

11 March 2021
I-ACQUIRE Webinar
for Site PIs, Co-Is, and Study Coordinators

Sharon Ramey and Warren Lo, Multiple 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



Agenda for Monthly I-ACQUIRE Webinar:
11 March 2021 12:00 – 1:00 p.m. (ET)

1. Calendar of I-ACQUIRE Events – Sharon Ramey
2. Update about sites enrollment – Sharon Ramey
3. Assessment Center Update – Jill Heathcock
4. Treatment Implementation Center Update – Mary Rebekah Trucks
5. Publication Committee Update – Steve Wolf
6. Parent Council Update – Amy Darragh
7. I-ACQUIRE Assessment Process – Karen Harpster – Cincinnati site
8. WebDCU and Data Entry Timeliness – Sara Butler
9. Study Updates – Warren Lo
10. Q & A



Calendar of I-ACQUIRE Events

- **Upcoming dates for Monthly Webinars for PIs, Co-Is, and SCs:**
 - Thursday 22 April (12-1pm ET) – (calendar invite sent)
 - Thursday 13 May (12-1pm ET) – (calendar invite to be sent)
 - Thursday 10 June (12-1pm ET) – (calendar invite to be sent)
- All PowerPoints loaded onto I-ACQUIRE Website for “Webinars” (please encourage all key people to please review these presentations). Very important to have at least one lead representative join Webinar and communicate new information to others at the local site.
- Monthly Webinars separately for Therapists, Assessors, Study Coordinators, and Parent Council (see Website for details).



I-ACQUIRE Clinical Site Progress (11 March 2021)

Clinical Sites	CTA	Released to enroll	Enrolled
Ann Arbor	✓	✓	6
Baltimore	✓	✓	
Birmingham	✓	✓	
Boston	✓	✓	15
Chicago	✓	✓	1
Cincinnati	✓	✓	4
Columbus	✓	✓	5
Houston	✓	✓	
La Jolla	✓	✓	5
New Haven	✓	✓	3
Philadelphia	✓	✓	2
Roanoke	✓	✓	4
St. Louis	Pending	Pending	
Total	12	12	45

Update from Assessment Center



Update from Treatment Implementation Center

Excited by the uptake in recruitment.

Currently, following 8 children and providing feedback on I-ACQUIRE Treatment
VERY BUSY!

Next Therapist Webinar is This Thursday Night

Please remember to let us know ASAP when you have children starting the I-ACQUIRE treatment

Trainings

Multiple periods for this to occur for sites that may need this in the Spring
We now have Summer dates set

Excited for potential new sites



Update Publication Committee

Scheduled call with a few individuals about ideas for development

New user friendly form for gathering information

Thanks to Jenny Murray from the Parent Council



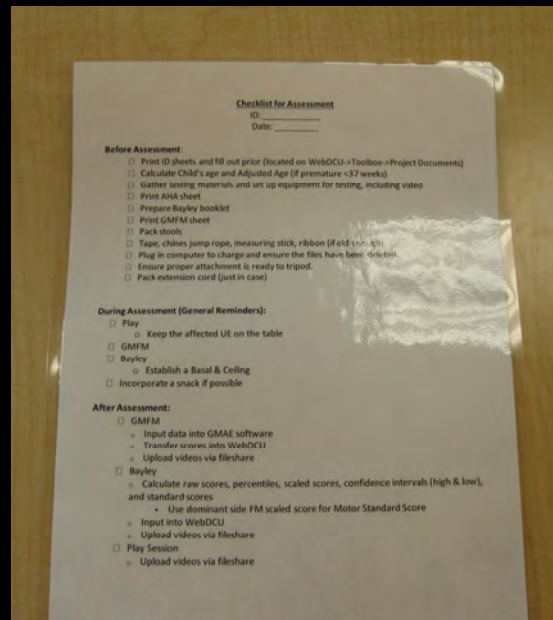
Update Parent Council

- Website is updated – waiting for a couple of items
- Parent Council working on mirroring the website on Facebook to increase opportunities for families
- Parent Council members are fielding questions on community sites (e.g. CHASA) about I-ACQUIRE and referring families to site study coordinators



