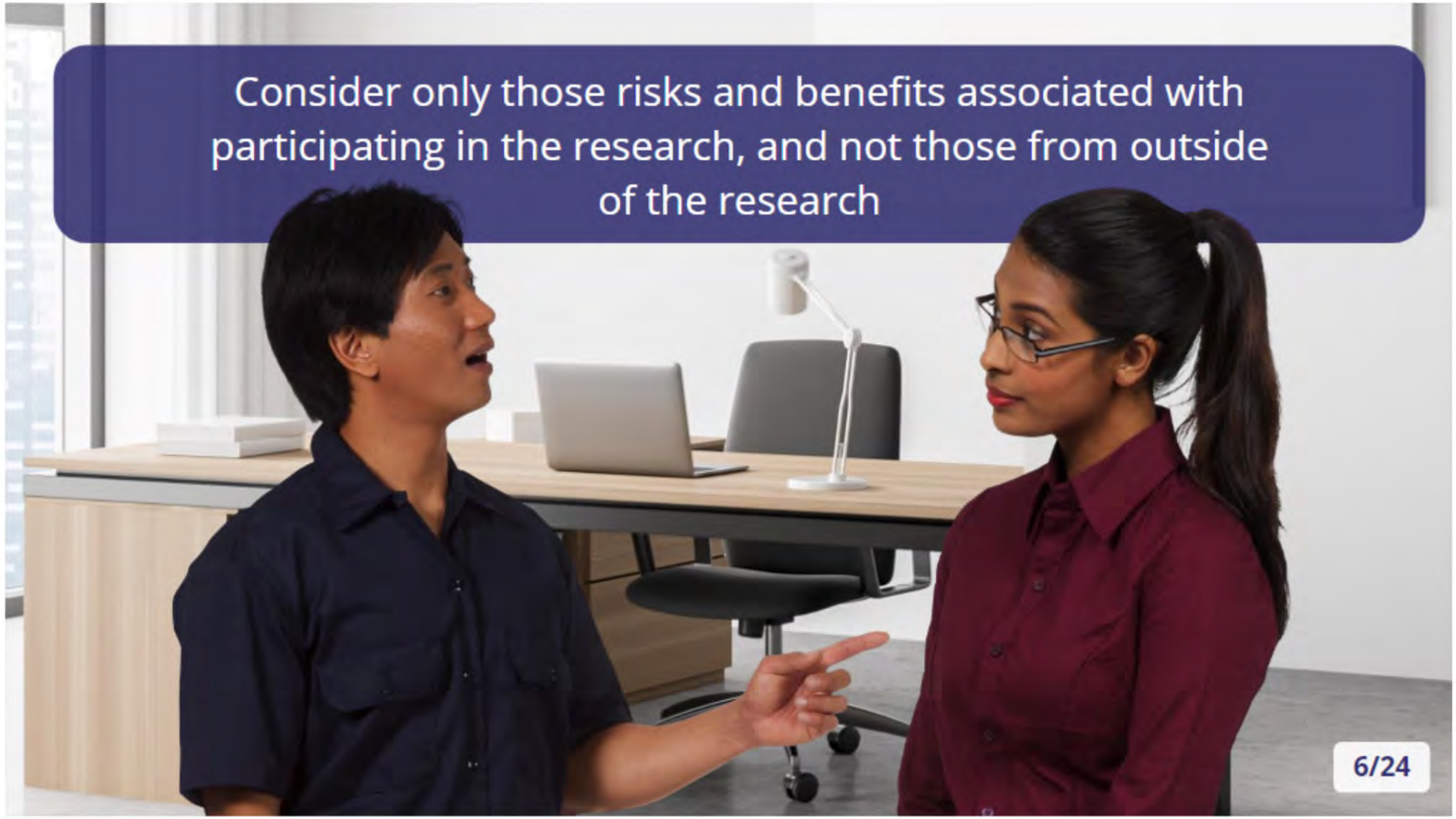


- [ ] A. Adverse events are promptly reported
- [ ] B. There are provisions for data monitoring, when appropriate
- [ ] C. Risks to subjects are minimized
- [ ] D. There is adequate documentation of IRB decisions
- [ ] E. Research risks are reasonable in relation to potential benefits
- [ ] F. There are provisions to protect the privacy of subjects and to maintain the confidentiality of data, when appropriate

