



**NIH Collaboratory Ethics and Regulatory Core: UG3 Consultation Call**  
**Using Artificially Intelligent Text Messaging Technology to Improve American Heart Association’s Life’s Essential 8 Health Behaviors (Chat 4 Heart Health)**  
**August 9, 2023; 4:00-5:00 pm ET (via Zoom)**

**Attendees:**

- Core, Coordinating Center, and NIH: Joe Ali (Johns Hopkins University), Alex Fist (Duke University), David Magnus (Stanford University), Stephanie Morain (Johns Hopkins University), Pearl O’Rourke (retired), Tammy Reece (Duke University), Damon Seils (Duke University), Wendy Weber (NCCIH)
- Demonstration Project team: Sheana Bull (University of Colorado), Michael Ho (University of Colorado)

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	CURRENT STATUS as of October 7, 2024
Brief review of Demonstration Project	<p>Meeting attendees received the Research Strategy and Data and Resource Sharing Plan for Chat 4 Heart Health with the meeting agenda (see supplementary materials attached). Stephanie Morain facilitated the discussion. Core members, study team members, NIH representatives, and staff from the NIH Pragmatic Trials Collaboratory Coordinating Center introduced themselves. The Chat 4 Heart Health team members present included co–principal investigators Sheana Bull and Mike Ho.</p> <p><b>Project overview:</b> Sheana Bull gave an overview of the project. Chat 4 Heart Health grew out of the study team’s previous work on Nudge, an NIH Pragmatic Trials Collaboratory Demonstration Project. The study will use an artificially intelligent chatbot (but not a generative chatbot) to design and test messages that are persuasive, motivating, medically accurate, and helpful for patients with diabetes, hypertension, or hyperlipidemia in adopting the American Heart Association’s Life’s Essential 8 (LE8) lifestyle changes . Patients will be able to ask questions in their own way, and the system will use artificial intelligence to match responses that meet the intent of the users’ questions.</p>		The study team changed enrollment procedures to follow their institution’s interpretation of Federal Communications Commission (FCC) guidelines for patients opting into receiving text messages.

Approved: September 12, 2023

These minutes were circulated to all participants in the call for 1 round of review and reflect all corrections that were received. The project’s Specific Aims, Research Strategy, and Resource Sharing Plan are included as supplementary material.

Updated: October 7, 2024

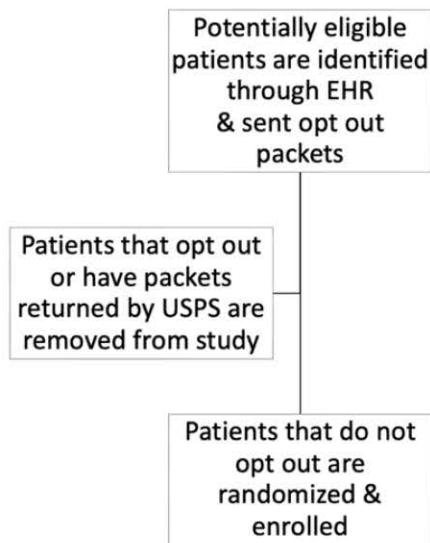
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	<p><b>Healthcare system partners:</b> Denver Health and Hospital Authority, Salud Family Health Centers, STRIDE Community Health Center</p> <p><b>NIH Institute Providing Oversight:</b> National Heart, Lung, and Blood Institute (NHLBI)</p> <p><b>Study design:</b> The study will have 3 arms: (1) generic text message to participants on the topic of the week (for example, tips for healthy eating); (2) chat bot; and (3) chat bot plus pharmacist support. The study will use an opt-out approach similar to that used in Nudge.</p> <p><b>Outcomes:</b> The outcomes of interest are cardiovascular risk factors (such as blood pressure, cholesterol level, blood sugar).</p>		
Status of IRB approval	<p>The study will use the Colorado Multiple Institutional Review Board (COMIRB) as the single IRB of record.</p> <p>The study team has obtained IRB approval for qualitative formative work in the UG3 phase. They are working with patients and providers in the partnering healthcare systems to gain insight into how much tutoring will be needed on what a chatbot is and how it will be used so that participants can feel comfortable being exposed to and encouraged to use it. These qualitative interviews are underway.</p> <p>In addition, the study team has obtained IRB approval for pilot studies at 2 of the partnering healthcare systems.</p>		The study team has received IRB approval for patient enrollment at all sites.
Risk (Does the project meet regulatory criteria for being considered minimal risk?); and consent (planned	<p>The study team anticipates that the project will meet the regulatory criteria to be considered minimal risk.</p> <p>The study team plans to seek a waiver of consent. Pearl O'Rourke advised the study team to avoid referring to the materials as a consent form.</p>		The study met the regulatory criteria to be considered minimal risk, and the study team received a waiver of consent.

