

GPC Learning Exchange Conference – 2016
GPC IRB Meeting Notes

Thursday Session 2 – With Site PIs

1. Introductions
2. Genesis was feedback from last year – good to have dialogue between the Site PIs and IRB representatives
3. Reviewed key definitions
4. Reviewed responsibilities of Lead PI and Lead Study Team
5. Reviewed responsibilities of Relying Site Study Team
6. IRB team will provide an example of a Communications Plan (will use INVESTED as an example)
 - a. Could be highly templated in advance
 - b. NIH will provide a model communication plan potentially (?)
7. Recap by Russ Waitman
 - a. Execution of IRB review/approval generally good
 - b. Jim McClay – for Bariatric study, had to disassemble what he got from Group Health and submit to UNMC. Project Manager was primary point person for following up
 - c. Jim suggests Communication Plan (and template) will help
8. ADAPTABLE
 - a. Russ gave background
 - i. GPC only has one site active (Iowa)
 - b. Carol Pech – Struggle with this “in between” type study
 - c. Michele Countryman – Big mix of things to sort out. Difficulty in getting sites participating on calls. Lots of things to sort out – many variables that created a challenge. Potential protocol change coming at a time of final IRB review.
9. Carol Pech – Trying to be agile as things evolve. Can take approach of ramping up a site at a time.
10. Jim McClay – For sustainability discussion, each study requires a body of work. What is the saturation point? Carol – Been lucky that the studies have been distributed between GPC institutions in terms of IRB leadership.
11. SMART IRB overview
 - a. Institutions need to join
 - b. Focused on CTSA and affiliates first
 - c. Each region has an ambassador
 - d. “Enable”
 - e. “Harmonize”