NIH Collaboratory Rethinking Clinical Trials®
Health Care Systems Research Collaboratory

Ethics and Regulatory Core

Lumbar Image Reporting with Epidemiology (LIRE)

Jeffrey Jarvik, MD, MPH

Meeting Participants (May 16, 2013):

☒	Jeremy Sugarman (Johns Hopkins)	☒	Barbara Young (Group Health)	☒	Julie Kaneshiro (OHRP)	☒	Cheri Janning (Coord Center)
☒	Rob Califf (Duke)	☒	Heidi Berthoud (Group Health)	☒	Catherine Meyers (NIH)	☐	
☒	Jerry Jarvik (Univ Wash)	☒	Jerry Menikoff (OHRP)	☒	Jim Panagis (NIH)	☐	
☒	Katie James (Univ Wash)	☒	Irene Stith-Coleman (OHRP)	☒	Amy Patterson (NIH)	☐	

The minutes from the May 16, 2013 meeting were circulated to all participants on the call for two rounds of review and they reflect all corrections that were received.

AGENDA ITEMS	DISCUSSION May 16, 2013	PROPOSED ACTION May 16, 2013	CURRENT STATUS as of May 11, 2015
Review of Demonstration Project	• Dr. Jarvik gave an overview of the LIRE project. The study's main hypothesis is that, for patients referred from primary care providers, inserting epidemiological evidence in lumbar spine imaging reports will reduce unnecessary subsequent diagnostic and therapeutic interventions, including cross-sectional imaging (MR/CT), opioid prescriptions, spinal injections, and surgery.		

	• Sites: ▪ Group Health Cooperative (GHC) Site PI: Dan Cherkin, PhD ▪ Henry Ford Health System (HFHS) Site PI: Safwan Halabi, MD ▪ Kaiser Permanente of Northern California (KPNC) Site PI: Andy Avins, MD, MPH ▪ Mayo Clinic Health System (MCHS) Site PI: David Kallmes, MD		
Minimal risk	• The rationale for considering the project to be minimal risk was presented by the study team. • The rationale as presented by the study team is included in the appended document. • No objections or concerns were raised by participants regarding a minimal risk determination.	• A case study will be drafted to provide guidance for others wishing to evaluate similar decision support that does not direct therapy.	
Consent (patient and physician)	• Justification for a waiver of consent was reviewed and no objections or concerns were raised by the group regarding it. • The rationale as presented by the study team is included in the appended document.	• This will be added to the case study.	The project is using a minimal risk protocol with waiver of consent for both patients and providers. Thus, there has been no change since the initial discussion.
HIPAA	• Dr. Jarvik feels that criteria for HHS Regulation 45 CFR 164.512 were satisfied and a waiver of HIPAA is acceptable.	• This will be added to the case study.	The project is using a minimal risk protocol with waiver of HIPAA authorization. Thus, there has been no change since the initial discussion.

Monitoring and oversight	• The designated Safety Officer, Steven Atlas, MD, has agreed to review study data at regular intervals for any safety concerns. • The data safety and monitoring plan is not yet finalized but this will be done prior to the beginning of the study. • Dr. Jim Panagis indicated that this approach is in compliance with NIH/NIAMS data and safety monitoring policies.	• Finalize the data safety and monitoring plan. • This will be added to the case study when it is complete.	The project is using a Data and Safety Monitoring Plan with two safety officers. Safety endpoints of emergency department visits within 90 days of index image and death within 6 months.
Issues beyond the LIRE trial	• There was a brief discussion regarding decision support tools that include therapeutic recommendations. Several opinions were expressed that if the recommendations were within the standard of care for the condition being studied, minimal risk might still pertain, but not when recommendations extended beyond the standard of care. • No definitive conclusion was reached.	• Further discussion needed.	
Conclusion of meeting	• All meeting participants felt that it was reasonable for the LIRE project to continue its planning activities for implementation.		
Additional regulatory or ethics issue(s) that arose after the meeting			No additional regulatory issues have been encountered other than the inability to consolidate IRB review beyond KPNC ceding to GHC for review. The other two implementation sites have their own IRB and were unwilling to cede.
Additional follow-up information			None noted.