Study ID #: 18-02705
THE MOUNT SINAI HEALTH SYSTEM/ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI
RESEARCH INFORMATION SHEET

Research Title: Realtime Streaming Clinical Use Engine for Medical Escalation (ReSCUE-ME)

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You have been previously selected to participate as a **research subject** in a trial of a new type of medical alerting system because you are being admitted to either the 10W or 10E nursing units, are over 18 years of age, and are not being admitted for labor and delivery or in-patient psychiatric care. The purpose of this IRB approved research study is to see if machine learning and artificial intelligence can help predict and prevent unwanted clinical deterioration and harm.

A sophisticated computer algorithm will monitor laboratory, vital signs, nursing notes and other data and generate an alert to your nurse and doctor should the computer suspect you are at risk of getting sicker while in the hospital.

You will be enrolled for the duration of your hospitalization. **Your participation in this study will not take any additional time or effort on your part**. We expect that over 18,000 people will take part in this study.

Being in this research study is completely voluntary. You can choose **not** to be in this research study. You can also say yes now and change your mind later. Deciding not to be in the research study, now or later, **will not** affect your ability to receive medical care at Mount Sinai Medical Center and will involve no penalty or loss of benefits to which you are otherwise entitled.

If you agree to take part in this research, there will be **no** change to the standard of care that you receive. The computer algorithm will continuously monitor your condition and generate a prediction score. If this score is above a certain level, an **alert** will be sent to your nurses and doctors. The nurses and doctors will then evaluate you and decide if are getting sicker and need more monitoring or an intervention. **The computer will never decide on its own how to care for you.** All interventions will be at the discretion of the care provider.

To opt out or withdraw from this study**, simply tell your nurse, doctor, or the Business Associate that you do not wish to participate**. You may also email **clinicaldatascience@mountsinai.org** with the subject line "**ReSCUE-ME OptOut**", leave a message for the PI Dr. Levin at 212-241-8382, or visit **https://is.gd/rescuemeoptout**. You will need to provide your first name, last name, date of birth and callback number in order to be removed from the study.

If you opt-out, no data will be collected, and no alerts will be sent. You will continue to receive the best possible care. If you withdraw, data and alerts up until the time at which you withdraw will remain part of the study database. After you withdraw no further data will be collected and no alerts will be sent.

The possible risks to you in taking part in this research are minimal. There is a chance that you may receive additional monitoring or care when you didn't really need it. There is a chance that your nurses or doctors may ignore an alert and thus not intervene when you truly needed an intervention, or that in the process of responding to an alert for another patient, your nurses and doctors are not able to immediately care for you or respond to your requests. However, these risks exist for all forms of clinical alerts and notifications, not just the alert in this trial.

The possible benefits to you for taking part in this research is that if you start to get sicker during your hospital stay, that your care will be increased more promptly. This is also an opportunity to participate in a study which can validate the effectiveness of a new technology for predicting the need for increased care while in the hospital. This could have future benefit to society.

There are some pieces of your protected health information (PHI) that are needed in order for the system to function correctly. Your name is needed in order for the computer system to properly route any alerts generate to the correct nurse and doctor. In order to protect your identity as a research subject, the researcher(s) will not share your information with anyone. All data collected for the study will be stored in secure, password protected databases and servers located within Mount Sinai's secure data center. If the results of this trial are published, your identity will remain confidential.

Research monitors, auditors, IRB, and regulatory authorities will be granted direct access to your original medical records for verification of clinical trial procedures and data, without violating your confidentiality, to the extent permitted by applicable laws and regulations.

If you have any questions about this research, please contact the Principal Investigator Dr. Levin at the address above.

If wish to speak to someone independent of this research regarding questions, concerns, or complaints about the research; questions about your rights; to obtain information; or to offer input, **you may contact**:

Mr. Jim Leader
Research Administrative Manager
Department of Anesthesiology, Perioperative & Pain Medicine
james.leader@mountsinai.org
212-241-5468

You can also call the Program for the Protection of Human Subjects Office at 212-824-8200.