GPC IRB Meeting/October 1 and 2, 2015

All sites had IRB representation at the meeting. On October 2, 2015, guests that attended the meeting included Gary Rosenthal (University of Iowa), Dan Hale (University of Texas Health Science Center at San Antonio), and Ryan McDowell (Children's Mercy Hospital)

IRB Attendees:
Lynn Baker, University of Texas Southwestern Medical Center
Karen Blackwell, University of Kansas Medical Center
Connie Byrne, Medical College of Wisconsin
Nichelle Cobb, University of Wisconsin-Madison
Laura Conger, University of Minnesota
Michelle Countryman, University of Iowa
Steve Fennel, University of Kansas Medical Center
Germaine Hughes, Children's Mercy Hospital
Michele Kennett, University of Missouri
Gail Paulsen, University of Nebraska Medical Center
Carol Pech, University of Wisconsin-Madison
Lori Scheller, Marshfield Clinic
Kimberly Summers, University of Texas Health Science Center at San Antonio
Amy Waltz (via teleconference), Indiana University

Topic	Notes
Update on status of cohort studies	• **ALS:** this study is up and running and almost complete; no apparent problems occurred during the study; all sites participating • **Breast cohort:** this study is up and running; > 50% response • **Obesity:** most sites up and running except the University of Wisconsin • It was noted that the IRBs spent more time spent on these survey studies than they would if the research had been reviewed internally, but it was further observed that these studies served as a demonstration that the institutions could cede IRB review to one another.

Discussion of survey studies	*Lessons learned*
	• The group discussed the need for study team education
	  ○ Noted that difficult for study teams to understand what the review process is, what ceded review means, and who they are supposed to talk to
	  ▪ An example provided that study teams talking to the wrong IRB office for ceded studies (relying IRB referred relying site study team to the reviewing IRB to address questions)
	  ○ University of Wisconsin noted it is working on multi-site education for PIs – could potentially adapt this for the GPIC
	  ○ Several sites have materials that they developed
	• Issues the group identified
	  ○ PIs not on cohort calls, not connected to regulatory personnel
	  ○ Study teams not aware of local institutional requirements, such as the need to register a study locally
	  ○ Study did not come as a package (e.g., IRBs not receiving complete materials, study being sent to IRBs before all site PIs are identified)
	  ○ GPC lacks a central coordinating center that could assist study teams
	  ○ Some issues not in the IRB's wheelhouse, but not clear that anyone else addressing them
	  ○ PIs do not appear to have a detailed understanding of how to run a multi-site study
	  ○ PIs not aware of variation across sites in resources (e.g., not all sites have i2B2)
	  ○ Concerns raised that IRBs serving the role that coordinating centers/regulatory staff/study coordinators usually fulfill

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	• The need for a position to help study teams and IRBs was identified – the reliance facilitator
	  ○ University of Wisconsin has been allocated a 40% position for a reliance facilitator to provide study teams and IRBs support
	  ○ The group discussed the role and responsibilities of this position
	  ▪ Essentially will act as a "traffic cop" to direct study teams regarding the review process from their perspective and to ensure the IRB review processes is on track (before and after a study is IRB approved)
	  ▪ Orients study teams and serves as liaison between IRBs and study teams
	  ▪ Does not write documents for study teams
	  ▪ Would ensure study teams obtain GPC Governing Council approval of the studies and communicate this information to the IRBs
	  ▪ Assists in the identification of the reviewing IRB
	  ▪ Would be familiar with each site's requirements (local context issues) and help make study team aware of them
	  ▪ Connects Lead Study Team with reviewing IRB
	  ▪ Can make referral should challenging ethical and regulatory issues be identified during the protocol development process
	  ▪ Assembles package that would be submitted to the IRBs, which would include the cede review request, study protocol, delegation of authority log (which includes a list of personnel and the activities they perform for each site), informed consent and HIPAA documents
	  ○ Group agrees that supporting materials not needed at this point (e.g., recruitment materials, study questionnaires)
	  ▪ Ensures the study protocol includes sufficient information about each site, including the communication plan (especially lead PI and all the sites and includes a description of the distribution of IRB-approved documents), data transfer plan, recruitment plan (including how subjects/study cohort will be identified), compliance plan (how information is communicated across participating sites and to the IRB), safety monitoring plan (as applicable), information for the coordinating site
	  ▪ Helps ensure that study teams are aware of and complete required training
	  ▪ Helps ensure study teams have addressed conflict of interest requirements
	  ▪ Assists study teams in identifying any additional institutional requirements that need to be addressed and completed before a study can be activated (e.g., ancillary reviews)
	  ▪ Tracks reliance process metrics
	→ FOLLOW-UP: IRB group agrees that we need to -
	  ○ Develop guidance for study teams on the GPC process, their responsibilities, and what relying on an external IRB means
	  ▪ Several sites, including Children's Mercy (video), University of Minnesota (presentation), and UT Southwestern Medical Center (policies and forms), already have developed educational materials that they will share with the group
	  ▪ University of Texas group has a reciprocity toolkit
	  ○ Develop responsibilities documents for Overall PI/Lead Study Team and Relying Site Study Teams
	  ○ Think about how we qualify investigators and sites for participation
	  ▪ Suggestion to create a site selection questionnaire for this purpose
	  ○ Identify who else at our institution serves as relevant contacts for study team for non-IRB issues (e.g., protocol development resources, data security experts)
	  ○ Use the GPC website as a place to post information for study teams and others about -

