NIH Collaboratory Ethics and Regulatory Core: Initial Consultation
Population Health Management Approaches to Increase Lung Cancer Screening in Community Health Centers (LungSMART)
March 19, 2025; 4:00-5:00 pm ET (via Zoom)

Attendees:

- Core, Coordinating Center, and NIH: Joe Ali (Johns Hopkins University), Luke Gelinas (Advarra), David Magnus (Stanford University), Kayla Mehl (Johns Hopkins University), Stephanie Morain (Johns Hopkins University), Pearl O'Rourke (retired), Tammy Reece (Duke University), Damon Seils (Duke University), Jeremy Sugarman (Johns Hopkins University)
- Study team: Guilherme Del Fiol (University of Utah)

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Overview of the trial	Meeting attendees received the project's data management and resource sharing plan and data and safety monitoring plan with the agenda (see supplementary material attached). Jeremy Sugarman facilitated introductions and described the purpose of the consultation. Co–principal investigator Guilherme Del Fiol represented the LungSMART team. Co–principal investigators David Wetter and Kensaku Kawamoto did not join. **Project overview**: Guilherme gave an overview of the project, which is supported by the National Cancer Institute through a UG3/UH3 award mechanism. The goal of LungSMART is to increase the uptake of US Preventive Services Task Force–recommended lung cancer screening among patients in federally qualified health centers in Utah. **Research team**: University of Utah. **Healthcare system partners**: Community health centers in Utah and the Association for Utah Community Health.	No major changes have been made to the trial since the March 2025 consultation. As noted below, the study team obtained approval for a waiver of documentation of informed consent, with a notification sent to eligible participants via mail and email, including information about the trial and the option to opt out. This process was refined based on the March 2025 consultation and the "Consent, Disclosure, and Non-disclosure for Pragmatic Trials" chapter of the Living Textbook.

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	NIH Institute Providing Support/Oversight: National Cancer Institute. **Study design**: The study team plans to conduct a 2-phase trial with a sequential multiple assignment randomized trial (SMART) design. The study population will be identified through automated cohort selection algorithms in the electronic health record and will include all patients aged 50 to 80 years who are smokers or former smokers and who had a visit to a participating community health center in the previous 3 years. Identified patients will receive information about the trial by mail and email. The aim of phase 1 of the trial is to increase patients' completion of an eligibility assessment for lung cancer screening. The interventions to be compared in phase 1 include: 1A. Repeated text messages notifying the patient that they may be eligible for lung cancer screening, asking 2 validated eligibility screening questions, and offering a response option that allows the patient to opt out of the study. Depending on the responses to the eligibility screening questions, the patient will be notified that a registered nurse will call to talk about lung cancer screening. 1B. Intervention 1A plus a scripted, interactive chatbot that addresses commonly asked questions about lung cancer screening. 1C. Intervention 1A plus an educational video about lung cancer screening. 1D. Interventions 1A, 1B, and 1C combined. David Magnus asked why the study team chose not to use generative artificial intelligence for the chatbot. Guilherme replied that, although the study team has been testing an interactive feature based on a large language model, it is premature to release this feature without more development and better safeguards. The aim of phase 2 of the trial is to increase the completion of lung cancer screening by patients who completed the eligibility assessment in phase 1 and were referred for screening. Patients in phase 2 of the trial will receive repeated	An unexpected challenge has been a delay in the approval of the project's use case by third-party reviewers of Twilio, which is the text messaging provider contracted by the University of Utah CTSA for SMS delivery to research participants. For the UG3 phase, which included the pilot study, the third-party reviewers approved the study team's approach. Due to recent tighter enforcement of FCC regulations, these reviewers now expected explicit "opt in" to text-based communication, which is currently obtained as part of routine clinic registration at the study sites. The study team is working with the University of Utah CTSA, study sites, and Twilio to address this issue. Other CTSA sites that use Twilio are facing similar challenges.

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	text messages plus an interactive chatbot that addresses general questions about lung cancer screening, and patient navigation by a community health worker that includes phone calls that address hesitancy and barriers and provide logistics for completing the screening appointment. All patients in phase 2 will be randomly assigned to 1 of 2 modes of engagement for patient navigation: (2A) reactive patient navigation provided upon request by the patient, or (2B) proactive patient navigation in which a community health worker calls every patient unless the patient requests not to be called. Every text message will include a reply option to opt out of the study. **Outcomes**: The primary outcome for phase 1 is completed eligibility assessments for lung cancer screening among randomized patients. The primary outcome for phase 2 is completed lung cancer screening among patients randomized into phase 2. **Discussion**: Pearl asked whether patients will be informed about potential costs associated with receiving text messages. Guilherme replied that any such costs will depend on the patient's telephone service provider and that the trial materials will inform patients about these potential costs. Jeremy asked about potential challenges with cell phone signals, especially in remote areas. Guilherme explained that the text messaging software being used in the study will give an error message when a text message cannot be delivered. To address instances of patients changing cell phones, the software platform will ping patients' phones to confirm they are still active. Joe asked about patients who share phones with other people. Guilherme described that the text messages will begin with the patient's name to indicate who the message is intended for. In addition, Guilherme explained the study team's procedure for identifying and either excluding patients with duplicate phone numbers or using alternative phone numbers. Guilherme offered to share a paper the study team is writing about their phone validation algorithm.	The study team's manuscript about the phone validation algorithm is in development.

