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## Neurocognitive Study Group Infrastructure

The Neurocognitive Longitudinal sub-study is embedded in the cohort protocol and will be carried out at all sites. The Data Coordinating Center (DCC) at The University of Pittsburgh is responsible for maintaining the study protocol and ensuring the regulatory compliance of all participating study sites. The Neurocognitive Core Center located at the Ann & Robert H. Lurie Children's Hospital of Chicago (Chicago) will evaluate and score tests and surveys related to neurocognitive function, mood, and post-traumatic stress disorder (PTSD) obtained by site coordinators and site psychologists and provide data to the DCC.

## Neurocognitive Longitudinal Sub-Study Overview

The Neurocognitive Longitudinal sub-study is designed to measure 1) neurocognitive function including IQ, executive skills, attention, visuomotor skills, and adaptive skills, and 2) mood and PTSD in patients with ALF.

- Patients who meet additional eligibility requirements (including age restrictions) will complete surveys of executive function at 6 months after PALF enrollment, and comprehensive neurocognitive testing, surveys, and assessment of mood and PTSD at 12 months after PALF enrollment. Some surveys will also be completed by parents and teachers at both time-points.
- Some data related to pre-existing neurocognitive co-morbidities and socio-economic status will be collected at the time of enrollment into the Cohort Study.

Appendix A includes detailed descriptions of instruments used in the Neurocognitive Comprehensive Battery.

## Scheduling

The Neurocognitive Longitudinal visits can be scheduled in conjunction with the PALF Cohort follow-up visits, clinic visits, or as separate visits, as long as the date of the visit complies with the testing windows.

The DCC will provide weekly reports to coordinators and site investigators of those patients who are due for their 6 or 12 month follow-up and their eligibility for the neurocognitive study. This report will be provided 2 months prior to the due date of the 6 or 12 month follow-up. This report will serve as a notice for coordinators to begin scheduling the patient for an in-person follow-up visit with the appropriate amount of time and resources (e.g. psychologist appointment at the 12 month visit) for the neurocognitive measures to be completed. The DCC will provide the window in which the patient is able to be seen, based on the enrollment date and age requirements provided at study enrollment. It is the responsibility of the site PIs and coordinators to identify events not yet reported to the DCC (those outlined in the inclusion/exclusion criteria) and adjust the scheduling for each patient appropriately.

## Administration and Completion of Neurocognitive Battery Testing

At the 6 and 12 month visit the Neurocognitive Enrollment Criteria form must be reviewed and completed to confirm patient eligibility prior to administrating any forms and testing.

If eligibility is confirmed and patient is participating in the Neurocognitive Battery:

**6 month visit**

| | |
|---|---|
| PALF coordinator: | administers the executive function surveys (BRIEFs). |
| Parent/guardian: | complete executive function surveys. |
| Teacher: | complete executive function survey. |

**12 month visit**

| | |
|---|---|
| Site psychologist: | administers neurocognitive testing to assess IQ, visuo-motor function, attention, adaptive function, mood, executive function, and PTSD surveys. |
| Parent/guardian: | complete executive function, mood, PTSD and adaptive skills surveys. |
| Teacher: | complete executive function survey. |

## SECTION I: CRITERIA FOR PARTICIPATION IN NEUROCOGNITIVE SUB-STUDY

**Inclusion/Exclusion Criteria:**

Inclusion

a. Patient's parent/guardian (completing the surveys) is fluent in English.
b. Patient is fluent in English.
c. Patient is between 2 yrs, 0 months, 0 days and 16 years, 0 months, 0 days at PALF study enrollment and between 3 yrs, 0 months, 0 days and 16 yrs, 11 months, 29 days at the 12 month timepoint.

Exclusion

a. Patient is awaiting liver transplantation*
b. Patient has a cancer diagnosis.
c. Patient has been hospitalized within the past 4 weeks prior to testing.
d. Patient with weakness or abnormality of muscle tone or coordination, such as cerebral palsy, sufficiently severe that it impairs their ability to perform physical tasks required for testing.†
e. Patient with no speech (no intelligible words) and/or those unable to follow simple commands.
f. Patient with uncontrolled seizures.‡

* Patient can be on the transplant list but must have no evidence of cirrhosis with portal hypertension.

† A subset of the NIH Stroke Scale can be performed to determine eligibility. Please see the Neurocognitive Enrollment Criteria Form MOP for specific instructions.

‡ Patients with a history of seizures must fulfill two of the following criteria to be eligible for participation

i) Patient must be seizure free for at least one month
ii) Patients with refractory seizures, must have had no recent increase in seizure frequency above their established baseline during the previous month
iii) Patients should not have had a change in anti-epileptic regimen in the last month.

The goal of these exclusion criteria are to enable coordinators to exclude children with impairments that would preclude their ability to participate in the testing process or that would lead to testing results that do not demonstrate the child's actual ability. The criteria are detailed and specific to reduce subjectivity in determining eligibility. It is expected that any given participating center will only have one or two potential candidates for which these criteria will need to be considered. Children that are excluded due to neurological disease will be recorded and included in descriptive analysis of the population of transplant survivors. The level of their impairment will be recorded by noting their specific exclusion criteria, the level of severity of cerebral palsy (see Table 1).

