Required Health and Safety Procedures and Policies during the Coronavirus Pandemic

From Central I-ACQUIRE Study Operations Committee (Sharon Ramey and Warren Lo, Co-PIs; Stephanie DeLuca and Craig Ramey, Directors for the Treatment Implementation Center, Virginia Tech; Jill Heathcock and Amy Darragh, Directors for the Assessment Center, OSU) (4 June 2020)

Purpose: This document serves as an informational source and guide for the policies and procedures required for sites to re-open in the I-ACQUIRE trial after stopping due to the coronavirus pandemic. Recommendations are based on current CDC requirements. It is our intention that the most current CDC requirements be followed throughout The I-ACQUIRE Study period.

Foundational Guidelines: In the interest of the health and safety of our study participants, families, and I-ACQUIRE personnel, the I-ACQUIRE leadership requests that all personnel follow guidelines issued by CDC, NIH, and local & state officials to minimize the spread of the coronavirus that causes COVID-19. Similarly, I-ACQUIRE local sites are required to engage the cooperation of families enrolled in The I-ACQUIRE Study to adhere to the publicly available CDC guidelines as well as local guidelines. We recognize that the CDC guidelines will change as new knowledge becomes available about effective ways to prevent and treat coronavirus/COVID-19. In addition, local and state guidelines vary in response to their conditions, and thus are not always in precise agreement with CDC guidelines. To ensure timely and up-to-date compliance, each local site is responsible for monitoring CDC and local regulations about coronavirus/COVID-19, for communicating these to personnel and families, for providing training as needed for procedures, and for overseeing high levels of adherence to these guidelines as related to conducting The I-ACQUIRE Study.

OVERVIEW. To lift the official designation of "study suspension" for The I-ACQUIRE Study each clinical site must agree to adhere to a plan for re-opening that addresses critical issues to mitigate the spread of contagions. All sites will submit their plan through WebDCU, which should address all health and safety behaviors listed below and including plans for communication with families and review and update of procedures as needed.

Local sites can adopt the Core Health and Safety Procedures (below) as their plan for re-opening.

Local Site Modifications: If a site requires additional procedures or cannot enact the recommended Core Health and Safety Procedures (as recommended by CDC), these must be identified in the site's plan along with an explanation for their inclusion and whether the site anticipates this could affect any aspect of The I-ACQUIRE Study protocol (refer to version 4.0) These additions and/or modifications must be reviewed and approved by the Executive Steering Committee for The I-ACQUIRE Study. The criteria for approval are that the site-specific changes: 1) are unlikely to impact the fidelity of assessment or treatment protocols; 2), meet health and safety standards set by CDC and NIH; and 3) demonstrate respect for and sensitivity to the child and family.

Primary responsibility for health and safety activities. The Local Site PI has primary responsibility to ensure the site plan is implemented and actively monitored for adherence, with corrective actions for any deviations. The PI needs to provide all staff with an orientation and training; to have ready access to all forms for its local documentation; to initiate and be available for needed communication with staff, families, and the I-ACQUIRE leadership; and to monitoring regulations that impact the conduct of the I-ACQUIRE trial at their site.

All plans must address the Core Health and Safety Procedures below. **Click on the blue links below to go directly to each webpage.**

1. **Physical Distancing**: **We require that all I-ACQUIRE staff and family members - other than the child receiving treatment - maintain distances of at least 6 feet whenever possible**. The local I-ACQUIRE team will discuss this in advance with the family to affirm this important safety behavior.

Important to note: The assessor and the therapist cannot socially distance from the child due to the nature of the assessment and treatment activities respectively.

