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## Supplementary Material

**Article Title:** Participants With Schizophrenia Retain the Information Necessary for Informed Consent During Clinical Trials

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### List of Supplementary Material for the article

1. [Rating Scale](#) Modified Evaluation to Sign Consent

### Disclaimer

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**Supplementary Material.**

Note: [U]= Understanding, [A]= Appreciation, [R]= Reasoning, [TM]= Therapeutic Misconception items (based on face validity).

**Modified Evaluation to Sign Consent (mESC) Template**

Question:		Anchors:
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.	<b>Y N</b> (circle)	If <b>YES</b> , proceed  If <b>NO</b> , consent cannot be validated at this time
<b>Assignment of medication during research</b>		
1. [U] What is being studied in this research project?  (If patient responds “schizophrenia” ask, “What is it about schizophrenia that we/the researchers are trying to figure out?”)	_____	0: Does not know 1: 2: Some reference to schizophrenia treatment 3: 4: Clear knowledge that _____ (study medication) treatment is being studied
2. [U] What problems or symptoms is the project medication designed to help?	_____	0: Does not know 1: 2: Some reference to relevant symptoms 3: 4: Clear knowledge of key symptoms (i.e. _____)
3. [A] Do you have any of these symptoms? (Briefly state key symptoms)	_____	0: Does not admit to having the symptoms or problems 1: 2: States only that the doctors think he/she has the symptoms 3: 4: States has key symptom or problem
4. [A] Do you think the project medication could affect your symptoms? How?	_____	0: No 1: 2: Maybe; unsure 3: 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 1: 2: Knows about only _____ (study medication) OR placebo, not both 3: 4: Specifies _____ (study medication) and placebo as possible treatments
6. [A] If you join the project, will you get to choose the medication you think is best for your problem?	_____	0: Yes 1: 2: 3: 4: No
7. [TM] Will your doctor or therapist be		0: Yes; I think so or I hope so

able to make sure you get the project medication instead of placebo?	_____	1: 2: 3: 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" 1: 2: Research team decides 3: 4: Acknowledges random assignment; flip of a coin
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 1: 2: Knows it is different, but vague about how 3: 4: Clear about the difference
<b>Project Burden Issues</b>		
10. [A] People in research projects are asked to do certain activities, like come for extra visits. Can you name some activities you would be asked to do if you joined this project?	_____	0: Unaware of extra requirements 1: 2: Names some requirements but not ones which are very burdensome or painful 3: 4: Fairly clear view of burdensome or painful requirements (e.g. _____[time spent on study visits, blood draws, neuroimaging, etc.]
<b><i>After above scoring is complete, show visual aid listing the extra activities the subject would be expected to participate in if enrolled in this project.</i></b>		
11. [R] Are any of these project activities different from what you do in your normal routine? Why?	_____	0: Does not relate to requirements in a personal manner/ No opinion 1: 2: Some awareness of personal effect/ Opinion but can't say why 3: 4: Realistic view of personal effect/ Opinion and can give examples of considering extra burdens
12. [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: To make sure he/she is getting well 1: 2: Does not know why 3: 4: Because it is part of what is being studied and not for clinical reasons

## Risks and Benefits

<p>13. [U] What good things might happen to patients who join this project?</p>	<p>_____</p>	<p>0: No benefit for participants; guaranteed clinical improvement            1:            2: Sees potential benefits, but overestimates potential for subjects to benefit –OR- only mentions monetary reward            3:            4: Realistic understanding of benefits (does not need to mention “closer monitoring” as benefit)</p>
<p>14. [A] How likely is it that good things will happen to <i>you</i> if you join this project?</p>	<p>_____</p>	<p>0: Guaranteed            1:            2: Unrealistic Expectations            3:            4: Realistic; Chance</p>
<p>15. [R] How could those good things make it easier for you to do the things you like to do?</p>	<p>_____</p>	<p>0: No concept of how life would be affected            1:            2: Knows it would help but unsure exactly how            3:            4: Can point to specific activities that could be improved</p>
<p>16. [U] What problems might people have because of joining this project?</p> <p>(Minor side-effects: _____ [List];            Major side-effects: _____ [List])</p>	<p>_____</p>	<p>0: Denies risk            1:            2: Partially understands risks            3:            4: Clear understanding of primary risks (_____ [List important risks])</p>
<p><b><i>After above scoring is complete, show visual aid listing important side-effects and other risks related to the project.</i></b></p>		
<p>17. [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?</p>	<p>_____</p>	<p>0: No            1:            2: Admits <i>some</i> risks but minimizes possibility unrealistically            3:            4: Acknowledges all are possible</p>

18. [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 1: 2: Knows it would interfere but unsure exactly how 3: 4: Can point to specific activities that could be hindered
19. [U] Will this research benefit people in the future? How?	_____	0: No benefit to others; Don't know 1: 2: Acknowledges gain in information but not sure how that is beneficial 3: 4: Acknowledges that new treatment information can help future patients
20. [R] How do you decide whether to join a project or not?	_____	0: Doesn't know; doesn't think about those things 1: 2: Some appreciation of areas reviewed 3: 4: Weighs risks and benefits (Does not need to say that is what he/she does if it is obvious that is what is happening)
<b>Project Withdrawal</b>		
21. [U] Do the research participants <i>have</i> 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 1: 2: Can quit but not sure how to do it 3: 4: Clear on right to withdraw; talk to Drs./Mr./Ms. _____ [List PI and study coordinator] (does not need to remember names if knows where to find them, i.e. consent form)
22. [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: Cannot quit; cannot receive regular treatment if quit 1: 2: Realizes he/she can quit, but unsure how that affects treatment 3: 4: Acknowledges right to quit and still receive treatment
<b><i>After above scoring is complete, show visual aid listing: symptoms getting worse, side-effects are uncomfortable, too much time in testing.</i></b>		
23. [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 1: 2: Vague thoughts about things that would lead to withdrawal 3: 4: Notes specific things that would make him/her uncomfortable continuing in the project (does not need to name something on the visual aid)