

GPC Learning Exchange Conference – 2016
GPC IRB Meeting Notes

Friday session

1. Recap of Thursday
 - a. Education for research teams
 - i. Didn't really flush things out in terms of continuous reinforcement
 - b. Michele – Outlined what is covered when they meet with Site teams to explain reliance process
 - i. Cover expectations. Want PI and Research Coordinator in attendance
 - c. KUMC does similar approach
 - d. Should there be (or is there from before) a summary of each site's reportable events?
 - e. Iowa has PI sign-off on responsibilities when it is a multi-site study
 - f. Need flow chart or summary of responsibilities as discussed.
 - g. SMART IRB question – Regarding affiliated sites
 - i. Requiring an assessment for affiliates will be difficult
 - h. Reviewed the Joinder process
2. Suggestions for continuing education
 - a. Will come to front and center when NIH requires a communication plan
 - b. Institutional profiles will be applicable to both researchers and IRBs
 - i. Will include local/unique requirements
3. Is there an opportunity for patients to assist IRB?
4. What could we have learned earlier on ADAPTABLE?
 - a. Patients had good recommendations.
 - b. Many questions early on Iowa IRB team had asked about.
 - c. Duke had already approved when they shared the study more broadly – approach was very problematic.
 - d. Need to pick and choose battles.
 - e. Duke IRB should have shared their perspective on why they approved it the way they did. Could have helped.
5. Steve F. to send Mike the RELIANCE trial info.