**BASELINE Assessments**

\*\*\*\*\*Understanding the child’s functioning prior to cardiac arrest is essential for outcome analysis\*\*\*\*\*

Within 48 hours of enrollment, the PCPC (Pediatric CEREBRAL Performance Category) and POPC (Pediatric OVERALL Performance Category) should be completed by the Study Hospital (RC/PI) using the medical record or medical history. If the information is not available in the medical record, it can be obtained by family interview as well.

**PCPC/POPC Decision Tree Instructions**

* *Review the medical record for the pre-CA level of impairment, medical conditions, AND etiology of the delays of functional impairments.*
* *If you cannot find information in the record, please ask the caregiver about any medical diagnoses or conditions the child had prior to the cardiac arrest.*
* *For all identified diagnoses or conditions, please ask whether the diagnosis/condition limited the child’s functioning (prior to the cardiac arrest) in any way.*

**Decision Tree for Determining Level of Impairment on Both the PCPC and POPC:**

1. Normal/Good = If the child has no disability or medical conditions, and is functioning appropriately, the child should be classified as “Normal” on the PCPC and “Good” on the POPC.
2. Mild Disability = If the child has minor delays or functional impairments and most skills are within age-appropriate limits, or the child has well-controlled medical conditions, the child should be classified as “Mild Disability”.
3. Moderate Disability = If the child is significantly delayed or functionally impaired in most areas and demonstrates some level of independence in activities of daily living, the child should be classified as “Moderate Disability”.
4. Severe Disability = If the child is responsive to the environment but dependent on others for daily support because of impaired brain functioning or other medical conditions (excluding age), the child is classified as “Severe Disability”.
5. Coma/Vegetative State = If the child has any degree of coma, is unaware and unresponsive, even if awake in appearance, without interaction with environment, the child is classified as “Coma/Vegetative State”.

Difference between Pediatric **Cerebral** Performance Category and Pediatric **Overall** Performance Category

*Neurological Disease* is coded on the PCPC **and** the POPC. If the identified functional impairments are the result of *neurological disease (e.g. cerebral palsy),* the PCPC **and** POPC get coded based on level of functional impairments.

If *non-neurological medical conditions* (e.g., asthma, amputation) impair functioning above and beyond any impairment caused by neurological disease, score disability **ONLY** on the POPC.

**BASELINE Questionnaires**

Within 48 hours of enrollment, *3 brief questionnaires* will be completed at baseline to determine the participant’s function prior to cardiac arrest and provide key demographics about the family.

These questionnaires are to be answered by a primary caregiver and refer to the participant’s function PRIOR to cardiac arrest. Answers to these questions become less accurate with time.

All three forms can be found in the **P-ICECAP Toolbox** and in WebDCU™.

1. Family and Household Information Form: The Study Hospital representative will hand caregiver the form for completion. If necessary, the Study Hospital representative will sit with family and assist. The completed form should be entered directly into WebDCU™
2. PedsQL: Please be sure to verify date of birth and date of administration and calculate exact age in order to choose the appropriate form. The current age of the child is often displayed in the EMR. The appropriate PedsQL form is *based on the age of the child on the day the form is completed*.

This age calculator may be used to determine exact age.

<http://images.pearsonclinical.com/images/ageCalculator/ageCalculator.htm>

Based on the child’s exact age (do not round up or down), pick the appropriate form. See options below (only pick one):

Infant Scales (Pick One)

PedsQL Infant Scales (2 days-12 months)

PedsQL Infant Scales (13 months to <2 Years)

**OR**

Generic Core (Pick One)

PedsQL Generic Core – Toddler Version (2-4 years)

PedsQL Generic Core – Child version (5-7 years)

PedsQL Generic Core – Child version (8-12 years)

PedsQL Generic Core – Teen version (13-18 years)

The Study Hospital representative will hand caregiver the printed form for completion. If necessary, the Study Hospital representative will sit with family and assist. This CRF includes questions related to administration of the PedsQL, including which version was used (either Infant Scales or Generic Core).

The completed PedsQL questionnaire should be uploaded to the UofM secure dropbox so that Kennedy Krieger can score the measure and enter scores into WebDCU™ (Instructions for uploading to U of M secure dropbox can be found below and in the MOP.)

1. Baseline Contact Form: Within 48 hours of enrollment, the Study Hospital will obtain contact information from caregiver. The Study Hospital should ask the caregiver for all their available contact information and alternates who we can contact to complete the 3-month telephone follow-up interview. (The Study Hospital will use this form to contact the family at 2 months to prep them for this phone interview. The same process applies at 11 months for the 12-month telephone follow-up interview.)

