

Assessment of Consent Capacity – Interview Research (ACC-IR)
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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.

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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 – TRANSCRIPTION - CODER FORM

**ASSESSMENT OF CONSENT CAPACITY –
INTERVIEW RESEARCH (ACC-IRC)**

INTERVIEWER: Please read the following to the participant:

My name is _____. I work with Professor _____ at _____ University.

Today I am going to ask you if you would like to be in my research.

[INTERVIEW] I am going to explain what the research is about and ask you some questions to make sure you understand. Sometimes I will read the information again or ask you the question again to help you understand.

I will keep your answers private. Is it okay if I tape what you say so I can remember it later?

PLEASE CHECK WHETHER RESPONDENT INDICATED ___YES, ___NO, ___ NO RESPONSE TO TAPING

INTERVIEWER: If respondent says “yes” to taping, make sure tape recorder is on and that you have pressed record prior to beginning the interview. If the respondent says “NO” or doesn’t answer after repeated question, do not tape.

ATTENTION RATING FOR COMPUTER LESSON: (*See definition of attention below)

*Attention is NOT determined by the number of questions the consumer got right nor the number of prompts he or she required, rather, it reflects the extent to which the consumer looked at the illustrated materials and had appropriate eye contact and timely responses to the interviewer disclosures and questions.

Using the definition of attention provided above, circle the number that best describes the extent to which the consumer **ATTENDED** to the DISCLOSURE

5 = the entire time 4 = most of the time 3 = about half the time 2 = rarely 1 = not at all

IR QUESTION #1

INTERVIEWER/TRANSCRIPTION /CODER FORM: ACC-IR

Consumer 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 an "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, P1B, or P2 (see prompts below)

PROMPT INSTRUCTIONS

- Scoring criteria are provided after the question
- P1A: If the consumer gives a no credit response ask, "What is my job?"
- P1B: If consumer's partial response initially or in response to P1A is "You are a researcher" ask: "What does a researcher do?" If consumer's partial response is, "You want to know about people with disabilities" ask "What is the name of my job?"
- P2: If consumer's response to P1A or P1B is a no credit or partial credit response say, "Lets read that again to help you remember" and reread the part of the disclosure statement or page of the COMPUTER BOOK immediately preceding the question page that states "I am a researcher, my job is to learn what people with developmental disabilities think and do" and ask the question again. Do NOT repeat the line that says "Here is your first question."

Disclosure Statement #1: A Researcher's Job: *My name is _____. I am a researcher. I am not a doctor. I am not a counselor. I do not help people with their problems. A researcher's job is to learn. To do my job I talk to a lot of people with developmental disabilities. I am a researcher. My job is to learn what people with developmental disabilities think and do.*

Question 1: Here is your first question. What is my job?

FULL CREDIT (2 POINTS): Must indicate that his/her job is [1] as a researcher OR to learn (to know, to test, to understand) AND (2) that s/he wants to learn about/talk to people with developmental disabilities OR learn about people with developmental disabilities OR learn what people think and do.

PARTIAL CREDIT (1 point): Mentions one of the above (e.g., to learn/a researcher, talk to people with disabilities, test people, what people think and do, find out about people, help doctors or counselors help other people).

NO CREDIT (0 points): No response, incorrect or irrelevant answer. An incorrect response would be that researchers directly help people.

IR QUESTION #2

INTERVIEWER/TRANSCRIPTION/CODER FORM: ACC-IR

Consumer 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 an "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, P1B, or P2 (see prompts below).

PROMPT INSTRUCTIONS

- Scoring criteria are provided after the question
- P1A: If the consumer gives a no credit response REPEAT THE QUESTION.
- P1B: If the consumer gives a partial credit response, say, "What else you can remember about why I want you to be in the research?"
- P2: If consumer's response to P1A or P1B is a no credit or partial credit response, say, "Lets read that again to help you remember" and reread the disclosure statement below or, if using the COMPUTER BOOK, read page immediately preceding the question and ask the question again.

