NIH Collaboratory *Rethinking Clinical Trials®*
Health Care Systems Research Collaboratory

Ethics and Regulatory Core

UH2 Project: Pragmatic Trial of Video Education in Nursing Homes
PROVEN

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Meeting Participants (April 22, 2015):

☒ Josie Briggs, MD *NIH / NCCIH*	☒ Jonathan McCall, MS *Duke Clinical Research Institute*	☒ Tammy Reece, MS, PMP, CCRA *Duke Clinical Research Institute*
☐ Elaine Collier, MD *NIH / NCATS*	☒ Jerry Menikoff, MD, JD *OHRP*	☐ Marcel Salive, MD, MPH *NIH / NIA*
☐ Brett Hagman, PhD *NIH / NIAAA*	☒ Cathy Meyers, MD *NIH / NCCIH*	☒ Irene Stith-Coleman, PhD *OHRP*
☒ Catherine Hammack, JD, MA *Duke Clinical Research Institute*	☒ Jeri Miller, PhD *NIH / NINR*	☒ Jeremy Sugarman, MD, MPH, MA *Johns Hopkins University*
☒ Lauren Johnson Hartsmith, JD *OHRP*	☒ Susan Mitchell, MD, MPH *Hebrew Senior Life*	☐ Angelo Volandes, MD, MPH *Massachusetts General Hospital*
☒ Adrian Hernandez, MD, MHS *Duke Clinical Research Institute*	☒ Vincent Mor, PhD *Brown University*	☒ Wendy Weber, MD, PhD, MPH *NIH / NCCIH*
☐ Cheri Janning, BSN, RN, MS *Duke Translational Medicine Institute*	☐ Andrew Narva, MD *NIH / NIDDK*	☒ Kevin Weinfurt, PhD *Duke Clinical Research Institute*
☒ Julie Kaneshiro, MA *OHRP*	☐ Jane Pearson, PhD *NIH / NIMH*	☐ Barbara Wells, PhD *NIH / NHLBI*
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The original discussion minutes were circulated to all attendees for two rounds of review and they reflect all corrections that were received.

Agenda Item	**Discussion** April 22, 2015	**Current Status** as of August 30, 2016

Brief review of *Pragmatic Trial of Video Education in Nursing Homes* (PROVEN)	• Dr. Mitchell gave an overview of the PROVEN project.
	  ○ PROVEN is a pragmatic cluster randomized controlled trial.
	  ○ The study will involve two (2) nursing home systems with a combined total of approximately four hundred and twenty-five (425) nursing homes. The PROVEN team estimates that approximately four hundred and five (405) will meet the eligibility criteria. Of those nursing homes, 230 will be randomly selected and then randomly assigned to the control and intervention arms (115/arm) , stratified based on healthcare system and hospitalization rate of patients with advance disease in the prior year. Rate of hospitalization in long-stay patients with advanced dementia, COPD, CHF over 12 months is the primary outcome.
	  ○ The intervention is a set of five (5) videos meant to enrich advance care planning by nursing home patients.
	  ▪ Nursing homes in the intervention arm will be rolling out the video program using the existing processes for rolling out new clinical programs, such that the
		• The study implementation period began March 1, 2016. Ultimately, 360 nursing homes were randomized: 119 in the intervention arm and 241 in the control arm. The intervention has been rolled out in all experimental facilities. Data exchange is ongoing.

	nursing homes will be using the videos as a standard operating procedure in their facilities. ▪ Each video is four to six minutes long, uses visual images and verbal descriptions of three levels of care: comfort, intermediate/basic, and aggressive. ▪ These videos have been previously tested in traditional efficacy studies. They have been generally well-received and no adverse events have been reported; in fact, all four pilot sites have requested permission to use the videos after the pilots ended, and the videos are currently going through state-wide implementation in Hawaii. ▪ The videos will be shown within seven days of admission; they will be re-shown to long-stay patients approximately every six months. ▪ Patients and family can refuse to watch the videos with no undue effect. ▪ For intervention nursing homes, the team will be providing the videos and training, which will include a "toolkit" instructing staff on how to implement the video program in the existing work flow of the nursing home *and* how to use the videos with individual patients. This toolkit is meant to guide nursing	

