Death Prediction and Physiology after Removal of Therapy
The DePPaRT Study

Frequently Asked Questions
For study Coordinators & Investigators

Inclusion/Exclusion Criteria

Q: Are patients who consented to organ donation eligible for this study?

A: Yes. Patients who consent to DCD are eligible for the study and will be considered to be in Group 3 (if organ donation proceeds to procurement) or Group 2 (if donation does not proceed to procurement)

Q: Are patients who are going for tissue donation (cornea, skin, etc.) eligible for the study?

A: Yes. Their assigned patient group will also depend on whether they are eligible/have consented for organ donation.

Q: Why is declaration of NDD ("brain death") an exclusion criterion?

A: One of the objectives of the DePPaRT study is to collect information that would help with the development of a definition for the declaration of circulatory death. For this reason, we cannot include patients where death has already been declared.

Q: Should I be screening/approaching for consent those patients where a decision has been made not to further escalate care/re-intubate/re-start compressions?

A: No. For the purposes of this study, we are interested in collecting observational data from those patients where a consensual decision with the family and care team has been made *to remove life-sustaining therapy/therapies*. In order to meet this criterion, the patient must be on an intervention that is maintaining their life (such as a ventilator or vasoactive drugs), and a decision has been made to remove this life-sustaining intervention with the expectation that the patient will die imminently.

Study Procedures

Q: What is the period where waveforms will be collected?

A: Waveform data capture will begin15 minutes prior to the start of WLST and end 30 minutes after the declaration of death, or at the time of organ procurement (for organ donors).

Q: When is WLST considered to "begin"?

A: The practice of WLST is different in each ICU. We would consider the start of WLST to be when an intervention currently sustaining life is stopped, removed, or when the gradual step down of this intervention begins. The life sustaining intervention and the process used to withdraw it may differ. Please indicate which "action" you are considering as the "start of WLST" in question 12.6 in section 12 of the CRF.

Q: The patient's family has requested removal of the arterial line. Is this allowed?

A: Yes. Please defer to the family's requests during the WLST process and report this as a protocol violation in section 18 of the CRF. Please keep a record of when the line was removed. Depending on when this is removed we may still be able to use some of the data collected.

Case Report Form & Reporting

Q: How often should we send screening logs?

A: Please send a record of all screened patients at least once a month. You can send the completed paper screening log by fax or email, or you can enter screened patients in real time into the study website (www.deppart.org). Simply click "add a new patient" and indicate that this was a "screen failure" to add a screened but not enrolled patient to your site list.

Q: How often should we send waveform and subject data?

A: Please upload the collected waveforms for each patient as close to completion of collection as possible. This will help us to check waveform files for completeness and ensure the patient data is useable. Basic information such as subject study group, date of enrollment, and whether or not the subject's substitute decision maker has consented to the follow up study should also be uploaded to the website regularly so the central study team can keep accurate records of study progress.

Q: Who should complete the CT Head & Marshall Score form if the site investigator does not have time to do this for each patient?

A: The site investigator is responsible for completing the CT Head & Marshall Score form for each patient who had a CT Head scan prior to WLST. It is acceptable to batch these forms and have the site investigator complete all forms at one time after subject enrollment.

Q: Which patients should I be including in the screening log?

A: Please screen all patients where a decision for withdrawal of life sustaining therapy has been made by the family and the care team. Complete the screening log with all relevant information – you can check all exclusion criteria that apply/leave unchecked

all inclusion criteria that the patient did not meet. If you did not approach the family for consent, leave all questions regarding consent blank or select "N/A".

Complimentary Qualitative Study (For Participating Sites)

Q: Who will consent the substitute decision makers to the DePPaRT Qualitative follow-up study?

A: At participating sites, research coordinators will ask substitute decision makers whether they agree to be contacted in 4-6 months for the complimentary qualitative study. The research coordinator will get a "yes" or "no" answer to this question, and if the substitute decision maker consents, the coordinator will record the contact information for the substitute decision maker. The research coordinator will then enter this contact information into the website, where it will be sent to the qualitative study team. A member from the qualitative study team will then contact the substitute decision maker in 4-6 months to explain and ask for consent to the qualitative study.