Assessment of Consent Capacity – Randomized Clinical Trials (ACC-RCT) © 2006 Fisher, Cea, Davidson, & Fried

Fisher, C. B., Cea, C. D., Davidson, P. W., & Fried, A. L. (2006). Capacity of persons with mental retardation to consent to participation in randomized clinical trials. *American Journal of Psychiatry*, 163, 1813–1820.

National Institute of Child Health and Human Development (#1 R01 HD39332-01)

Abstract

Amidst changing patterns of accommodation and conflict among American ethnic groups, there remains a paucity of research on the nature and impact of racial and ethnic discrimination on development in multiethnic samples of youth. The Adolescent Discrimination Distress Index along with measures of caregiver racial bias preparation and self-esteem was administered to 177 adolescents drawn from 9th–12th graders self-identified as African American, Hispanic, East Asian, South Asian, and non-Hispanic white. Youth from all ethnic backgrounds reported distress associated with instances of perceived racial prejudice encountered in educational contexts. Instances of institutional discrimination in stores and by police were higher for older youth and particularly for African American and Hispanic teenagers. Encounters with peer discrimination were reported most frequently by Asian youth. Reports of racial bias preparation were associated with distress in response to institutional and educational discrimination and self-esteem scores were negatively correlated with distress caused by educational and peer discrimination. The importance of research on discrimination distress to understanding adolescent development in multiethnic ecologies is discussed here.

INTERVIEWER FORM
ASSESSMENT OF CONSENT CAPACITY-RANDOMIZED CLINICAL TRIALS (ACC-RCT) Female Version
Subject Initials:
Subject ID#:
Name of Interviewer: Date of Interview:

INTERVIEWER FORM: ACC-RCT/Female	SUBJECT ID#
INTERVIEWER: FOR PARTICIPANTS WHO REFUSED TO BE TO THE STUDY, SAY "I AM NOW GOING TO TURN ON THE TAPE."	,
Make sure tape recorder is on <u>and</u> that you have pre	essed record
IF PARTICIPANT STILL REFUSES TO BE TAPED, DON'T TURN THE PROTOCOL AND WRITE DOWN THE RESPONSES.	THE TAPE ON. CONTINUE TO ADMINISTER
NOTE: WHEN YOU BEGIN TO READ THE VIGNETTE ABOUT SHE IS FAMILIAR WITH SOMEONE OF THE SAME NAME, SAY CONTINUE THE STORY USING SUSAN AS THE CHARACTER.	SUSAN', IF PARTICIPANT MENTIONS THAT "THIS IS A DIFFERENT SUSAN"AND

- In the space below, write down everything that is said by you and the research participant in the order that it is stated
- Put and "I" for interviewer and an "R" for research participant to indicate who is speaking. Put an "S" next to a statement from the staff member if it is relevant to the interview.
- Indicate when a prompt was used with the letters P1, P2, or P3 (see prompts below).

PROMPT INSTRUCTIONS

- Criterion for a full-credit response is provided after the question
- P1: If subject's response is a 'no-credit' answer, repeat the question
- P2: If subject's initial response or response to P1 is a 'partial-credit' answer, say "Tell me more."
- P3: If after either P1 or P2, subject's response is still not a full-credit answer, say "To remind you" and then reread the disclosure statement and ask the question one last time

I'm going to tell you a story about Susan. Susan has a decision to make. Listen to the story carefully – I will be asking you some questions.

<u>Disclosure Statement #1: Nature of Disorder:</u> Susan has problems at the place where she works. She gets angry, shouts and starts fights. If she does not stop these behaviors soon, she will not be allowed to go to work.

Question 1: What are Susan's problems at work?