Table 1. Severity of Cerebral Palsy [1-3]

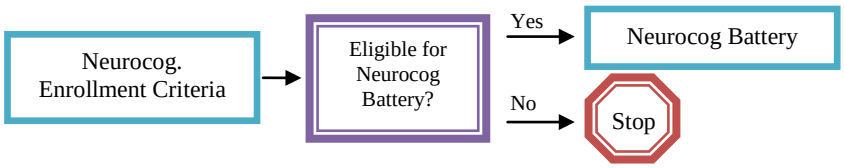
| | Gross Motor | Fine Motor | Cognitive | Speech | Overall |
|---|---|---|---|---|---|
| **Mild** | Independent walker | Unlimited Function | IQ > 70 | More than 2 words | Independent life |
| **Moderate** | Supported walk or creep | Limited Function | IQ 50-70 | Single words | Needs assistance |
| **Severe** | No locomotion | No function | IQ < 50 | Indistinct | Total Care |

References:
1) Russman BS, Disorders of motor execution I Cerebral Palsy. In Child and Adolescent Neurology. Editor David RB. 1998: 453-68.
2) Minear WL: A classification of cerebral palsy, *Pediatrics* 1956 18;841
3) Veelken N et al Diplegia cerebral palsy in Swedish term and preterm children. Neuropaediatrics 1983 14;20.

Patients who do not complete the Neurocognitive comprehensive battery at the 6 month follow-up are still eligible to participate in the neurocognitive battery at the 12 month follow-up. The inclusion/exclusion criteria will be assessed by the PALF coordinator at both the 6 and 12 month time-points.

## SECTION II: DATA COLLECTION

**Neurocognitive Battery Flow Diagram:**




**Form Descriptions:**

**Neurocognitive Enrollment Criteria form:**
The Neurocognitive Enrollment Criteria form lists the inclusion and exclusion criteria for the neurocognitive sub-study. This form should be completed by the coordinator at the 6 and 12 month neurocognitive follow-up visit, when patient eligibility is determined, prior to completion of any neurocognitive assessments.

**6 Month Neurocognitive Battery:**
Coordinator - materials

- BRIEF, BRIEF-Preschool, BRIEF-Self Report, and BRIEF-Teacher forms
- Teacher Letter and Postage Paid Return Envelopes for BRIEF
- FedEx envelope and FedEx checklist for BRIEF
- Teacher Contact Information Form (parent completes, remains at site)

**12 Month Neurocognitive Battery:**
Site psychologist – materials are provided in a study folder containing necessary forms by age.

Study Folders Include:

Child Forms

1. WISC-IV – Wechsler Intelligence Scale for Children – 4th Edition OR
   WPPSI-IV - Wechsler Preschool and Primary Scale of Intelligence – 4th Edition
2. VMI-6 – Beery-Buktenica Developmental Test of Visual Motor Integration – 6th Edition.
3. CPT-II – Conners' Continuous Performance Test – 2nd Edition OR K-CPT (Kiddie version)*
4. CDI-2– Child Depression Inventory, 2nd edition
5. BRIEF-SR– Behavior Rating Inventory of Executive Functioning – Self Report
6. PTSD-RI – Abbreviated UCLA PTSD Reaction Index

Parent Forms

1. ABAS-2 – Adaptive Behavior Assessment System – 2nd Edition
2. BRIEF or BRIEF-Preschool – Behavior Rating Inventory of Executive Functioning
3. CDI-2 – Children's Depression Inventory, 2nd Edition
4. PTSD-RI – UCLA PTSD Reaction Index, Parent Screening Version
5. Teacher Contact Information Form (remains at site)

Teacher Form

1. BRIEF – Behavior Rating Inventory of Executive Functioning

Additional Items

1. Letter to Psychologist (detailing procedures)
2. Testing Flow Sheet
3. Teacher Letter and Postage Paid Return Envelope
4. FedEx envelope and FedEx checklist
5. Validity Rating Form (completed by examiner)

* Not a form, but rather a test taken on the computer. The psychologist will print out the data report and return to Lisa Sorensen, PhD.

If there are questions regarding the BRIEF or if additional study folders are needed contact Dr. Lisa Sorensen at Chicago.

Any identifiable information that is not a data element (i.e., parent/child name, initials, signature, etc.) on the forms or questionnaires that will be forwarded to the Neurocognitive Core must be blacked out with permanent marker to ensure patient confidentiality. There may be forms (i.e., the teacher contact information form, the teacher consent form, or the neurocognitive report) that will have identifying information on it; these are only to be kept in the patient's local file and the identifying information does not have to be redacted.

## SECTION III: TESTING

### Testing Battery with Time Intervals (age at time of study visit)

| TIMEPOINT | DOMAIN | 2 years to <6 years | | 6 years to <17 years | |
|---|---|---|---|---|---|
| | | PARENT | CHILD | PARENT | CHILD |
| 6 MONTH | Executive Function | BRIEF-preschool (parent only) (10 min) | -- | BRIEF (parent and teacher) (10 min) | BRIEF-self report (age 11+) (10 min) |