If these forms are not completed within 72 hours of enrollment, an email reminder will be sent to the site study team to obtain this information.

**Instructions and tips for Selecting the Respondent and Completing the Questionnaires**

The respondent must be the adult who is very familiar with the everyday behavior of the child. In general, the respondent should have frequent contact with the child, preferably every day, over an extended period of time to allow multiple opportunities to observe the child’s response to environmental demands.

For the child living at home, a parent is usually the most appropriate respondent. In some cases, however, another adult family member may be a more suitable choice. If the child does not live with his/her family but lives with in a residential facility, then the respondent should be the caregiver who knows the child best.

In cases of lack of sufficient knowledge of the child’s activities in all domains, more than one respondent may be necessary. However, only one respondent should complete the questionnaires. Every attempt should be made to locate one respondent who is familiar with the child’s daily functioning.

Respondents must have sufficiently high reading skills to be able to read and understand the directions for completing the form and the items themselves. If poor reading skills are suspected, read items to the respondent.

It is important to identify obstacles that might exist which could impact the ability of the respondent to complete the questionnaire, including the respondent’s language, literary status, and/or level of distress.

If proficiency in English comprehension is thought to be poor and Spanish is the respondent’s primary language, please utilize the Spanish version of the questionnaires.

It is understandable that the family will be distraught after their child experiences a cardiac arrest. It is suggested that a member of the study team sit down with the respondent, and, if necessary (due to concerns with distress and/or literacy), read the questionnaires with them and assist with completing the information. However, this is not a requirement.

Establishing a relationship that encourages the respondent to provide accurate, unbiased information about the child’s typical functioning is an important precondition for obtaining valid results. Take time to establish rapport.

* Begin by briefly describing the purpose of the assessment: “Learning about [NAME’S] behavior and your family prior to this cardiac arrest will help us get a total picture of him/her”
* Explaining their role: “Given that you have spent the most time with [NAME], you will be the important person who is going to give us the information about his/her behavior.”
* Explaining the structure of the questionnaires: “You will be giving us information about [NAME’S] physical, emotional, social, and cognitive functioning as well as information about his/her family and household.”

**Data Entry/Management**

Research coordinator:

● Enter the Baseline PCPC/POPC into WebDCU™

● Enter the Family/Household information directly into WebDCU™.

● Upload the PedsQL to the secure UofM box for Kennedy Krieger to review and score.

Kennedy Krieger:

● Enter PedsQL scores into WebDCU™.

**Completion of and data entry of these forms into WebDCU™ (or sending the PedsQL to KENNEDY KRIEGER) should occur within 72 hours of admission.**

**Instructions for Uploading to UofM Dropbox coming soon!**

**Hospital Discharge or 30 days (whichever comes first) Assessments**

\*\*\*\*\*Understanding the child’s functioning at this time point is essential for outcome analysis\*\*\*\*\*

The PCPC/POPC score at the time of Hospital Discharge or 30 days (whichever comes first) is required. The POPC/PCPC should be completed from information available in the medical record or by consulting the care team as close to Hospital Discharge/Day 30 as possible, or from family interview prior to Hospital Discharge/30 days (within 24 hours of Hospital Discharge/Day 30).

Please refer to Decision Tree Instructions and Decision Tree for Determining Level of Impairment above.

**Additional instructions and tips for Hospital Discharge or 30 Days Ratings**

*Review records for information about development and functional skills at time of discharge or 30 days (whichever comes first).*

* If it is obvious by medical record review that the child has no functional impairments and was developing normally, score will be “Normal/Good” or “Mild Disability” on both measures.
* If it is obvious by medical record review that the child has functional impairments at the time of PICU discharge, the child will be classified as “Mild Disability”, “Moderate Disability”, “Severe Disability” or “Come/Vegetative” based on criteria above.

*Next, review the chart for past and current medical history.*

* Child with no neurological or other medical disease at discharge/30 days who is functioning normally will be coded as “Normal” on the PCPC or “Good” on the POPC.
* Child with mild controlled disease will be coded as “Mild Disability”. Neurological disease that is well controlled (e.g., seizures, headaches, shunts) results in classification of “Mild Disability” on the PCPC and POPC. Other non-neurological medical diseases that are well controlled (e.g., asthma, amputation) result in classification of “Mild Disability” on POPC, but not the PCPC.
* For children with” Moderate Disability,” “Severe Disability,” or “Coma/Vegetative State,” determine if the identified functional impairments are the result of neurological disease. If impairments are the result of neurological disease, the PCPC and the POPC are scored based on the child’s level of functional impairment.
* If *non-neurological medical conditions* (e.g., asthma, amputation) impair functioning above and beyond any impairment as a result of neurological disease, score disability ONLY on the POPC.