SCORING CRITERIA FULL CREDIT (2 points): must mention one problem behavior and that Susan will not be allowed to come to work
PARTIALCREDIT (1 point): mentions one problem behavior or that Susan will not be allowed to come to work
NOTE: subject can use a word to describe an aggressive behavior that is not used in story, e.g., "yells" instead of "shouts"
NO CREDIT (0 points): no response, incorrect or irrelevant answer, or behavior problem not associated with aggression

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INTERVIEWER FORM:	ACC BCT/Famala	
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- In the space below, write down everything that is said by you and the research participant in the order that it is stated
- Put and "I" for interviewer and an "R" for research participant to indicate who is speaking. Put an "S" next to a statement from the staff member if it is relevant to the interview.

SUBJECT ID#

Indicate when a prompt was used with the letters P1, P2, or P3 (see prompts below).

PROMPT INSTRUCTIONS

- Criterion for a full-credit response is provided after the question
- P1: If subject's response is a 'no-credit' answer, repeat the question
- P2: If subject's initial response or response to P1 is a 'partial-credit' answer, say "Tell me more."
- P3: If after either P1 or P2, subject's response is still not a full-credit answer, say "To remind you" and then reread the disclosure statement and ask the question one last time

<u>Disclosure Statement #2: Nature of current psychosocial treatment:</u> Susan's counselor put her on a behavior plan. In the behavior plan Susan's counselor gives her stars in a book if she does not get angry or shout or fight all day. Susan can trade the stars for a soda.

Question 2: What did Susan's counselor do to try to help her with her behavior?

SCORING CRITERIA FULL CREDIT (2 points):
must mention the behavior plan or stars or soda <u>and</u> the reason why they were given (e.g. not shouting or fighting, good behavior)
PARTIAL CREDIT (1 point): mentions either the behavior plan, stars, or soda <u>or</u> the reason why they were given
NO CREDIT (0 points): no response, incorrect or irrelevant answer

- In the space below, write down everything that is said by you and the research participant in the order that it is stated
- Put and "I" for interviewer and an "R" for participant to indicate who is speaking. Put an "S" next to a statement from the staff member if it is relevant to the interview.
- Indicate when a prompt was used with the letters P1, P2, or P3 (see prompts below).

PROMPT INSTRUCTIONS

- Criterion for a full-credit response is provided after the question
- P1: If subject's response is a 'no-credit' answer, repeat the question
- P2: If subject's initial response or response to P1 is a 'partial-credit' answer, say "Tell me more."
- P3: If after either P1 or P2, subject's response is still not a full-credit answer, say "To remind you" and then reread the disclosure statement and ask the question one last time

<u>Disclosure Statement #3: Efficacy of current psychosocial treatment:</u> The behavior plan is not working – so Susan's doctor gave her medicine to help her control her behavior.

Question 3: Why did Susan's doctor give her the medicine?

SCORING CRITERIA
FULL CREDIT (2 points): must mention that the behavior plan is not working and that medicine might help control behavior (e.g. she was still fighting and
medicine might help her stop)
partial credit (1 point): mentions one of the above or makes a statement like "so she'd be good"
NO CREDIT (0 points): no response, incorrect or irrelevant answer

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INTERVIEWER FORM: ACC-RCT/Female	SUBJECT ID#

- In the space below, write down everything that is said by you and the research participant in the order that it is stated
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- Indicate when a prompt was used with the letters P1, P2, or P3 (see prompts below).

PROMPT INSTRUCTIONS

- Criterion for a full-credit response is provided after the question
- P1: If subject's response is a 'no-credit' answer, repeat the question
- P2: If subject's initial response or response to P1 is a 'partial-credit' answer, say "Tell me more."
- P3: If after either P1 or P2, subject's response is still not a full-credit answer, say "To remind you" and then reread the disclosure statement and ask the question one last time

<u>Disclosure Statement #4: Efficacy of current pharmacological treatment:</u> The medicine is not working either. Susan still gets angry, shouts and starts fights at work.

Question 4: What happened to Susan's behavior when she took the medicine?

