Gmail

David Yachabach <yachabach@gmail.com>

FW: Rahm doppler study

2 messages

Neil Euliano <neil@conveng.com> Mon, Jul 21, 2025 at 5:12 AM
To: "Hu, Helen H." <hzhang6@peds.ufl.edu>, "yachabach@gmail.com" <yachabach@gmail.com>, "vik.ramprakash" <vik.ramprakash@rahmsd.com>

Helen,

You're standard NICU monitor is a Philips Intellivue system, right? If so, we have software that would allow us to read this data directly into the laptop PC. Is temperature taken from the intellivue system as well, or is that hand taken and entered manually into EPIC?

Thanks

Neil

From: Vik Ramprakash <vik.ramprakash@rahmsd.com>
Sent: Saturday, July 19, 2025 7:04 PM
To: Neil Euliano <neil@conveng.com>
Subject: FW: Rahm doppler study

FYI

Sent via mobile. Kindly excuse any unintended tone or typos.

-------- Original message --------

From: "Hu, Helen H." <hzhang6@peds.ufl.edu>

Date: 7/18/25 3:34 PM (GMT-05:00)

To: vik.ramprakash@rahmsd.com, 'Dave Yachabach' <dave.yachabach@rahmsd.com>, "Savani, Rashmin C." <rsavani@ufl.edu>

Subject: Rahm doppler study

Hi all,
Attaching the most recent version of the protocol. Apologies for delay, finally found some uninterrupted time to go through it more thoroughly and look through references. I've been in discussion with our contracts/grants person and Dr. Weiss from our IRB team. They had also reviewed the prior protocol and provided feedback which I have incorporated. I am also including a suggested budget based on this.

Key changes:

- Including only 28 weeks gestation and above. Because temperature probe measurements will be taken additional times than standard of care, it would introduce additional noxious stimuli particularly to <28w gestation patients.
- Refined inclusion/exclusion criteria
- Including NICU patients only- I don't think it's necessary to include patients from newborn since we are primarily interested in determining how closely the device matches traditional measuring systems. This will also help with feasibility in terms of consent and disruption to patient families.
- Temperature measurement I adjusted to 3 measurements 20 minutes apart in a 1 hour monitoring period rather than every 10 minutes. Standard of care for NICU patient would be every 3 hours, so this would be considered additional. If the patient's temperature is continuously monitored via probe rather than thermometer, more data points can be documented.
- $50/patient compensation- rest of budget attached. Will need to document SSN in order to provide gift cards to patients.
- I noticed we did not have a plan for statistical analysis initially so included one. I am by no means a biostatistician so it would be helpful to include one.
- Is there somebody who already has knowledge of how to download data from the monitor in the unit to a laptop? And also with knowledge of how to download the data from the doppler device?

Once I have your go-ahead and approval of the budget, I can initiate the process of inputting the IRB and also coordinating with the contracts/grants office.

Thanks!

Best,

Helen

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2 attachments

DRAFT Protocol_NICU_Rahm Neo-Guardian_July.docx
7805K

RahmBudgetRefs.xlsx
13K

Neil Euliano <neil@conveng.com> Mon, Jul 21, 2025 at 5:42 AM
To: "Hu, Helen H." <hzhang6@peds.ufl.edu>, "yachabach@gmail.com" <yachabach@gmail.com>, "vik.ramprakash" <vik.ramprakash@rahmsd.com>
Cc: "Savani, Rashmin C." <rsavani@ufl.edu>

- Minor comments:
  - In section 4.2 you say it is a non-inferiority study to show the system is within 95%. When you talk to the statistician, can you ask them if there are pros/cons to a non-inferiority study when mainly we are just “evaluating the system in a pilot study” to see how close we are and whether improvements are needed?
  - In 5.3.1 I agree that we will not be recording any protected patient information (at least not identifying information). However, you will need to manually store a linkage between “study id” and “patient id” for future reference. We don’t ever need to see this table.

- In section 8 and 10 we say “participant” several times (participants will be given…etc). Obviously we mean parents or legal guardians. Is participant broad enough to cover that?
- I can’t find, but it is probably in there, where the protocol says that the machine data and ground truth data from the hospital will be shared with the sponsor. This is important for us to improve the performance of the system. I know this is normally included in the informed consent as well.

Speaking of the informed consent, are we actively working on the other documents required beyond the protocol? Is the IRB team helping with these documents too?

Thanks

Neil

[Quoted text hidden]