| TIMEPOINT | DOMAIN | 3 years to <6 years | | 6 years to <17 years | |
|---|---|---|---|---|---|
| | | PARENT | CHILD | PARENT | CHILD |
| 12 MONTH | IQ | -- | WPPSI-IV (ages 3 to < 7) (45-60 min) | -- | WISC-IV (age 7+) (60-90 min) |
| | Visuo-motor | -- | VMI-6 (20 min) | -- | VMI-6 (20 min) |
| | Attention | -- | K-CPT (age 4-5) (7 ½ min) | -- | Connors CPT-II (15 min) |
| | Adaptive | ABAS-2 (20 min) | -- | ABAS-2 (20 min) | -- |
| | Executive Function | BRIEF preschool (parent only) (age 3+) (10 min) | -- | BRIEF (parent and teacher) (10 min) | BRIEF-self report (age 11+) (10 min) |
| | Post-Traumatic Stress Disorder | -- | -- | PTSD-RI (age 8+) (5 min) | PTSD-RI (age 8+) (10 min) |
| | Depression | -- | -- | Childhood Depression Inventory(CDI-2) (age 8+) (5 min) | Childhood Depression Inventory(CDI-2) (age 8+) (5 min) |
| | | **TOTAL TIME ( 30 min)** | **TOTAL TIME ( 1 hr, 30 min)** | **TOTAL TIME (40 min)** | **TOTAL TIME (2 hrs, 30 min)** |

### Testing/Survey Completion Guidelines

All questionnaires should be reviewed for completeness at the time the child and parent/guardian complete them.

Every effort will be made to have patients complete the required assessments at both timepoints, but patients can still complete the 12 month assessment if the 6 month assessment is not completed.

Each patient will be scheduled for testing at the 6 month and 12 month follow-up visits. Neurocognitive testing at the 6 month visit will take approximately 10 minutes, while testing at the 12 month visit will take approximately 1 to 3 hours, depending on age and other factors.

At the 6 month follow-up visit, study coordinators will administer the BRIEF surveys to parents and patients and send out the teacher BRIEF survey. At the 12 month visit, patient testing will be performed by a qualified staff psychologist or a trained technician under the supervision of a clinical psychologist.

The tools selected for this study are common instruments. If possible, testing should be completed earlier in the day to optimize energy and stamina levels. Brief breaks should also be given as needed. If the child has glasses or hearing aids they should use them during testing. All visits will take place in a quiet, private room without unnecessary interruptions.

**Parent Forms**
At both the 6 month and 12 month visits, the parent/guardian will complete questionnaires. Parent questionnaires can be completed independently in about 10 minutes at the 6 month visit and about 1-1.2 hours at the 12 month visit.

**Teacher Form**
For children age 6 and older, at both the 6 month and the 12 month visit, a teacher BRIEF is sent by the study coordinator to the child's primary teacher (the teacher with whom they spend the most time) for elementary students or the child's English/Language Arts teacher for middle and high school students. For children completing testing during the summer months, the study coordinator should prepare the teacher packet with the prior year teacher's contact info to send when school restarts. Dr. Lisa Sorensen will send a reminder email to the coordinator about this in the fall. The patient's teacher will receive, via regular mail, the BRIEF survey along with a copy of the cover letter signed by the parent and a self-addressed, stamped envelope for its return to Dr. Lisa Sorensen. If the completed questionnaires have not been returned to Chicago within one month post-neurocognitive testing, Dr. Sorensen and her research staff will ask the coordinator to call the teacher or parent to remind them about the questionnaires. The Neurocognitive Core will send additional teacher questionnaires to the site if necessary. The BRIEF can be completed in approximately 10 minutes. The teacher BRIEF cannot be collected from children who are home-schooled or attend "cyber-school".

**Red-Flag Procedures**
Psychologists at the individual participating centers will be responsible for making recommendations for appropriate interventions for abnormalities determined through this research study using good clinical practice guidelines. Trigger questions must be scored before the patient leaves the center. Any action taken must be documented and safety alerts must be reported to the site IRB, if required, and to the Data Safety Monitoring Board (DSMB) regarding referrals for inpatient treatment or for therapeutic interventions. Each site should abide by its institution's standard of care.

