

Parent Interview Informed Consent Form
NCT04152603
Approved July 7, 2022

**UNIVERSITY OF WASHINGTON
INFORMATION SHEET**

Better Research Interactions for Every Family (BRIEF): Family interviews

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

The goal of this research study is to improve how we ask people to do research. This interview research study will build on the information from our survey that you recently completed.

STUDY PROCEDURES

We will ask you to do one phone interview. This interview will take about 30 minutes. We will call you at a phone number and time that is convenient for you. We will ask you for your permission to audio record our conversation and we will review the information in this form with you. Then we will ask you to share your thoughts and experiences being asked to join the Darbe plus IV Iron (DIVI) study.

At the end of the interview, we will ask you if you want to share your contact information with us so we can send you a \$50 gift card as a thank you.

RISKS, STRESS, OR DISCOMFORT

You may be uncomfortable about answering some of our questions or being audio-recorded. If you are upset by any questions please let us know. You do not have to answer any question.

There is also a risk to your privacy. While we will do our best to keep your information and audio-recordings confidential, it is possible that someone outside the study team might find out that you participated in this research or hear your responses. The section on the next page titled Confidentiality of Research Information has more information about how we will protect your privacy.

BENEFITS OF THE STUDY

There is no benefit to you, but your responses will help us improve the process for families in the future.

SOURCE OF FUNDING

This study is funded by the National Institutes of Health.

CONFIDENTIALITY OF RESEARCH INFORMATION

We will keep your information confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities. We will save audio recordings on secure, password-protected computers. We will remove information that could identify you before we share any results of the study.

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.

We have a Certificate of Confidentiality from the federal 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 02/28/2026. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

USING YOUR INFORMATION IN FUTURE RESEARCH

The information you share with us for this study might be used in future research. We may remove anything that might identify you from the information. If we do, that information may be used for future research 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 information from you.

OTHER INFORMATION

You are free to withdraw from this study at any time. If you want to withdraw, please contact [contact information omitted]. You can decide not to participate or withdraw your participation without penalty. Your decision will not impact the care you or your child receive.

If you think you have been harmed from being in this research or have questions about your rights as a research participant, contact the University of Washington Institutional Review Board at hsdinfo@uw.edu or 206-543-0098.