**2-month Procedures (in preparation for the 3-month outcome)**

The primary endpoint of this study is the Vineland Adaptive Behavior Scales – Third Edition (VABS-3) Mortality Composite at 12 months; however, 3-month VABS-3 will be used for interim analyses and to add in adaptive allocation to cooling doses. Therefore, collecting the VABS-3 in 3-month survivors is essential for trial success.

Kennedy Krieger has 3 months ± 2 weeks to complete the 3 months’ assessment, thus it is important that the Study Hospital contact the family as soon as possible within the window (two to four weeks) prior to the 3-month date.

**Pre-interview Instruction for Study Hospitals**

Two to four weeks prior to the 3-month evaluation, the Study Hospital will contact the family to obtain the status of the participant and the current contact information, including the designated respondent’s name, preferred telephone number, preferred time of day for the interview and the preferred language of the respondent. If there is more than one possible respondent, contact information should be obtained on all possible respondents.

The Study Hospital can schedule the interview time directly with the family. Please let family know to expect the interview will take between 30 minutes and up to 1.5 hours. Kennedy Krieger will call caregiver at the designated time or will call/email/text to set up an appointment if one has not been made.

All attempts to contact the family must be documented on the Contract Tracking Form. Be sure to try different times of day and different modes to contact families.

There is no minimum or maximum number of contacts prescribed. If the Study Hospital is having trouble reaching the family, please reach out to Beth Slomine ([slomine@kennedyrieger.org](mailto:slomine@kennedyrieger.org)) and Nisthta Amin ([aminN@kennedykrieger.org](mailto:aminN@kennedykrieger.org)) from Kennedy Krieger and/or Moni Weber ([monij@umich.edu](mailto:monij@umich.edu)) from UofM for advice and suggestions. There are many strategies that can be provided to promote success at this stage.

For Participants Who Are Living

The 2-month Participant Contact Form will be uploaded to the secure UofM dropbox (see directions for uploading above). To ensure that the form has been received the Study Hospital should ALSO email Dr. Beth Slomine at [Slomine@kennedykrieger.org](mailto:Slomine@kennedykrieger.org) and Nishta Amin at [AminN@kennedykireger.org](mailto:AminN@kennedykireger.org) to confirm receipt.

**Please Note:** It is very important that the name of the participant, participant ID, and names and contact information (e.g., phone numbers and emails) of all possible respondents are recorded on the form. Once Kennedy Krieger staff completes the telephone interview, Kennedy Krieger staff will score and enter scores for all measures into WebDCU™. It is critical that the participant ID number is entered correctly on the contact form so that Kennedy Krieger enters information for the correct participant into WebDCU™.

For Participants Who Are Deceased

If the participant died between hospital discharge and the 3-month evaluation time point, DO NOT forward contact information to Kennedy Krieger. Kennedy Krieger will only be contacting families of participants who survived. Study Hospitals must complete the End of Study Form in WebDCU™.

For Participants Lost to Follow-Up

If, after discussion with local PI and Beth Slomine and/or Moni Weber, the Study Hospital is not able verify vital status or the participant is confirmed to be alive, but the Study Hospital cannot contact the family via the contact information provided at hospital discharge (including contacting the caregiver and the emergency contact), the participant will be considered lost to follow-up for the 3-month visit. **The participant will still be considered active and attempts should be made to contact the caregiver at 11 months**.

**11-month Procedures (in preparation for the 12-month outcome)**

There are two components to the 12-month evaluation. The first component is the 12-month telephone interview. This is done by Kennedy Krieger and closely resembles the 3-month evaluation. The second component is the on-site 12-month Neurologic Evaluation. This will be completed at the Study Hospital by a clinical neurologist.

*The primary endpoint of this study is the VABS-3 Mortality Composite at 12 months. Therefore, collecting the VABS-3 in 12-month survivors is essential for trial success* and should be completed PRIOR to the onsite neurological examination.

Kennedy Krieger has 12-months ± 2 weeks to complete the 12months assessment. Thus, it is important that the Study Hospital contact the family as soon as possible within the window (two to four weeks) prior to the 12-month date.

**Pre-interview Instruction for Study Hospitals**

Two to four weeks prior to the 12-month evaluation, the Study Hospital will contact the family to obtain the status of the participant and the current contact information, including the designated respondent’s name, preferred telephone number, preferred time of day for the interview and the preferred language of the respondent. If there is more than one possible respondent, contact information should be obtained on all possible respondents.

