



## IRB Reviewer Checklist Special Subject Populations Persons with Impaired Decision-Making Capacity

<b>Reviewer:</b>	<b>PRO#:</b>	<b>PI:</b>
In order to approve the use of Persons with Impaired Decision-Making Capacity, responses must be “yes” unless not applicable		
1. Adequate rationale to support research need to use persons with impaired decision-making capacity.	<b>Yes</b>	<b>No</b> <b>NA</b>
2. Adequate procedures presented to evaluate subjects’ capacity to consent.	<b>Yes</b>	<b>No</b>
3. Appropriate procedures to identify and use legally authorized representatives.	<b>Yes</b>	<b>No</b>
4. Adequate provisions in place to stop participation, obtain legally authorized representative, or obtain appropriate consent should capacity of the individual change.	<b>Yes</b>	<b>No</b> <b>NA</b>
5. Adequate plan describing how the PI will anticipate changes in capacity and a description of how such changes will be handled.	<b>Yes</b>	<b>No</b> <b>NA</b>
6. Persons with impaired decision-making capacity are not being proposed as participants simply because they are readily available.	<b>Yes</b>	<b>No</b>
7. The proposed research entails no significant risks, tangible or intangible, or if the research presents some probability of harm, there is at least a greater probability of direct benefit to the participant.	<b>Yes</b>	<b>No</b>
<b>The Informed Consent Process Addresses the Following Points:</b>		
8. The investigator obtains the legally effective consent of the participant or the participant’s legally authorized representative.	<b>Yes</b>	<b>No</b>
9. The circumstances of the consent process provide the prospective participant or the legally authorized representative sufficient opportunity to consider whether to participate.	<b>Yes</b>	<b>No</b>
10. The circumstances of the consent process minimize the possibility of coercion or undue influence.	<b>Yes</b>	<b>No</b>
11. The individuals communicating information to the participant or the legally authorized representatives during the consent process provide that information in language understandable to the participant or the legally authorized representative.	<b>Yes</b>	<b>No</b>
12. The information to be communicated to the participant or the representative during the consent process does not include exculpatory language through which the participant or the legally authorized representative is made to waive or appear to waive any of the participant’s legal rights.	<b>Yes</b>	<b>No</b>
13. The information to be communicated to the participant or the legally authorized representative during the consent process does not include exculpatory language through which the participant or the legally authorized representative releases or appears to release the investigator, the sponsor, the organizations, or its agents from liability for negligence.	<b>Yes</b>	<b>No</b>