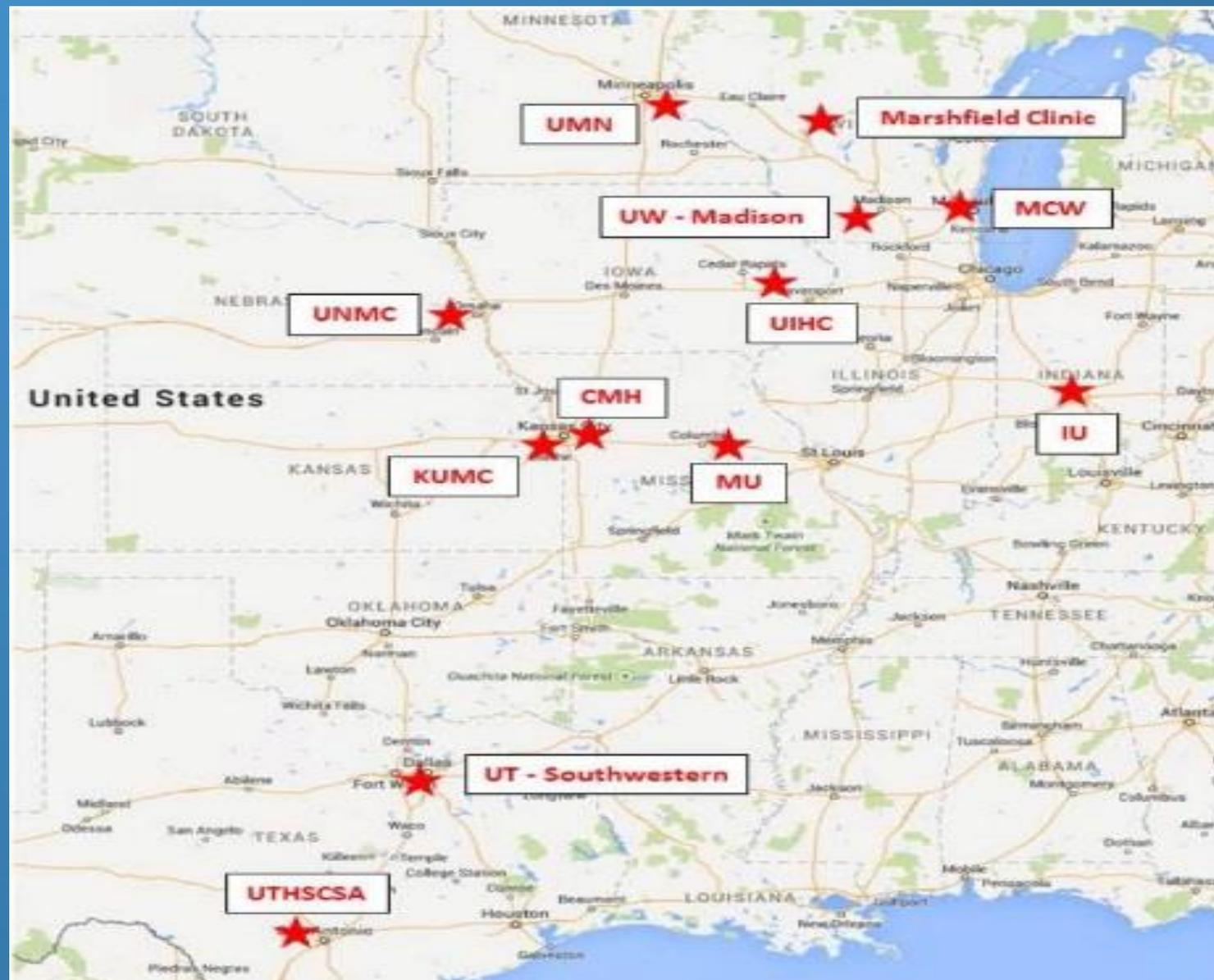


Greater Plains Collaborative IRB Consortium – 2016 LEC

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Introductions



Today's Plan

- 9:10 am – 10:20 am – This session
 - Review of 2015 LEC
 - Discussion on SOPs
 - Other Items/Discussion Topics
- 10:20 am – 10:40 am - Break
- 10:40 am– 12:00 pm – Site Pis
 - Discuss Roles and Responsibilities of Lead and Relying Site Study Teams
 - ADAPTABLE

Today's Plan

- 12:00 pm – 1:00 pm – Lunch
 - Please feel free to continue informal discussions.
- 1:00 pm – 2:30 pm – IRB Group
 - Continue any SOP discussion
 - SMART IRB
 - Debrief on PI Meeting
- 2:30 pm – 3:00 pm – Break
 - Please feel free to continue informal discussions.

Review of 2015 LEC

● Lessons Learned

- The group discussed the need for study team education.
- It was noted that it is difficult for study teams to understand what the review process is, what ceded review means, and who they are supposed to speak with.

