NIH Collaboratory Ethics and Regulatory Core: Initial Consultation Call
Maternal OutcoMes Program: Testing Integrated Maternal Care Model Approaches to Reduce Disparities in Severe Maternal Morbidity (MOMs Chat & Care Study)
November 20, 2023; 11:00 am-12:00 pm ET (via Zoom)

Attendees:

- Core, Coordinating Center, and NIH: Joe Ali (Johns Hopkins University), David Magnus (Stanford University), Kevin McBryde (NCCIH), Stephanie Morain (Johns Hopkins University), Pearl O'Rourke (retired), Caleigh Propes (Johns Hopkins University), Tammy Reece (Duke University), Kayte Spector-Bagdady (University of Michigan), Kevin Weinfurt (Duke University), Dave Wendler (NIH)
- Study team: Stephanie Fitzpatrick (Feinstein Institute for Medical Research, Northwell Health), Challace Pahlevan-Ibrekic (Institute for Health System Science, Northwell Health)

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	CURRENT STATUS as of October 21, 2024
Brief review of the trial	Meeting attendees received the Research Strategy, Data and Safety Monitoring Plan, and Protection of Human Subjects Plan for MOMs-CC with the meeting agenda (see supplementary material attached). Stephanie Morain facilitated introductions and the discussion. The MOMs-CC team members present were Stephanie Fitzpatrick (principal investigator) and Challace Pahlevan-Ibrekic (director of regulatory affairs for the Institute of Health System Science at Northwell Health). **Project overview**: Stephanie Fitzpatrick gave an overview of the project, for which both planning and implementation are supported through an R01 grant award. The goal of MOMs-CC is to test the effectiveness of an integrated care model approach at 2 levels of intensity ("low touch" and "high touch") designed to facilitate timely, appropriate care for Black birthing people to reduce their risk for severe maternal morbidity.		There have been no changes to the trial as described in the minutes of the November 20, 2023, consultation.

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	CURRENT STATUS as of October 21, 2024
	Healthcare system partners: Northwell Health **NIH Institute Providing Oversight**: National Institute of Nursing Research (NINR) **Study design**: The study is proposed to be a 2-arm pragmatic trial of adults at high risk for severe maternal morbidity. Participants will be assigned by individual randomization to either a low-touch or high-touch version of the MOMs integrated care model. The low-touch program will consist of standard-of-care procedures currently offered in the partnering healthcare system (including support via an automated conversation system, or chatbot, that will send alerts to a centralized care team to trigger care pathways as clinical or other issues come up, weekly check-ins to facilitate appointment scheduling and other services to help prevent morbidity in the early postpartum period, etc). Research-driven procedures in the low-touch study arm will include receipt of a fitbit wearable activity monitor. The high-touch program will consist of all of the features of the low-touch program (ie, delivery of all current standard-of-care procedures and the fitbit), plus a home blood pressure monitor and additional support and contact in the prenatal period through 12 biweekly sessions with a nurse or other care coordinator to facilitate chronic disease prevention and management. **Outcomes**: The primary outcome is severe maternal morbidity as defined by the Centers for Disease Control and Prevention. Other outcomes include preeclampsia diagnosis and initiation of treatment, changes in perceived social support domains, patterns of physical activity, and implementation outcomes. The chatbot is a preexisting resource available to all patients in the participating healthcare system. In this established program, conversation prompts flagged by the chatbot go directly to a centralized care team; the care team member then calls the patient for assessment before referring them to appropriate care or other services. Flags include clinical, behavioral health, and social need metrics or		

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	CURRENT STATUS as of October 21, 2024
	concerns. The centralized care team will then use established clinical pathways to assess the patient's situation and refer them to appropriate care. The chatbot program itself does not identify appropriate pathways but simply alerts the clinical team that an issue needs attention. The chatbot is not the focus of this study and will not be tested; it is offered to both study arms because it is a current standard-of-care practice for maternal health support in the partnering healthcare system.		
Status of IRB approval	The study will be conducted in a single healthcare system and will use the Northwell Health IRB. IRB approval has not yet been received.		This single-site study received IRB approval on February 29, 2024.
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. The chatbot is not being evaluated as part of this research. However, if the local IRB considers use of the chatbot to be a research-driven procedure, the study team anticipates that the use will meet FDA criteria for nondevice clinical decision support. The study team will identify potentially eligible patients using the electronic health record, will send them letters and study information, and will follow up by telephone after 7 days for a recruitment call. Patients who are interested and eligible will undergo a verbal consent process, complete baseline questionnaires, and be randomly assigned to a study arm.		The IRB determined that the study meets the regulatory criteria to be considered minimal risk. The IRB also agreed to consider the study's use of the chatbot to be standard of care because it is being offered to all birthing patients at Northwell. There have been no changes to the plan to use a verbal consent approach.

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	CURRENT STATUS as of October 21, 2024
Privacy (including HIPAA)	The group discussed questions related to the commercial vendor that developed the chatbot program; the reference dataset used to develop the program and its relevance to the study population; and whether and how patient data will flow back to the vendor and potentially be used to improve the product. The study team will confirm whether any data from Northwell Health will be provided to the vendor. • After the meeting, the study team confirmed that they will meet with the clinical team and the chatbot developer in early January to discuss data sharing, data generated, and data/information used for product development.		The IRB agreed to consider the study's use of the chatbot to be standard of care because it is being offered to all birthing patients at Northwell. When a patient goes to the chatbot, they encounter messaging regarding protected health information (PHI) and sharing of data, and a notification not to use the chat in place of medical care. Patients must agree to these terms, and the PHI warning is presented each time the patient receives a weekly chat. Note that the chatbot is not artificial intelligence and is not learning. The questions and the chatbot's responses to patients' responses were

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	CURRENT STATUS as of October 21, 2024
			programmed by the ob-gyn team at Northwell.
Monitoring and oversight	A data and safety monitoring board is not required. The study will have an independent safety monitor.		The plan for data monitoring and oversight has not changed since it was discussed during the consultation on November 20, 2023.
Issues beyond this project (regulatory and ethics concerns raised by the project, if any)	None.		
Other matters	The study team raised a question about whether the interventionists in the study (coordinators, nurses) will need to complete human subjects research training, even though they will simply be performing tasks they already perform as part of their regular clinical practice. It was noted that this may vary by institution, but in this case it seems likely that they will not need to complete additional training. Pearl O'Rourke asked whether the clinical personnel receiving the chatbot alerts will be aware of which patients are enrolled in the study, as this could help determine whether they are acting strictly in a clinical care capacity. • After the meeting, the study team confirmed that the care team will not be made aware of which patients are enrolled in the study. They will follow standard protocol for the MOMs program. The group discussed a number of questions related to what data will be entered into the chatbot by any connected devices, such as the fitbit. There especially was concern about the types and quantity of data that a linked fitbit might		

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	CURRENT STATUS as of October 21, 2024
	automatically load into the chatbot and how that data will be shared, given the potential privacy considerations. There was a related concern about what data generated by the fitbit might be also be shared with Fitbit, Inc. • After the meeting, the study team confirmed that they will meet with the clinical team and the chatbot developer in early January to discuss data sharing, data generated, and data/information used for product development.		
Additional follow-up information			The study team has not experienced any additional issues.