## SECTION IV: DATA ENTRY AND SCORING

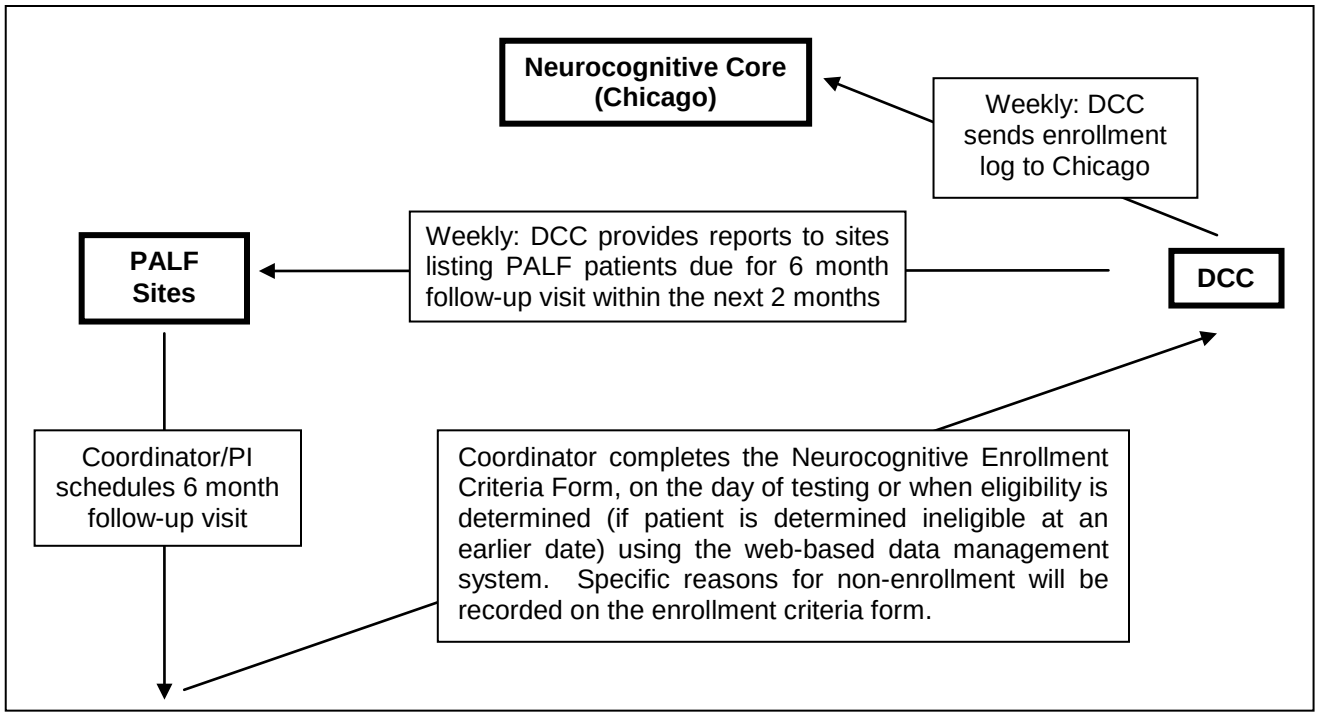
The Neurocognitive Enrollment Criteria form is entered by the coordinator into the PALF Data Management System. The originals are to be kept in the patient's study folder at the site.

The study coordinator will obtain completed surveys and instruments from the patient, parent(s)/guardian(s), and/or site psychologists to be copied. Copies are to be kept in the patient's study folder. The study coordinator will send questionnaires to the Neurocognitive Core Center for central data scoring. After the 6 month visit, BRIEF questionnaires can be sent via password-protected email and after the 12 month visit, originals can be shipped via FedEx. When shipping completed forms to the Neurocognitive Core Center, a FedEx checklist should be completed and included in the provided FedEx envelope.

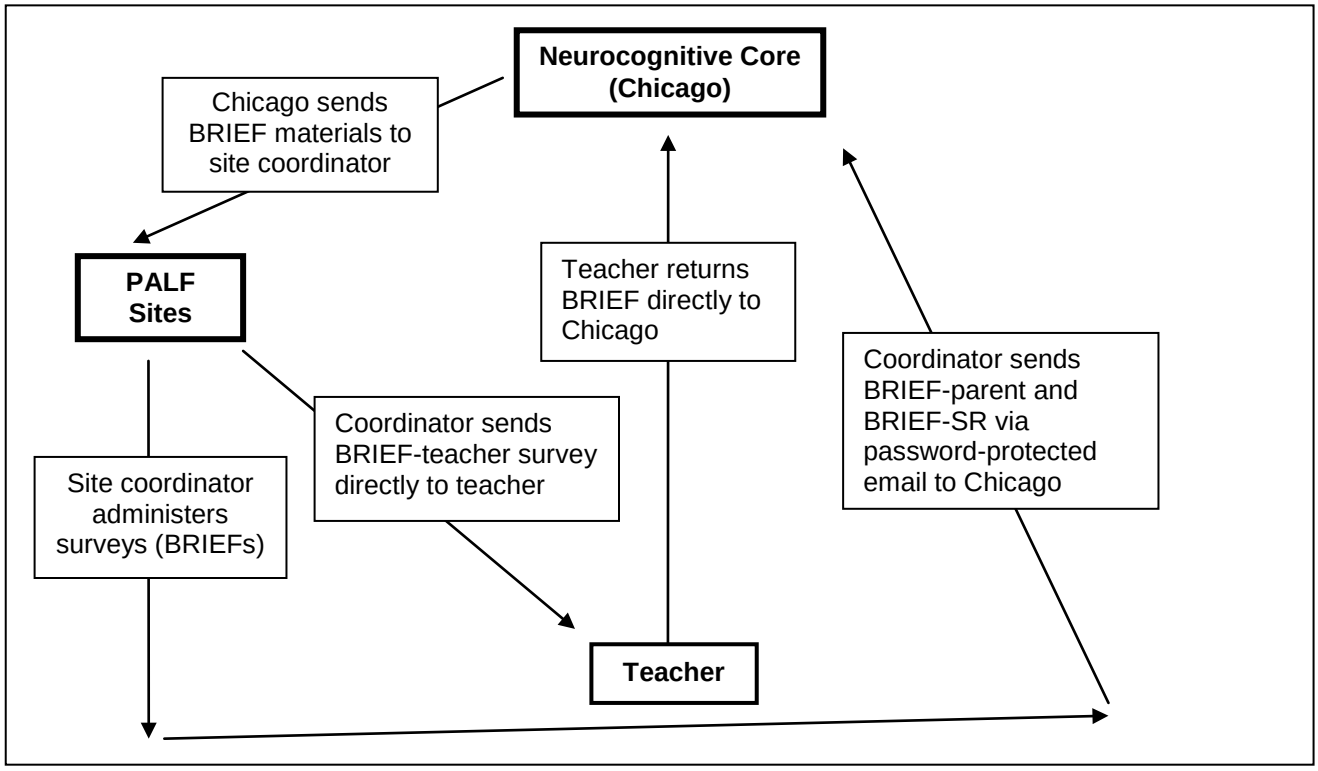
Once the 12 month tests are scored, results of those tests will be sent via password-protected email to the study site within approximately 4-8 weeks after data is received at the Neurocognitive Core. Please note that the results from the 6 month visit will not be sent to the site, unless specifically requested. If an urgent situation arises and the study site needs scores earlier, please contact Dr. Lisa Sorensen via email. The local staff psychologist will prepare a brief report that will be given to the parents. A copy of the report should be placed in the patient's study folder.

