Intervention Informed Consent Form
NCT04152603
Approved May 5, 2022

UNIVERSITY OF WASHINGTON
CONSENT FORM
Better Research Interactions for Every Family (BRIEF): Research Team Intervention

Researchers:

[contact information omitted]

We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this carefully. You may ask any questions about the study. Then you can decide whether or not you want to be in the study.

PURPOSE OF THE STUDY

Parents asked to enroll their infant in neonatal research commonly report stress around this decision. These issues are likely worse for under-represented populations, who are less likely to be included in neonatal research.

The purpose of this study is to test the feasibility of using a modified recruitment approach for the Darbe plus IV iron (DIVI) neonatal clinical trial. We have two overall goals: 1) improve the experience for parents asked to enroll their infant in a neonatal clinical trial with a special focus on the concerns that arise for those from under-represented populations and 2) decrease disparities in enrollment within a neonatal clinical trial.

STUDY PROCEDURES

If you participate in this study:

1. You will invite families whom you are approaching for participation in DIVI to participate in an **audio-recorded informed consent discussion** during the two periods of time, one before and one after the educational module described below. We will inform you when we enter the phase of the study that includes audio recording. You will audio-record your consent discussion with the parents that agree.
2. You will complete an online **self-assessment survey** after each audio-recorded informed consent discussion. Each self-assessment survey should last under five minutes.
3. You will complete an **educational module** about halfway through recruitment for the Darbe Plus IV Iron Study. The module has multi-media components. The first part will be online and self-directed (up to 30 minutes). The second part will be a single in-person (or virtual, if necessary) session (up to 90 minutes). The third part will be a brief, informal follow-up phone call about 2-4 weeks after the in-person session (up to 15 minutes).
4. You will complete an **end-of-study interview** to get your feedback about their experience using the intervention. The interview will be conducted over Zoom or on the phone at a time that is convenient for you and will last approximately 30 minutes.

You may refuse to answer any question or item in any assessment, questionnaire, or interview. Your participation in the study will end after the interview. The duration of your participation in this study will be approximately as long as you are doing recruitment for the Darbe Plus IV Iron Study.

RISKS, STRESS, OR DISCOMFORT

You might find it upsetting or annoying to talk with us about your experiences, so we can pause or stop our discussion at any time. You can also choose not to answer any particular questions.

There is a risk of a loss of confidentiality. We will take all measures to prevent this from happening, including removing all identifying information from the self-assessments and interview transcripts. Also, all publications that result from this research will not identify you specifically.

BENEFITS OF THE STUDY

There is no expected benefit to you of participating in this study.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support from the National Institutes of Health.

CONFIDENTIALITY OF RESEARCH INFORMATION

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

As grant-funded research, we have a Certificate of Confidentiality from the **National Institutes of Health**. This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;
- authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the NIH funding for this study ends. Currently this is 2/28/2026. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

The following describes the type of information the study will create, use or share, who may use it or share it, and the purposes for which it may be used or shared.

This information may include things like:

- Information specific to you like your name.

This information may be used by or shared with:

- Researchers (such as doctors and their staff) taking part in this study here and at other centers,
- Research sponsors – this includes any persons or companies working for, with, or owned by the sponsor,
- Review boards (such as the University of Washington Institutional Review Board), data and safety monitoring boards, and others responsible for watching the conduct of research (such as monitors),
- Governmental agencies like the U.S. Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS), including similar agencies in other countries, and
- Public health authorities to whom we are required by law to report information for the prevention or control of disease, injury, abuse, or disability.

This information may be used or shared to:

- Complete and publish the results of the study described in this form,
- Study the results of this research,
- Check if this study was done correctly, and
- Comply with non-research obligations (if we think you or someone else could be harmed)

There is no time limit for the use or sharing of your information. Researchers continue to analyze data for many years, and it is not always possible to know when they will be done.

If the results of the study are published, information that identifies you would not be used.

If you decide that we cannot use or share your information, you cannot participate in this study.

USE OF INFORMATION

Using Your Data in Future Research

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not

we need to get additional permission from you.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. If you wish to withdraw, please contact the researcher listed on page 1 of this consent form.

The research team will offer you the following incentives for participating in this study:

- $100 following completion of the educational module
- $100 after completion of closing interview at end of study.

A copy of the consent form will be emailed to you at an email address that you provide. It will be a "PDF" document. Most computers already have PDF viewer software installed, which will allow you to open, read, or print the consent form. The email we send you will include a link to PDF viewer software (such as Adobe Acrobat Reader) in case your computer doesn't already have it. If you would prefer to receive a paper copy of the consent form at no cost to you, please contact the researcher listed on page 1 of this consent form.

RESEARCH-RELATED INJURY

If you think you have been harmed from being in this research, contact [contact information omitted]

Consent Presenter Statement

I have provided this participant with information about this study. The participant has been given sufficient time to consider participation and I have answered any questions they had. The participant indicated that they understand the nature of the study, including risks and benefits of participating.

Printed name of study staff obtaining consent Date

Participant's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I will receive a copy of this consent form.

Printed name of participant Signature of participant Date

Copies to: Researcher
Participant