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NIH Collaboratory Ethics and Regulatory Core: UG3 Consultation Call
Implementation of the American College of Physicians Guideline for Low Back Pain (IMPACt-LBP)
October 14, 2021; 4:00-5:00 pm ET (via Zoom)

Attendees:

- Core and Coordinating Center: Joe Ali (Johns Hopkins University), Judith Carrithers (Advarra), Andrew Garland (Johns Hopkins University), David Magnus (Stanford University), Stephanie Morain (Johns Hopkins University), Pearl O'Rourke (retired), Tammy Reece (Duke University), Damon Seils (Duke University), Jeremy Sugarman (Johns Hopkins University), Kevin Weinfurt (Duke University), Dave Wendler (NIH)
- Demonstration Project team: Christine Goertz (Duke University), Adam Goode (Duke University), Jon Lurie (Dartmouth University), Kelley Ryan (Duke University)

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Brief review of Demonstration Project	Meeting attendees received the Research Strategy and Resource Sharing Plan for IMPACt-LBP's Coordinating Center and Data Coordinating Center with the meeting agenda. Core members, IMPACt-LBP team members, and staff of the NIH Collaboratory Coordinating Center introduced themselves. The IMPACt-LBP team members present included Christine Goertz, Adam Goode, Jon Lurie, and Kelley Ryan. **Project overview**: Principal investigator Jon Lurie gave a brief overview of the project. IMPACt-LBP is studying implementation of the primary spine provider (PSP) model of multidisciplinary collaborative care for low back pain in primary care. **Healthcare system partners**: Dartmouth-Hitchcock Medical Center, Duke University Health System, University of Iowa		The Demonstration Project is being implemented as described.

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	NIH Institute Providing Oversight: National Center for Complementary and Integrative Health (NCCIH). Additional support from National Institute of Arthritis and Musculoskeletal and Skin Diseases and National Institute of Child Health and Human Development. **Study design**: The project will be a pragmatic, multisite, 2-arm cluster randomized trial that will evaluate the effect of first-contact patient referral to PSPs (physical therapists and doctors of chiropractic). The study aims to determine if initial contact with these PSPs will improve outcomes for patients with a primary complaint of low back pain, compared with usual medical care. **Outcomes**: The co-primary outcomes will be patient-reported changes in PROMIS Pain Interference and PROMIS Physical Function from baseline to 3 months. Secondary outcomes include opioid prescriptions; PROMIS measures of pain intensity, catastrophizing, sleep, and depression; health-related quality of life and satisfaction; and procedures, prescriptions, and hospital and emergency department visits at baseline and 1, 3, 6, and 12 months. Additional data collection will be done through 24 months on a subset of patients enrolling during the first 18 months of recruitment. Core members had no questions about the project overview.		
Status of IRB approval	Jeremy Sugarman asked about the status of IRB approval in the project's UG3 planning phase. Jon Lurie responded that the UG3 phase does not include human subjects research and, thus, does not require IRB approval. The project team will likely want to conduct focus groups toward the end of the year to interrogate the detailed trial protocol and patient flow plan. IRB approval will be needed at the individual institutions where these focus groups are to be conducted.		Provider and patient interviews did not influence trial design per se, but did identify key concerns of stakeholders (PSP–primary care provider communication, copayments, insurance coverage issues, etc) that the study team has taken into account during implementation.

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	The team plans to submit the protocol for the UH3 implementation phase for IRB approval in December and plans to request a waiver of documentation of consent. Pearl O'Rourke asked whether all patients who call their primary care clinic with a complaint of low back pain will be informed about the study, invited to participate, and undergo randomization. Jon Lurie clarified that randomization will occur at the clinic level. All patients who call their clinic to schedule an appointment for evaluation of low back pain will be informed that the clinic is participating in a study, and the patients will have an opportunity to opt out of data collection at several time points. Pearl O'Rourke asked whether participants will be informed that they may be contacted later about opportunities to participate in the focus groups described in Aim 3d of the Research Strategy. Jon Lurie confirmed that this is correct. The study will use Copernicus as the central IRB.		Advarra is the IRB of record and the trial is approved at all sites. The study has a waiver of documentation of consent for enrolled subjects completing patient-reported outcome assessments and a waiver of consent for deidentified EHR data at the clinic level. Potential patient-participants are told during conversation with the scheduling assistant that completion of the questionnaires is voluntary and they can decline. If they orally agree, they are sent the questionnaires with the informed consent document as the preamble, which reiterates the voluntariness of participation. Patients can indicate that they read the consent form and do not wish to complete the surveys; or they can indicate that they read the consent form and are willing to complete the surveys but then choose not to anyway.
Risk (Does the project meet regulatory criteria for being considered minimal risk?); and consent (planned processes for relevant subjects)	David Magnus asked about the study team's plan to seek a waiver of consent or a waiver of documentation of consent. Jon Lurie responded that the study team is considering either as a possibility. The study team initially considered whether the project could be considered a quality improvement initiative—specifically whether the planned data collection would be considered part of routine care—because the sites gather some data on the patient outcome measures		Advarra approved the study as no greater than minimal risk.

