WELCOME TO PR-COIN!!





Agenda

Today's Agenda	
2 minutes	Welcome and agenda
5 minutes	Helpful information about pr-coin
10 minutes	Legal Documents and IRB Reliance
10 Minutes	Questions and Discussion
5 minutes	Next Steps



Helpful information about PR-COIN



Mission/Vision

The mission of the Pediatric Rheumatology Care and Outcomes Improvement Network (PR-COIN) is to improve dramatically, the outcomes of care for all children with rheumatic conditions.





































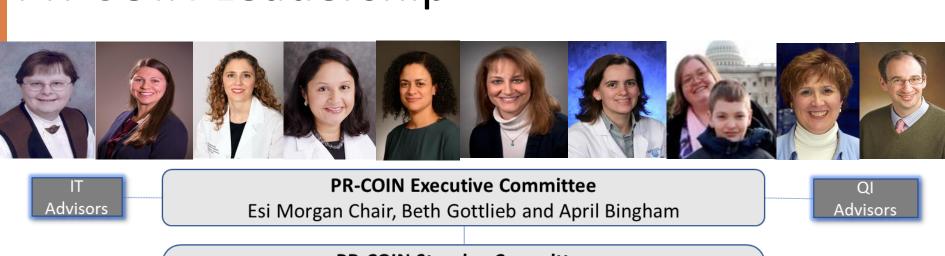






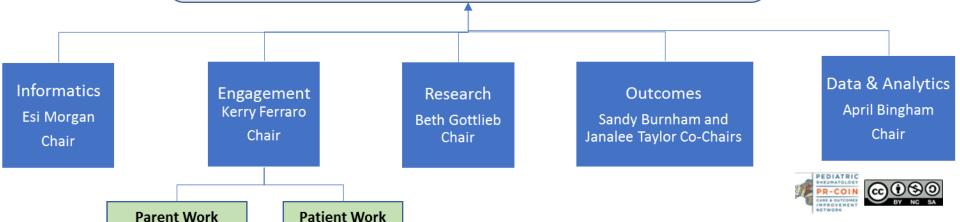
PR-COIN Leadership

Group



PR-COIN Steering Committee

Committee chairs, Judy Olson, Julia Harris, Sheetal Vora, Jen Weiss, Nancy Griffin, Anne Paul Parent representatives: Angela Young, Laura Curtis



Group

PR-COIN Coordinating Center















On-boarding items in progress...

- Doodle poll for QI training
- Choosing your QI focus
- Completing the on-boarding packet and getting access to Sharepoint and newsletter information



Regulatory



Single Institutional Review Board

(Reliance IRB)

Streamlines IRB process by serving as the single reviewing IRB for multi-site research

Your institution "cedes" IRB review to CCHMC Executing an IRB Authorization Agreement (IAA) or a Master Reliance Agreement (MRA)

Over the life of the study, IRB processes will be facilitated more efficiently

Amendments, continuing reviews, and staff changes are submitted, reviewed, and approved by a single IRB



Single IRB Approval Process

- Your site will receive an email with the reliance documents
 - Documents will need to be reviewed and signed by both the local site PI as well as IRB signatories and sent back to IROC IRB Specialist
- Template consents will need to be edited with track changes to comply with your site's IRB specifications
 - Your IRB may require a formal review and approval of these changes prior to sending them to CCHMC
 - Consult with your IRB contact person about the reliance process at your site
- Your site will need to complete the staff listing for staff consenting participants for research
 - Signed and dated CVs, CITI Training, and Licensure will be required for those on the staff listing



Consenting

- All patients that qualify to participate in PR-COIN registry, should be registered into the registry – no consent needed
- Consent is required for the same data to be used for research
- We recommend to enroll all eligible patients and seek consent as time in clinic allows



Review Documents







Legal



DUA and BAA

Data Use Agreement

DUA

 Contract between your center and CCHMC that clarifies how CCHMC handles your center's specific data and how we protect that data.

Business Associate Agreement

BAA

 Clarifies that CCHMC is the business associate, once signed – center agrees that CCHMC acts as business associate and agrees to share PHI with CCHMC.



Legal agreements









Key take away

- Use CCHMC legal templates
- Check if BAA already signed
- Limit changes to what's necessary
- Signature of <u>both</u> legal and IRB required for data to be submitted into registry
- Packet of documents to be emailed and shared with legal/contracts at Site
- Contacts identified within legal team at your site
- Inform IRB that DUA/BAA are getting signed and vice versa

Next Steps

- Anne to email slides and next steps
- TBD to be connected with IRB representative to kick of reliance process
- IRB Contact:
- Legal Contact:



Thank You!



