

**Determinations & Decisions Checklist for Use of Surrogates in
Decision Making Capacity to Provide Consent for Research
(including Research Involving Subjects with Diminished Capacity)**

Determinations relative to Risks and Benefits

- Risk is minimal ___Yes ___No
- Risk is greater than minimal ___Yes ___No
- There is no benefit ___Yes ___No
- There is direct benefit to subject ___Yes ___No
- There is indirect benefit (e.g., societal, info) ___Yes ___No

Review of protocols involving the use of surrogates will be done by the Full Board review process. However, the Full Board may determine that the protocol is exempt under 45CFR46.

Determination relative to Category of Review

- Research is exempt ___Yes ___No

A. Procedures Required of the Person Obtaining Consent

Decisions of the IRB: Procedures are in place for the “Person Obtaining Consent for All Subjects” to lead the potential subject through the entire consent process. The following procedures are in place:

- **All aspects of the study, as described in the consent form, are first discussed with the potential subject** ___Yes ___No ___NA
Note: If answer is “No,” an application for a waiver must be approved.
- **The consent form is thoroughly reviewed with the potential subject and answers to the potential subject’s questions are provided** ___Yes ___No ___NA
Note: If answer is “No,” an application for a waiver must be approved.
- **While reviewing the consent form, the person obtaining consent asks questions designed to assess the potential subject’s understanding of the material. The person will specifically state this intent to the potential subject (i.e., the person is making sure the potential subject appreciates what s/he is being asked to do, and why)** ___Yes ___No ___NA
Note: If answer is “No,” a procedural change is necessary.
- **The potential subject is given ample opportunity to decide, without coercion or undue influence, whether or not to be in the study** ___Yes ___No ___NA
Note: If answer is “No,” a procedural change is necessary.

- The consent process does not end with the formal signing of the consent document. Rather, it is an ongoing process that continues throughout the subject's participation in the study. The person obtaining consent remains responsible for continued assessments of the subject's understanding of what is happening to him/her, his/her willingness to participate and for providing the subject with any new information that may affect the willingness to participate _____Yes _____No _____NA

Note: If answer is "No," a procedural change is necessary.

- The Principal Investigator accepts the responsibility to train and supervise the study personnel who are obtaining consent _____Yes _____No

Note: If answer is "No," a procedural change is necessary.

B. Procedures Related to Consent of a Potential Subject

Components of a Potential Subject's Capacity to Consent to Research

Subject demonstrates an appreciation:

- That the activity is research, not standard treatment
- Of the risks and benefits of a study
- Of the alternatives that are available if s/he does not participate
- That, if s/he chooses not to participate, this decision will be accepted without penalty, i.e., without jeopardizing clinical care.

AND

Subject demonstrates the ability:

- To use the information described above in a rational manner
- To consider his/her own uniqueness in terms of the research study.

Decision of the IRB: Procedures are in place to allow the subject to demonstrate capacity to consent given the considerations listed above _____Yes _____No _____NA

Note: If answer is "No," a procedural change is necessary.

Determinations relative to Acceptability of Inclusion in Subject Population

Determinations relative to Capacity to Consent and Level of Risk

- Risk is minimal (Subject may participate.) _____Yes _____No

OR

- Risk is greater than minimal but there is a possibility of direct benefit to the subject. (Subject may participate.) _____Yes _____No

Note: One of the two determinations above must be answered in the affirmative in order to proceed further.

Determinations relative to Potential Level of Impairment and Assessment of Capacity to Consent

- Procedures and rationales for the procedures for assessment of potential impairment to capacity to consent are included for the following categories. (Check all that apply.)
 Temporary Permanent Progressive Fluctuating None
Note: If answer is "None," the investigator must submit a revision to procedures or rationales.
- Additional procedures for assessment of potential impairment to capacity to consent need to be included in the following categories.
 Temporary Permanent Progressive Fluctuating None

Decision of the IRB: Appropriate procedures are in place to assess subjects' potential impairment to capacity to consent Yes No NA

Note: If answer is "No," a procedural change is necessary.

Determinations relative to Whether Formal Attestation/Documentation of Capacity Assessment for Each Subject Should Be Required

- The information to be presented is simple Yes No
- The information to be presented is complex Yes No
- The risks are minimal, as are the benefits Yes No
- The risks are minimal, benefit may be direct Yes No
- The risks are minimal, benefit may be indirect Yes No
- Risks are greater than minimal, benefit may be direct Yes No

Decision of the IRB: Given the relationships among the factors relative to potential impairment to capacity of subjects to consent, the complexity of information to be communicated and the risks and benefits of the proposed study:

- **Formal assessment¹ of capacity to consent is not required.** Yes No
- **Formal assessment of capacity to consent is required. It may be performed by a member of the research team, who is an M.D. or a mental health professional with familiarity with capacity to consent issues in human subjects research.** Yes No
- **Formal assessment of capacity to consent is required. It must be performed by an independent evaluator, who is an M.D. or a mental health professional**