Disclosure Statement #2: Purpose of Participation: *I would like you to be in the research to help me learn how to teach people with developmental disabilities to make choices.*

Question 2: Why do I want you to be in the research?

FULL CREDIT (2 POINTS): Mentions [1] helping researcher learn OR help you, OR help interviewer AND [2] what s/he wants to learn about is people with developmental disabilities OR how people make choices OR about people like me/or about me OR how to teach OR how to teach me OR helping other people. [*The important concepts are that the consumer will be helping the researcher and that the topic of the research is about people with developmental disabilities. [If given the **lesson**, it would also be appropriate for them to indicate that the research could help OTHER people]*]

PARTIAL CREDIT (1 POINT): Mentions one of the above.

NO CREDIT (0 POINTS): No response, incorrect or irrelevant response. An incorrect response is that the researcher wants to help the specific consumer or just "teach" the consumer, without any indication that the researcher is trying to learn how to do this.

IR QUESTION #3

INTERVIEWER/TRANSCRIPTION/CODER FORM: ACC-IR

Consumer 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 an "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, P1B, or P2 (see prompts below)

PROMPT INSTRUCTIONS

- Scoring criteria are provided after the question
- P1A: If the consumer gives a no credit response REPEAT THE QUESTION.
- P1B: If the consumer gives a partial credit response, say "What else you can remember about what you will do?"
- P2: If consumer's response to P1A or P1B is a no credit or partial credit response, say "Lets read that again to help you remember" and reread the disclosure statement below or, if using the COMPUTER BOOK, read page immediately preceding the question and ask the question again.

Disclosure Statement #3: Participant's Activities: *If you are in the research, you will listen to a story and answer questions.*

Question 3: If you are in the research, what will you do?

FULL CREDIT (2 POINTS): Must mention any two of the following: listen to story and answer questions.

PARTIAL CREDIT (1 POINT): Must mention one of the above activities.

NO CREDIT (0 POINTS): No response, incorrect or irrelevant answer

IR QUESTION #4

INTERVIEWER/TRANSCRIPTION/CODER FORM: ACC-IR

Consumer 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 an "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, P1B, or P2 (see prompts below)

PROMPT INSTRUCTIONS

- Scoring criteria are provided after the question
- P1A: If the consumer gives a no credit response REPEAT THE QUESTION.
- P1B: If the consumer gives a partial credit response say, "What else you can remember about what I will do?"
- P2: If consumer's response to P1A or P1B is a no credit or partial credit response say, "Lets read that again to help you remember" and reread the disclosure statement below or, if using the COMPUTER BOOK, read page immediately preceding the question and ask the question again.

This should take about 1 hour.

Disclosure Statement #4: Investigator Activities: *If you are in the research, I will also ask your counselors questions about you and use a tape recorder to help me remember what you say.*

Question 4: *If you are in the research what will I do?*

FULL CREDIT (2 POINTS): Mentions asking counselor(s) questions AND tape recording their answers.

PARTIAL CREDIT (1 POINT): Mentions one of the above.

NO CREDIT (0 POINTS): No response, incorrect or irrelevant answer

IR QUESTION #5

INTERVIEWER/TRANSCRIPTION/CODER FORM: ACC-IR

Consumer 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 an "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, P1B, or P2 (see prompts below)

PROMPT INSTRUCTIONS

- Scoring criteria are provided after the question
- P1A: If the consumer gives a no credit response REPEAT THE QUESTION.
- P1B: If the consumer gives a partial credit response, say "What else will I do to keep your answers private?"
- P2: If consumer's response to P1A or P1B is a no credit or partial credit response say, "Lets read that again to help you remember" and reread the disclosure statement below or, if using the COMPUTER BOOK, read page immediately preceding the question and ask the question again.

Disclosure Statement #5: Nature of Confidentiality: *If you are in the research, I will keep your answers private. I will not tell anyone what you say. I will not write your name on any papers.*

Question 5: What are 2 things I will do to keep your answers private?