 SCORING CRITERIA
 FULL CREDIT (2 point):
must mention that the medicine is not working
(e.g., "nothing," "not
 working") and that she
has behavior problems
(shouts, starts fights)
DARTIAL CREDIT /4
PARTIAL CREDIT (1 point): mentions one of
the above
 NO CREDIT (0 points):
 no response, incorrect or irrelevant answer
irrelevant answer

INTERVIEWER FORM:	ACC-RCT /Female	SUBJECT ID#
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- In the space below, write down everything that is said by you and the research participant in the order that it is stated
- Put and "I" for interviewer and an "R" for research participant to indicate who is speaking. Put an "S" next to a statement from the staff member if it is relevant to the interview.
- Indicate when a prompt was used with the letters P1, P2. or P3 (see prompts below).

PROMPT INSTRUCTIONS

- Criterion for a full-credit response is provided after the question
- P1: If subject's response is a 'no-credit' answer, repeat the question
- P2: If subject's initial response or response to P1 is a 'partial-credit' answer, say "Tell me more."
- P3: If after either P1 or P2, subject's response is still not a full-credit answer, say "To remind you" and then reread the disclosure statement and ask the question one last time

<u>Disclosure Statement #5: Purpose of the research:</u> Susan goes to see Bob Smith at the clinic. Bob is a researcher. He tests new medicines. Bob asks Susan to be in a study to help him test whether a new medicine called Paygo can help people control their behavior problems.

Question 5: Why does Bob Smith want Susan to be in the study?

SCORING CRITERIA FULL CREDIT (2 points):
must mention that purpose of study is to test the medicine <u>and</u> that the medicine might help people with behavior problems
PARTIAL CREDIT (1 point): mentions one of the above (e.g., "test Paygo", "test medicine", "control behavior")
NO CREDIT (0 points): helps people, no response, incorrect or irrelevant answer

- In the space below, write down everything that is said by you and the research participant in the order that it is stated
- Put and "I" for interviewer and an "R" for research participant to indicate who is speaking. Put an "S" next to a statement from the staff member if it is relevant to the interview.
- Indicate when a prompt was used with the letters P1a/b, P2a/b, or P3a/b (see prompts below).

PROMPT INSTRUCTIONS

- Criterion for a full-credit response to 'a' and 'b' are provided after the questions
- If subject gives a "full-credit" answer to question 'a', go right to disclosure statement 'b'
- P1a: If subject's response to question 'a' is a 'no-credit' answer, repeat the question
- P2a: If subject's initial response or response to P1a is a 'partial-credit' answer, say "Tell me more."
- P3a: if after either P1 or P2, subject's response is still not a full-credit answer, say "To remind you" and then reread the disclosure statement and ask question 'a' one last time.
- · Read disclosure statement 'b' and ask question 'b'
- P1b: If subject's response to question 'b' is a 'no-credit' answer, repeat the question
- P2b: If subject's response to 'b' is still not a full-credit answer, say "Tell me more."
- P3b: If after either P1 or P2, subject's response is still not a full-credit answer, say "To remind you" and then reread the disclosure statement and ask question 'b' one last time.

<u>Disclosure Statement #6a: Random assignment to treatment or control conditions</u>: Many other people with behavior problems will be in the study. Some people will get the Paygo and some will get a fake medicine. Comparing Paygo to the fake medicine will help Bob test whether the Paygo really works.

Question 6a: Why will some people in the study take a fake medicine?

Disclosure Statement #6b: If Susan is in the study, she will not know which medicine she will take.

Question 6b: Will Susan know which medicine she will take?

