Process for Approaching/Approving Projects

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Gary:

1. Give overview of where GPC was
2. Talk about PCORnet Centralized effort that may tie in
3. Get issues on the table that people think may not be addressed by the PCORnet workgroup

- Before funded for Phase 2, GPC recognized need for regulatory process of what kinds of projects were appropriate for GPC
- Initial effort to put together committee with reps from 5-6 sites, plus patients, to develop process for review
- Several conference calls
- Quickly realized information received regarding projects varied widely; developed form asking investigators to succinctly describe project (what it was, what was needed from PCORnet)
- Simultaneously, this issue became priority for CDRN PIs and PCORnet developed Front Door Workgroup

Front Door Workgroup

- Chaired by Adrian Hernandez from coordinating center. 6-7 other people, including G Rosenthal
- Biweekly conference calls
- Developed draft document to go to steering cmte that articulates procedures for projects that could be considered by PCORnet.
    - include at least 1 network
    - must use common data model if it involves CDM elements
    - Would use data sharing agreements, service agreements
    - Clear demonstration how patients were involved in design and conduct, dissemination of findings.
- Goal would be to be let many projects through and then be considered by individual CDRNs. Desire to be equitable wrt to engagement for CDRNs with recognition that some project may be better for some CDRNs.
- Goal also to articulate the process, but then disband. Actual review would be done by research subcommittee. Have not named members of subcommittee.

Recognition that there would be different types of projects that would require different types of reviews. Workgroup has ID'ed 5 types of projects:

1. Rapid Queries – to determine feasibility, in general IRB-exempt
2. Complex Queries – rely just on existing data within i2b2 warehouses or that is within CDM; no other data collection involved. Would generally require IRB approval, no patient consent
3. Utilize existing data and make a linkage to another data source without contacting patients, i.e. CDM links to Medicare data. IRB-approved, waiver of consent.
4. Observational studies – non-randomized that would utilize existing data, but with patient contact for additional patient-reported outcomes data. Typically would require IRB approval, but with minimal risk, abbreviated consent mechanism
5. Full scale interventional – randomizing patients and collecting prospective data from patient and CDM. I.e. Adaptable study.

Some queries would be reviewed by CC and forwarded to CDRNS. Report back numbers of queries done.

Info required to approve projects would differ. ID'ed 3 intake forms- some drafts completed. Used GPC form as a model. Currently undergoing iterative discussion and revision.

Goal is to develop form that could be standard across PCORnet.

GPC approach

- wait for this PCORnet Front Door Workgroup to finish and review their process, then build own committee to look at projects that came out of PCORnet.
- It is possible and likely that we'll get approached by investigators directly who have not gone through PCORnet process.
- Want to make reviews consistent.

Discussion:

- Intake forms are available for review, Gary can send out.
- Standard request form can help standardize data collection.

Will there be a triage process?

- Don't want to lose a promising project, but don't want to be barraged.
- That issue hasn't come up that much. It has been more, what if there is a great project/question, but the proposing team maybe isn't that strong.
- People have different thoughts about how much a GPC committee could work with investigators to hone a project.

There are other models to point to how this has been done nationally, i.e. NCI for 30 years. Why are we reinventing the wheel?

- There is scientific merit question and also is it fit for the network? Fit for network question could be achieved with intake form.
- An underlying tension here is resource needs required to move a great concept forward. How is it done at NCI when someone has a great idea, but their design is not good?
- Currently, NCI asks for a 10page concept application (enough to contain some science but not a full proposal), they consider many aspects like economic feasibility, adaptability, science. A criterion is how does the project match up with the institution and resources? For Brad's group, 7 out of 10 proposals have been rejected. Can't review in isolation. Can also look at ROI. Co-chairs assign reviews each month – multiple scientific, biostats, and others. NCI gets one vote on each proposal. There are 2-hr discussions about reviews. NCI is not driving scientific review process. No direct ask for money on these – they are already funded.
- Pointing out that proposals to NCI are coming from funded research bases meant to drive research; many of them have formed their own committees to vet research. These investigators are submitting as a cooperative group and they are getting guidance and triage at that level.