I-ACQUIRE

Kelly McHugh and Cari Oakes
Cincinnati Children's Hospital Medical
Center



Set up- Seated



Set up- Seated



Set up- Gross Motor



Play Session



Play Session



Play Session



Play Session



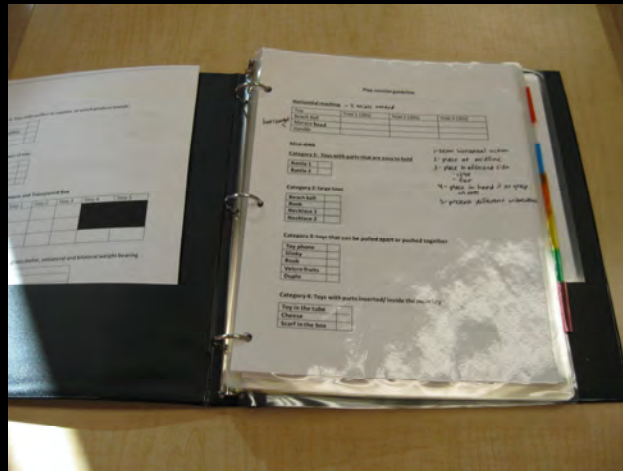
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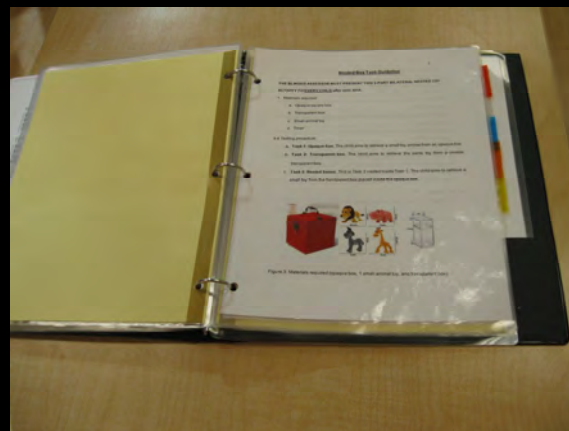
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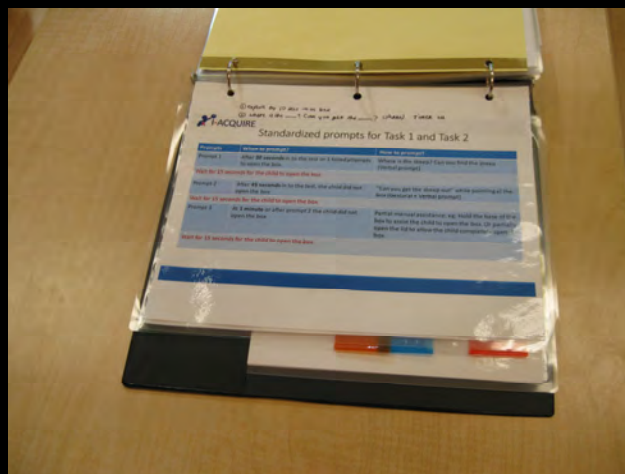
Play Session



Play Session



Play Session



Bayley



Bayley



Bayley



Bayley



Bayley



Bayley



Bayley



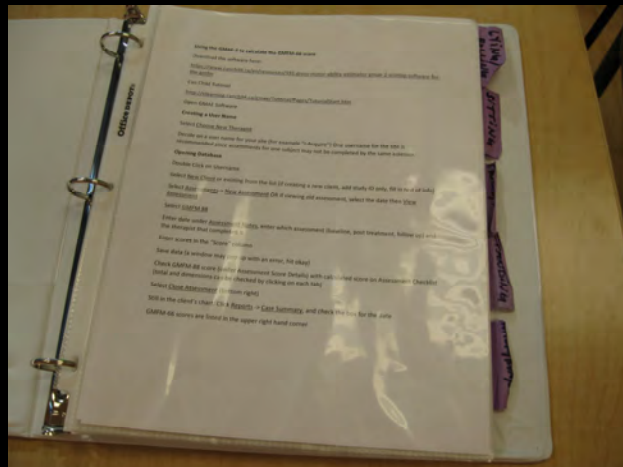
Bayley



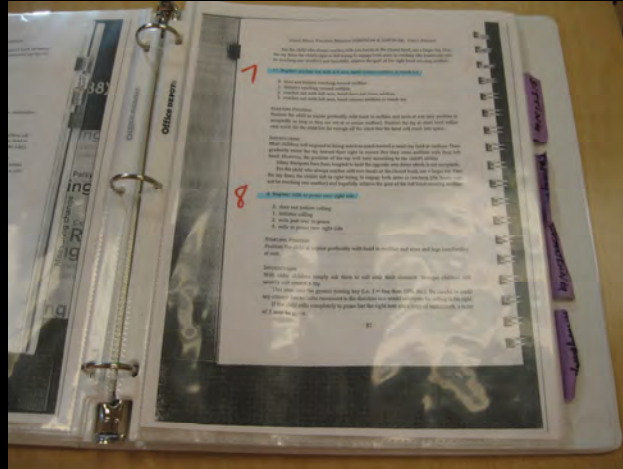
Bayley



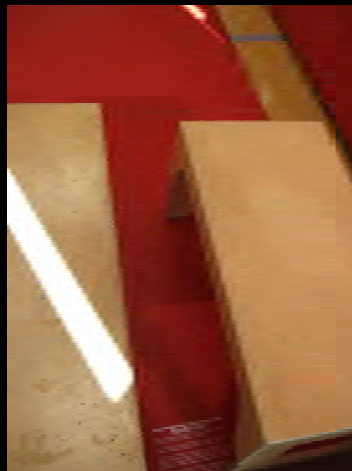
GMFM



GMFM



GMFM- cruising



GMFM- cruising



GMFM- crawling/creeping, transitioning from sitting to quadruped



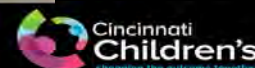
GMFM- crawling/creeping, transitioning from sitting to quadruped



