Overview
The Greater Plains Collaborative (GPC) is a PCORnet funded network of 12 medical centers (below), located across eight states. Each participating institution signed an IRB Authorization Agreement in December 2014 and the institutions also agreed to establish Standard Operating Procedures (SOPs).

Review and Approval of the Reliance Process

1. Serving as a resource for educating both lead and relying site study teams about the GPC IRB review process.
2. Coordinating and vetting required documents to be submitted by the lead study team to the potential reviewing IRB to help in their determination as to whether they will serve as IRB of Record.
3. Coordinating and vetting required documents to be submitted by the lead study team to the potential reviewing IRB to help in their determination as to whether they will serve as IRB of Record.
4. After a reviewing IRB has been identified, working with relying site IRB POCs to submit reliance decisions, as well as all supporting documentation, to the reviewing IRB.
5. Maintaining information on each institution’s local review requirements and educating study teams on such requirements.

Methods
To implement this approach, the RF utilizes a range of tools and methods to ensure the single IRB review process flows as smoothly as possible for researchers.

• Working With Study Team Before Submission: The RF works with the lead study team early in the protocol design process to help ensure that the protocol addresses sufficient information (e.g., communication plan, recruitment plan) about each potential relying study site. After a reviewing IRB is selected, the RF hosts a conference call with the relying IRB POC, and members of the lead and relying site study teams. The purpose of this call is to review the protocol and address any questions about the IRB review process. The RF also assists study teams in identifying, on a protocol-by-protocol basis, if any local ancillary reviews are needed.

• Vetting of Submission Materials: After the GPC Governance Council approves a study, the RF is responsible for sending a packet of materials to the potential reviewing IRB. The lead study team prepares the following documents: 1) Study Protocol, 2) Template Consent/Authorization Forms and 3) a list of key personnel from each site to create this packet. The RF reviews the documents for completeness. In addition, the RF ensures that the protocol and/or appendices include sufficient information about each study site, including the communication plan, data transfer plan, recruitment plan, and safety monitoring plan. After review, the RF forwards this information to the potential reviewing IRB. The potential reviewing IRB notifies the RF of their reliance decision, after which the RF coordinates with the lead site study team (Figure A).

• Relying Site Reliance Decisions: Once a reviewing IRB has been identified, the RF coordinates with each relying site IRB POC to forward the required reliance documentation, including the GPC Reliance Checklist (developed in 2014 by GPC IRB Administrators – Figure B) to the reviewing IRB.

• Regularly Scheduled IRB Administrator Meetings: The full group of GPC IRB POCs take part in a conference call once a month and meet in person once a year. The RF is charged with creating the agenda, leading the discussion, and taking minutes during the monthly calls. Each ongoing GPC study is discussed and each respective reviewing IRB POC is asked to provide any updates. Additional agenda items are added as needed.

• Participating in GPC Project Manager Meetings: The RF takes part in bi-weekly GPC Project Manager Meetings. During this meeting, the RF presents any IRB updates and is also available to answer questions from project managers and other study team members.

Conclusion
The addition of the RF position has led to several positive changes for both IRBs and study teams within the GPC. There is now one “go-to” person that both study teams and IRB POCs can approach with updates and questions, and my experience is that both groups greatly appreciate being able to call one person to respond to questions. This approach allows the RF to be involved in each step of the reliance process, greatly reducing the chances for errors or confusion during the complex reliance process. Single IRB review can be a difficult task for IRBs and study teams, and this approach can benefit both of these audiences.

References

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