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# Ensuring Informed Consent in Research with Co-Occurring Serious Mental Illness and Substance Use Disorders: The Modified Evaluation to Sign Consent

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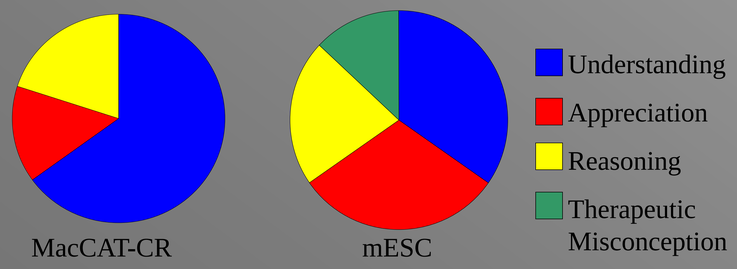
## Abstract

Ethical research must respect the rights of potential participants. Critics have questioned whether involving people with serious mental illness (SMI) in research exploits a vulnerable population. When addiction further complicates SMI, it becomes vital to demonstrate individual rights are respected during clinical trials. The ability to provide informed consent has traditionally been tested in 4 domains (also used by U.S. law to assess competency): Understanding of the basic facts, appreciation that the facts apply to you, reasoning about the information in order to make a decision, and the ability to express a choice. Our new scale, the modified Evaluation to Sign Consent (mESC), is an improvement over currently available tools. It is quick to administer, has scoring anchors, uses visual prompts, and evaluates the 4 domains with a good balance between understanding, appreciation, and reasoning (with 8, 7, and 5 items respectively). Additionally, the mESC specifically evaluates therapeutic misconception (the confusion between research and clinical care; 3 items). Therapeutic misconception is common in clinical trials throughout medicine and should be corrected prior to study enrollment. Screening with the mESC will enhance clinical trials, especially when working with co-occurring addiction and SMI.

## Background

- Popular assessment tools for informed consent in research include the original Evaluation to Sign Consent (ESC) & MacArthur Competency Assessment Tool for Clinical Research (MacCAT-CR).
- The ESC is a 6-item free-response test of understanding.
- MacCAT-CR is a 20-item manualized interview requiring training, weighted towards understanding, and does not include therapeutic misconception.




## The modified Evaluation to Sign Consent (mESC):

| Determine if the potential subject is able to communicate and maintain a meaningful conversation, and if the patient is willing to discuss the research project. | If YES, proceed<br>If NO, consent cannot be validated at this time |
|---|---|
| **Assignment of medication during research participation.** | |
| 1. [U] What is being studied in this research project?<br>(If patient responds "schizophrenia" ask, "What is it about schizophrenia that we/the researchers are trying to figure out?") | 0: Does not know<br>1:<br>2: Some reference to schizophrenia treatment<br>3:<br>4: Clear knowledge that drug treatment is being studied |
| 2. [U] What problems or symptoms is the project medication designed to help? | 0: Does not know<br>1:<br>2: Some reference to relevant symptoms<br>3:<br>4: Clear knowledge of key symptoms |
| 3. [A] Do you have any of these symptoms? (Briefly state key symptoms) | 0: Does not admit to having the symptoms or problems<br>1:<br>2: States only that the doctors think he/she has the symptoms<br>3:<br>4: States has key symptom or problem |
| 4. [A] Do you think the project medication could affect your symptoms? How? | 0: No<br>1:<br>2: Maybe; unsure<br>3:<br>4: Believes the treatment could affect his/her symptoms |
| 5. [U] In this research project, what is/are the experimental medication(s) being studied? What is a placebo or "sugar pill"? Could you get a placebo? | 0: Does not know<br>1:<br>2: Knows about only treatment OR placebo, not both<br>3:<br>4: Specifies experimental drug and placebo as possible treatments |
| 6. [A] If you join the project, will you get to choose the project medication you think is best for your problem? | 0: Yes<br>1:<br>2:<br>3:<br>4: No |
| 7. [TM] Will your doctor or therapist be able to make sure you get the project medication instead of placebo? | 0: Yes; I think so or I hope so<br>1:<br>2:<br>3:<br>4: No |
| 8. [U] How do the researchers know which medication to give to the people in the project? | 0: Subject does not know; "the one that works best"<br>1:<br>2: Research team decides<br>3:<br>4: Acknowledges random assignment |
| 9. [TM] (Clarify random assignment if necessary.) Is that how your doctor usually decides which medications you need most? How is it different? | 0: Decision made in the same way; don't know if same or different<br>1:<br>2: Knows it is different, but vague about how<br>3:<br>4: Clear about the difference |

| **Project Burden Issues.** | |
|---|---|
| 1. [A] People in research projects are asked to do certain activities, like come for extra visits. Can you name one or two activities you would be asked to do if you joined the project? | 0: Unaware of extra requirements<br>1:<br>2: Names some requirements but not ones critical to the project or which pose risk to the subject<br>3:<br>4: Fairly clear view of requirements |
| *After above scoring is complete, show visual aid listing extra activities (like blood draws) the subject would be expected to participate in if enrolled in this project.* | |
| 2. [R] Are any of these project activities different from what you do in your normal everyday routine? How? | 0: Does not relate to requirements in a personal manner/ No opinion<br>1:<br>2: Some awareness of personal effect/ Opinion but can't say why<br>3:<br>4: Realistic view of personal effect/ Opinion and can give examples of considering extra burdens |
| 3. [TM] If you weren't in a research project, would you have to do these things? Are you doing them for your personal well-being or as part of the research? | 0: Yes, for my benefit<br>1:<br>2: Yes, for research =or= No, for my benefit<br>3:<br>4: No, for research |

