

Tests of Understanding and Decisional Capacity

1: Mini-Mental State Examination (MMSE)

The MMSE is a standardized paper-and-pencil assessment for which one purchases a kit (<http://www.minimental.com>).

“The MMSE is a brief, quantitative measure of cognitive status in adults. It can be used to screen for cognitive impairment, to estimate the severity of cognitive impairment at a given point in time, to follow the course of cognitive changes in an individual over time, and to document an individual’s response to treatment” (from the webpage)

On the MMSE, a score of 24 is the minimum score for an educated person. However, other factors should be taken into account when using the Mini-Mental exam as an indicator for mental capacity. In some cases, a score of 24 may be too low; in others, lower scores may still allow an individual to be included. Consult the publisher for further information.

2: MacArthur Competence Assessment Tool-Clinical Research (MacCAT-CR)

The MacCAT-CR is a standardized, commercial product available through its publisher at: www.pypress.com/mactcrset-fr.html.

“The MacCAT-CR provides a structured format for capacity assessment that is adaptable to the particulars of any given research project. With the introduction of the MacCAT-CR, researchers enrolling human participants in their studies have available for the first time a reliable and valid means of assessing their potential subject’s capacity to consent to participation. The MacCAT-CR can typically be administered in 15-20 minutes.

Beginning with project-specific disclosures to potential participants, the MacCAT-CR measures the four generally accepted components of decision-making competence: understanding, appreciation, reasoning, and the ability to express a choice. Quantification of subjects’ responses permits comparisons across subject and age groups, and allows the MacCAT-CR to be used for not only screening individual participants but also for conducting research on the characteristics of subject populations and for assessing the effectiveness of interventions designed to increase subjects’ capacities” (from the webpage)

3: Dartmouth Informed Consent Evaluation Feedback Tool (ICE ET)

This tool was developed by Elizabeth Bankert at the Dartmouth Committee for the Protection of Human Subjects. It can be seen at:

http://www4.od.nih.gov/oba/rac/pdfs/IC_Evaluation_Tool_Dartmouth_CPHS.pdf.

4: Evaluation to Sign Consent Form (ESC)

This tool (on the following page) has been designed by and used in the UMB MPRC by Dr. Robert Conley and his staff. It can be used as is or adapted to the specifics of your study or your study population.

EVALUATION TO SIGN CONSENT FORM

Participant Name: _____

PROCEDURE:

Make a subjective judgment regarding item 1 below. Ask the patient questions 2-6. The evaluator may select the language to use in asking the questions in order to help the patient understand them.

ITEMS:

SCORE

1. Is the patient alert and able to communicate with the examiner? **yes = 2 no = 0** _____

2. Ask the patient to name at least two (2) potential risks incurred as a result of participating in the study.
 0=not able to list potential risks, 1= able to list one risk, 2 =able to list two risks _____

3. Ask the patient to name at least two (2) things that will be expected of him/her in terms of patient cooperation during the study.
 0=not able to list expectations, 1= able to list one expectation, 2=able to list two expectations _____

4. Ask the patient to explain what he/she would do if he/she decides that they no longer wish to participate in the study.
 0=doesn't know, 1=answers but not the most appropriate response, 2=talk to any staff member _____

5. Ask the patient to explain what he/she would do if he/she is experiencing distress or discomfort.

