NIH Collaboratory Rethinking Clinical Trials®
Health Care Systems Research Collaboratory

Ethics and Regulatory Core

Collaborative Care for Chronic Pain in Primary Care (PPACT)

Lynn DeBar, PhD

Meeting Participants (May 31, 2013):

☒	Jeremy Sugarman (Johns Hopkins)	☒	Natalie Thurman (Kaiser Permanente)	☒	Jerry Menikoff (OHRP)	☒	Josephine Briggs (NIH)
☒	Rob Califf (Duke)	☒	Lori Jennings (Kaiser Permanente, HI)	☒	Julie Kaneshiro (OHRP)	☒	Linda Porter (NIH/NINDS)
☒	Lynn DeBar (Kaiser Permanente)	☒	Melanie Plaut (Kaiser Permanente, IRB)	☒	Catherine Meyers (NIH)	☒	Valery Gordon (NIH)
☒	William Vollmer (Kaiser Permanente, NW)	☒	Ashli Owen-Smith (Kaiser Permanente)	☒	Wendy Weber (NIH)	☒	Jonathan McCall (Duke)
☒	Lindsay Kindler (Kaiser Permanente)	☒	Aileen Uchida (Kaiser Permanente, HI)	☒	Sarah Carr (NIH)	☒	Tammy Reece/Cheri Janning (Coord Center)
☒	Sandy Heinz (Kaiser Permanente, NW)	☒	Ivor Pritchard (OHRP)	☒	Sarah Duffy (NIH/NIDA)	☒	Monique Anderson (Duke)

The minutes from the May 31, 2013 meeting were circulated to all participants on the call for two rounds of review and they reflect all corrections that were received.

Collaborative Care for Chronic Pain in Primary Care (PPACT)
Lynn DeBar, PhD

AGENDA ITEMS	DISCUSSION May 31, 2013	PROPOSED ACTION May 31, 2013	CURRENT STATUS as of May 12, 2015
Review of Demonstration Project	• Dr. DeBar gave an overview of the Pain Program for Active Coping and Training (PPACT) trial, a pragmatic trial that aims to test the effectiveness of a primary-care-based collaborative care intervention for adult patients with chronic, non-cancer-related pain who are receiving long-term opioid therapy. The intervention will involve: 1. A comprehensive intake evaluation with periodic re-evaluation (evaluations performed by a behavioral health specialist or nurse case manager, physical therapist, and a chart-based medication review by a pharmacist); 2. Group coaching sessions (led by the behavioral health specialist, nurse case manager, and/or physical therapist); and 3. Interim case management contacts (performed by the behavioral health specialist or the nurse case manager). • The trial will take place in the Kaiser Permanente NW (KPNW), KP Georgia, and KP Hawaii health plans. • Trial design: 2-arm cluster randomized trial with 200 primary care clusters. o Arm 1: Routine administration used in KP centers. o Arm 2: Intervention. • Eligible participants will be identified through the EHR. Clinicians interested in the study will be given a list of their eligible patients and can assess whether a given patient is an appropriate study candidate.		

	• Invitation/informational letters will be mailed to eligible patients; these letters will be signed by their primary care clinicians. The letter will include all required elements of informed consent, including a clear statement of the option to opt out of the study by calling the provided study telephone number. The letter will also state that study staff will follow-up with patients within 1 week if they have not called to opt out.		
Minimal risk	• Each component of the intervention is currently available to KP members as a separate resource within the respective healthcare systems. The intervention to be tested coordinates these services by organizing them into a single program within primary care and applying an interdisciplinary approach to systematically coordinating patients' use of these services. Patients not randomized to the intervention will continue to receive treatment as usual. • The intervention is not expected to pose any additional risks. • Teleconference participants expressed that the study seemed to meet criteria for a determination of minimal risk. OHRP representatives expressed the opinion that it would be reasonable for an IRB to reach the conclusion that the study is minimal risk.		
Consent (patient and physician)	• Oral consent and oral review of HIPAA elements will be sought from all participants enrolled in the study. A request will be made to IRBs for a waiver of documentation of informed consent and an alteration of HIPAA privacy rule authorization (no signature). The study interviewer will obtain oral consent from prospective study participants via		The team is obtaining oral consent from all patient participants but received a waiver of written documentation of informed consent and an alteration of HIPAA privacy rule authorization (no signature).

	telephone call. During the conversation, the interviewer will indicate that each element of informed consent and HIPAA privacy guidelines/study use of health data has been reviewed with the KP member by checking the requisite element within the patient record in the study electronic tracking system. It is felt that obtaining oral rather than written consent is an appropriate consent procedure because intervention activities involving coordination of clinical care services are already available to most KP members and study participation is expected to pose minimal risk. Further, because the intervention is embedded directly in primary care clinics and conducted in partnership with participating patients' primary care providers, in the event that a patient's symptoms significantly worsen during the intervention, that patient's clinician will be immediately contacted by a PPACT intervention team. • Clinicians will receive an informational letter detailing the study. Their participation will imply consent. • No objections or concerns were raised by the group regarding the waiving of documentation of informed consent.		Thus, there has been no change since the initial teleconference discussion.
HIPAA	• Dr. DeBar believes the criteria for 45 CFR 164.512 are satisfied and waiver of HIPAA is acceptable; no concerns were mentioned. • Because written consent will not be obtained, the investigators are seeking alteration of the privacy rule. Patients will be informed that their data are being used for research.		As above with no change since the initial teleconference.

Monitoring and oversight	• All NIH clinical trials require a data and safety monitoring plan, which must be approved by the primary NIH IC prior to study implementation. • The safety plan currently involves EHR monitoring of all study participants every 6 months to identify deaths and hospitalizations. • If a safety event occurs, a chart review will be completed by an independent KP clinician in that specific KP region and by an independent medical monitor to determine whether the event was related to the study. • Currently there is no DSMB identified and the group agreed that a DSMB was not necessary.	• The study team will identify an independent monitor entirely independent of the study team and health care systems. Linda Porter noted that NINDS will work with the project to identify this person and ensure that resulting monitoring processes are compliant with the appropriate NIH and NINDS policies.	The project is utilizing an independent monitor who reviews subject accrual, serious adverse events, and clinician/patient compliance with treatment every six months. Thus, there has been no change since the initial teleconference discussion.
Issues beyond the PPACT trial	• None noted.		None noted.
Conclusion of meeting	• Follow-up needed, as noted in action items.	• A case study will be written to provide guidance for others on the process and value of open dialogue with regulators.	
Additional regulatory or ethics issue(s) that arose after the meeting			None noted.
Additional follow-up information			None noted.