FULL CREDIT (2 POINTS): Mentions any two of the following: not telling anyone, not writing their name on any papers, not saying their name, not letting anyone listen to the tape, [the following are responses that indicate the consumer understands the word "private" but not that s/he is remembering how the information will be kept private so mention of any one of the following receives 1 point: "keeping it secret, putting papers in a safe place or locking them up."]

PARTIAL CREDIT (1 POINT): Mentions one of the above.

NO CREDIT (0 POINTS): No response, incorrect or irrelevant response. Repeating the word private is a no credit response.

IR QUESTION #6

INTERVIEWER/TRANSCRIPTION/CODER FORM: ACC-IR

Consumer 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 an "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, P1B or P2 (see prompts below)

PROMPT INSTRUCTIONS

- Scoring criteria are provided after the question
- P1A: If the consumer gives a no credit response REPEAT THE QUESTION.
- P1B: If the consumer gives a partial credit response say, "What is your other choice?"
- P2: If consumer's response to P1A or P1B is a no credit or partial credit response say, "Lets read that again to help you remember" and reread the disclosure statement below or, if using the COMPUTER BOOK, read page immediately preceding the question and ask the question again.

Today you can decide if you would like to be in my research.

Disclosure Statement #6: Choices of Participation: *You have two choices. You can say "YES I want to be in the research" or you can say "NO I do not want to be in the research".*

Question 6: What two choices do you have?

FULL CREDIT (2 POINTS): Mentions both choices, yes and no prior to any prompting.

PARTIAL CREDIT (1 POINT): Mentions one of the two choices, yes or no.

NO CREDIT (0 POINTS): No response, incorrect, or irrelevant answer

IR QUESTION #7

INTERVIEWER/TRANSCRIPTION/CODER FORM: ACC-IR

Consumer 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 an "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, P1B, or P2 (see prompts below)

PROMPT INSTRUCTIONS

- Scoring criteria are provided after the questions
- P1A: If the consumer gives a no credit response REPEAT THE QUESTION.
- P1B: If the consumer gives a partial credit response such as "I can go back" ask "What will I do if you say stop?" If the consumer gives a partial response such as "You will give me gift certificates" ask "What can you do after you say stop?"
- P2: If consumer's response to P1A or P1B is a no credit or partial credit response say, "Lets read that again to help you remember" and reread the part of the disclosure statement or page of the COMPUTER BOOK immediately preceding the question page that states "if you say stop, I will stop the research...."

Disclosure Statement #7: Right to withdraw: *If you say YES I will give you a gift certificate to say thank you for your help. Even if you first say YES you can say STOP at any time if you do not want to be in the research any more. If you say "STOP" I will stop the research and still give you the certificate to say thank you, and you can go back to what you were doing before we sat down.*

Question 7: What will happen if you say "STOP"?

FULL CREDIT (2 POINT): Must mention two of the following: I will still get/you'll give me the certificate, interviewer will stop, or going back to what he/she was doing before they sat down.

PARTIAL CREDIT (1 POINTS): Mentions one of the above

NO CREDIT (0 POINTS): No response, incorrect or irrelevant answer

IR QUESTION #8

INTERVIEWER/TRANSCRIPTION/CODER FORM: ACC-IR

Consumer 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 an "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, P1B, or P2 (see prompts below)

PROMPT INSTRUCTIONS

- Scoring criteria are provided after the question
- P1A: If the consumer gives a no credit response REPEAT THE QUESTION.
- P1B: If the consumer gives a partial credit response, say "What is another good thing about being in the research?"
- P2: If consumer's response to P1A or P1B is a 'no credit' or partial credit response, say "Lets read that again to help you remember" and reread the disclosure statement below or, if using the COMPUTER BOOK, read page immediately preceding the question and ask the question again.

To make the best choice for you, you need to know about the good and bad things about being in the research.

Disclosure Statement #8: Research Benefits: *Good things about the research are I will learn how to teach other people with developmental disabilities to make choices, and you may find talking with me interesting.*

Question 8: What are some good things about being in the research?