IRB status and approval	home staff while allowing each facility some leeway in determining which patients see which video, who shows the videos to them (for example, social workers or registered nurses), and other logistical matters. ○ The study population is all nursing home patients in the control and intervention sites during the 18-month implementation period. ▪ The target population for analyses is long-stay patients who have very advanced diseases (specifically, congestive heart failure, lung disease, and dementia). ▪ Secondary analyses include hospitalization rates in short-stay patients with advanced disease and patients without advanced disease. ▪ Other secondary outcomes include hospice enrollment and rates of completion of advance directives. ○ The team will use existing databases; thus, all data used in PROVEN will have already been collected for clinical or administrative purposes. It was noted that the video status report will become part of the patient's medical record. ○ Dr. Mitchell explained that advance care planning is required in every nursing home by federal law. Thus, advance care planning is already being done in every nursing home	

	involved. The video program is meant to facilitate these ongoing activities, *not* replace them. In other words, advance care planning is already standard practice in every nursing home regardless of PROVEN. • In response to questions regarding the relationship between the showing of the videos and hospitalization, Dr. Mitchell explained that the intent of the videos is to enhance advance care planning. In all the prior efficacy studies, generally patients with the aforementioned advanced diseases prefer *less aggressive* care. Therefore, the PROVEN team expects that once patients in the target population see the videos, as a group they will tend to opt for less aggressive care, which will be translated into advance directives that reflect their preferences, which should translate into fewer avoidable hospitalizations. • There was some concern raised regarding the videos' potential effects on the care of patients with advanced dementia; those on the call questioned the possibility of the videos' influencing the views of proxy or surrogate decision-makers (or others who may be included in a decision about whether to hospitalize a patient or not). o Dr. Mitchell explained that there is a specific video that is *about* patients with advance dementia that is intended for proxy or surrogate decision makers. All other videos are all meant to be seen by patients	

	themselves as well as proxy or surrogate decision makers. • In response to questions regarding whether or not the study could include a survey of patients (or proxy or surrogate decision makers) to analyze how (if at all) the intervention influenced their decision making, Dr. Mitchell explained that this is currently being done in more traditional R01s, and that they know from prior studies that patients and families like these videos and would recommend them to others. However, in this instance they opted to *not* include such a survey because it would not be in the rubric of pragmatic trials, citing the number of nursing home patients and the undue burden on nursing home staff. • Dr. Mitchell explained that the main trial protocol was submitted to the Brown University IRB in March; approval will likely come through soon. [Post call note: Protocol approval from the Brown IRB was received on April 22, 2015.] • There was a brief discussion regarding attendees' request to view PROVEN's complete and final protocol, insofar as some details of the study were not included in the Summary Document [*attached*], as it is an extraction of a much larger version. o Dr. Sugarman explained that the UH2 Demonstration Projects, including PROVEN, are in varying stages of "protocol" development. Prior to approval from each project's Institutional Review and Data and	

	Safety Monitoring Boards (IRBs and DSMBs), there does not exist a complete and final protocol insofar as each is continuously evolving through these review processes. In an attempt to maintain version control and to avoid burdening meeting attendees with additional information which may change pursuant to the pending IRB and DSMB reviews, draft protocols were not circulated. The Core and NIH is assessing potential processes for the dissemination of final protocols upon IRB and DSMB approval. • Additional information is included in the Summary Document attached to the original minutes.	
Risk *Does the project meet regulatory criteria for being considered minimal risk?*	• Dr. Mitchell explained her team's justification for proposing that the PROVEN study constitutes minimal risk. o As previously explained earlier, advance care planning is currently part of routine clinical practice as required by federal law. The PROVEN intervention is merely an adjunct to the current standard practice. Thus, the intervention is not expected to pose any additional risk. o In addition, all data to be used in PROVEN has already been (or will be) collected as part of routine clinical care except that the video status report will be embedded as part of the	• *No changes reported.*

	nursing home's usual workflow. Thus, data collection will not pose any additional risk. • While the video(s) may cause some viewers to become upset, this is not likely to be meaningfully different from existing advance care planning processes. Accordingly, attendees agreed that watching the video(s) likely constitutes minimal risk. However, discussion returned to the issue of the videos' purpose or effect on patients' (or proxy or surrogate decision makers') decisions. So, the question is the possibility of changing a person's decisions in a way that is "*incorrect*"—or, in other words, in a way that poses *more* risk to them (than what they would have otherwise decided). o Drs. Mitchell and Mor explained that the study's goal is *not* to change patients' (or proxy or surrogate decision makers') minds or otherwise affect their decisions. Rather, the goal is to provide people with *informed* decision making such that patients will get care that is aligned with their actual preferences and choices. So, if someone happens to watch a video and thinks that *more aggressive* care is what they actually want, then this goal is nonetheless met because that decision was *informed* by the video. ▪ Dr. Mitchell noted that it is difficult to measure the outcome of alignment with goals of care, particularly in a pragmatic trial of this scale.	

