Ensuring informed consent in research with co-occurring serious mental illness and substance use disorders: The modified evaluation to sign consent

Bernard A. Fischer, IV
*University of Maryland - Baltimore*

Kristen J. Prentice
*University of Maryland - Baltimore*

William T. Carpenter, Jr.
*University of Maryland - Baltimore*

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Bernard A. Fischer, IV, M.D., M.A., Kristen J. Prentice, PhD., & William T. Carpenter, Jr., M.D.

1University of Maryland/Sheppard Pratt Residency in Psychiatry, Baltimore, Maryland
2Maryland Psychiatric Research Center (MPRC), University of Maryland School of Medicine, Baltimore, Maryland

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):
- 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

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.