NIH Collaboratory Rethinking Clinical Trials™
Health Care Systems Research Collaboratory

Regulatory/Ethics Consultation Call:

Advance Care Planning: Promoting Effective and Aligned Communication in the Elderly (ACP PEACE)

Monday, August 13, 2018
Meeting Participants

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AGENDA ITEMS	**DISCUSSION** August 13, 2018	**PROPOSED ACTIONS** August 13, 2018	**CURRENT STATUS** As of August 28, 2019
Review of Demonstration Project	• Study Co-Principal Investigator Angelo Volandes (Harvard) provided a summary of the ACP PEACE pragmatic clinical trial. The study tests the combination of 2 evidence-based, complementary advance care planning (ACP) interventions: communications skills training in serious illness for clinicians (VitalTalk) and advance care planning video decision aids for older patients with cancer (ACP Decisions). The goal is to evaluate the effects of the intervention on the rate of patients' completion of ACP documents, resuscitation preferences, palliative care consultations, and hospice use in the electronic health record (EHR). • **Collaborative network partners:** ○ Mayo Clinic ○ Duke Health ○ Northwell Health		

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	○ Dana-Farber Cancer Institute ○ Boston Medical Center • **NIH Institute:** National Institute on Aging (NIA) • **Study design:** ACP PEACE is designed as a stepped-wedge, cluster-randomized trial evaluating a comprehensive ACP program among older oncology patients conducted in 3 large U.S. healthcare systems (Duke, Mayo, Northwell). In the UG3 phase, the study team will develop the organization, processes, and infrastructure of the ACP program and pilot the intervention in one oncology clinic in each of the partner systems. In the UH3 phase, the effects of the intervention will be tested using electronically collected EHR data from 4500 patients >65 years of age with advanced cancer across 36 randomized clinics. Other elements of the UH3 phase will involve in-person surveys, video ACP declarations, EHR chart reviews of a subgroup of patients, and implementation webinars with clinic staff and executive sponsors (see details in attached supplemental material). ○ **Primary outcome:** Rate of completion of ACP documents in the EHR from patients >65 years with		

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	advanced cancer, before and after the intervention. ○ **Secondary outcomes:** (1) Rate of completion of patient preferences for resuscitation, use of palliative care services, and hospice use and (2) evaluation of patient-centered outcomes (confidence, decisional satisfaction or regret) via in-person survey in a subset of 450 patients. • Since ACP PEACE is a stepped-wedge trial, there will be a control phase and an intervention phase for the 36 clinics in the UH3 implementation. The control phase consists of standard of care. • Clinician and other staff participation in communications skills training is voluntary. Those who do participate will receive an email survey after the intervention.		
Status of IRB approval	The Dana-Farber Cancer Institute is serving as the central IRB, has approved the study, and all sites have ceded to this IRB.		In the preparation of the IRB application for multisite signoff, we encountered minor issues related to consent form formatting, timely sign off by local IRBs with reliance agreements, and strict adherence to new rules related to Dana Farber Cancer Institute (DFCI) oversight as lead IRB. We have successfully adhered to DFCI Office for Human

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			Research Studies (OHRS)/IRB guidelines and requirements.
Risk classification	• The team anticipates the study to be minimal risk to participants. The intervention components (VitalTalk and ACP Decisions) are the standard of care in many healthcare systems. The intervention will be available to all patients with advanced cancer in the clinic, not only patients >65. • The IRB determined that ACP PEACE poses only minimal risk to participants.		
Consent	• Categories of participants related to requirement for informed consent: **Category 1:** 375 patients (UG3)/4500 patients (UH3) from whom data are collected via the EHR from a data repository. The study team seeks a waiver of consent for this category since no identifiable health data will be shared between systems. As an ethical matter, the study team will consider providing some type of general notification to patients about the study and use of their health data. If an opt-out mechanism is provided, it would be important to track how and when this is actually used if feasible.	Completed: The Collaboratory coordinating center sent the team the article, "Use of altered informed consent in pragmatic clinical research" about different approaches to disclosure.	**Category 1:** We received a waiver of consent from the IRB for the data collected from the electronic health record. We are providing any potential patients (subjects) with the opportunity to opt out of this project, let them know that it is "OK" if they say no. We have created "broadcast notifications" in the form of a poster in the clinic/patient areas that explains this research study and their choice to participate or not to participate. We will track these opt-outs to ensure that these patients' data are not included in the study and for better understanding of opt-outs.