5/24

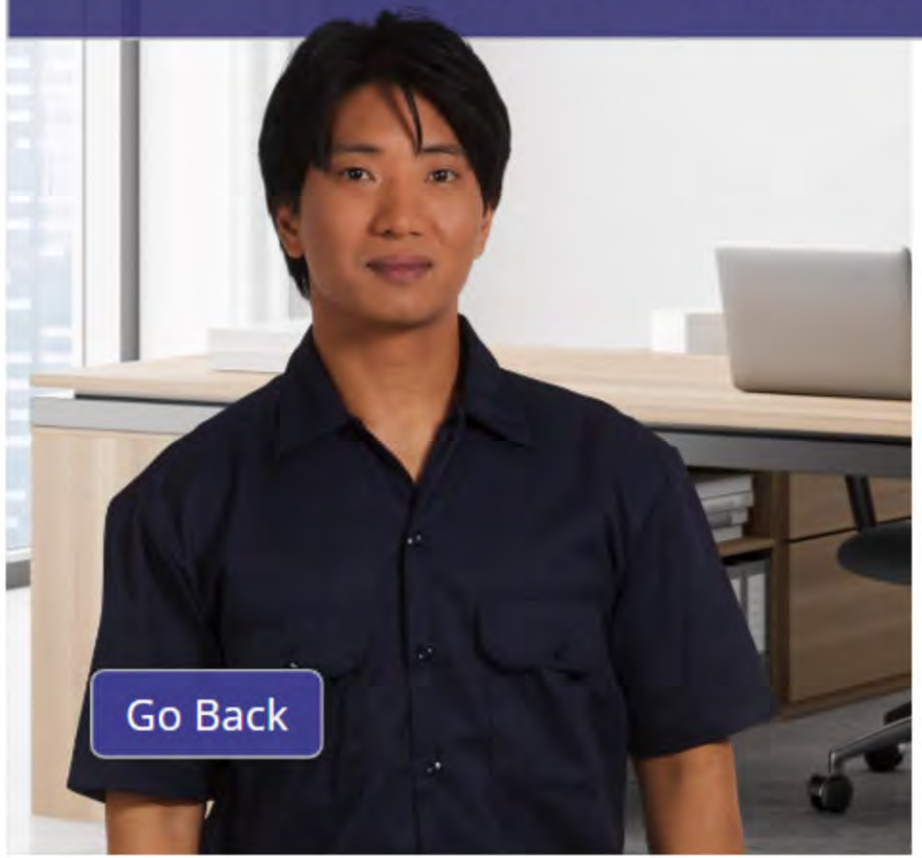

How should we think about the benefits of research?
6/24

Balancing Risks and Benefits



PREV NEXT

Which of the following statements are true about benefits from research participation that IRBs would consider when reviewing a study for approval under the Common Rule? (select all that apply)