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	In response to a question from Jeremy about the aggregate patient burden associated with receiving text messages from multiple screening initiatives, Guilherme noted that the community health centers share this concern and that the study team takes steps to minimize messages, spread out their timing, and in some cases exclude patients who are participating in other studies. The study team also only pursues projects the community health centers themselves have expressed interest in partnering in. Jeremy asked about cultural differences in hesitation around the word "cancer." Guilherme responded that a member of the study team is leading all message development and user-centered design, which includes cultural adaptation and testing. They also completed a large message testing study that compared multiple versions of questions with attention to understandability and preferences.	The study team published a paper that discusses an acceptance criteria framework for determining the implementation fit of custom large language models used in public health interventions: King et al. An acceptance criteria framework for determining the implementation fit of custom large language models in public health interventions. *J Med Internet Res*. 2026 Jul 16;28:e92356. doi: 10.2196/92356. PMID: 42462047. The study team also published a paper that discusses the findings from a mixed-method formative evaluation and cultural adaptation process for LungSMART: King et al. Mixed-method formative evaluation and cultural adaptation of digital health communication content and delivery promoting lung cancer screening shared decision-making. *Cancer Control*. 2026 Jan-

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		Dec;33:10732748261456371. doi: 10.1177/10732748261456371. PMID: 42201308. Key findings include (1) the importance of indicating that messages are sent on behalf of the patient's clinic to foster trust; (2) translation to Spanish included many terms that were not clear to participants, especially regarding medical terminology and cost; and (3) messages produced some anxiety about access to the recommended services (CT scans), especially due to sociopolitical concerns, such as immigration status, that were the same risks patients face when seeking any sort of medical care or public services.
Status of IRB approval	The study team received IRB approval for their work on user-centered design in the UG3 planning phase of the project. The trial planned for the UH3 implementation phase of the project is currently under IRB review. The University of Utah is the single IRB of record.	The study team received IRB approval for 9 of 10 sites on May 7, 2026. There is an amendment in review to add the final site, which needed to go through the reliance agreement process.
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 trial will meet the criteria for being considered minimal risk with a waiver of informed consent. Potential participants will be informed about the trial and will have an up-front opportunity to opt out.	The IRB determined the study to be minimal risk. For recruitment of participants, the IRB approved a waiver of HIPAA authorization to allow the research

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	Discussion: Given that the study team plans to use an opt-out strategy, Pearl asked how they will know whether patients have read the trial materials. Guilherme agreed they will not know. Jeremy asked about opt-out rates in other studies that have used this approach. Guilherme replied that the opt-out rate in an ongoing smoking cessation trial is very low, in single digits. Joe predicted that the up-front opt-out approach might reduce the rate of subsequent opting out in response to the text messages. Luke Gelinas observed that the study's screening procedure with its opt-out strategy arguably does not constitute a research procedure because it is the standard of care. Jeremy shared the following article reporting on the Core's collaboration with the study team for Nudge, another NIH Collaboratory Trial, to explore patients' reasons for opting out of that trial: • Sandy et al. Leave me out: Patients' characteristics and reasons for opting out of a pragmatic clinical trial involving medication adherence. *Medicine* (Baltimore). 2021 Dec 23;100(51):e28136. PMID: 34941059. https://pubmed.ncbi.nlm.nih.gov/34941059/	team to access patient records for the purpose of identifying eligible patients. For study participation, the IRB approved a waiver of documentation of informed consent and an alteration of HIPAA authorization to remove the requirement for participants to sign a consent and authorization document. The research team will send a notification to eligible participants via mail and email, including information about the trial and the option to opt out.
Privacy (including HIPAA)	Concerns about the privacy of communications with patients will be addressed by hosting all digital health infrastructure at the University of Utah's Center for High Performance Computing, a HIPAA-compliant space designed for this kind of work. A data transfer agreement will govern data exchanges between the community health centers' central data warehouse and the University of Utah.	
Monitoring and oversight	The study will use a data and safety monitoring board. The data and safety monitoring plan is attached as supplementary material.	The institution's research compliance office has since clarified that the data and safety monitoring board is intended for treatment interventional trials and typically does not review minimal-risk research like LungSMART. Their recommendation is that they not monitor this study given the low risk.

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		The study team is in the process of submitting a prior approval request to change the monitoring and oversight plan to PI-led monitoring.
Issues beyond this project (regulatory and ethics concerns raised by the project, if any)	None.	
Additional follow-up information		None.