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processes for relevant subjects)	<p>Pearl O’Rourke asked whether the study team will follow patients who opt out. Mike Ho responded that, in Nudge, the study team went back to the IRB to obtain approval to access electronic health record data for patients who opted out. The study team can try a similar approach in Chat 4 Heart Health. Pearl O’Rourke asked if the study team would collect information on why patients opt out. Mike Ho responded that the study team can deploy a similar survey as was used in Nudge to collect this information. Stephanie Morain supported including a follow-up survey on reasons for opting out.</p> <p>David Magnus asked whether patients who receive the chatbot messages will know the messages are from a chatbot. Sheana Bull responded that the first message patients receive will explain this. David Magnus asked whether patients in the general text message arm will know that their messages are not from a chatbot, or if everyone will be informed that their messages might come from a chatbot. Sheana Bull shared her recollection that the initial message does not indicate this; rather, if a patient replies to the text message, it is standard practice to respond with an automated reply clarifying that the text messages are not from a live person and offering information about how to access resources. David Magnus encouraged the study team to consider whether sending an introductory message to participants may influence how they react to receiving the messages. If all participants receive the same introductory message, this could be important for how participants feel about receiving subsequent messages. David Magnus shared a link to the following article:</p> <ul style="list-style-type: none"> <li>• Hohenstein J, Kizilcec RF, DiFranzo D, et al. Artificial intelligence in communication impacts language and social relationships. <i>Sci Rep.</i> 2023 Apr 4;13(1):5487. doi: 10.1038/s41598-023-30938-9. <a href="https://pubmed.ncbi.nlm.nih.gov/37015964/">PMID: 37015964.</a></li> </ul>		The study team added a survey to ask patients who opt out why they chose to opt out.
Privacy (including HIPAA)	The chatbot system logs telephone numbers; however, there is no exchange of names from the researchers’ side. The study team will not disclose any personal information or protected health information. All content will be stored behind the university’s firewalls. The opt-out letter will include this information.		

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	The study team will use healthcare system data to identify patients with diabetes, hypertension, or hyperlipidemia for the purpose sending out the initial messages.		
Monitoring and oversight	The study team intends to use the same data and safety monitoring board (DSMB) as was used for the Nudge study.		The study is using the same DSMB as was used for the Nudge study.
Issues beyond this project (regulatory and ethics concerns raised by the project, if any)	<p>David Magnus asked for more information about how the study team will use Amazon Mechanical Turk (MTurk). Sheana Bull responded that MTurk will help the study team get started on figuring out different ways people ask questions. The goal is for 85% of the chatbot responses to meet the intent of the question. In the beginning, this will likely be 65% to 70%, and it will increase with experience with organic users. David Magnus asked whether the study team is calculating the time it takes to complete MTurk tasks, and whether they will compensate MTurk workers accordingly. Sheana Bull thanked David Magnus for this point and responded that the study team will look into this.</p> <p>Pearl O'Rourke asked about the role of the pharmacist in the third study arm and whether it is reasonable to expect them to do what the study team is asking. Mike Ho responded that both of the healthcare systems that have approved the protocol employ pharmacists who are dedicated to population health, and the study team is hoping to leverage these pharmacists for the study. Pearl O'Rourke clarified that she likes the idea but is worried about potential workforce challenges. Mike Ho agreed and expressed surprise that the healthcare systems already have these types of pharmacist roles.</p> <p>Pearl O'Rourke suggested that the study team review the FDA's June 2023 <a href="#">Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff</a>. She added that Chat 4 Heart Health appears to meet the criteria for not being considered a device; however, the IRB may ask</p>		There has been no change to the assessment that the chatbot is not a device.

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	<p>questions about this. David Magnus expressed his view that the chatbot in the study is definitely not a clinical decision support tool, but that we do not yet know how the FDA will think about chatbots that communicate directly with patients. Sheana Bull added that the study team has a contact on the university's innovations team with whom they have discussed the issue, and the contact's thinking was consistent with the study team's view that the chatbot is not a medical device. The study team will monitor changes in the guidance, as this is an evolving issue.</p> <p>Joe Ali asked for confirmation that all of the chatbot data will remain in house. Sheana Bull replied yes.</p>		
Other matters	None.		
Additional follow-up information			<p>Because of their interpretation of the FCC regulation for opting into text messaging campaigns, the study team's institution required patients to opt in to the text messages. See the attached diagram showing the change in the enrollment process.</p>

## Original plan



## New plan due to change in FCC guidance