	▪ Drs. Mor and Mitchell explained that they are not requiring anyone to complete an advance directive after viewing the video (or ever)—instead, they are merely trying to augment these important advance care planning conversations. • There was some confusion regarding why PROVEN's primary outcome is *hospitalization*, which may suggest greater risk, rather than the completion of advance directives regardless of whether they result in hospitalizations or not; attendees believed that the latter would be most informative. o Dr. Mitchell reminded the group that they will, indeed, be assessing the rate of advance directive completion as one secondary outcome, or one factor, of many—they believe that it is a link in the causal chain. However, the team is analyzing how the intervention impacts actual *care*, rather than mere decisions or perceptions about care. o Dr. Mitchell explained that the primary hypothesis of PROVEN is reduced hospitalization in people with advanced diseases when it is not concordant with their goals of care; the relationship between having an advance directive (specifically, a "do not hospitalize order" (DNH)) translates into a reduced rate of hospitalization. The existing literature supports this hypothesis.	

	• Similarly there was some concern that there will be many instances in which patients' families will be watching a video which may be perceived to be suggesting that they should not hospitalize a family member. In other words, well-intentioned attempts to improve advance care planning and facilitate these conversations may be perceived differently by observers of this study. • Attendees agreed that some concern regarding a minimal risk determination remains. Some indicated that the complete, final protocol may be critical to helping make this determination. [Post-call note: Additional information regarding the selection of hospitalizations for the primary outcome was prepared by the investigators and is appended to the minutes.]	

Consent
Planned processes for relevant subjects
	• Dr. Mitchell explained her team's justification for proposing that individual informed consent should be waived.
	  ○ Dr. Mitchell explained that because all patients are already engaged in advance care planning per routine practice and the videos are enriching this process, they are not adversely affecting the rights or welfare of patients; if anything, they are *enhancing* their rights and welfare.
	  ▪ She noted that all patients are free to refuse to view the videos and otherwise decline to participate in the existing
		• Consent was waived. There was no change in the consent plan after the discussion.

	advance care planning process; in other words, patients will be offered the intervention, but they can refuse it just the same as they can refuse any part of their clinical care. ▪ Furthermore, consent it is not otherwise required or part of standard practice in the course of everyday advance care planning. o Dr. Mitchell cited practicability also as an issue related to a waiver of consent. Requiring individual informed consent would not be feasible given the large number of nursing homes that are geographically dispersed for an intervention that is delivered in the context of clinical care (and not by research personnel). Dr. Mitchell clarified that the team is not planning to use any public postings or other notifications, nor will there be any opt-out provisions (in addition to waiver); rather, what the team proposes is a simple waiver.	
Privacy *Including HIPAA*	• Dr. Mitchell explained her team's justification for proposing a HIPAA waiver for the use of protected health information. o With respect to data management and its effect on privacy and confidentiality, the PROVEN team explained that they will be receiving data directly from the two partners described above, and that these data will be	• HIPAA waiver was granted.

	comparable to what they otherwise receive from the Centers for Medicare and Medicaid services (CMS) on a regular basis. ▪ They described their existing procedures as a "well-oiled machine" for bringing information together from various sources, integrating it, protecting it by keeping it in restricted area, and they added that they have passed each of their previous inspections "with flying colors."	
Monitoring and Oversight	• The PROVEN team explained that their Data Safety and Monitoring Board (DSMB), assembled by the National Institute of Aging (NIA) with help from Marcel Salive, MD, MPH, will be providing oversight to this study. The DSMB charter has been outlined, and its initial meeting was held last week and a follow-up meeting will occur on Monday (April 27, 2015). ○ In response to questions regarding any plans for periodic looks at data, Dr. Mitchell explained that the DSMB will receive data on an ongoing basis. ▪ Each of the three (3) principal investigators (PIs)—Drs. Mor, Mitchell, and Volandes—will be blinded, but the statisticians will be able to review data as it comes in to the extent necessary.	• There is a DSMB. There was no change in the monitoring and oversight plan after the discussion.

	▪ The DSMB has not yet decided or communicated to the team what will be required in terms of monitoring, but the team is in position to do whatever is necessary; in other words, they are prepared to adhere to whatever reporting structure the DSMB may require.	
Issues beyond this project *Regulatory and ethics concerns raised by the project, if any*	• *No questions or concerns raised.*	• *No additional information reported.*
Other	• There was some discussion regarding whether or not the nursing homes themselves and/or the staff thereof will be engaged in human subjects research. , o Control sites will not know that they are part of the research study due to pre-randomization; intervention nursing homes will know that a new program is being integrating into the existing advance care planning procedures. o The Brown University IRB likely would not consider NH staff in the control and intervention sites to be engaged in research. o The nursing homes and/or staff are not *direct* subjects because the team will not be collecting any data about them.	• Brown IRB deemed that nursing home staff were not engaged in human subjects research.

Additional regulatory or ethics issue(s) that arose after the meeting		• *No additional information reported.*
Additional follow-up information		• *No additional information reported.*