## Flow Diagrams for the Neurocognitive Battery Testing

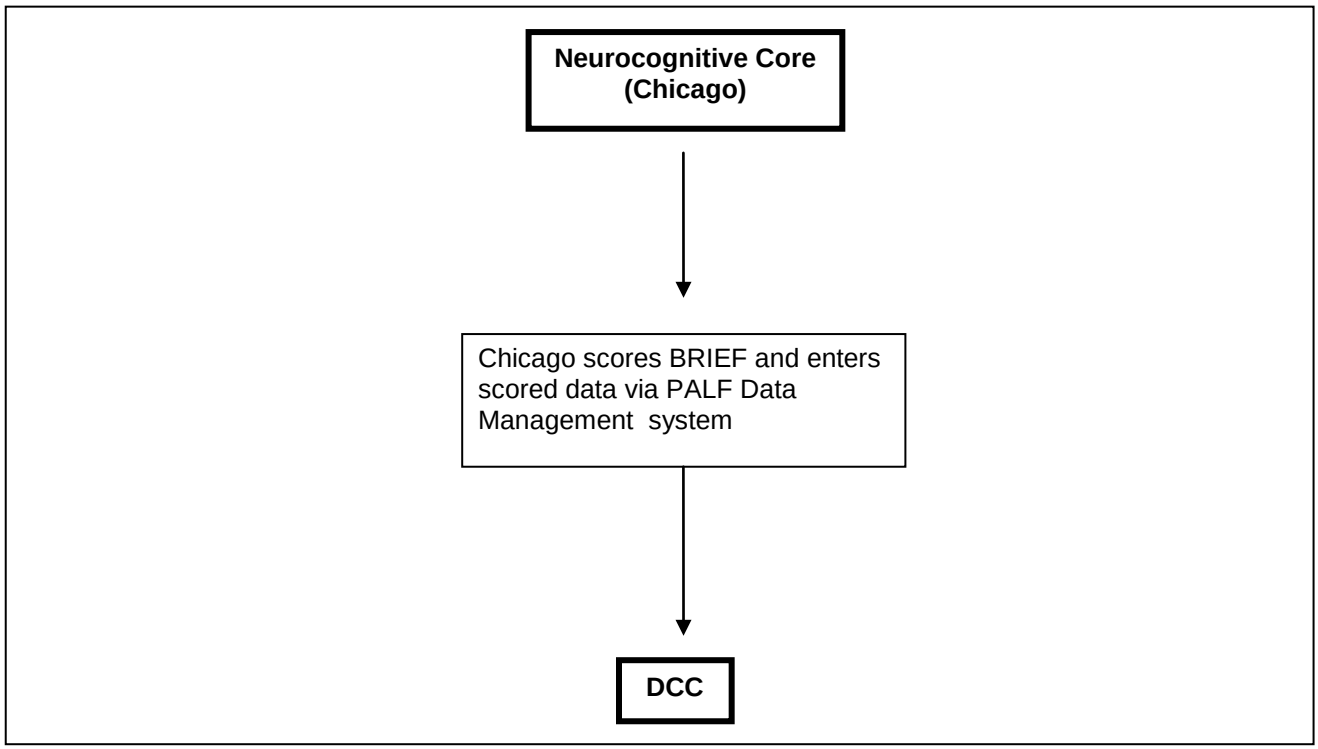
### 1. Enrollment for 6 month visit (window = 5-7 months)