SCORING CRITERIA
FULL CREDIT FOR (a) (2 points): to see if "Paygo" works by comparing it to the fake medicine.
PARTIAL CREDIT FOR (a) (1 point) Mentions either of the above (e.g., test Paygo, If Paygo works, compares Paygo)
FULL CREDIT FOR (b) (1 point) "no" or indicates understanding of randomization (e.g. she will not have a choice of which medicine she will take)
NO CREDIT (0 points): no response, incorrect or irrelevant answer

INTERVIEWER FORM: ACC-RCT/Female	SUBJECT ID#
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- Put and "I" for interviewer and an "R" for research participant to indicate who is speaking. Put an "S" next to a statement from the staff member if it is relevant to the interview.
- Indicate when a prompt was used with the letters P1a/b, P2a/b, or P3a/b (see prompts below).

PROMPT INSTRUCTIONS

- Criterion for a full-credit response to 'a' and 'b' are provided after the questions
- If subject gives a full-credit" answer to question 'a', go right to disclosure statement 'b'
- P1a: If subject's response to question 'a' is a 'no-credit' answer, repeat the question
- P2a: If subject's initial response or response to P1a is still not a full credit (e.g., "AM") say "Tell me more."
- P3a: if after either P1 or P2, subject's response is still not a full-credit answer, say "To remind you" and then reread the disclosure statement and ask question 'a' one last time.
- Read disclosure statement 'b' and ask question 'b'
- P1b: If subject's response to question 'b' is a 'no-credit' answer, repeat the question
- P2b: If subject's initial response or response to P1b is still not full-credit (e.g., "months") say "Tell me more."
- P3b: If after either P1 or P2, subject's response is still not a full-credit answer, say "To remind you" and then reread the disclosure statement and ask question 'b' one last time.

<u>Disclosure Statement #7a: Nature of the treatments</u>: If Susan agrees to be in the study, she would take 2 pills a day – one pill in the morning and one pill at night.

Question 7a: How many times a day would Susan have to take the pills?

Disclosure Statement #7b: Susan would take the pills every day for 6 months.

Question 7b: How long would Susan have to take the pills?

SCORING CRITERIA
FULL CREDIT FOR (a) (1 point): (2 times, or AM and PM, or twice a day)
FULL CREDIT FOR (b) (1 point): (6 months, ½ a year)
NO CREDIT (0 points): no response, incorrect or irrelevant answer

INTERVIEWER FORM: ACC-RCT/Female	SUBJECT ID#
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- Put and "I" for interviewer and an "R" for research participant to indicate who is speaking. Put an "S" next to a statement from the staff member if it is relevant to the interview.
- Indicate when a prompt was used with the letters P1, P2, or P3 (see prompts below).

PROMPT INSTRUCTIONS

- Criterion for a full-credit response is provided after the question
- P1: If subject's response is a 'no-credit' answer, repeat the question
- P2: If subject's initial response or response to P1 is a 'partial-credit' answer, say "Tell me more."
- P3: If after either P1 or P2, subject's response is still not a full-credit answer, say "To remind you" and then reread the disclosure statement and ask the question one last time

<u>Disclosure Statement #8: Treatment benefits</u>: If Susan takes the Paygo pills, a <u>good thing</u> that might happen is that she won't feel so angry. She won't feel like shouting or starting fights and she will be allowed to come to work.

Question 8: What good things could happen if Susan takes the Paygo pills?

SCORING CRITERIA
FULL CREDIT (2 points): Must mention one behavior that will be improved by Paygo ("feel good" not acceptable) and that she will be allowed to come to work
PARTIAL CREDIT (1 point): Mentions one of the above or other reasonable option (e.g. would feel better, could work)
NO CREDIT (0 points): medicine helps, no response, incorrect or irrelevant answer

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- Indicate when a prompt was used with the letters P1, P2, or P3 (see prompts below).