CDC information:
https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/social-distancing.html

2. **Health Tracking and Reporting**: **We require that The I-ACQUIRE Study personnel and participating families monitor and report signs and symptoms of COVID-19 and exposure to others with COVID-19 within 24 hours prior for any in-person study activity (e.g. assessment or in-person screening or consenting) and during treatment**. We provide below the current CDC list of signs and symptoms that can be used along with a question about direct exposure to others with coronavirus/COVID-19 conditions. The child's parent will report to the study personnel (i.e., the Study Coordinator for assessments and the I-ACQUIRE therapist during the 20 days of I-ACQUIRE treatment).The I-ACQUIRE staff members having contact with a study child will report to the local PI and, when appropriate, the family will be notified. NOTE: local sites do not need to submit data to WebDCU from this process of monitoring of signs and symptoms of COVID-19; we do encourage sites to develop a systematic method to assist in local reporting (e.g., distributing a daily reporting log).
CDC information:
CDC signs and symptoms of COVID-19 are updated routinely. Common signs and symptoms, as currently described by CDC, are provided below. This list may not describe all possible symptoms, and the CDC will update this list as more is learned about COVID-19.
https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

Given that assessors, therapists, and study personnel will have prolonged (≥15 minutes) close contact (within six feet or exposure to secretions or excretions) with children, all personnel and families during I-ACQUIRE treatment will monitor and report their symptoms on a daily basis. Note: because items on the checklist overlap with many other health conditions, individuals who have these due to other known conditions would take this into account when they report about new onset of signs and symptoms.

Common signs and symptoms of COVID-19 include:
- Fever (100.4 or higher) or chills
- Cough
- Shortness of breath or difficulty breathing
- Fatigue
- Muscle pain/body ache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Headache
- Nausea, Vomiting, or Diarrhea

3. **Personal Protective Equipment (PPE)**: **We require that I-ACQUIRE staff wear PPE in the form a face mask that meets safety standards for limiting transmission of the coronavirus; optional but highly recommended PPE include hospital scrubs or gown and protective eye gear. Guidelines for cleaning and/or re-using (versus discarding) PPE should be followed strictly**.
CDC information:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html
Consistent with CDC guidelines I-ACQUIRE personnel should wear a mask when interacting with families. For assessment and therapy we highly recommend that goggles & gown/scrubs will be worn in addition to the strict requirement to wear face masks.

4. **Hygiene, Cleaning, and Disinfecting**: **We require that all I-ACQUIRE staff adhere to guidelines about proper hand washing and hand hygiene, as well as cleaning/disinfecting frequently**

touched objects and surfaces. During I-ACQUIRE treatment, we also require I-ACQUIRE staff ask families to adhere to these guidelines about hygiene, cleaning, and disinfecting.

CDC and EPA information:
https://www.cdc.gov/handwashing/when-how-handwashing.html
https://www.cdc.gov/coronavirus/2019-ncov/community/pdf/Reopening_America_Guidance.pdf
https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2

5. **Quarantine and Return to Work/Treatment**: **We require I-ACQUIRE personnel with signs and/or symptoms of COVID-19, a positive test for the coronavirus being active, or close extended contact with a family member or other person known to have the active coronavirus or showing signs and symptoms of COVID-19 to immediately withdraw from all I-ACQUIRE activities involving contact or near proximity to others and to seek prompt medical care.** That individual can return to work only after being medically cleared to do so or fulfilling self-quarantine standards in place (currently, 14 days after exposure or 10 days after positive results from coronavirus test). Similarly, if any family member living with or in contact with the enrolled child meets the above criteria for risk of COVID-19 or transmission of the active coronavirus, then I-ACQUIRE Study in-person activities will cease immediately until affected individuals are cleared medically and/or have fulfilled self-quarantine measures.
CDC information:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html
https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html

6. **What to do if I-ACQUIRE activities are disrupted by adherence to these guidelines?**
If disruptions occur, we will follow the CIRB-approved guidelines in Table 1 below for re-starting treatment and allowing exceptions to the general timeframes for assessments when affected individuals are considered safe and well to return to participation. (see The I-ACQUIRE Study Protocol 4.0.)

