

**Lumbar Image Reporting with Epidemiology (LIRE)**

Jeffrey Jarvik, MD, MPH



**Ethics and Regulatory Core**

**Lumbar Image Reporting with Epidemiology (LIRE)**

Jeffrey Jarvik, MD, MPH

**Meeting Participants (May 16, 2013):**

<input checked="" type="checkbox"/>	Jeremy Sugarman (Johns Hopkins)	<input checked="" type="checkbox"/>	Barbara Young (Group Health)	<input checked="" type="checkbox"/>	Julie Kaneshiro (OHRP)	<input checked="" type="checkbox"/>	Cheri Janning (Coord Center)
<input checked="" type="checkbox"/>	Rob Califf (Duke)	<input checked="" type="checkbox"/>	Heidi Berthoud (Group Health)	<input checked="" type="checkbox"/>	Catherine Meyers (NIH)	<input type="checkbox"/>	
<input checked="" type="checkbox"/>	Jerry Jarvik (Univ Wash)	<input checked="" type="checkbox"/>	Jerry Menikoff (OHRP)	<input checked="" type="checkbox"/>	Jim Panagis (NIH)	<input type="checkbox"/>	
<input checked="" type="checkbox"/>	Katie James (Univ Wash)	<input checked="" type="checkbox"/>	Irene Stith-Coleman (OHRP)	<input checked="" type="checkbox"/>	Amy Patterson (NIH)	<input type="checkbox"/>	

**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.**

<b>AGENDA ITEMS</b>	<b>DISCUSSION</b> May 16, 2013	<b>PROPOSED ACTION</b> May 16, 2013	<b>CURRENT STATUS</b> as of May 11, 2015
<b>Review of Demonstration Project</b>	<ul style="list-style-type: none"> <li>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.</li> </ul>		

**Lumbar Image Reporting with Epidemiology (LIRE)**

Jeffrey Jarvik, MD, MPH

	<ul style="list-style-type: none"> <li>• Sites:             <ul style="list-style-type: none"> <li>▪ Group Health Cooperative (GHC) Site PI: Dan Cherkin, PhD</li> <li>▪ Henry Ford Health System (HFHS) Site PI: Safwan Halabi, MD</li> <li>▪ Kaiser Permanente of Northern California (KPNC) Site PI: Andy Avins, MD, MPH</li> <li>▪ Mayo Clinic Health System (MCHS) Site PI: David Kallmes, MD</li> </ul> </li> </ul>		
<b>Minimal risk</b>	<ul style="list-style-type: none"> <li>• The rationale for considering the project to be minimal risk was presented by the study team.</li> <li>• The rationale as presented by the study team is included in the appended document.</li> <li>• No objections or concerns were raised by participants regarding a minimal risk determination.</li> </ul>	<ul style="list-style-type: none"> <li>• A case study will be drafted to provide guidance for others wishing to evaluate similar decision support that does not direct therapy.</li> </ul>	
<b>Consent (patient and physician)</b>	<ul style="list-style-type: none"> <li>• Justification for a waiver of consent was reviewed and no objections or concerns were raised by the group regarding it.</li> <li>• The rationale as presented by the study team is included in the appended document.</li> </ul>	<ul style="list-style-type: none"> <li>• This will be added to the case study.</li> </ul>	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.
<b>HIPAA</b>	<ul style="list-style-type: none"> <li>• Dr. Jarvik feels that criteria for HHS Regulation 45 CFR 164.512 were satisfied and a waiver of HIPAA is acceptable.</li> </ul>	<ul style="list-style-type: none"> <li>• This will be added to the case study.</li> </ul>	The project is using a minimal risk protocol with waiver of HIPAA authorization. Thus, there has been no change since the initial discussion.

## Lumbar Image Reporting with Epidemiology (LIRE)

Jeffrey Jarvik, MD, MPH

<p><b>Monitoring and oversight</b></p>	<ul style="list-style-type: none"> <li>The designated Safety Officer, Steven Atlas, MD, has agreed to review study data at regular intervals for any safety concerns.</li> <li>The data safety and monitoring plan is not yet finalized but this will be done prior to the beginning of the study.</li> <li>Dr. Jim Panagis indicated that this approach is in compliance with NIH/NIAMS data and safety monitoring policies.</li> </ul>	<ul style="list-style-type: none"> <li>Finalize the data safety and monitoring plan.</li> <li>This will be added to the case study when it is complete.</li> </ul>	<p>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.</p>
<p><b>Issues beyond the LIRE trial</b></p>	<ul style="list-style-type: none"> <li>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.</li> <li>No definitive conclusion was reached.</li> </ul>	<ul style="list-style-type: none"> <li>Further discussion needed.</li> </ul>	
<p><b>Conclusion of meeting</b></p>	<ul style="list-style-type: none"> <li>All meeting participants felt that it was reasonable for the LIRE project to continue its planning activities for implementation.</li> </ul>		
<p><i>Additional regulatory or ethics issue(s) that arose after the meeting</i></p>			<p>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.</p>
<p><i>Additional follow-up information</i></p>			<p>None noted.</p>