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The purpose of this form is to provide support for investigators who plan to conduct medical research that includes adult individuals with cognitive impairments, lack of decisional capacity, or serious physical or behavioral conditions that limit their ability to provide informed consent. This form outlines the steps for determining decisional capacity and a subject's wishes to take part in research pursuant to the **NJ Access to Medical Research Act Statute 26:14.1-26:14.5** and other consent considerations pursuant to the Common Rule 45 CFR 46. When conducted outside of New Jersey, the research must comply with the applicable surrogacy laws in the jurisdictions where the research is taking place. This worksheet is to be used. It does not need to be completed or retained.

**IMPORTANT: Read all steps carefully before executing any of the steps.**

**BACKGROUND INFORMATION:**

**Per the New Jersey Access to Medical Research Act or Common Rule:**

- Inability to consent shall mean that a prospective subject is unable to consent if s/he is unable to voluntarily reason, understand, and appreciate the nature and consequences of proposed health research interventions, including the subject's diagnosis and prognosis, the burdens, benefits, and risks of, and alternatives to, any such research, and to reach an informed decision.
- All adults are presumed to have the ability to consent unless determined otherwise pursuant to the Act or other provisions of NJ State law.
- A determination that a subject is unable to consent, as well as the extent of his/her incapacity and the likelihood of regaining decision-making capacity shall be made by an attending physician with no connection to the proposed research and shall be made to a reasonable degree of medical certainty.
- An assessment whether a subject, who is otherwise unable to consent, is able to assent to take part in the research shall be made by the investigator.
- A decision to enroll an adult lacking decisional capacity in research must be consistent with instructions outlined in an Advanced Directive for Health Care, if one exists.
- **NOTE:** Notwithstanding a determination of incapacity, a subject's objection to a determination of incapacity or objection to the proposed research intervention shall be binding, unless a court of competent jurisdiction determines that the subject lacks decision-making capacity.

**INSTRUCTIONS:**

**To comply with New Jersey Law, the following steps must be followed to determine a potential subject's capacity to consent to research and whether surrogate consent must be pursued instead:**

- 1) Assess the possibility that the subject is able to provide legally valid consent to take part in research. If yes, attempt to obtain informed consent directly from the subject.
- 2) Confirm whether an Advance Directive for Healthcare exists and, if so, whether it gives a directive about participation in research.
- 3) If it is not possible to obtain informed consent directly from the subject, a physician independent of the research must determine whether the subject lacks capacity to consent to participate in research, and the anticipated duration and extent of the incapacity.
- 4) The physician's determination of lack of capacity to consent must be given promptly to the subject and at least one person in the highest order of priority to serve as surrogate (per NJ State Statute 26:14-5).

**Each step is detailed below:**

**STEP 1** Assess the possibility that a subject is able to provide consent. Attempt to obtain informed consent directly from the subject, if applicable.

***Does the subject have the capacity to make informed decisions to take part in research?***

- YES: The subject is able to understand the details of the research and s/he made a decision about taking part in the research. [STOP. Obtaining surrogate consent is not necessary when an adult subject has the capacity to make informed decisions in his/her own best interests.]
- NO: It is not possible to obtain informed consent directly from the subject. [Proceed to Step 2.]

**STEP 2** Confirm whether an Advance Directive for Health Care exists. If so, determine whether it gives a directive about taking part in research.

***Does the subject have an advance directive for healthcare that indicates whether s/he would have any objections to taking part in a research study?***

- YES: An advance directive exists and it indicates the potential subject would not want to take part in the proposed medical research. [STOP. Do not enroll the individual in the research against his/her wishes.]
- NO: An advance directive for healthcare does not exist **OR** an advance directive exists but it does not indicate that the subject would object to taking part in the proposed medical research. [Proceed to Step 3.]

**STEP 3** Obtain a determination of a subject's capacity to consent to research from a physician independent of the research.

***Has a physician, independent of the research, determined that the subject lacks the capacity to consent to the research, and the extent and duration of the incapacity?***

- YES: A physician independent of the research has determined that the subject lacks the capacity to consent to research, the extent of the subject's incapacity, and the likelihood that s/he will regain decision-making capacity with a reasonable degree of medical certainty. Note: Be



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	sure the physician documents his/her determination in the record according to clinical site requirements. Make clear in the protocol where the physician's assessment will be documented. <b>[Proceed to Step 4.]</b>
<input type="checkbox"/>	NO: A physician independent of the research has not made a determination of lack of capacity to consent to research <b>[STOP]</b> . Do not enroll the potential subject in research or secure surrogate consent until such time as a determination of lack of capacity to consent to research has been made.]
<p><b>STEP 4</b> Provide the decision of determination of incapacity to the subject and to at least one person at the highest level reasonably available on the list of surrogates. [See <b>6.204 (HRP-391) WORKSHEET: Surrogate Consent – Selecting a Surrogate</b> for instructions on how to select a Surrogate in highest order of priority per State law.]</p> <p><b><i>Has the investigator provided the determination of incapacity to the subject and to a surrogate in the hierarchy of priority and the subject does not object to the determination of incapacity or to taking part in the research?</i></b></p>	
<input type="checkbox"/>	YES: The determination of incapacity to consent to research has been given to the subject and a surrogate. The subject does not object to the determination of incapacity or to taking part in the research. <b>[Proceed to Obtaining Surrogate Consent &amp; Subject Assent]</b> See <b>Rutgers Guidance for Surrogate Consent</b> for more information.
<input type="checkbox"/>	NO: The determination has not been disclosed <u>OR</u> the determination has been disclosed to the subject and the surrogate but the subject objects to the determination of incapacity or to take part in the research. <b>[STOP]</b> . Do not enroll the potential subject in research against her/his wishes.]