Table 1

TIME WHEN ACTIVITIES ARE DISPRUPTED	RE-SCHEDULING PARAMETERS AND IMPACT
Between Baseline and Treatment Day 1	Re-schedule Baseline Assessment.
During the 4 weeks of I-ACQUIRE Treatment (Tx) but prior to Day 17	For a child who has completed 10 or more days, the child would meet the original study exclusion criterion of having had a prior high-dose CIMT treatment. Despite this protocol deviation, we will offer the fully planned I-AQCUIRE treatment when the disruption is mitigated as described in other parts of this document. *The re-scheduling will necessitate collecting a new pre-treatment (baseline) assessment as well as implementing the full I-ACQUIRE treatment.* We anticipate that parents who already have been providing the home component of the I-ACQUIRE treatment will, understandably and ethically, continue to implement their own best version of being supportive of their child's continued positive development. We should not instruct parents to "stop" this –we do not think it could be harmful, nor do we think the coronavirus risk would be affected by this.
Between Day 17 and Day 20 of I-ACQUIRE treatment.	The child will have qualified for receiving what was a priori defined as a sufficiently "full dose" of the treatment. However, we realize that Days 17 – 20 are distinctive because: i) we remove the cast; ii) we concentrate our focus on promoting bilateral activities – during formal therapy session and during parent-enacted home treatment; and iii) at the end, parents and the therapist finalize a post-treatment plan.

During Usual and Customary Treatment (UCT), from start to end of the 4-week period	For children in the UCT group, the local study coordinator or a team member needs to be in contact with a family to determine if there are disruptions in the child's receipt of usual therapy. Note: we will not be advising parents about whether to continue or to stop the UCT that they arrange and for which they are responsible. Any disruption to the child's UCT will result in the need to re-schedule when the trial resumes. As above, this will necessitate scheduling a new pre-treatment (baseline) assessment as well as the treatment month. The child can be > 24 months old when re-scheduled, up to 36 months old.). Finally, it is likely a disrupted UCT period will be associated with a disruption to the Post-treatment Assessment 1 (see below).
At Post-treatment Assessment 1	This can be re-scheduled when the trial resumes. IMPACT: At this time, we are recommending allowing a protocol deviation for this to extend to 3.49 months after treatment ends (rather than the current recommendation of 2 weeks). We may need to re-consider this proposed endpoint for this assessment depending on duration of study suspension.
At Post-treatment Assessment 2 (6 months later)	Re-schedule when the disruption is mitigated. Current protocol allows up to 2 months delay. We hope that this will be adequate for most disruptions. However, we are not certain. We will re-consider whether we will permit obtaining this assessment even later than 8 months post-treatment and notify sites if we propose extending this time window.
For Phase 2, UCT families only: Pre-treatment up to day 1 I-ACQUIRE	Okay to re-consent and re-schedule. All of the above guidelines are the same for the crossover children. If treatment is re-scheduled after the family has re-consented but before treatment has started, then the child will need to have a new pre-treatment assessment 1 (baseline). (For the UCT children, their 6-month assessment serves as their new baseline for the crossover treatment phase.).
During the 4 weeks of Treatment Between Day 17 and Day 20 of Treatment	See above
At Post-treatment Assessment 1	See above
At Post-treatment 2 Assessment (6 months later)	See above

7. **Communication Plan with Families**: **We require that local sites communicate these plans clearly and frequently with participating I-ACQUIRE families**. Centrally, the I-ACQUIRE leadership team will communicate with the Parent Council, StrokeNet, and NIH as appropriate.

Suggested Supplies for I-ACQUIRE Personnel.

The following items are recommended for in-person assessments and I-ACQUIRE therapy sessions:

a. Thermometer
b. Facial Tissue
c. Paper towels
d. Liquid soap
e. Hand sanitizer
f. Disinfecting wipes
g. Gloves
h. Masks
i. Goggles (highly recommended)
j. Covering scrubs or gowns or change of clothes (personally provided) (highly recommended)