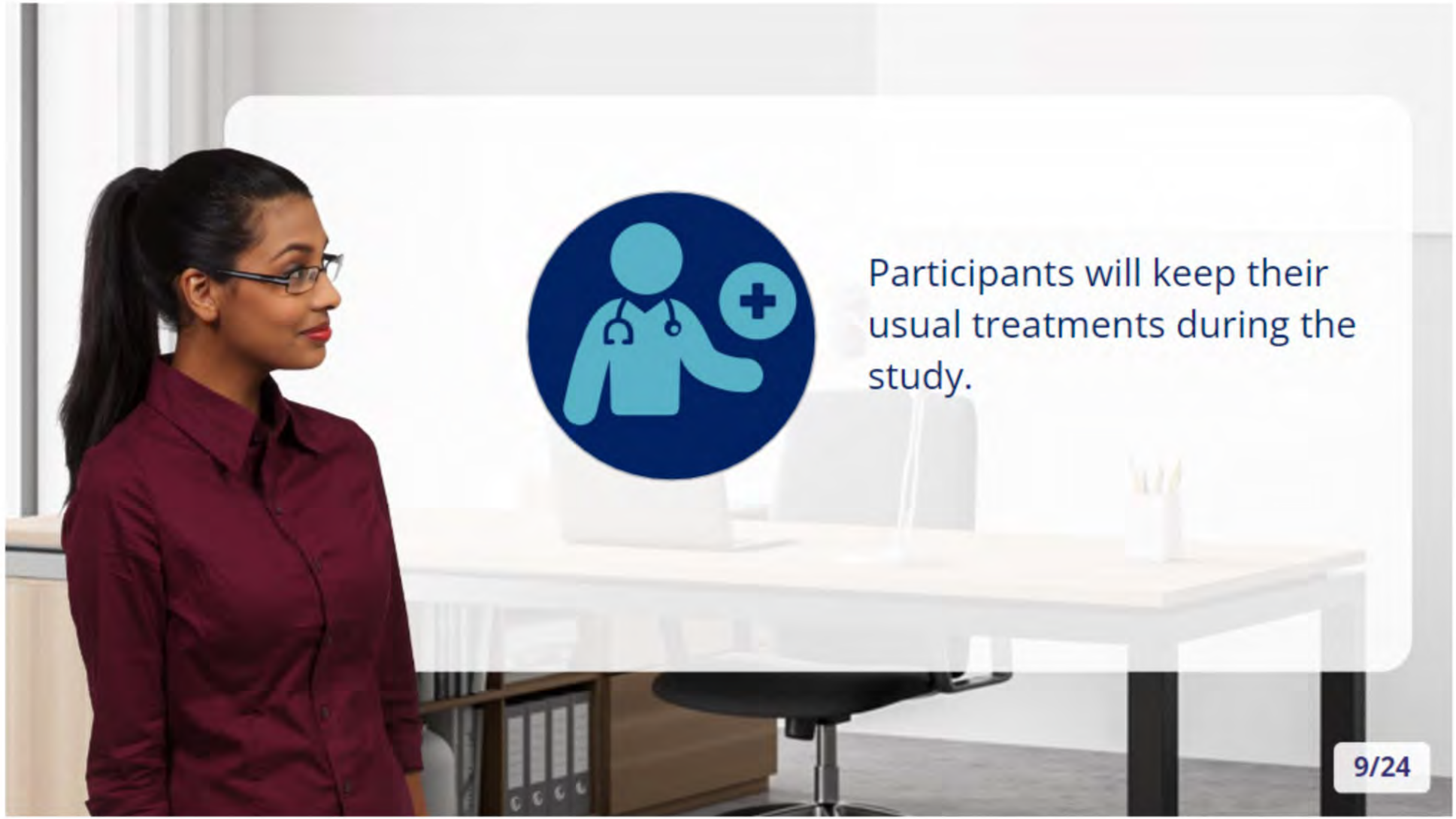


- [ ] A. Knowledge that may reasonably be gained from the research
- [ ] B. How much research participants will be reimbursed for their travel expenses
- [ ] C. The research participants getting a promising drug through their participation in the clinical trial studying that drug
- [ ] D. Benefits from the treatment that participants would receive anyway as part of clinical care with or without the research study
- [ ] E. Potential for the participants to learn more about their medical condition through their participation


Benefits include any direct and indirect benefits that people may receive from their participation in the research.
Direct
Chance of getting a new drug that could help reduce the symptoms caused by their medical condition
Indirect
Help researchers learn more about a health condition, generate new knowledge, and further scientific advances
8/24