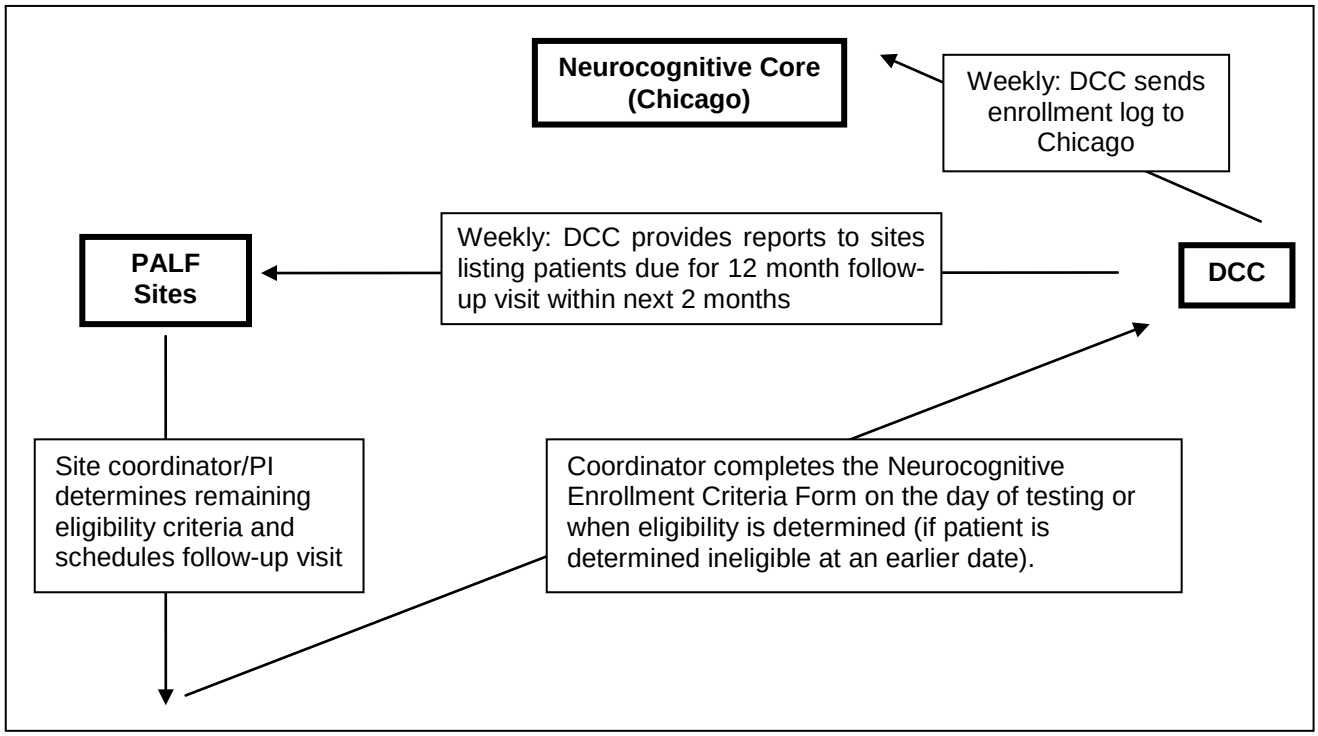

### 2. Testing for 6 month visit (window = 5-7 months)



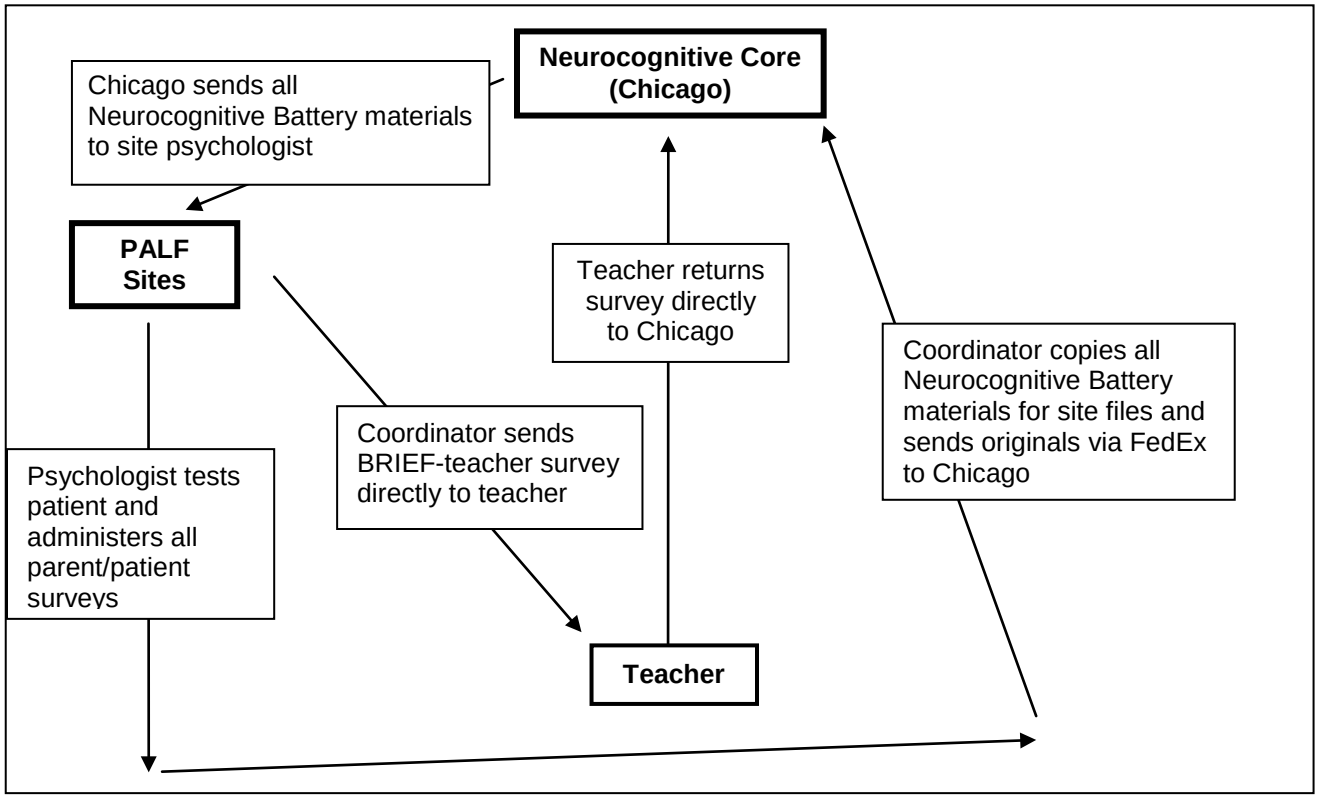
### 3. Scoring and Data Entry for 6 month visit (window = 5-7 months)