The CDRNs could help play a triage role before projects go to PCORnet. There should be refinement, vetting, and customization at a sub-level. Without that, could be a free for all.

If GPC plays a role in making projects methodologically better, what are the resources to help improve those projects?

- SCHILS has a committee (Pollock is on it) for this.
- We may do a substantial portfolio of GPC-only projects as we are 12 institutions. For those projects, institutions could pre-vet those proposals before GPC-review.
- The money is going to CDRNs, not a national level, so makes sense to park some of this in GPC.

Individual institutions would have incentive to help mobilize their investigators. What about requests from other entities?

- There is probably a different standard. Our onus is not help the outside people necessarily.
- People can use network for projects looking for PCORI funding as well as outside funding, ie pharma.
- GPC should want to be building partnerships and be inclusive, even with for-profit entities. Would work at a cost – an initial fee? There is some gray area there.
- You have a proposal, two options: partner with someone in a CDRN institutions. Or, you go solo. For someone going solo, there should be a fee for a review. Want to encourage collaboration. Someone going solo could be a pharma company. It's going to be hard to adjudicate this, but may have to be done by GPC.

Big issue in sorting this out is knowing the volume of studies that will come in. There was a period with a lot of requests, people proposing projects to go to PCORI for pragmatic trials.

- It's a good idea to do some screening/intake form or else we might get clobbered.
- Sometimes people are looking for collaborators or participating sites. Letters of support to know that multiple institutions are on board? Would be good to know what CDRNs/institutions are on board. It is more work for the investigator, but that will be respected by reviewers.

May want to consider assigning a level of priority.

- Recognize that moving forward with a project is an investment for GPC.
- May need to specify more request requirements and more complex review for a more complex project request (project types 4 and 5 as outlined by PCORnet).
- Consider that funding is not necessarily coming. Funding type 1 projects are a "loss leader" – at least at first. Make it up on back end on project types 4 and 5.
- GPC will look good if we participate in the national network and open ourselves up for brownie points. Though there may not be more PCORI funding down the road that brownie points are good for.

The only certain way to maintain the network is to have projects that can pay the way. Idea of sustainability for prioritizing or investing in projects is important.

What do projects mean for GPC down the road, do they help us be more viable?

- You could centralize all the small projects for brownie points to show that GPC is doing something, showing usage. Look at what people are using it for to inform where projects are going.
- Classify studies performed and use that information strategically. Portfolio management – what the heck is your institution/CDRN doing? Data elements for each projects – could be used for planning and budget development. Could set that up easily

Principles of a GPC committee

Originally: patient reps, blend of expertise, did not insist that there be a member from each site

The more it works together and performs reviews, it will become more effective – smaller seemed better than larger in this case

Moving forward

- Motivation was that committee could save time on projects that don't need to escalate; making all sites work on every project defeats that time saving
- Agreed that smaller is better and reduce workload through efficiency
- Need biostat and epi reps for study design

- Emphasis that Front Door Group and GPC group be efficient, mindful that investigators may be working towards hard funding deadlines. Front Door Group aimed for ~2wk turnaround
- How do you choose the sites represented on this committee? So far, people we knew, people identified. Did not have a formal nominating process. Need to account for that, consider a process.
    - Potential nominees get categorized by needed expertise.
    - Final selection through governance council.

Comment: Committee should include GPC bandwidth in consideration of a project. Network will reach capacity for some things at different times. Match the review process with resource availability downstream.

- Front Door Group has taken position that they do not want to be exclusionary; want as many as possible to flow to CDRNs.
- GPC definitely need business and projects.
- GPC institutions may have different capacities.
- Always an institution's decision whether to participate.

Comment: We don't want to just dismiss projects that are not strong. We want to help them so that they will get funded and then help GPC. Maybe; that is a very costly process.