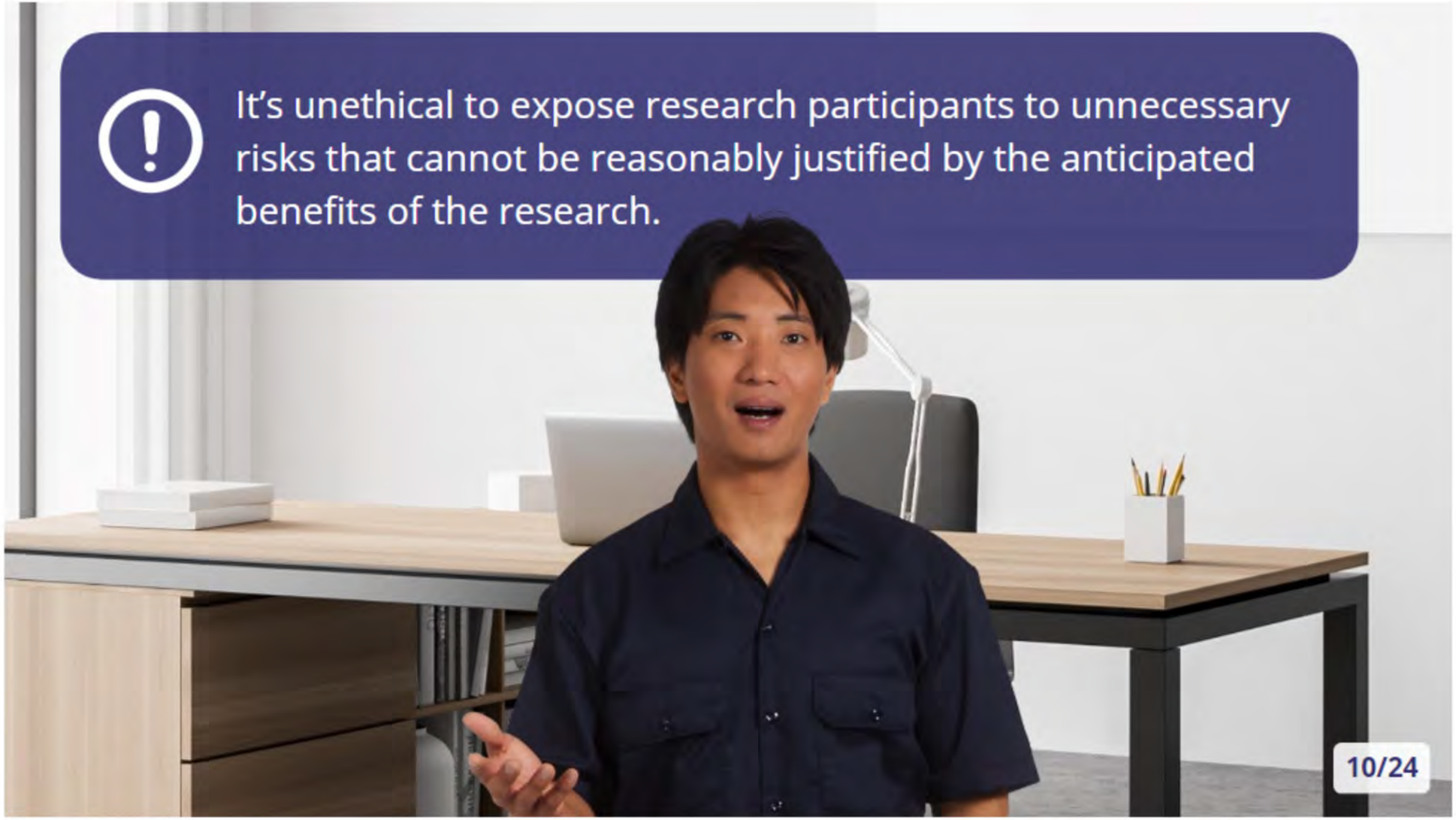

Tell me more so we can think about the risks and the benefits more concretely?
Direct
Chance of getting a new drug that could help reduce the symptoms caused by their medical condition
Indirect
Help researchers learn more about a health condition, generate new knowledge, and further scientific advances
8/24


Small Phase 2 study
Ketamine infusions
Teenagers, aged 12 to 18, with depression resistant to treatments
9/24


Participants will keep their usual treatments during the study.
9/24


Participants will receive 0.5 mg per kg of ketamine infusion three times a week over a 2-week period.
They will have a blood draw before the first and after the last infusions.
They will complete surveys and participate in interviews to assess their depression symptoms.
9/24


9/24


It’s unethical to expose research participants to unnecessary risks that cannot be reasonably justified by the anticipated benefits of the research.
10/24


Tell me about the use of IV ketamine.

Balancing Risks and Benefits

PREV NEXT

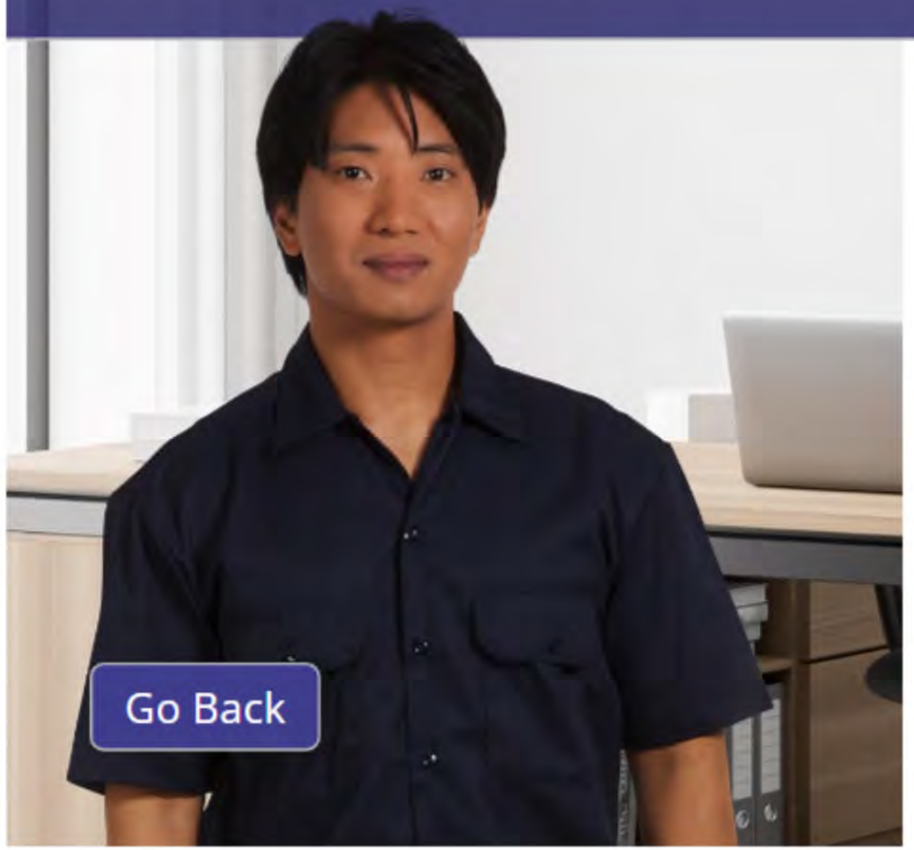

Side effects are usually mild and temporary.
Examples of side effects may include:
Dizziness
Headache
Gastrointestinal upset
Confusion
Recent research of low dose ketamine in adults rapidly reduced depressive symptoms.
11/24


You'll need good justifications for enrolling children for the research study.
12/24


Treatment-resistant depression is debilitating and relatively common in adolescents.
13/24


Adolescent brains may be more responsive to low dose ketamine as a treatment for depression.
13/24

Do you think that Zara has provided generally appropriate justification for conducting this clinical study with adolescents?



