NIH Collaboratory Ethics and Regulatory Core: UG3 Consultation Call
Improving Completion, Accuracy, and Dissemination of Surgical Advanced Care Planning (I CAN DO Surgical ACP)
October 27, 2023; 3:00-4:00 pm ET (via Zoom)

Attendees:

- Core, Coordinating Center, and NIH: Joe Ali (Johns Hopkins University), Kevin McBryde (NCCIH), Kayla Mehl (Johns Hopkins University), Stephanie Morain (Johns Hopkins University), Pearl O'Rourke (retired), Caleigh Propes (Johns Hopkins University), Barbara Radziszewska (NIA), Tammy Reece (Duke University), Marcel Salive (NIA), Damon Seils (Duke University), Kayte Spector-Bagdady (University of Michigan), Ben Wilfond (University of Washington)
- Demonstration Project team: Molly Diethelm (University of Minnesota), Elizabeth Wick (University of California, San Francisco)

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	CURRENT STATUS as of October 23, 2024
Brief review of Demonstration Project	Meeting attendees received the Research Strategy and Data and Resource Sharing Plan for I CAN DO Surgical ACP with the meeting agenda (see supplementary material attached). Pearl O'Rourke facilitated the discussion. Core members, I CAN DO Surgical ACP team members, NIH representatives, and staff from the NIH Pragmatic Trials Collaboratory Coordinating Center introduced themselves. The I CAN DO Surgical ACP team members present included principal investigator Elizabeth Wick and project manager Molly Diethelm. **Project overview**: Elizabeth Wick gave an overview of the project. The goal of I CAN DO Surgical ACP is to identify a system-based approach to help older adults undergoing elective surgery engage in ACP. The project will leverage the existing electronic health record (EHR) and patient portal, PREPARE for Your Care materials to assist patients with completion of ACP, virtual healthcare navigators, and electronic nudges. Another goal of the study is to understand digital engagement, language, and social drivers of health that drive engagement in the intervention.		The only change to the trial since the October 27, 2023, consultation is that the study team is using an outcome of clinically meaningful ACP, which includes an advance directive plus specific ACP documentation in the ACP section of the EHR.

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	Healthcare system partners: University of California, San Francisco (UCSF), University of California, Irvine (UCI), University of Minnesota (UMN) **NIH Institute Providing Oversight**: National Institute on Aging (NIA) **Study design**: The study is proposed to be a 3-arm pragmatic trial of older adults being seen in surgical clinics for new patient visits. ACP engagement is a standard of care in the participating healthcare systems. In arm 1, patients will receive a message through the patient portal ahead of their visit with information and materials for ACP. In arm 2, patients will receive the patient portal message and reminder messages. In arm 3, patients will receive the patient portal message and reminder messages plus a call from a healthcare navigator to help them work through the process. Randomization will be at the patient level. **Outcomes**: The primary outcome is the presence of an advance directive in the EHR. The secondary outcome is engagement in the ACP intervention as measured by an 11-question survey.		
Status of IRB approval	The study will use Advarra as the single IRB of record. Reliance agreements are complete at UCSF, almost complete at UMN, and in process at UCI.		The study has received IRB approval.
Risk (Does the project meet regulatory criteria for being considered minimal risk?); and consent (planned processes for relevant subjects)	The study team anticipates that the project will meet the regulatory criteria to be considered minimal risk. If considered research, the study will likely have a waiver of consent. Pearl O'Rourke asked about notification of research at the time of the first contact. Ben Wilfond and Joe Ali agreed that notification is important, even if just in the form of an additional 1 or 2 sentences in the patient portal letter. For the follow-up surveys, consent will be embedded in the electronic survey.		The IRB determined that the study meets the regulatory criteria to be considered minimal risk. The MyChart letter will not have information about

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	The study team will obtain consent for focus groups or one-on-one interviews with an ethnographer. Stephanie Morain shared the reasons Core member Dave Wendler has previously outlined for why to provide notification about research, independent of consent: "(1) Preparation, (2) understand what doing/relationships, (3) understanding what individuals are contributing to, (4) allow participants to express concerns, (5) can promote participant engagement/support, (6) reduce chances of unethical research, (7) promote public trust."		this being a research study, as this MyChart letter is currently standard of care at UCSF and UCI. There was a concern, reviewed by the DSMB, that adding such a statement could be detrimental to ACP in general, as ACP is the standard of care and is not experimental. Patients will receive a follow-up survey at 2 weeks via MyChart, will be notified that the survey is considered research, and will provide consent as part of answering the survey.
Privacy (including HIPAA)	The study team is finalizing the approach to data sharing and how to share data for the natural language processing which will be done in Minnesota.		
Monitoring and oversight	The study team intends to use a data and safety monitoring board (DSMB) and has discussed the membership criteria with NIH representatives. The study will also be reviewed by the UCSF Learning Health System Oversight Committee.		The DSMB recommended that a single question be added to the ACP

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			engagement survey to ask if there was anything that could be improved in the process. This survey will be sent via MyChart, and responses to this question will be reviewed in real time by the healthcare navigator.
Issues beyond this project (regulatory and ethics concerns raised by the project, if any)	None.		
Other matters	Joe Ali shared a recent article and encouraged the study team to consider looking for variability in the study outcomes by race/ethnicity. • Mpody et al. Current trends in mortality attributable to racial or ethnic disparities in post-surgical population in the United States: a population-based study. *Ann Surg*. 2023;4(4):e342. doi:10.1097/AS9.0000000000000342. Stephanie Morain encouraged the study team to consider finding a way to share what is learned from the trial with the patients who contributed to that learning.		
Additional follow-up information			The study team has not experienced any additional issues.