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	as part of routine care. However, because some of the questionnaires to be used in the study go beyond the data collected as part of routine care, the activity is properly considered as research. Nevertheless, the team considers the research to be minimal risk and thinks it desirable to use an oral consent process. Accordingly, the study team will seek a waiver of documentation of consent. David Magnus recommended that the study team be more precise in their language when describing that the study presents "minimal risk" (rather than "low risk," which was used in the grant application and is not an applicable regulatory standard). Pearl O'Rourke asked whether patients in clinics assigned to the usual care arm will be allowed to seek care from PSP practitioners. Jon Lurie responded that some patients in the usual care clinics may have seen a PSP before contacting the clinic. Because of the pragmatic nature of the trial, the study team does not want to try to require patients to adhere strictly to the provisions of their study arm. When patients in usual care clinics hear about the study, they may decide to seek care from PSPs, but the study team does not expect this to be a common enough occurrence to jeopardize the study. Joe Ali asked whether the disclosure script used for obtaining oral consent will contain language about the patient's clinic being assigned to a particular study arm. Jon Lurie responded that patients will be informed that their clinic is providing care in a certain way and that the researchers will collect data to measure the outcomes of that care. The disclosure script will not disclose the randomization assignment per se. (In correspondence after the meeting, Jeremy Sugarman asked the study team whether patients will be given this information if they ask. Kelley Ryan responded that patients requesting additional details will be provided with them.) David Magnus asked about the consent strategy, since it has implications for the type of waiver the study team should seek. Jon		

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	Lurie clarified that the study team will need to conduct some kind of oral consent process because they will gather patient data that may not otherwise be collected in routine care. The study team has considered whether to seek an alteration of consent to streamline the process. An important factor in this decision will be the length of the disclosure conversation, because this conversation will also serve as the scheduling call for the patient's clinic appointment. Jeremy Sugarman asked who will conduct the scheduling and consent conversation. Jon Lurie responded that a staff member dedicated to the project will be granted privileges to access the clinic's scheduling system and will conduct both the research disclosure and appointment scheduling. Jeremy Sugarman agreed that the study team should be able to make a satisfactory argument for a waiver of documentation of consent. Dave Wendler recommended that the study team write out and time the disclosure script. He agreed it is possible that the study will likely be eligible for a waiver of documentation of consent. However, if the disclosure script is so long that it would prevent the study team from answering the research question by excessively interrupting or burdening the clinic workflow, the study team could consider shortening the script and requesting approval for an alteration of consent. Jeremy Sugarman asked whether any members of the Core had further questions or concerns about whether the project meets the regulatory criteria to be considered minimal risk. None were voiced.		
Privacy (including HIPAA)	Jeremy Sugarman asked if the study team will collect both patient-reported outcomes and data from the electronic health record. He asked whether there were any concerns about privacy when using those data. Jon Lurie confirmed that both data sources are planned		The IRB has approved the following Alteration of HIPAA Authorization: • Alteration of HIPAA Authorization (waive signature) for the Main Cohort (completing PROs).

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	and responded that the study team has not identified any privacy concerns. Judith Carrithers noted that the disclosure will require a HIPAA privacy statement and that the study will require an alteration of the requirements of written HIPAA authorization.		• The Advarra IRB has approved the Full Waiver of HIPAA Authorization for the Longitudinal Cohort (de-identified EHR data at the clinic level)
Monitoring and oversight	Jeremy Sugarman asked about the plan for monitoring and oversight of the study. Jon Lurie responded that NCCIH will have its own DSMB monitor the trial. Jeremy Sugarman also noted that the study team will receive a certificate of confidentiality as a condition of the grant award and will need to be aware of the requirements associated with it, especially with regard to populating the EHR with research data. He recommended the following article: • Sugarman J, Carrithers J. Certificates of confidentiality and unexpected complications for pragmatic clinical trials. *Learn Health Syst*. 2020 Jul 14;5(2):e10238. doi: 10.1002/lrh2.10238. PMID: 33889738; PMCID: PMC8051346.	Share the article by Sugarman and Carrithers with the study team. [Tammy] (Completed)	There have been no changes to data monitoring and oversight. There is an NCCIH DSMB. No research data are entered into the EHR.
Issues beyond this project (regulatory and ethics concerns raised by the project, if any)	Jeremy Sugarman asked whether the PSPs will be "engaged in research." Principal investigator Christine Goertz responded that they would be aware of the research activity and that they will be asked to write a follow-up letter to the patient's primary care provider to inform them that the patient has begun a course of care. This practice is a standard of care for these practitioners. Judith Carrithers and Pearl O'Rourke noted that, if this practice is a standard of care, it may be possible to describe the practitioners as not being "engaged in research," even if the practice is not implemented in every case in real-world routine care.		
Other matters	Pearl O'Rourke asked about the percentages of PSPs treating patients enrolled in the study who will be doctors of chiropractic or physical		The PHQ-9 is routinely used in clinical practice in some of the participating

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	therapists. Jon Lurie responded that this will be an interesting outcome of the study, because it will depend on patients' preferences. Christine Goertz noted that the study team hopes to include a qualitative component in the study to explore patients' choice of PSP. Joe Ali asked whether the study team will use a standard description of the PSPs when patients are informed about the study and whether a particular type of practitioner could refer a patient to another type of practitioner. Christine Goertz responded that the script will include a description of the practitioners. It is theoretically possible that one practitioner will refer a patient to another type of practitioner, but the study team does not believe this is likely. Pearl O'Rourke and Joe Ali asked how the study team will deal with receiving information in the study that may not have been collected in routine clinical care and that could trigger some follow-up, such as outcomes that may indicate risk related to depression, anxiety, or suicidal ideation. Jon Lurie responded that the PHQ-9 measure is used in the clinics as part of routine care and that the study team will be alert for these indicators of risk.		health systems but is not being used by the study, thus no issues have emerged in regard to its use.
Adjourn	Jeremy Sugarman noted that the minutes of the meeting will be published on the NIH Collaboratory website at https://rethinkingclinicaltrials.org/demonstration-project-ethics-and-regulatory-documentation/. Tammy Reece noted that IMPACt-LBP will be included in the Core's biannual meetings.	Send the Core's biannual meeting invitations to the study team. [Tammy]	
Additional follow-up information			No additional issues.