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	▪ GPC and the IRB reliance review process ▪ studies and contact and IRB information ▪ educational items ▪ eventually would like to have a restricted area of the website to post confidential information about studies o Develop and post "spec" sheets for each participating institution → FOLLOW-UP: University of Wisconsin will work with their leadership to implement the reliance facilitator position
GPC and GPIC processes	• GPC processes for approving a study were clarified o Governing Council comprised of site PIs meets monthly - Steve Fennel presents to the group and takes a vote ▪ Some IRBs did not know there is a governing body that signs off as a GPC study o It was noted that some non-survey studies went through the Governing Council approval process and some did not o Need sites to "brand" studies as GPC so that IRBs can recognize them as such and route them through the appropriate processes o Questions raised about when site PIs and others have input on the protocol – can this be done earlier? • It was confirmed that GPIC process not just intended to include minimal risk studies and the agreement is not limited to GPC or PCORI studies • Discussed what constitutes a "GPC" study – noted that this is defined broadly and that the Reliance Facilitator to be hired would support any study going through the process • Group agreed that it would be helpful to: o Provide checklist to the study team so they have it before they submit to the IRB. o Identify a designated study team contact to work with reliance facilitator o Revise cede review checklist to encompass 3 options – Will cede: ready, Will cede: pending, Will not cede • Group identified topics for discussion with investigator group on Friday o What does it look like from their perspective (this could help the IRB group better understand the workflow for a study) o Can IRB personnel have about a joint call with the DROC to discuss data exchange issues? o Should IRB personnel attend the global GPC call, which is biweekly ▪ Anyone can listen in on updates to GPC activities – calls are Thursdays at 4 pm o Who is giving IRB updates? ▪ Marc Drezner is providing updates – Cobb to talk with Drezner about providing information o Emphasize the frontloading nature of the information o Ask PIs what they need and whether a reliance facilitator role would be helpful • Other issues raised o Concerns noted that informatics personnel not aware of IRB processes o Concerns raised by a researcher about ensuring IRB staff (e.g., intake personnel) are educated regarding the GPC IRB process • Sites discussed serving as the reviewing IRB o Sites not currently ready to assume such a role - University of Minnesota, University of Nebraska Medical Center, and University of Texas Southwestern Medical Center • Kimberly Summers provided an overview of the process they implemented at University of Texas Health Science Center at San Antonio (UTHSCSA) to separate IRB review from other institutional/regulatory requirements o UTHSCSA has a separate office for institutional reviews, co-located with the IRB