PROMPT INSTRUCTIONS

- Criterion for a full-credit response is provided after the question
- P1: If subject's response is a 'no-credit' answer, repeat the question
- P2: If subject's initial response or response to P1 is a 'partial-credit' answer, say "Tell me more."
- P3: If after either P1 or P2, subject's response is still not a full-credit answer, say "To remind you" and then reread the disclosure statement and ask the question one last time

<u>Disclosure Statement #9: Research risks</u>: If Susan takes the Paygo, <u>bad things</u> could also happen. She might feel dizzy or sleepy and her mouth might feel very dry. She might also have a stomachache and may have to go to the bathroom a lot. Also, it might be hard for Susan to move her arms and legs, or her hands might begin to shake. The shaking might last for a long time.

Question 9: What are some of the bad things that might happen if Susan takes the Paygo pills?

SCORING CRITERIA FULL CREDIT (2 points): Must mention two specific and different types of risks associated with taking Paygo
"Feel SICK" should not be scored as one of the two correct responses for a full-credit score
PARTIAL CREDIT (1 point): Mentions one risk of taking Paygo or other reasonable option (e.g. would feel sick)
NO CREDIT (0 points): mentions benefits of Paygo, no response, incorrect or irrelevant answer

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- Indicate when a prompt was used with the letters P1, P2, or P3 (see prompts below).

PROMPT INSTRUCTIONS

- Criterion for a full-credit response is provided after the question
- P1: If subject's response is a 'no-credit' answer, repeat the question
- P2: If subject's initial response or response to P1 is a 'partial-credit' answer, say "Tell me more."
- P3: If after either P1 or P2, subject's response is still not a full-credit answer, say "To remind you" and then reread the disclosure statement and ask the question one last time

<u>Disclosure Statement #10: Risks of placebo</u>: If Susan takes the fake medicine, it won't help her. The fake medicine won't stop her from getting angry, shouting, and fighting at work.

Question 10: What will happen if Susan takes the fake medicine?

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- Indicate when a prompt was used with the letters P1, P2, or P3 (see prompts below).

PROMPT INSTRUCTIONS

- Criterion for a full-credit response is provided after the question
- P1: If subject's response is a 'no-credit' answer, repeat the question
- P2: If subject's initial response or response to P1 is a 'partial-credit' answer, say "Tell me more."
- P3: If after either P1 or P2, subject's response is still not a full-credit answer, say "To remind you" and then reread the disclosure statement and ask the question one last time

<u>Disclosure Statement #11: Altruistic reason for participation</u>: Even if being in the study does not help Susan with her behaviors, other good things about being in the study are that she will help Bob test the medicine <u>AND</u> help other people with disabilities.

Question 11: What other good things will happen if Susan is in the study?

SCORING CRITERIA
FULL CREDIT (2 points): Mentions two good things (e.g., helps Bob test/learn about the medicine or helps other people or she gets better)
PARTIAL CREDIT (1 point): Mentions one of the above, or helps Bob
NO CREDIT (0 points): helps Susan, no response, incorrect or irrelevant answer
molevant answer

INTERVIEWER FORM: ACC-RCT/Female	SUBJECT ID#

GENERAL INSTRUCTIONS

In the space below, write down everything that is said by you and the research participant in the order

that it is stated

- Put and "I" for interviewer and an "R" for research participant to indicate who is speaking. Put an "S" next to a statement from the staff member if it is relevant to the interview.
- Indicate when a prompt was used with the letters P1, P2, or P3 (see prompts below).

PROMPT INSTRUCTIONS

- Criterion for a full-credit response is provided after the question
- P1: If subject's response is a 'no-credit' answer, repeat the question
- P2: If subject's initial response or response to P1 is a 'partial-credit' answer, say "Tell me more."
- P3: If after either P1 or P2, subject's response is still not a full-credit answer, say "To remind you" and then reread the disclosure statement and ask the question one last time

<u>Disclosure Statement #12: Nature of assessment</u>: If Susan is in the study, Bob will ask her counselor at work about her behavior <u>AND</u> ask Susan questions about her behavior.

Question 12: What will Bob do to find out about Susan's behavior?

