

2015 Learning Engagement Conference
October 2, 2015

Breakout Session – Data Request Oversight Committee (DROC)

Attendees:

Tamara McMahon, University of Kansas Medical Center
Rachel Gyore, University of Kansas Medical Center
Warren Teachout, Children’s Mercy
Robin Kruse, University of Missouri
Eneida Mendonca, University of Wisconsin-Madison
Kathleen McKay, University of Minnesota
Sarah Gravlin, Cerner
Abu Mosa, University of Missouri

Discussion –

There is a need for requestors to provide better descriptions (more detail) in their data requests – needed are inclusion/exclusion criteria, deliverables, and output variables.

Steps for submitting data requests –

1. Pre-approval: scientific review of the research topic. This is hard to do if not in your area of expertise. All agreed that this step is not the role of the DROC.
2. DROC members review the request, ask questions for clarification, and either approve or deny.
3. Currently, the GPC Governing Council approves the research topic for limited data requests.

The external collaborator agreement is still pending.

Sustainability is important – consideration being given to charging for queries, and rates are still being determined.

What data should be in i2b2 – each site needs to discuss with their technical team.

Turnaround time to review a request – target is 1 week for de-identified data, and 2 weeks for limited data.

Ongoing challenges –

- when requestors meet with their honest brokers, but then submit a request different than what was discussed
- reliance on local IRB’s
- situations where there is no local PI for a study
- investigators access to Babel & ability to use it to develop queries – this is an honest broker issue
- Validating Babel queries – this is an honest broker issue

Questions –

- Is it effective to use the same request form for both the feasibility counts & limited data requests?

- Are different expectations needed for each type of data request – feasibility counts, de-identified, and limited data?
- Feasibility counts – is approval needed?

Links –

<https://informatics.gpcnetwork.org/trac/Project>

Processes for GPC data requests –

1. De-identified data
 - a. Requestor works with local honest broker to discuss request
 - b. Local review of request (may be IRB at some institutions)
 - c. Requestor submits GPC request form
 - d. GPC DROC members
 - i. Review request with their local DROC members (amount of time needed for review varies by institution; target is 1 week review but we haven't reached that goal yet)
 - ii. Address questions or concerns with requestor
 - iii. Approve or deny request on behalf of their institution
 - e. Local honest brokers are responsible for running queries at approving sites
2. Limited data
 - a. Requestor works with local honest broker to discuss request
 - b. Requestor works with local IRB for study approval
 - c. IRB of record approval (this step is coordinated by the GPC IRB rep at the local institution)
 - d. Requestor submits GPC request form
 - e. GPC DROC members
 - i. Review request with their local DROC members (amount of time needed for review varies by institution; target is 2 week review)
 - ii. Review request with local IRB if needed
 - iii. Address questions or concerns with requestor
 - iv. Approve or deny request on behalf of their institution
 - f. Local honest brokers are responsible for running queries at approving sites