NIH Collaboratory Ethics and Regulatory Core: UG3 Consultation Call
Nonpharmacologic Pain Management in Federally Qualified Health Centers Primary Care Clinics (BeatPain Utah)
December 7, 2020

Attendees: Judith Carrithers (Advarra), Julie Fritz (Utah), Andrew Garland (Johns Hopkins), Bryan Gibson (Utah), John Lantos (Children's Mercy), Martha Matocha (NIH),David Magnus (Stanford), Stephanie Morain (Baylor), Pearl O'Rourke (Retired), Vaso Rahimzadeh (Stanford), Tammy Reece (Duke), Kayte Spector-Bagdady (Michigan), Victor Solis (Utah), Jeremy Sugarman (Johns Hopkins), Kevin Weinfurt (Duke), Dave Wendler (NIH), Ben Wilfond (Washington), Liz Wing (Duke)

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Overview of Demonstration Project	**Overview**: BeatPain Utah is an embedded pragmatic clinical trial that will compare the effectiveness of nonpharmacologic intervention strategies for patients with back pain seeking care in 13 federally qualified health centers (FQHCs) throughout Utah. The strategies being evaluated are designed to overcome barriers specific to rural and low-income communities served by FQHC clinics through the innovative use of an electronic referral (through theEHR) and telehealth resources. The intervention consists of counseling, physical therapy (PT), and brief consultation sessions. Referrals will be done through the EHR in the clinics and connect participants with clinicians at the University of Utah. **Collaborative network partners**: 13 FQHC clinics overseen by the Associationfor Utah Community Health **NIH Institute**: National Institute of Nursing Research **Study design**: BeatPain Utah will evaluate the effectiveness and the implementation of telehealth nonpharmacologic pain treatments delivered asadaptive treatment strategies. In the UG3		The Demonstration Project is being implemented as described. The UG3 activities were altered to adapt to COVID-19 restrictions; sociotechnical assessments were done remotely. Currently the study has been activated in 4 of the 13 FQHC organizations in Utah.

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	phase, the study team will finalize procedures and conduct sociotechnical assessments at implementation sites, including intervention procedures, protocols, e-referral workflow, data collection methods, and training of the FQHC staff. In the UH3 phase, the intervention will individually randomize patients and include: • A telehealth strategy that provides a brief pain teleconsult along withphone-based physical therapy. • An adaptive strategy that provides the brief pain teleconsult first, followedby phone-based physical therapy among patients who are nonresponsive to treatment. **Outcomes**: • Primary: pain interference • Secondary: opioid use **Other important notes about the study**: BeatPain Utah will also evaluateimplementation outcomes to inform future efforts to scale effective strategies into other low-resource health care settings.		
Status of IRB approval	The study team is still finalizing key components of their IRB submission, with an eye toward harmonizing the HEAL Initiative's core domain elements (CDE) across the network of participating health clinics. The University of Utah will be the single IRB of record.		IRB approval was received from the University of Utah on July 13, 2021. The NIH HEAL Initiative's core domain elements have been harmonized for all centers. The protocol has been IRB-approved for all sites.
Risk classification	The study team anticipates that the intervention will qualify as minimal risk. However, collecting data related to some of the required HEAL domains may alter this assessment.	Joe Ali will schedule a conversation regarding the required HEAL domains with the study team.	The IRB determined that the study is minimal risk.

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Consent	After a connection is made between a referred patient and a pain teleconsultant, an explanation of the study will be provided to the patient. If the patient is eligible and interested, oral consent will be obtained. Those on the call agreed that the study would likely qualify for a waiver of documentation of consent.		Plans for oral consent have not changed since they were discussed during the December 7, 2020, consultation. The oral consent process and the request for a waiver of documentation of consent have been approved. Oral consent is documented in REDCap.
Privacy/HIPAA	The only research data entered in the clinical record is the initial referral. Those on the call discussed potential implications for the Certificate of Confidentiality (see below) related to this.		The study team is obtaining data transfer agreements with the sites to address confidentiality and security.
Monitoring and oversight	The National Institute of Nursing Research (NINR) requires that the study team set up an external Data and Safety Monitoring Board (DSMB). Tammy was asked to forward the Collaboratory's template for a Data Monitoring Committee (DMC) Charter for PCTs to the NIH Project Officer and study team. This document contains helpful guidance for establishing a DSMB/DMC with PCT-specific expertise. The PI asked if the Collaboratory has suggestions for best practices for safety monitoring for adverse events. It was suggested that during the UG3 phase, the study team could figure out a mechanism for participants to voluntarily report harms.	Tammy will send the study team and Project Officer the Collaboratory template for Data Monitoring Committees Charter forPCTs and the DSMB article from thespecial series in *Clinical Trials*. **Sent 12/7/20**	The DSMB is in place and has met once. Study personnel have been trained in reporting adverse events.
Issues beyond the study	There was a discussion around the telehealth modality, which has raised some unanticipated issues around privacy for virtual medical encounters. The PI said their encounters will be by phone only, without a video or camera component. It was suggested that the study team could provide guidance to the patient about ensuring they are in a private space during the phone calls.		The study is using a HIPAA-compliant platform for video conferencing. The manual of procedures specifies that patients are asked if they are in a private place to talk with the research assistant or clinician.

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	The group discussed the project's initial plans for data sharing/secondary use of the study data. In particular, what would be permissible uses of the data (including aggregating study data with other data) and plans for minimizing risk of re-identification of study subjects if the data are shared. Since similar issues are being faced across the Demonstration Projects, this issue will be addressed across the Collaboratory. A Certificate of Confidentiality (CoC) will be automatically provided per NIH policy. This certificate adds provisions for future research uses and confidentiality obligations for future data sharing.		The study team continues to participate in NIH data sharing webinars and trainings. The data sharing plans have not been finalized.
Additional follow-up information			The study team has not encountered any additional regulatory or ethics issues since the December 7, 2020, consultation.