

17. Inclusion of Incompetent Participants

For inclusion only in studies where incompetent participants are recruited and who may become competent at a later date, the following is required:

Mandatory and Verbatim:

PARTICIPANT’S ACCEPTANCE OF THIRD PARTY AUTHORIZATION

Because your illness (or injury) made it impossible for you to participate in the informed consent process, a third party authorization (e.g. family member) was obtained on your behalf. Your surrogate believed you would have wished to participate in this research if you had been able to express your own opinion at the beginning of the research.

The process of informed consent must be continuous throughout the research project. This means that you have the right to change your mind and, therefore, must be given opportunities to read all relevant consent materials, ask questions and then agree or disagree with the decision made by your surrogate to enroll you in this research project.

If you agree with the decision made by your surrogate to enroll you, your signature will affirm your participation in this study. If you do not agree with the decision made by your surrogate to enroll, you may withdraw now or at any other time from the study.

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a participant. In no way does this waive your legal rights nor release the investigators, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing the health care you are entitled to receive. Your continued participation should be as informed as your initial consent. You will be informed in a timely manner if information becomes available that may affect your willingness to continue participating in this study. You should also feel free to ask for clarification or new information throughout your participation.

Please check the appropriate boxes to indicate your decision:

- Agree with your surrogate’s decision.
- Wish to remain in the study.
- Do not agree with your surrogate’s decision.
- Wish to withdraw from the study.

| | | |
|------------------------------------|-------|-------|
| Participant’s name (please print) | _____ | _____ |
| | | Date |
| Participant’s signature | _____ | |
| Investigator’s name (please print) | _____ | _____ |
| | | Date |
| Investigator’s signature | _____ | |
| Delegate’s name (please print) | _____ | _____ |
| <i>(Optional)</i> | | Date |
| Delegate’s signature | _____ | |
| <i>(Optional)</i> | | |
| Witness’ name (please print) | _____ | _____ |
| <i>(Optional)</i> | | Date |
| Witness’ signature | _____ | |
| <i>(Optional)</i> | | |

A copy of this form has been given to you to keep for your records and reference.