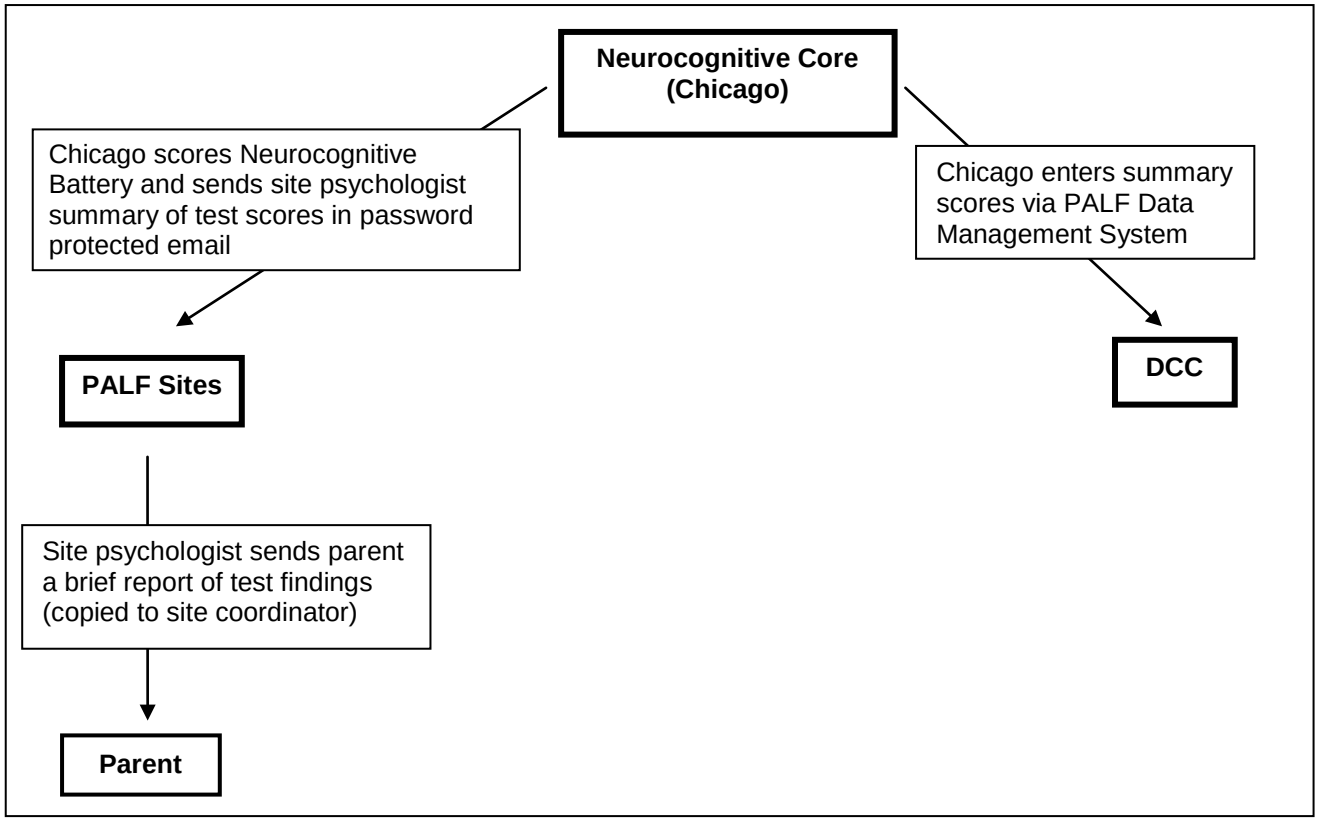

### 4. Enrollment for 12 month visit (window = 10-14 months)



**5. Testing for 12 month visit (window = 10-14 months)**




**6. Scoring and Data Entry for 12 month visit (window = 10-14 months)**



## Appendix A: Descriptions of Instruments used in Neurocognitive Comprehensive Battery

Adaptive Behavior Assessment System-Second Edition (ABAS-II) (5)

The ABAS-II is a comprehensive survey of adaptive skills for individuals birth to 89 years. The parent-report form is designed for use with age 0-21, and yields an overall score: General Adaptive Composite, as well as 3 domain scores: Conceptual (communication, functional academics, self-direction), Social (social skills, leisure skills), and Practical (self-care, home or school living, community use, health and safety). The demographically stratified norm sample included 3,300 individuals.

The Beery-Buktenica Developmental Test of Visual-Motor Integration, 6th Edition (VMI-6) (2)

The Beery VMI-6 is a measure that uses abstract designs to assess visual perception (matching), motor skills (tracing emphasizing speed and precision), and visual-motor integration (copying). The test is normed from age 2-100. The norms for children age 2-18 were derived from a national sample of 1,737 individuals published in 2010. Psychometrics are strong.