SCORING CRITERIA FULL CREDIT (2 points): mentions both of the above
PARTIAL CREDIT (1 point): mentions one of the above
NO CREDIT (0 points): no response, incorrect or irrelevant answer

INTERVIEWER FORM:	ACC-RCT/Female	SUBJECT ID#

- In the space below, write down everything that is said by you and the research participant in the order that it is stated
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- Indicate when a prompt was used with the letters P1, P2, or P3 (see prompts below).

PROMPT INSTRUCTIONS

- Criterion for a full-credit response is provided after the question
- P1: If subject's response is a 'no-credit' answer, repeat the question
- P2: If subject's initial response or response to P1 is a 'partial-credit' answer, say "Tell me more."
- P3: If after either P1 or P2, subject's response is still not a full-credit answer, say "To remind you" and then reread the disclosure statement and ask the question one last time

<u>Disclosure Statement #13: Nature of confidentiality</u>: Bob says that everything Susan and the counselor tell him is private. He will not tell anyone else. He will not put her name on any of the papers that he writes.

Question 13: How will Bob keep Susan's answers private?

SCORING CRITERIA
 FULL CREDIT (2 points): mentions 2 ways of maintaining confidentiality (e.g., keeping things private, not telling anyone, not putting her name on any of the papers, not revealing her name)
PARTIAL CREDIT (1 point): mentions one of the above
NO CREDIT (0 points): talks to Susan, no response, incorrect or
_ irrelevant answer
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- In the space below, write down everything that is said by you and the research participant in the order that it is stated
- Put and "I" for interviewer and an "R" for research participant to indicate who is speaking. Put an "S" next to a statement from the staff member if it is relevant to the interview.
- Indicate when a prompt was used with the letters P1, P2, or P3 (see prompts below).

PROMPT INSTRUCTIONS

- Criterion for a full-credit response is provided after the question
- P1: If subject responds with only a "yes" or only a "no" type of response, repeat the question emphasizing the word two.
- P2: If subject's response is still not a full-credit answer, say "Tell me more."
- P3: If after P1 or P2, subject's response is still not a full-credit answer, say "To remind you" and then reread the disclosure statement and ask the question one last time

<u>Disclosure Statement #14: Voluntary nature of participation</u>: Bob tells Susan that she has <u>two</u> choices. One choice is that she can <u>say "yes"</u> she wants to be in the study and take the medicine. The other choice is that she can <u>say "no"</u> she does not want to be in the study.

Question 14: What two choices does Susan have?

FULL CREDIT (2 points): mentions both options prior to any prompting (yes and no)
PARTIAL CREDIT (1 point): mentions one option (yes or no)
NO CREDIT (0 points): has to ask her parents/counselor, no response, incorrect or irrelevant answer

In the space below, write down everything that is said by you and the research participant <u>in the order</u> that it is stated

Put and "I" for interviewer and an "R" for research participant to indicate who is speaking. Put an "S" next to a statement from the staff member if it is relevant to the interview.

Indicate when a prompt was used with the letters P1a/b, P2a/b, or P3a/b (see prompts below).

PROMPT INSTRUCTIONS

- Criterion for a full-credit response to 'a' and 'b' are provided after the questions
- If subject gives a full-credit" answer to question 'a', go right to disclosure statement 'b'
- P1a: If subject's response to question 'a' is a 'no-credit' answer, repeat the question
- P2a: If subject's response to 'a' is still not a full-credit answer, say "Tell me more."
- P3a: if after either P1 or P2, subject's response is still not a full-credit answer, say "To remind you" and then reread the disclosure statement and ask question 'a' one last time.
- Read disclosure statement 'b' and ask question 'b'
- P1b: If subject's response to question 'b' is a 'no-credit' answer, repeat the question
- P2b: If subject's initial response or response to P1b is a 'partial-credit 'answer, say "Tell me more."
- P3b: If after either P1 or P2, subject's response is still not a full-credit answer, say "To remind you" and then reread the disclosure statement and ask question 'b' one last time.