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	office ▪ More personnel are in this office than in IRB office – 4 analysts and a manager o Use an electronic system to route a study to appropriate entities for review and sign off o Issue a letter after all requirements met to indicate when a study can be activated - letter releases the approved documents, which prevents the study teams from preceding with just IRB approval o Took 2 years to set up
SOP discussion	*SOP Review: Reliance Process* • Group agreed to eliminate timeframe in this SOP • Need to revise the SOP to not require sign off from the GPC Governing Council for non-GPC studies *SOPs in general* • Everyone agreed that the parent-child model of IRB review continues to be acceptable (i.e., IRBs can go ahead with review and approval for sites that are ready with others will added via an amendment) • Once reliance facilitator role finalized, SOPs need to be revised to reflect the role and responsibilities of this position • IRBs will need to communicate with reliance facilitator about any changes to site consent documents
National IRB model discussions and initiatives	• IRBrely updates o The NCATS initiative was described ▪ IRBrely proposes to implement a standard IRB authorization agreement and SOPs that can be used among CTSA sites and beyond ▪ The agreement and SOPs are almost complete and are being tested through a pilot project ▪ An informatics platform is being developed to support IRBrely, especially to allow participating institutions to communicate with one another regarding reliance requests and determinations regarding whether to serve as the reviewing IRB or cede IRB review o Several GPC members reviewed the draft agreement and SOPs and provided feedback o Several GPC members also are participating in the IRBrely pilot project that involves Duke University as the reviewing IRB for a registry study • PCORI IRB Working Group updates o The working group was formed to identify a national IRB model for PCORI studies o The group has met via teleconference several times and involves IRB personnel from across the country o Presentations to the working group thus far have been about IRBShare, IRBChoice, and the NeuroNeXT model o IRBrely will present in a couple of weeks o Cobb asked for feedback from GPIC regarding the model they would prefer ▪ Group consensus is the reliant review model, similar to what is used for the GPC ▪ Did not support IRBShare or a central IRB model ▪ Recommended raising the issues of having a reliance facilitator role
Responsibilities of lead PI	• The group reviewed the document, *Guidance on Investigator-Initiated Multicenter Research*, created by Northshore/LIJ Health System Office of Research Compliance and agreed that the Overall PI/Lead Study Team are responsible for: o Promptly responding to questions or requests for information from study teams at Relying Institutions or the Relying IRB.

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	○ Providing the study teams with the IRB policies of the Reviewing Institution, including reporting unanticipated problems, noncompliance, and subject complaints. ○ Obtaining and collating information regarding local variations in study conduct, such as in regard to recruitment materials and process, consent process and language, and subject identification processes. This responsibility would involve working with the Reliance Facilitator. ○ Participating in conference calls regarding a study as requested. ○ Providing participating Relying Site Study Teams with the IRB-approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials). ○ Assisting Relying Site Study Teams in ensuring consent documents follow the Reviewing IRB's template form and include applicable site-specific required language from each Relying Site. This responsibility would involve working with the Reliance Facilitator. ○ Promptly reporting to the Relying Study Team any unanticipated problems involving risks to subjects or others, subject injuries, or subject complaints that are related to or may affect subjects participating in the Research (i.e., the specific study or studies ceded to the Reviewing IRB) at the Relying Site. ○ Notifying Relying Site Study Teams of all Reviewing IRB determinations and communications, including those for initial review, continuing review, amendments, and reportable events. ○ Reporting to the Reviewing IRB as part of its continuing review submission if a Relying Site Study Team does not provide the Lead Study Team (or designee) with the required information before the continuing review application is submitted to the Reviewing IRB, reporting the absence of this information as part of the continuing review and notifying affected Relying Site Study Team of lapse in approval for their site and any applicable corrective action plans. ○ Providing access, upon request, to study records for audit by the Relying Site, the Reviewing IRB, and other regulatory or monitoring entities. ○ Following all requirements of the Relying IRB or organization with regard to ceded review, such as ensuring administrative requirements for documenting ceded review have been met before study activation occurs at a Relying Site. ○ Creating a communication plan for the study that includes dissemination of information, collection of information from sites for initial review, continuing review, amendments, reportable events ○ Identifying the relying site PIs and key study personnel (e.g., study coordinator) ○ Having a plan for monitoring protocol compliance at all sites, which includes quality control of data, informed consent documents, eligibility checklists, data entry, AE reporting ○ Ensuring adequate personnel and/or resources to manage the study ○ Having a data storage and exchange plan ○ Having a plan for sample shipping and storage ○ Identifying laboratories that will be used for the study ○ Having a plan for return of laboratory or study results ○ Consulting with prospective PIs to determine study feasibility
ADAPTABLE study	• Slide deck distributed for prior review • Informed Consent Document discussion still underway • Central group open to incorporating standardized language for HIPAA or allowing sites to including a link that would allow them to go for additional information • Looking to modify exclusion/eligibility criteria to make it minimal risk (want to avoid compensation for injury language)