Review of 2015 LEC

- Issues the Group Identified
 - Study teams not aware of local requirements.
 - Study did not come as a package.
 - GPC lacks a coordinating center.
 - PI's do not have a detailed understanding of how to run multisite studies.
 - PI's not aware of variations across sites.

Review of 2015 LEC

● Reliance Facilitator

- Act as a “traffic cop” to direct study teams regarding the review process.
- Act as liaison between study teams and IRB.
- Familiarity with each site’s requirements.
- Connect lead study team with reviewing IRB.
- Assemble packet that will be distributed to IRBs.
- Ensure protocol contains sufficient information about each site, including communication plan.
- Alert study teams to institutional requirements.

Updated GPIC SOPs

Reliance Review Process 2014

- Most communication flows between the GPIC POC and the lead study team POC.
- Potential exists for study team to submit incomplete or incorrect documents to the GPIC POC, resulting in delays in a determination of serving as IRB of Record.

Updated GPIC SOPs

Reliance Review Process 2016

- Most communication will now flow directly through the GPIC RF.
- The GPIC RF will work with the lead study team POC to ensure that the package of materials are complete before being sent to the potential reviewing IRB.
- Once package of materials are complete, GPIC RF will distribute to GPIC POC.
- GPIC POC will inform GPIC RF of reliance decision.

Updated GPIC SOPs

GPIC Points of Contact - 2014

- GPIC POC serves as main point of contact for study team POCs.
- GPIC POC responsible for uploading documentation to the GPIC website.
- GPIC POC responsible for coordinating and hosting a conference call with the lead and relying study teams to address any questions about the reliance process.

Updated GPIC SOPs

GPIC Points of Contact – 2016

- GPIC RF will now serve as main point of contact for study team POCs.
- GPIC RF will now be responsible for uploading documentation to the GPIC website.
- GPIC RF will now be responsible for coordinating and hosting a conference call with the lead and relying study teams to address any questions about the reliance process. The GPIC POC will still participate in the call.

Updated GPIC SOPs

Study
Teams
2014 and
2016

- No significant changes to SOP.

Updated GPIC SOPs

Reliance Facilitator Roles and Responsibilities – 2016

- New SOP to reflect GPIC RF role.
- General responsibilities of the position.
- Responsibilities during the GPIC reliance review process.
- Responsibilities after the GPIC reliance review process is complete and 1 or more GPC institutions have agreed to rely on a single IRB of record.

Updated GPIC SOPs

Initial Review Applications and Consent/Authori- zation Documents – 2014

- GPIC POC from reviewing IRB emails
GPIC POCs from relying sites re: study approval.
- GPIC POC from reviewing IRB is responsible for notifying GPIC POCs from relying sites if institutionally required language is updated.

Updated GPIC SOPs

Initial Review Applications and Consent/Auth orization Documents – 2016

- GPIC RF will email GPIC POCs from relying sites re: study approval.
- GPIC RF is responsible for tracking institutionally required language from all sites and notifying relying sites of any updated language.

Updated GPIC SOPs

Review of Continuing Reviews and Amendments – 2014

- GPIC POC notifies all of the GPIC POCs from relying sites of a lapse in IRB approval and any corrective action plans.
- GPIC POC corresponds with relying site POCs on changes in local context, new conflicts of interest and verification of training for new personnel.

Updated GPIC SOPs

Review of Continuing Reviews and Amendments – 2016

- GPIC POC now notifies GPIC RF of a lapse in IRB approval and any corrective action plans. GPIC RF will reach out to relying site POCs.
- GPIC POC will now correspond with GPIC RF on changes in local context, new conflicts of interest and verification of training for new personnel. GPIC RF will work with relying site GPIC POCs.

Updated GPIC SOPs

Access To
IRB and
Study
Documents
– 2014 and
2016

- No changes made to SOP.

Updated GPIC SOPs

Reportable Events, Suspensions, Terminations and Other Notifications – 2014 and 2016

- Updated so that the GPIC RF is included in notifications.
- Discussion topic: This may be an area where we want POCs working directly together on these issues.

Questions/Discussion

- Next Up: SMART IRB Overview

Recap from Thursday

- First Morning Session
 - Review of SOPs
 - Discussion of RF duties
- PI Session
 - Continuing Education
 - ADAPTABLE
- Afternoon Session
 - Continuation of Morning Discussion
 - SMART IRB

Wrap-Up

- Mike will distribute final copies of SOPs next week. We can begin to follow immediately thereafter.
- Steve will work to get Mike notifications of studies after they receive Governance approval.
- Mike will work with Steve to get the updated SOPs and slides onto the GPC website.
- Mike will put together some educational materials based on the slides (such as flowcharts, etc.)

Wrap-Up

- Communication Plan Template
- ADAPTABLE
 - What if we get one of these again? What would help us in the future with a study like this?