<u>Disclosure Statement #15a: Right to withdraw</u>: Bob tells Susan that even if she starts to take the medicine, if she doesn't want to be in the study any more she can say "STOP" or "NO, I don't want to take this medicine anymore."

Question 15a: What can Susan say or do if she doesn't want to be in the research study anymore?

Disclosure Statement #15b: If Susan says stop, Bob will stop. Bob will not be mad at Susan and he will help her stop taking the medicine.

Question 15b: What will Bob do if Susan wants to stop being in the study?

 SCORING CRITERIA
FULL CREDIT for (a) (1 point): Says "stop" or "no, I don't want to be in the study, "not take the medicine", or other response indicating understanding right to withdraw
FULL CREDIT for (b) (2 point) indicates 2 of the following: Bob Smith will stop, Susan will not have to be in study, Bob Smith will not be mad.
PARTIAL CREDIT (b) (1 point) one of the above
NO CREDIT (0 points): no response, incorrect or irrelevant answer

Review: Now lets review what we just talked about

Remember I told you that Susan is having a behavior problem. She gets angry, shouts and starts fights at work. If she does not stop, she'll lose her job.

Susan's counselor put her on a behavior plan—BUT the plan did not work.

Then Susan's doctor gave her medicine to help stop the behaviors – BUT the medicine did not work either.

Bob Smith, the researcher wants Susan to be in a research study to help him find out if a new medicine called Paygo helps people control their behavior.

If Susan is in the study, she will not know if she will take the Paygo pills or a fake medicine.

If Susan takes the Paygo pills, it might help her control her behavior so that she could stay at work.

The Paygo pills might also make Susan feel sick, have to go to the bathroom a lot, make her arms and legs stiff or her hands shake.

Even if the Paygo pills do not help Susan control her behavior, if she is in the study she would be helping Bob Smith learn something that could help other people.

Susan must now decide if she wants to be in the study.

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- Put and "I" for interviewer and an "R" for research participant to indicate who is speaking. Put an "S" next to a statement from the staff member if it is relevant to the interview.
- Indicate when a prompt was used with the letters P1, P2 or P3 (see prompts below).

PROMPT INSTRUCTIONS

- Criterion for a full-credit response is provided after the question
- P1: If subject did not give a valid reason, repeat the question
- P2: If subject gives 1 valid reason in response to P1, say "Tell me more."
- P3: If after either P1 or P2, subject still does not give 2 valid reasons, say "Tell me <u>another reason</u> that Susan might <u>want</u> to be in the study."

$\underline{\text{Question 16: Reasoning about research:}} \ \ \text{Tell me some of the reasons Susan might } \underline{\text{want}} \ \text{to be in the study.}$

SCORING CRITERIA
FULL CREDIT (2 points): Gives more than one valid and specific reason for wanting Susan to be in the study (e.g. might help her keep her job, control behavior, help Bob Smith, not fight), or any reasonable explanation not mentioned in the disclosure
NOTE: "WILL FEEL BETTER/GET BETTER" DOES NOT RECEIVE CREDIT WHEN EVALUATING A FULL- CREDIT ANSWER
PARTIALCREDIT (1 point): Gives one valid reason
NO CREDIT (0 points): no response, incorrect or irrelevant answer

INTERVIEWER FORM: ACC-F	RCT/Female	SUBJECT ID#

- In the space below, write down everything that is said by you and the research participant in the order that it is stated
- Put and "I" for interviewer and an "R" for research participant to indicate who is speaking. Put an "S" next to a statement from the staff member if it is relevant to the interview.
- Indicate when a prompt was used with the letters P1, P2 or P3 (see prompts below).

PROMPT INSTRUCTIONS

- Criterion for a full-credit response is provided after the question
- P1: If subject did not give a valid reason, repeat the question
- P2: If subject gives 1 valid reason in response to P1, say "Tell me more."
- P3: If after either P1 or P2, subject still does not give 2 valid reasons, say "Tell me <u>another reason</u> that Susan might <u>not want</u> to be in the study."