FULL CREDIT (2 POINTS): Mentions helping researcher learn (know, test) to teach people with developmental disabilities AND this may help people make choices OR help other people, or it may be interesting to talk to the interviewer/you

PARTIAL CREDIT (1 POINT): Mentions one of the above

NO CREDIT (0 POINTS): No response, incorrect or irrelevant response. A response indicating that the researcher will help the consumer directly is incorrect.

IR QUESTION #9

INTERVIEWER/TRANSCRIPTION/CODER FORM: ACC-IR

Consumer 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 an "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, P1B, or P2 (see prompts below)

PROMPT INSTRUCTIONS

- Scoring criteria are provided after the question
- P1A: If the consumer gives a no credit response REPEAT THE QUESTION
- P1B: If the consumer gives a partial credit response, say "What is another bad thing about being in the research?"
- P2: If consumer's response to P1A or P1B is a no credit or partial credit response say, "Lets read that again to help you remember" and reread disclosure statement below, or if using the COMPUTER BOOK, reread page immediately preceding the question and ask the question again.

Disclosure Statement #9: Research Risks: *Some bad things about being in the research are it might be boring, it might take too long, and it might be hard to understand.*

Question 9: What are some bad things about being in the research?

FULL CREDIT (2 POINTS): Mentions two of the following: may get upset, may take too long, may be too difficult, or something reasonable like "I might want to go to my dinner instead"

PARTIAL CREDIT (1 POINT): Mentions one of the above

NO CREDIT (0 POINTS): No response, incorrect or irrelevant answer

Now let's review:

The purpose of the research is to learn how to teach people with developmental disabilities to make better choices.

If you are in the research you will listen to a story and answer questions.

I will also ask your counselor questions about you.

I will keep all your answers private.

The research might help other people with developmental disabilities make choices and you might find it interesting.

The research might be boring, take too long, or be hard to understand.

Would you like to ask me a question about the research? If you do you can ask me now.

INTERVIEWER: RECORD AND ANSWER ANY QUESTIONS

IR QUESTION #10

INTERVIEWER/TRANSCRIPTION/CODER FORM: ACC-IR

Consumer 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 an “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 or P2 (see prompts below)

PROMPT INSTRUCTIONS FOR ‘YES’ OR ‘NO’ RESPONSE

- Scoring criteria are provided after the question
- P1: If the consumer gives a no credit response REPEAT THE QUESTION
- P2: If consumer’s response to P1 is a no credit or partial credit response say, “Lets read that again to help you remember” and reread the disclosure statement below, or if using the COMPUTER BOOK, reread page immediately preceding the question and ask the question again.

JUST LEAVE THE COMPUTER PAGE ON THAT HAS THE YES/NO

Disclosure Statement #10: Ability to Make a Choice: *Now you will decide if you want to be in the research. To make the best choice for you, think about the good and bad things about being in the research. Don’t forget you can say YES or you can say NO. Now make your choice.*

Question 10: Would you like to be in the research?

FULL CREDIT (1 POINT): Indicates yes or no (verbally or non-verbally)

NO CREDIT (0 POINTS): No response, incorrect or irrelevant response

IR QUESTION #11

INTERVIEWER/TRANSCRIPTION/CODER FORM: ACC-IR

Consumer ID#: _____

GENERAL INSTRUCTIONS

- **MAKE SURE TAPE RECORDER IS ON AND THAT YOU HAVE PRESSED RECORD.**
- In the space below, write down everything that is said by you and the research participant in the order that it is stated.
- Put an "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, P1B (see prompts below)

PROMPT INSTRUCTIONS

- Scoring criteria are provided after the question
- P1A: If the consumer gives a no credit response SAY "There are good things and bad things about being in the research" and REPEAT THE QUESTION
- P1B: If the consumer gives a partial credit response, say " There are good things and bad things about being in the research. What is another reason you said _____ ?"

FOR THE COMPUTER BOOK CONDITION, LEAVE THE COMPUTER PAGE THAT HAS THE YES/NO ON THE SCREEN

"There are good things and bad things about being in the research"

Question 11: Reasoning about choice:

1. Tell me two reasons why you said yes.
2. Tell me two reasons why you said no.
3. Tell me two reasons why you said I don't know.
4. Tell me two reasons why you did not answer the question.