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	Category 2: 15 patients (UG3)/450 patients (UH3) participate in a 5-minute in-person survey data collection. For a simple survey, this category meets criteria for waiving written consent in favor of oral consent. However, the study team will proceed with written consent for the UG3 phase but may consider a different plan for UH3 based on the expected number of patients involved and the nature of the activity. **Category 3:** Subset of 450 patients (UH3) who consent to giving a video ACP declaration via a tablet device. This category requires written opt-in consent; videos will be sent to Boston Medical Center for analysis. **Category 4:** 30 clinicians (UG3)/360 clinicians (UH3) who participated in the skills training who respond to an anonymous email survey. Survey contains language about the intent of the research and that survey completion is voluntary. Written consent is not required and consent is implied upon completing the survey. **Category 5:** 15 clinicians and administrators (UG3) interviewed by telephone about their experience with the intervention. Written consent is not required and an altered consent process		**Category 2:** For the 450 patients to be surveyed, the IRB did not require written consent, but requested we provide a Detailed Information Sheet and obtain oral consent. This approach was taken because the data collected in the RedCap Survey will be anonymous. This represents a change from our original plan in which we considered obtaining written consent for these surveys. **Category 3:** A subset (N=240) of the patients undergoing Category 2 surveys (N=450) will also provide a video declaration of their goals for care. We will obtain written informed consent for this population. **Category 4:** The clinicians who participated in the Vital Talk skills training voluntarily responded to anonymous surveys, no sociodemographic data were collected. Explicit consent was not obtained. **Category 5** Thus far, we have interviewed one Nurse Practitioner (NP) from one clinic who provided oral consent; , the physician at this site was not available. We will eventually follow up with the

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	is reasonable. The study team will seek email consent in advance and oral consent at the time of interview. No information about participants will be retained. **Category 6:** 72 clinic staff and executive sponsors who participate in webinars to discuss barriers and facilitators around implementation. These webinars do not occur until the intervention is turned on at their site. Because clinics will need to be prepared to share challenges and process experiences, the study team plans to seek oral consent in advance of the webinars. Regardless, it is unclear whether the informants here would be considered to be human subjects under federal regulations, so the team will consider this issue and discuss with the IRB.		other sites going forward, once we have outcomes from some of the other clinics. **Category 6:** We are still planning to have 72 clinic staff and executive sponsors participate in webinars or individual interviews. We have added the option of an individual interview that would occur after the webinar. These interviews will be with different participants and will not be replacing those mentioned in Category 5. The goal of the interviews is to discuss barriers and facilitators around implementation. The study team plans to seek oral consent in advance of the webinars and interviews.
Privacy/HIPAA	• The method of harvesting patient data for Category 1 meets criteria for general HIPAA waiver. The other categories involving PHI (protected health information) currently have plans in place for obtaining consent where a HIPAA authorization could be obtained. • Participants will be trained on using the tablets for the video declarations. Patients		The method of harvesting patient data from the EHR meets criteria for a general HIPAA waiver. The survey will be done using RedCap and all answers will be anonymous; therefore, written authorization is not required. The video declaration involves protected health information and we plan to obtain written consent. The HIPAA authorization is embedded in the consent form, which is standard Dana-Farber practice.

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	will set a password and use a USB, so no videos will reside on the tablets.		
Monitoring and oversight	• ACP PEACE plans to establish a Data and Safety Monitoring Board (DSMB) that will include a biostatistician and researchers from outside Dana-Farber and MGH with expertise in geriatrics, oncology, ACP, and cluster RCTs (details in supplemental material). • Per NIH policy, the overseeing institute, NIA, will identify 3 members to sit on the DSMB to review the protocol and identify any safety issues every 6 months. • It was suggested that the study team consider supplementing DSMB members with members who have expertise in EHR data and health data access since the timing of harvesting data in the trial may have an impact on when reviews are scheduled, ensuring the informatics are in place, etc. • To demonstrate the capacity to harvest data during the UG3 phase, the study team plans to have an interim data retrieval from each clinic.		• A DSMB has been set up comprised of Scott Halpern, MD PhD, Dan Matlock, MD PhD, and James Hughes, PhD. They have expertise in ACP, cluster RCTs, biostatistics, EHR data and health data access, and geriatrics. The current DSMB charter does not mention the "issues beyond the study" such as using the DSMB to monitor that the intervention is actually being delivered. We will communicate this request to the DSMB. • The study team has been doing interim data retrieval from each clinic to demonstrate the capacity to harvest data during the UG3 phase. Given the stepped wedge design in the UH3, the study team will be pulling data every 6 months to correspond to each step in the stepped wedge design.
Issues beyond the study	• A certificate of confidentiality will be automatically provided per new NIH policy. This certificate adds provisions for		

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	future research uses and confidentiality obligations for future data sharing. • One goal of the NIH Collaboratory demonstration projects is to learn generalizable issues from pragmatic trials as distinct from traditional trials. For example, using a data monitoring committee (DMC) to ensure that the intervention is actually being delivered and ensuring the quality of the data. Need to be clear on instructions given to the DSMB or DMC. • A global question for the Collaboratory involves whether vulnerable subjects might be inadvertently enrolled in PCTs, and how that would be handled. • Consider discussing with PIs of the TiME and ICD Pieces demonstration projects how their studies approached opt-out and how/when it was actually used.		