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	• Reimbursement per patient nominal – study will only work if patients can be enrolled online
	• Discussion of informed consent process vs. informed consent document
	• Discussion of subject identification and potential challenges
	  ○ Rosenthal notes that potential subjects will be identified through query of electronic medical records based on certain criteria then contacting participants; could contact via letter or email and then given a link to read
	  ○ Questions raised about
	  ▪ Who is going to review the lists to eliminate certain individuals (e.g., prisoners, individuals with impaired decision-making capacity)
	  ▪ How it will subject comprehension will be ensured
	  • May be links to questions to confirm
	  ▪ How it will be ensure that subjects have the capacity to provide consent on their own behalf
	  ▪ How it will be assured that the person providing consent is the person intended to be enrolled in the study
	  ▪ How it will be ensured that someone is only enrolling once
	  ▪ How enrollment of prisoners would be handled
	  ▪ Whether potential subjects are already on aspirin
	  • Concerns about whether minimal risk for aspirin naïve
	  ▪ How information that a person is now on aspirin or a particular dose is recorded in the medical record
	• Discussion of use of email addresses to research participants - letter had a link to electronically
	• Vanderbilt expected to complete its review by early November
	• Want to enroll first patient in early January
	• Appears to be flexibility in IRB model
	• Sites' involvement appears to be limited to identification and recruitment but also might be involved with follow-up contact if the coordinating center cannot reach participant; follow-up is through coordinating center
	• Agree that study not FDA-regulated (notes electronic consent issues there and that this study could help work out some of these issues)
	• Fennel to send Countryman/Iowa a list of ADAPTABLE site leads

Future Friday session topics	*Add to calls* • How do we work with Sponsored Programs groups on studies/trials that utilize IRB cede models ○ Iowa doing a presentation on External/Central IRB models • Medical College of Wisconsin using LEAN process to assess reliance process – cover findings at February 2016 call
Action Items	• Blackwell and others will attend the study investigator section later in the afternoon to provide and obtain feedback about IRB processes for the next stage of the grant • Fennel to send Countryman/Iowa a list of ADAPTABLE site leads • Cobb will work with a subgroup of the IRB group (Byrne and Countryman) to adapt documents developed by Cindy Hahn for study teams conducting multi-site research for the GPIC (this includes development of a site selection questionnaire) – get draft to Baker by 10/30 • ALL sites will send to list-serv materials or links to materials they have developed to educate study teams regarding multi-site research or what reliant review means ○ Pech will work with new education person at University of Wisconsin to develop study team educational materials for GPIC • Cobb and Pech will work with University of Wisconsin leadership to implement reliance facilitator role – Pech to flesh out reliance facilitator position description • Pech to revise SOPs to address revised cede review form, reliance facilitator role, and to

Topic	Notes
	eliminate in the reliance review SOP the references to timeframes and sign off from GPC Governing Council when study is not a GPC study • Cobb to bring idea of a facilitator role back to central PCORNet • Countryman to revise cede review form in accordance with categories identified at meeting (i.e., Will cede: ready, Will cede: pending, Will not cede) • ALL sites will develop "spec" sheets regarding key institutional requirements • Fennel will share GPC Governance Policy and Milestones with the IRB group • Fennel will work with Pech to identify IRB information that should be posted on the GPC website – Hilary Weedman can assist with updating the website o Would like to post documents about ▪ Overall PI/Lead Study Team responsibilities ▪ Implications for study teams when IRB review is ceded • Fennel to share information about schedule and how to access global GPC calls o Cobb to talk with Marc Drezner about IRB updates being provided on global GPC calls