A. Yes. Treatment-resistant depression is a serious condition affecting adolescents and needs better treatments. Prior studies with adults suggest that ketamine might be effective but data are needed for children.

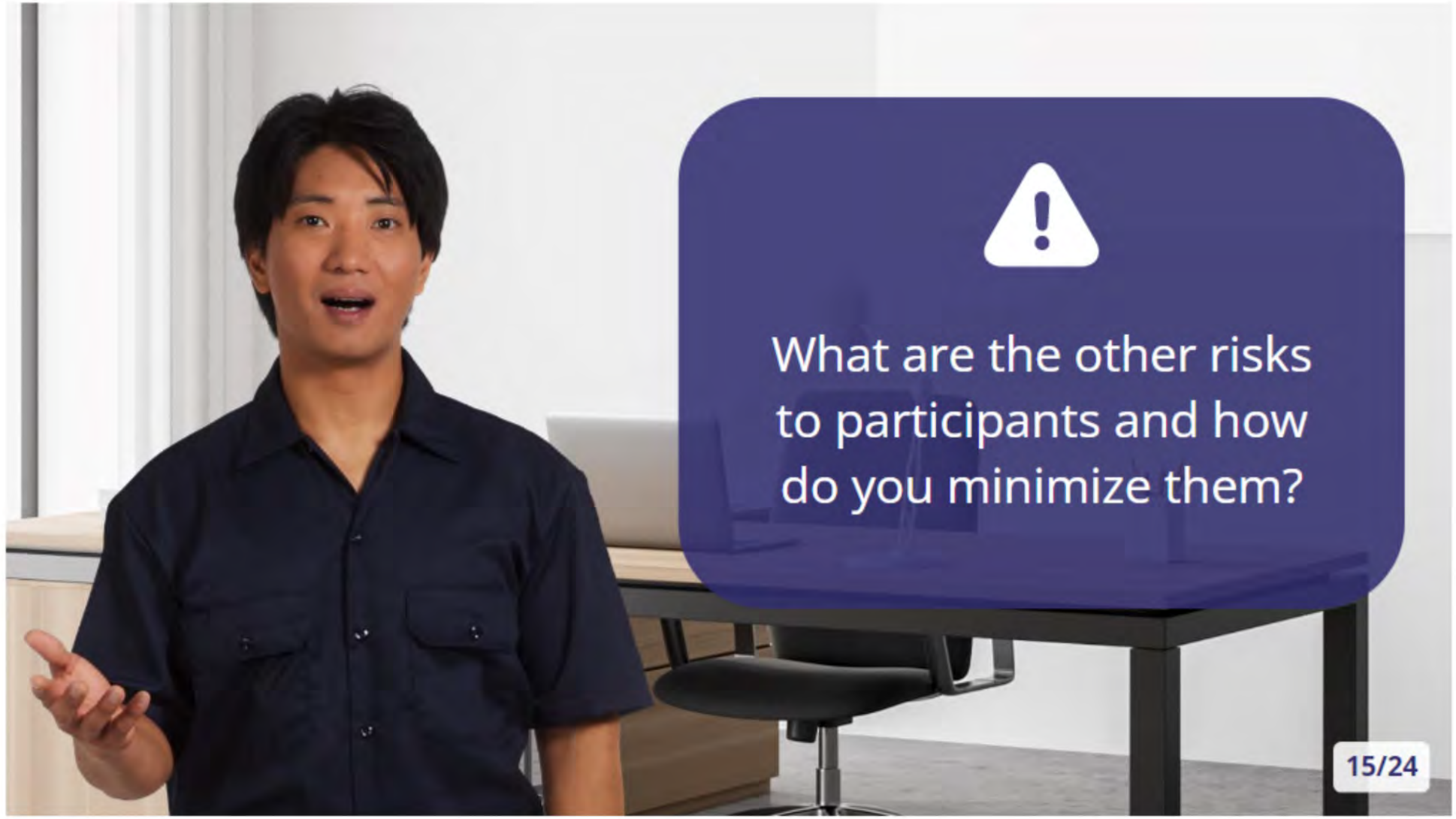
B. No. This research should not be conducted with adolescents because ketamine is a dangerous and potentially addictive drug.