GMFM- stepping over

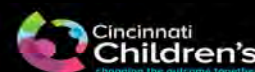


GMFM- stepping over



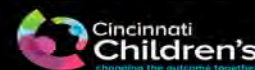
Additional Considerations

- Order of testing
 - Seated tasks first: reaching tasks, seated play session/AHA, then move onto seated Bayley tasks
 - Put lines on floor ahead of time
 - Move to free floor play to complete play session, then Bayley GM and GMFM as able
 - Day 2: Complete any remaining seated tasks from Bayley, then move to floor to complete any remaining GM Bayley and GMFM
 - Day 3 scheduled and canceled if not needed



Additional Considerations

- Have coversheets prepared ahead of time, then briefly stop camera and re-start with new coversheet when starting a new assessment.
- Have additional toys ready ahead of time to use during the GMFM.
- Use caregivers to help motivate during the GMFM and handle the child when appropriate.
- Have a second staff member assist to ensure proper recording, assist with set up, and if another trained BA is available, to help record and score items on GMFM and Bayley.
- Jot down words the child says throughout the assessment.
- Try to put stair items for Bayley and GMFM together



Overview



- Data timeliness has always been important for trials, but new national guidance has put an emphasis on the PIs responsibility to monitor for unanticipated events that on their own do not represent a problem, but in aggregate for the trial may signal something that needs to be corrected.
- This has been an issue for other trials, and I-ACQUIRE has SOOO much data, we want to be proactive now before so much has accumulated that its hard to turn back the statistics from 'bad' timeliness.

Late Visits

- Visit Windows
 - Treatment visits should start ideally 1 – 2 days after the baseline visit but could be up to 14 days after the baseline visit.
 - Post-Treatment visit should be scheduled ideally 1 – 2 days after treatment but could be up to 14 days after the treatment visit.
 - 6 Month Post Treatment Assessment should be scheduled 180 days after treatment (+/- 2 months).
- WebDCU defines a window around each scheduled visit.
- For I-Acquire, since the U&CT and active subjects have different visit sequences its not possible to program the 'usual' narrow windows
- Instead, NDMC statistical programmer is generating reports from the data
 - Visit may appear 'on-time' in WebDCU, but considered late by protocol
- Tools
 - Visit calendar tool
 - Individual site report cards (in progress)



Data Entry Timeline

- DCRs should be responded to within **5 days**
- Enter CRFs within **5 days** of visit date
- Add visit within **5 days** of visit
- Dismiss rule violations within **5 days**
- Reported to Study team bi-weekly
- Reported to DSMB semi-annually
 - To review these violations please go to the [Data Management] tab and click on "CRF Data Entry Report". You can see how these fields are calculated by clicking on the blue number hyperlink next to your sites name.



Monthly Data Entry Emails

- Open DCRs
 - To review these DCRs please go to the [Data Management] tab and click on “DCR Query”. You can filter for open DCRs by clicking on the dropdown page action list in the right-hand corner and select “Open DCRs”. You can go straight to the CRF by clicking on the green arrow under the CRF ID column
- Open Rule Violations
 - To review these rule violations please go to the [Data Management] tab and click on “Rule Violations”. You can go straight to the CRF by clicking on the green arrow under the CRF# column. To address the rule violations, you can either edit the CRF and edit the missing data or dismiss the rule violation explaining why the data is missing. You can only dismiss warning rule violations.
- COVID-10 Impact Assessment
 - Under the [Project Management] tab you will need to click on “COVID-19 Impact Assessment V2”. Click the blue number hyperlink for your site and click “Edit Record”.
- CRFs Pending Submission
 - To review these CRFs please go to the [Data Management] tab and click on “Subject CRF List”. You can filter for pending CRF by clicking on the dropdown page action list in the right-hand corner and select “Passed Validation Not Submitted”. You can go straight to the CRF by clicking on the green arrow under the CRF ID column



Study Updates

- Dr. Sean Savitz is the site PI at Houston
- It is important that we can recruit participants from racial and ethnic minorities so that the study results are relevant to the general population.



Q and A session