<u>Question 17: Reasoning about research:</u> Tell me some of the reasons Susan might <u>not</u> want to be in the study.

SCORING CRITERIA
FULL CREDIT (2 points): Gives more than one valid and specific reason for not wanting to be in the research study (e.g. two side effects of Paygo, lack of benefit of fake medicine) or any reasonable explanation not mentioned in the
disclosure. INTERVEIWER: SIMPLY SAYING "GET SICK" NOT SUFFICIENT FOR RECEIVING CREDIT
FOR A FULL-CREDIT ANSWER. SUBJECT MUST SAY "GET SICK FROM PAYGO/MEDICINE" AND THEN GIVE A SECOND REASON
UNRELATED TO PAYGO SIDE EFFECTS OR 2 SPECIFIC PAYGO SIDE EFFECTS PARTIALCREDIT (1
point): Gives one valid reason NO CREDIT (0 points): no response, incorrect or irrelevant answer

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INTERVIEWER FORM: ACC-RCT/Female	SUBJECT ID#

- In the space below, write down everything that is said by you and the research participant in the order that it is stated
- Put and "I" for interviewer and an "R" for research participant to indicate who is speaking. Put an "S" next to a statement from the staff member if it is relevant to the interview.
- Indicate when a prompt was used with the letters P1or P2 (see prompts below).

PROMPT INSTRUCTIONS

- Criterion for a full-credit response is provided after the question
- P1: If subject's response is not a 'yes' or 'no' answer, repeat the guestion
- P2: If after P1, subject's response is still not a full credit answer, say "To remind you" and then reread the disclosure statement and ask the question one last time

<u>Disclosure statement #18: Communicating a decision about research participation:</u> Susan has a decision to make. She can decide to be in the study or she can decide not to be in the study.

Question 18: What do you think Susan should do? Should she say "yes" she wants to be in the study or "no" she doesn't want to be in the study?

SCORING CRITERIA FULL CREDIT (1 points): Gives a choice
NO CREDIT (0 points):
cannot decide, no response, incorrect or irrelevant answer

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- In the space below, write down everything that is said by you and the research participant in the order that it is stated
- Put and "I" for interviewer and an "R" for research participant to indicate who is speaking. Put an "S" next to a statement from the staff member if it is relevant to the interview.
- Indicate when a prompt was used with the letters P1, P2, or P3 (see prompts below).

PROMPT INSTRUCTIONS

- Criterion for a full-credit response is provided after the question
- P1: If subject does not give a valid reason, repeat the question
- P2: If subject gives 1 valid reason in response to P1, say "Tell me more."
- P3: If after P1 or P2, subject still does not give 2 valid reasons, say "Tell me <u>another reason</u> why you think that Susan should say yes/no" or "Tell me <u>another reason</u> why you don't know what Susan should say."

Question 19:

INTERVIEWER: ASK ONE OF THE FOLLOWING QUESTIONS DEPENDING UPON THE SUBJECT'S RESPONSE TO QUESTION 18

- 1. SUBJECT RESPONDED "YES"
 - Tell me some of the reasons you think Susan should say "yes" she would like to be in the study.
- 2. SUBJECT RESPONDED "NO"
 - Tell me some of the reason you think Susan should say "no" she would not like to be in the study.
- 3. SUBJECT GAVE NO RESPONSE OR SAID "THEY DIDN'T KNOW"

 Tell me some of the reasons you did not tell me whether you think Susan should or should not be in the study.

SCORING CRITERIA FULL CREDIT (2 points): Gives two valid reasons for their choice
PARTIAL CREDIT (1 point): gives one valid reason for their choice
NO CREDIT (0 points): cannot give a valid reason for their choice, no response, incorrect or irrelevant answer

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