C. No. Risks for children in research are not acceptable regardless of the potential benefits.

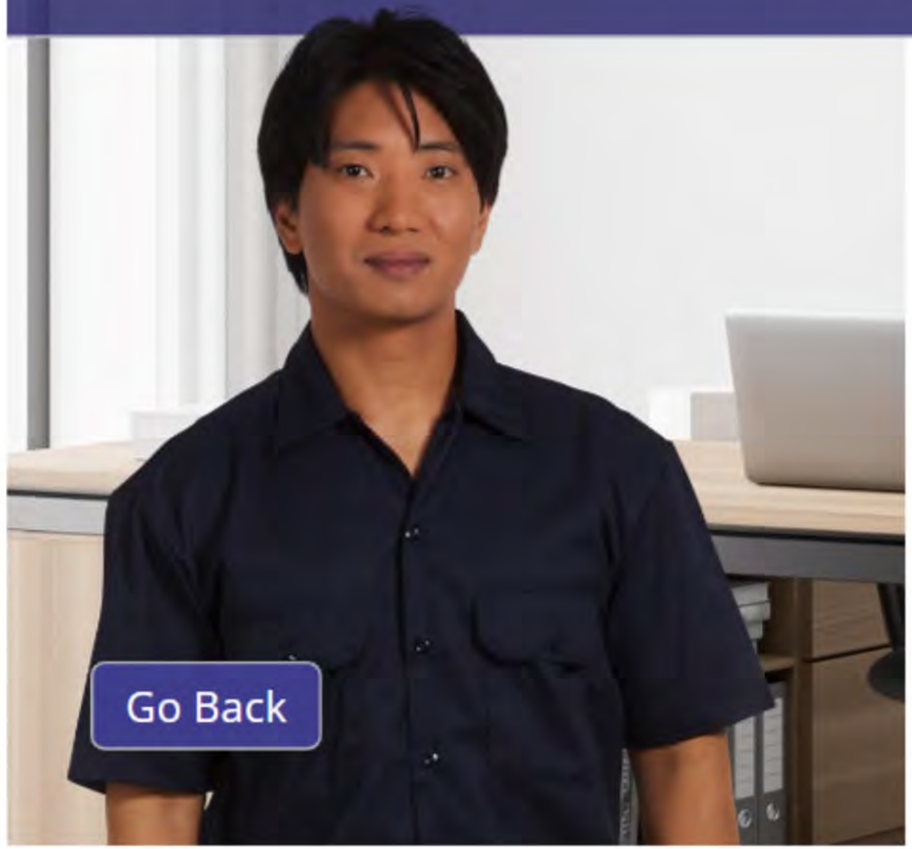
D. No. Data generated from studies with adults should be sufficient to provide clinical information for children.

14/24

SUBMIT


What are the other risks to participants and how do you minimize them?
15/24

The ketamine infusion is the only research risk that needs to be considered. True or false?



Go Back

- [ ] True. The research is only studying the effect of ketamine so it is the only source of research risk.
- [ ] False. Even though ketamine is the research intervention being studied, there are other procedures that are being conducted specifically for the research. These are also sources of research risks that the IRB must consider.

16/24

Balancing Risks and Benefits

PREV NEXT


Will you take participants off their usual medications, i.e., do washouts?
19/24


When washouts are done, researchers need to carefully consider the risks and describe them in detail in the research protocol.
19/24


When washouts are done, researchers need to carefully consider the risks and describe them in detail in the research protocol.
19/24