The Study Hospital can schedule the interview time directly with the family. Please let family know to expect the interview will take between 30 minutes and up to 1.5 hours. Kennedy Krieger will call caregiver at the designated time or will call/email/text to set up an appointment if one has not been made.

All attempts to contact the family must be documented on the Contract Tracking Form. Be sure to try different times of day and different modes to contact families.

There is no minimum or maximum number of contacts prescribed. If the Study Hospital is having trouble reaching the family, please reach out to Beth Slomine ([slomine@kennedyrieger.org](mailto:slomine@kennedyrieger.org)) and Nisthta Amin ([aminN@kennedykrieger.org](mailto:aminN@kennedykrieger.org)) from Kennedy Krieger and/or Moni Weber ([monij@umich.edu](mailto:monij@umich.edu)) from UofM for advice and suggestions. There are many strategies that can be provided to promote success at this stage.

For Participants Who Are Living

The 11-month Participant Contact Form will be uploaded to the secure UofM dropbox (see instructions above). To ensure that the form has been received the Study Hospital should ALSO email Dr. Beth Slomine at [Slomine@kennedykrieger.org](mailto:Slomine@kennedykrieger.org) and Nishta Amin at [AminN@kennedykireger.org](mailto:AminN@kennedykireger.org) to confirm receipt.

**Please Note:** It is very important that the name of the participant, participant ID, and names and contact information (e.g., phone numbers and emails) of all possible respondents are recorded on the form. Once Kennedy Krieger staff completes the telephone interview, Kennedy Krieger staff will score and enter scores for all measures into WebDCU™. It is critical the participant ID number is entered correctly on the contact form so that Kennedy Krieger enters information for the correct participant into WebDCU™.

For Participants Who Are Deceased

If the participant died between hospital discharge and the 12-month evaluation time point, DO NOT forward contact information to Kennedy Krieger. Kennedy Krieger will only be contacting families of participants who survived. Study Hospitals must complete the End of Study Form in WebDCU™.

For Participants Lost to Follow-Up

After discussion with Beth Slomine and/or Moni Weber, if the Study Hospital is not able verify vital status or the participant is confirmed to be alive, but the Study Hospital cannot contact the family with the information provided at hospital discharge (including contacting the caregiver and the emergency contact), the child will be considered lost to follow-up for the -month visit. The Study Hospital must complete the End of Study Form in WebDCU™, indicating that that the child was lost of follow-up and completed the Neurological Exam CRF to indicate that neuro exam was not done.

**12-month Onsite Neurologic Evaluation**

**Instructions for Study Hospital prior to administration**

Each Study Hospital will need to schedule the Month 12 Neurologic Evaluation. The Study Hospital will need to remind the participant/caregiver of the appointment at the time of contact for the 12-month Evaluations and discuss site specific reimbursement policies for travel costs with the caregiver. **The neurologic examination must be completed AFTER the 12-Month Kennedy Krieger Evaluation.**

The Study Hospital is responsible for providing a paper copy of the correct neurologic exam form to the neurologist. There are two versions of the form, one for children < 3 years of age and another version for those ≥ 3 years of age at the time of evaluation.

**Instructions for Neurologist**

The neurologist should perform the clinical evaluation, noting all findings on the Neurology Exam Form.

**Note:** Results from the neurological examination will be provided to the family/participant and the children’s primary physician in narrative form (i.e. a letter) at the discretion of the neurologist and the Study Hospital.

**Instructions for Study Hospital after administration**

The Study Hospital should collect the Neurology Exam Form as soon as possible after the exam is completed. A copy of the form should be retained by the neurologist. The Study Hospital should ensure that the form is complete, including all elements of the Global Assessment Score. The Study Hospital should ask the neurologist to provide any missing or unclear information. The Study Hospital should then enter the information from the paper Neurology Exam Form directly into WebDCU™

The Study Hospital should retain the Neurology Exam Form with the research filesand upload a copy of the form to secure UofM dropbox (see instructions above) for review by Drs. Silverstein or Ichord.

Drs. Silverstein or Ichord will review all comment fields in the Neurology Exam Form and will reach back out to site neurologists if there are any questions or concerns.

If necessary, site neurologist will correct the form and the Study Hospital will revise the WebDCU™ entries.

Once the Neurology Exam is completed, the Study Hospital should complete the End of Study CRF.

As noted above, if participant is lost of follow up, please indicate exam was not done on the Neurological Exam CRF