FULL CREDIT (2 POINTS): Gives two valid reasons why they:

1. Want to be in the research (e.g. gift certificate, hear a story, help others)
2. Don't want to be in the research (e.g. get bored, have something else to do)
3. Don't know if they want to be in the research (e.g. don't understand, scared, I can't make up my mind)

FULL CREDIT ANSWER CAN ALSO REFLECT A BALANCING OF GOOD AND BAD THINGS: E.G., EVEN THOUGH IT MIGHT BE BORING, I WANT TO GET THE CERTIFICATE.

PARTIAL CREDIT (1 POINT): Gives one valid reason

NO CREDIT (0 POINTS): No response, incorrect, or irrelevant answer

GENERAL RULES FOR FOLLOW-UP QUERY

**IF: (A) CONSUMER ANSWERED, "I DON'T KNOW" OR GAVE NO RESPONSE TO QUESTION 10
(B) BUT THE CONSUMER DID PROVIDE A VALID RESPONSE TO QUESTION 11:**

ASK: "WOULD YOU LIKE TO BE IN THIS STUDY?" _____ YES _____ NO

continue with the study if the consumer indicates "yes"

An indication is a verbal statement such as "yes", "okay", "I do," or a nodding of the head that any reasonable person would agree is an indication of agreement. If the nonverbal communication is unclear or ambiguous it should be taken as a "no."

Discontinue the study if the consumer indicates "no"

An indication is a verbal statement such as "no", "don't", "go back", "leave" or a shaking of the head or no response.

GENERAL RULES FOR DISCONTINUATION

If consumer gave a verbal or non-verbal 'NO' in response to Question 10 the consumer is not to be in the ECC-RCT part of the study.

If consumer **did not give a response** or said 'I DON'T KNOW' to Question 10 and did not indicate a positive response to either question 11 or the above "follow-up query [where that query was appropriate] and there is **no** parent/guardian/correspondent consent, the consumer is **NOT** to be in the ECC-RCT part of the study.

Say "Thank you very much for answering these questions, you can now go back to what you were doing."

If a consumer who has indicated they do not want to be in the study, asks for the gift certificate

Say "I am sorry, but remember, you had to start listening to the story to get the gift certificate".

GENERAL RULES FOR CONTINUING THE STUDY

If consumer responded positively, **continue the study**.

If the consumer **did not** give a response to Question 10 OR 11 or said 'I DON'T KNOW' and parent/guardian/correspondent **gave consent**, **continue** with the ECC-RCT and K-BIT part of the study.

Say, "I will continue with the story, Remember, you can say STOP at any time."

***PLEASE NOTE: FOR CONSUMERS WHO CONTINUE THE STUDY HAVE THEM SIGN THE CONSENT FORM, HAVE THE STAFF PERSON SIGN, GIVE THEM A BLANK COPY OF THE CONSENT AND SAY:**

"If you think of any questions later, you or your supervisor can telephone Professor _____. Here is a paper with the names and telephone numbers of the people you can call."

ATTENTION RATINGS: (*See definition of attention below)

*Attention is NOT determined by the number of questions the consumer got right nor the number of prompts he or she required, rather, it reflects the extent to which the consumer looked at the illustrated materials and had appropriate eye contact and timely responses to the interviewer disclosures and questions.

ATTENTION RATING FOR COMPUTER BOOK:

Using the definition of attention provided above, circle the number that best describes the extent to which the consumer ATTENDED to the COMPUTER BOOK.

5 = the entire time 4 = most of the time 3 = about half the time 2 = rarely 1 = not at all

ATTENTION RATING FOR INTERVIEW:

Using the definition of attention provided above, circle the number that best describes the extent to which the consumer ATTENDED to the INTERVIEWER.

5 = the entire time 4 = most of the time 3 = about half the time 2 = rarely 1 = not at all