Tell me about the surveys and interviews done for the research?
20/24


21/24

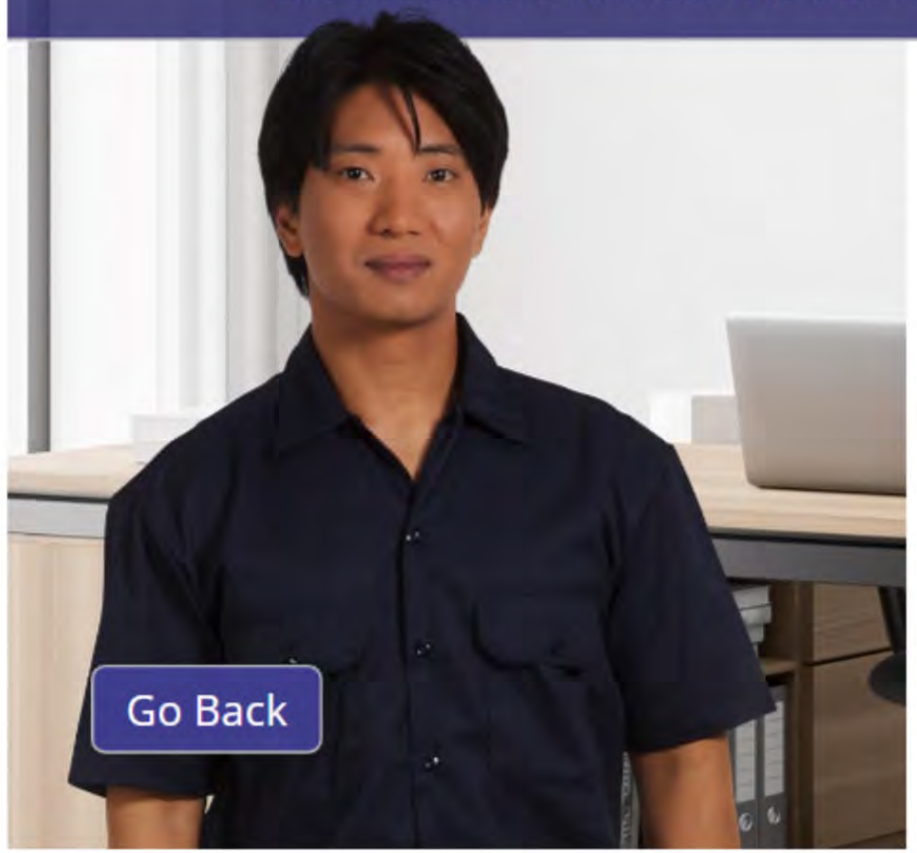

21/24

Balancing Risks and Benefits

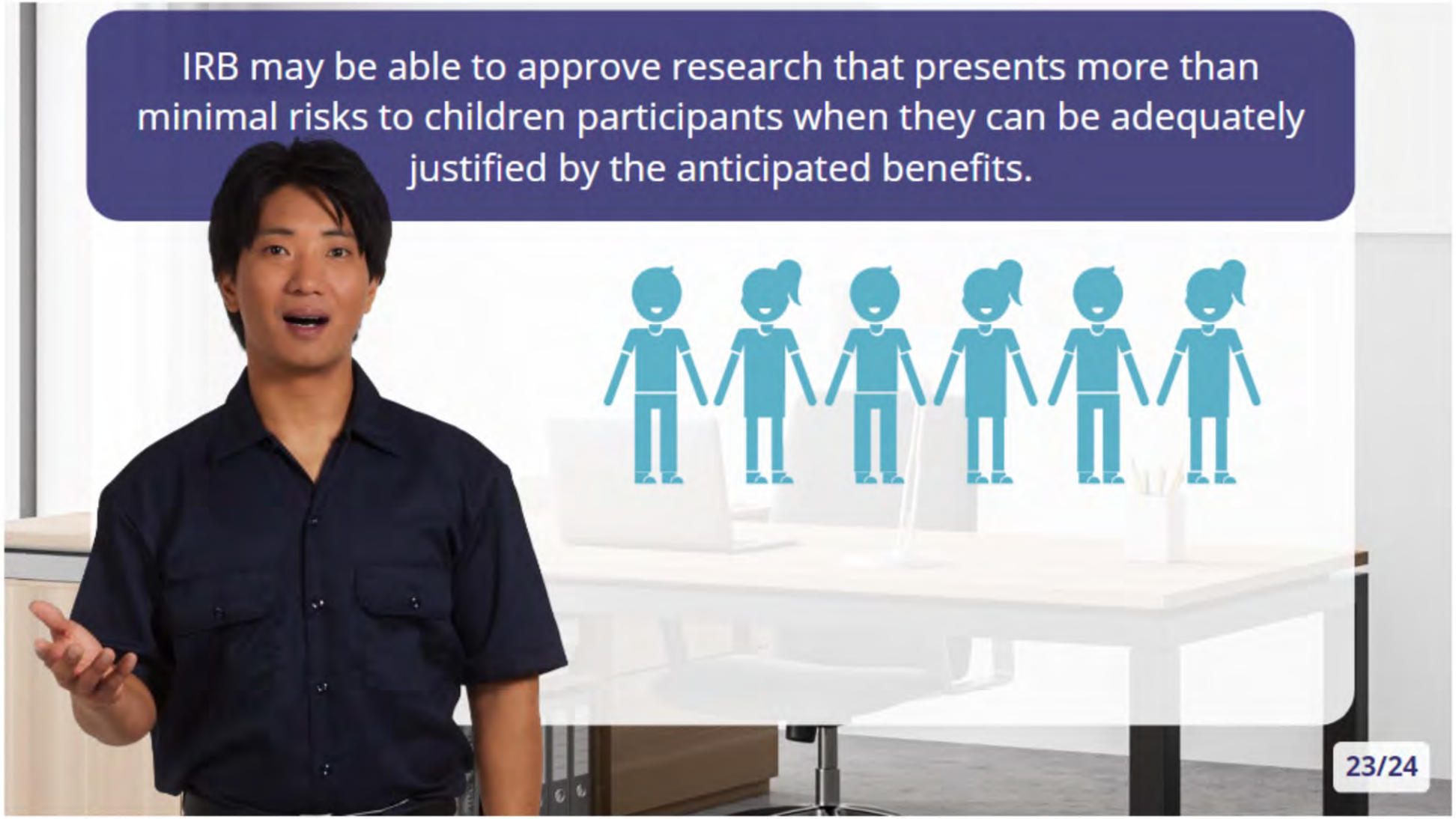
PREV NEXT


What are the additional regulatory requirements for research involving children?
21/24

For research involving children, the regulations at 45 CFR 46 subpart D have additional requirements that need to be satisfied before the IRB can approve the research. Review the following and select all true statements.