Behavior Rating Inventory of Executive Functioning (BRIEF) (6-7)

The BRIEF is a survey of symptoms related to attention and executive functioning, designed to be completed by parents and teachers for children age 5-18. The survey yields composite scores including the Global Executive Composite (GEC), the Metacognition Index (MI) and the Behavioral Regulation Index (BRI). This scale offers the opportunity to quantify observations of naturalistic behaviors related to executive functioning that are difficult to tap in a formal testing situation. In addition, there are measures of negativity and inconsistency of raters. The BRIEF was normed on a demographically balanced sample including 1,419 parent rating forms and 720 teacher rating forms. The BRIEF has been shown to be a stable, reliable measure with high internal consistency and moderately correlated ratings between parents and teachers. Evidence for convergent and divergent validity has been demonstrated with other behavior rating scales such as the BASC and Achenbach Child Behavior Checklist. Empirical evidence for the validity and clinical utility of the BRIEF has been demonstrated in a variety of populations including Attention-Deficit/Hyperactivity Disorder, Traumatic Brain Injury, Low Birth Weight, Mental Retardation and Documented Brain Lesions. In addition, the self-report version of the BRIEF (BRIEF-SR) is designed for use with patients age 11-18 and has the same composite scores and validity scales. The Behavior Rating Inventory of Executive Function – Preschool Version (BRIEF-P) is designed for use with age 2-5 years and yields a Global Executive Composite, as well as three broad indices: Inhibitory Self Control, Flexibility, and Emergent Metacognition (8).

Children's Depression Inventory 2 (CDI-2) (10)

The self-report form is a 28-item survey completed by children age 7-17 that yields a total score and two scale scores (Emotional Problems and Functional Problems) which are derived from 4 subscales (Negative Mood, Negative Self-Esteem, Ineffectiveness, and Interpersonal Problems). The corresponding parent version is also validated for age 7-17 and yields a total score and the same 2 scale scores, but no subscales.

Conners' Continuous Performance Test II (CPT-II) (3)

The CPT-II is a computerized test of sustained attention with strong psychometric characteristics. The patient must respond to frequent targets as quickly as possible and inhibit responses to infrequent distracters over the course of 14 minutes. This test is normed for patients age 6 through adult.

Conners' Kiddie Continuous Performance Test (K-CPT) (4)

The K-CPT is based on the CPT-II and yields the same scores, but is designed for children age 4-5. The K-CPT is half the length of the original CPT-II (7.5 minutes) and requires recognition of pictures rather than letters. This test also has strong psychometric characteristics.

Wechsler Intelligence Scales for Children-4th edition (WISC-IV) (1)

The WISC-IV is the most recent revision (2003) of the Wechsler Scales for school age children. It is a commonly used, well-standardized measure of general intellectual functioning for children ages 6 years 0 months through ages 16 years 11 months. The WISC-IV was normed on a stratified sample of 2200 children. The WISC-IV is comprised of four indices: Verbal Comprehension (VC), Perceptual Reasoning (PR), Working Memory (WM), and

Processing Speed (PS), in addition to the Full Scale IQ (FSIQ). Psychometric characteristics are strong, with reliability estimates ranging from 0.88 to 0.97 for composite scales. Exploratory and confirmatory factor analytic studies strongly support the four index model used in the WISC-IV. For the all ages combined group, the primary loadings for each core subtest onto its corresponding factor are all above 0.62, except Picture Concepts, which is 0.45. The highest primary loadings are for the Verbal Comprehension subtests. All secondary loadings are below 0.20.

Wechsler Preschool and Primary Scale of Intelligence-Fourth Edition (WPPSI-IV) (9)

The WPPSI-IV is an individually administered battery for assessing the intelligence of children aged 2 years 6 months through 7 years 7 months. Published in 2012, it is the most recently updated form of the Wechsler scales for this age range. Several changes have been incorporated into this version including the addition of working memory subtests, new processing speed measures, and expanded test structure to provide more clinical information. The WPPSI-IV provides composite scores in the following areas: Full Scale IQ, Verbal Comprehension, Visual Spatial, Working Memory, Vocabulary Acquisition, Nonverbal, and General Ability for children age 2-3. Additional composites for age 4-7 include Fluid Reasoning, Processing Speed, and Cognitive Proficiency. Normative data for the WPPSI-IV was provided by a sample of 1700 children stratified on key demographic variables based on U.S. census data. The WPPSI-IV is a psychometrically sound measure with reliability estimates ranging from 0.91 to 0.96 for all composite scores except Visual Spatial Index (0.89) and Processing Speed Index (0.86). Several lines of research based on test content, response processes, internal structure, and relationships to other variables support the scale's use as a measure of intellectual ability. The primary composite scores of the WPPSI-IV and WISC-IV are highly correlated (0.84 for General Abilities Index and full Scale IQ; 0.73-0.77 for Verbal Comprehension, Visual Spatial / Perceptual Reasoning, and Fluid Reasoning / Perceptual Reasoning Indices; 0.55 for Working Memory and 0.60 for Processing Speed).

The Abbreviated UCLA PTSD Reaction Index (PTSD-RI) and the UCLA PTSD Reaction Index, Parent Screening Version (11)

The abbreviated PTSD-RI is a nine item screen that can help screen for PTSD after any type of trauma exposure. The abbreviated PTSD-RI is a reliable and easy to administer paper-pencil measure assessing symptoms of trauma in children and adolescents age 8-18. The abbreviated version has good convergent validity and excellent sensitivity (0.93) and specificity (0.87) in detecting PTSD.

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