

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



IT
Advisors

PR-COIN Executive Committee
Esi Morgan Chair, Beth Gottlieb and April Bingham

QI
Advisors

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

Informatics
Esi Morgan
Chair

Engagement
Kerry Ferraro
Chair

Research
Beth Gottlieb
Chair

Outcomes
Sandy Burnham and
Janalee Taylor Co-Chairs

Data & Analytics
April Bingham
Chair

Parent Work
Group

Patient Work
Group



PR-COIN Coordinating Center



Anne Paul
Network Manager



Nancy Griffin: Quality
Improvement Consultant



Stephanie Sullivan: IRB
Specialist



Stephanie Loos:
Registry Informatics
Manager



Kathie Pendergraft:
Communication



Lauren Grooms
Operations



Tingting Qiu: Data
Management Specialist

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



Adobe Acrobat
Document



Adobe Acrobat
Document

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



Microsoft Word
Document



Microsoft Word
97 - 2003 Document



Adobe Acrobat
Document

Key take away

- Use CCHMC legal templates
- Check if BAA already signed
- Limit changes to what's necessary
- Signature of both 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 off reliance process
- IRB Contact:
- Legal Contact:

Thank You!