| **Risks and Benefits.** | |
|---|---|
| 1. [U] What good things might happen to patients who join this project? | 0: No benefit for participants; guaranteed clinical improvement<br>1:<br>2: Sees potential benefits, but overestimates potential for subjects to benefit<br>3:<br>4: Realistic understanding of benefits (does not need to mention "closer monitoring" as benefit) |
| 2. [A] How likely is it that good things will happen to *you* if you join this project? | 0: Guaranteed<br>1:<br>2: Unrealistic Expectations<br>3:<br>4: Realistic; Chance |
| 3. [R] How could those good things make it easier for you to do the things you like to do? | 0: No concept of how life would be affected<br>1:<br>2: Knows it would help but unsure exactly how<br>3:<br>4: Can point to specific activities that could be improved |
| 4. [U] What problems might people have because of joining this project?<br>(If the patient only mentions side-effects, and there are other risks [like medication wash-out], prompt him/her with "What are problems people might have *other than* side-effects?") | 0: Denies risk<br>1:<br>2: Partially understands risks<br>3:<br>4: Clear understanding of primary risks (i.e. medication wash-out, placebo, ineffective project medication, side-effects- as appropriate) |
| *After above scoring is complete, show visual aid listing important side-effects and other risks related to the project [including medication wash-out, placebo etc. as appropriate].* | |
| 5. [A] These are some things that might be a problem for people who join the project. If you join the project, do you think any of these could happen to you? | 0: No<br>1:<br>2: Admits *some* risks but minimizes possibility unrealistically<br>3:<br>4: Acknowledges all are possible |
| 6. [R] How could those experiences make it harder for you to do the things you like to do? | 0: No concept of how life would be affected<br>1:<br>2: Knows it would interfere but unsure exactly how<br>3:<br>4: Can point to specific activities that could be hindered |
| 7. [U] Will this research benefit people in the future? How? | 0: No benefit to others; Don't know<br>1:<br>2: Acknowledges gain in information but not sure how that is beneficial<br>3:<br>4: Acknowledges that new treatment information can help future patients |
| 8. [R] How do you decide whether to join a research project or not? | 0: Doesn't know; doesn't think about those things<br>1:<br>2:Some appreciation of areas reviewed<br>3:<br>4: Weighs risks and benefits (Does not need to *say* that is what he/she does if it is obvious from patient that is what is happening) |

| **Project Withdrawal.** | |
|---|---|
| 1. [U] Do the research participants *have* to remain in the project until the researcher says they have finished? Are participants allowed to leave the project before it is finished? How should they do that? | 0: Cannot quit<br>1:<br>2: Can quit but not sure how to do it<br>3:<br>4: Clear on right to withdraw |
| 2. [A] If you join the project but you decide to pull out before it is finished, can you go back to your regular treatment? | 0: Can not quit; cannot receive regular treatment if quit<br>1:<br>2: Realizes he/she can quit, but unsure how that affects treatment<br>3:<br>4: Acknowledges right to quit and still receive treatment |
| *After above scoring is complete, show visual aid listing: sypmtoms getting worse, side-effects are uncomfortable, too much time in testing.* | |
| 3. [R] [Showing visual aid] These are some reasons why people leave research projects before the projects are finished. Would these things make you want to leave the project? What else might make you want to leave the project? | 0: Denies possibility of any adverse effect which would cause him/her to withdraw<br>1:<br>2: Vague thoughts about things that would lead to withdrawal<br>3:<br>4: Notes specific things that would make him/her uncomfortable continuing in the project |

This first question is not scored and is designed to determine if the individual can express a choice (One of the four domains assessing legal competency in the United States).

There is a hierarchy of domains in the instrument with Understanding required for some Appreciation questions and Appreciation required for some Reasoning questions.

The questions are labeled as to the most complex domain they address:

[U] Understanding (8 items)

[A] Appreciation (7 items)

[R] Reasoning (5 items)

[TM] Therapeutic Misconception (3 items)

The Instrument is divided into four sections to determine which area of consent information needs reinforcement:

Assignment of Medication

Project Burdens

Risks & Benefits

Project Withdrawal.

The questions elicit free-response answers, but there are anchors giving guidance in scoring.

The questions, visual aids, and anchors can easily be modified for specific trials.

There are three visual aids in the instrument. These allow individuals to think about study-related facts without having to simultaneously hold them in their working memory.

## Advantages of the mESC

- Quick to administer (Average time in preliminary study was about 16 minutes, n=18).
- Visual cues eliminate the need to hold facts in working memory while simultaneously thinking about them.
- More balanced testing of Understanding, Appreciation, and Reasoning.
- Addition of Therapeutic Misconception as a separate, scored domain.
- Anchors give guidance in scoring.
- Versatile- easily modified to a wide-range of clinical studies.
- Can be used to test interventions designed to enhance informed consent.
- Can be used to track degradation of elements of consent over long clinical trials.