¹ Formal assessments of a subject's capacity to consent include determinations of the psychiatric, medical and emotional status of the subject population, as well as the inherent risk/benefit ratio of the study design.

with familiarity with capacity to consent issues in human subjects research.
____ Yes ____ No

Rationale of IRB:

Note: If the decision of the IRB is that a formal assessment of capacity to consent is required, the following statement must be added to the end of the consent form:

“My signature below attests to the fact that I am a physician or mental health professional and I have interviewed)_____ (Name of Patient) on _____ (date). I have determined that s/he does ____ does not ____ have the capacity to consent to participation in this research activity, in that s/he is ____ is not____ capable of appreciating: a) that the activity described in this consent document constitutes research, not standard treatment; b) the risks and benefits of this study; c) the alternatives that are available is s/he chooses not to participate; and d) that the decision to not participate will be accepted without penalty, i.e., without jeopardizing his/her clinical care.”

Signature

Determination: Statement above is included in consent form as required.

____ Yes ____ No ____ NA

Note: If answer is “No,” a change to the consent form is necessary.

C. Procedures for Designees Providing Consent for a Subject to Participate

Procedural Determinations relative to Designees Providing Consent for a Patient/ Client to Participate in a Study if a Patient is Incapable of Doing So:

Note: Such patients can only be enrolled in minimal risk research, or more than minimal risk research where direct benefit is possible.

1. Individuals who may consent on behalf of the patient include:
 - a. Individuals granted legally documented authority to make decisions specifically regarding participation in research activities
 - b. Family member (in order of priority: spouse, adult child, parent adult sibling)

c. Individuals listed in a health care proxy, only for those research protocols generally recognized in the medical community as offering the optimal treatment choice (e.g., there are few if any, effective treatments for patients with multiple-recurrent cancer, and those with very rare or highly aggressive cancers. In such circumstances, the medical societies, and the National Cancer Institute, specifically recommend enrollment in a research protocol as the best possible care.)

Decision of the IRB: Consent procedures are appropriate for all of the individuals listed in the categories above.

___Yes ___No

Note: If answer is “No,” the IRB must specify which categories may apply.

Approval is restricted to the following categories: ___1.a. ___1.b.

2. Decision of the IRB: Procedures are in place for the patient who is able to provide initial consent, but may lose the capacity to decide whether to continue or withdraw consent during the study as a result of disease progression (e.g., Alzheimer’s Disease), for the person obtaining consent to discuss early on in the research activity with the subject the formal designation of a surrogate (via execution of the document presented in #1.a. above.)

___Yes ___No ___NA

Note: If answer is “No,” a change in procedure is recommended.

3. Decision of the IRB: Procedures are in place so that individuals who consent on behalf of a patient will be informed that they must make the decision for or against participation based on “substituted judgment,” reflecting views that the potential subject expressed while capable of making their own decision. If the views are not known, the decision will be based on that which is believed to be in the “best interests” of the subject.

___Yes ___No ___NA

Note: If answer is “No,” a change in procedure is necessary.

4. Decision of the IRB: Procedures are in place for education of individuals who consent on behalf of a patient about the importance of their role, the study, the health status of the patient, the rights to refuse to participate or to withdraw consent at any time without penalty. This person will be taken through the entire consent process, as described above.

___Yes ___No

Note: If answer is “No,” a change in procedure is necessary.

5. Decision of the IRB: Assent procedures are in place for patients whenever possible. Procedures include enrollment, continuation and withdrawal.

___Yes ___No ___NA

Note: If answer is “No,” a change in procedure is necessary.

6. Decision of the IRB: Procedures are in place for routine assessment throughout the study of the subject's capacity to consent (as is reasonable with respect to the subject's disease state or disorder). If the subject regains the capacity to consent, s/he will be presented with the information about the study, as in the initial consent process, and will be given the opportunity to decide to continue or withdraw from the study. Yes No NA

Note: If answer is "No," a change in procedure is necessary.

Final Decisions of the IRB:

Procedures required of the person obtaining consent are present as required in the *Policy and Procedures on the Use of Surrogates in Decision Making Capacity to Provide Consent for Research* and are appropriate to the subject population.

Yes No (Revisions needed.)

Procedures related to consent of a potential subject are appropriate. Determinations and decisions of the IRB have been made as per the *Policy and Procedures on the Use of Surrogates in Decision Making Capacity to Provide Consent for Research*.

Yes No (Revisions needed.)

Procedures for designees providing consent for a subject to participate are appropriate. Determinations and decisions of the IRB have been made as per the *Policy and Procedures on the Use of Surrogates in Decision Making Capacity to Provide Consent for Research*.

Yes No (Revisions needed.)

The use of surrogates in decision making is approved.

Yes No (Revisions needed.)

Research is certified exempt, Category _____.

Research is approved by the Full Board _____.