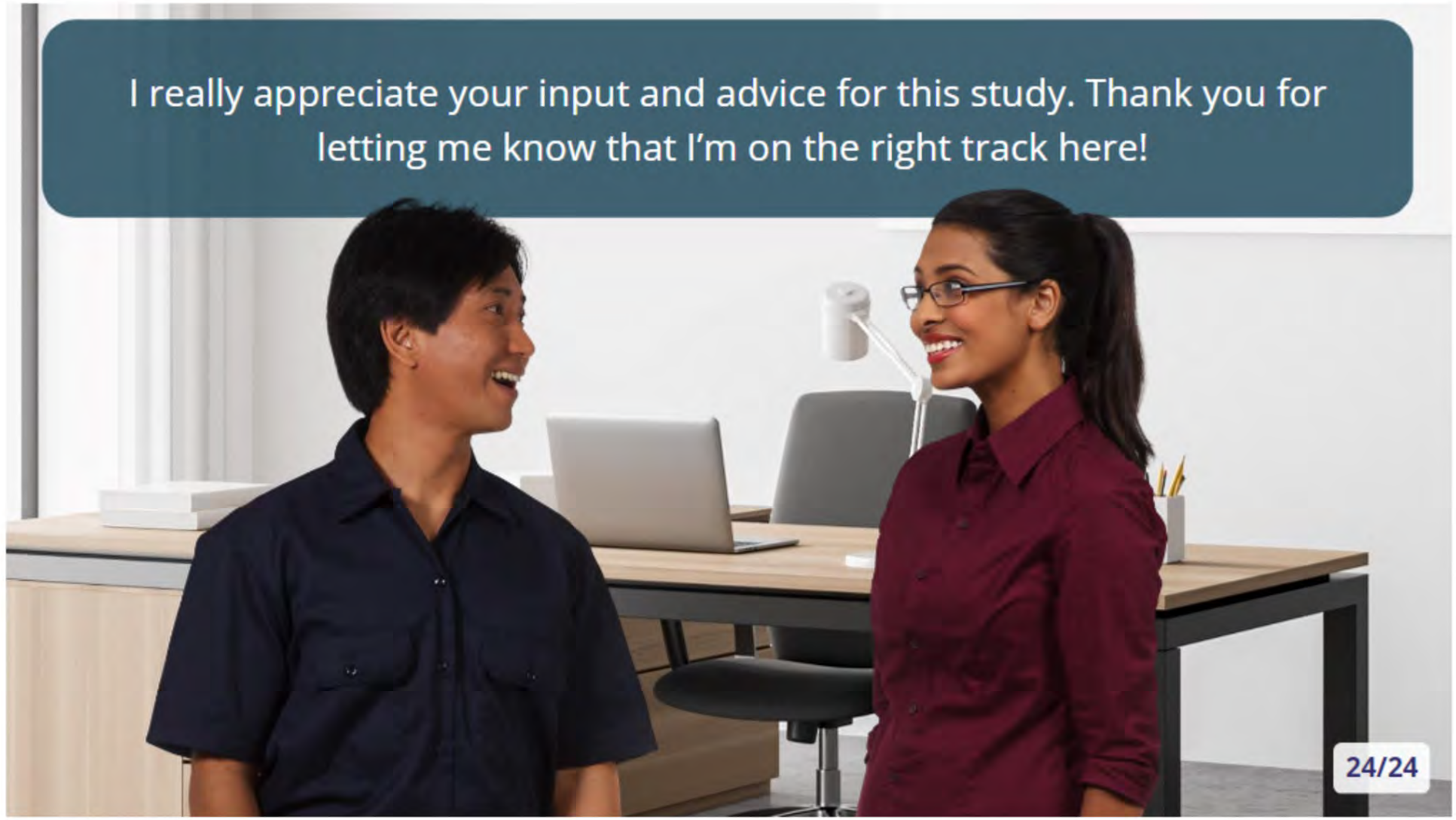
- [ ] A. When specific conditions are satisfied, IRBs can potentially approve research involving children that may be deemed greater than minimal risk
- [ ] B. All the researchers need to proceed with the research is the parents' permission
- [ ] C. IRBs cannot approve research that does not promise the prospect of a direct benefit for the child participant
- [ ] D. Generally, researchers are required to obtain the adolescent participant's agreement to participate in the research
- [ ] E. None of the above is true


IRB may be able to approve research that presents more than minimal risks to children participants when they can be adequately justified by the anticipated benefits.
23/24


Be sure to:
Thoroughly explain the anticipated benefits of the research study
Explain the risks to individual participants
Provide your plan to minimize the risks
Describe how the risks are reasonable to the anticipated benefits from the research.
23/24

Balancing Risks and Benefits

PREV NEXT


I really appreciate your input and advice for this study. Thank you for letting me know that I'm on the right track here!
24/24

Check out other educational resources at:

www.hhs.gov/ohrp/education-and-outreach/online-education/index.html

OASH | Office for Human Research Protections

Click Here for Completion Certificate

Restart Training