BRIEF Study
Manual of Procedures

Table of Contents

1 Introduction

A. Parents asked to enroll their infant in neonatal research commonly report significant stress around this decision and challenges building relationships with the research team. These issues are likely worse for under-represented populations, which are less likely to be included in neonatal research. This study aims to pilot test an intervention designed to improve the experience for parents asked to enroll in neonatal research, with a special focus on the concerns that arise for those from under-represented populations. This is necessary to improve parental experiences of recruitment, decrease disparities in the research population, and ultimately produce a more generalizable knowledge base within neonatology.

2 Brief Overview of the Study Protocol

A. The goal of this study is to pilot test the feasibility of implementing a modified recruitment approach, the Better Research Interactions for Every Family (BRIEF) Intervention, within a neonatal clinical trial. This intervention has two distinct aims: 1) improve the experience for parents asked to enroll their infant in a neonatal clinical trial; 2) decrease disparities in enrollment within a neonatal clinical trial. We will apply the BRIEF Intervention within a single site neonatal randomized control trial (RCT), the Darbe plus IV iron study, using apre/post approach. The objectives of this current ancillary study are to assess feasibility, gain preliminary experience to drive further refinement, and provide effect estimates for a future RCT of the BRIEF intervention.

This study is an ancillary study to the Darbe plus IV Iron study, which is a phase II RCT aiming to demonstrate the feasibility and potential benefit for darbepoetin plus slow-release intravenous iron to decrease transfusions, maintain iron sufficiency, and improve neurodevelopmental outcomes of preterm infants. In the BRIEF study, we will pilot a research team educational module to support recruitment for this neonatal clinical trial.

3 Study Staff Responsibilities

4 Study Flow Diagram

Figure 1. BRIEF Study Timeline

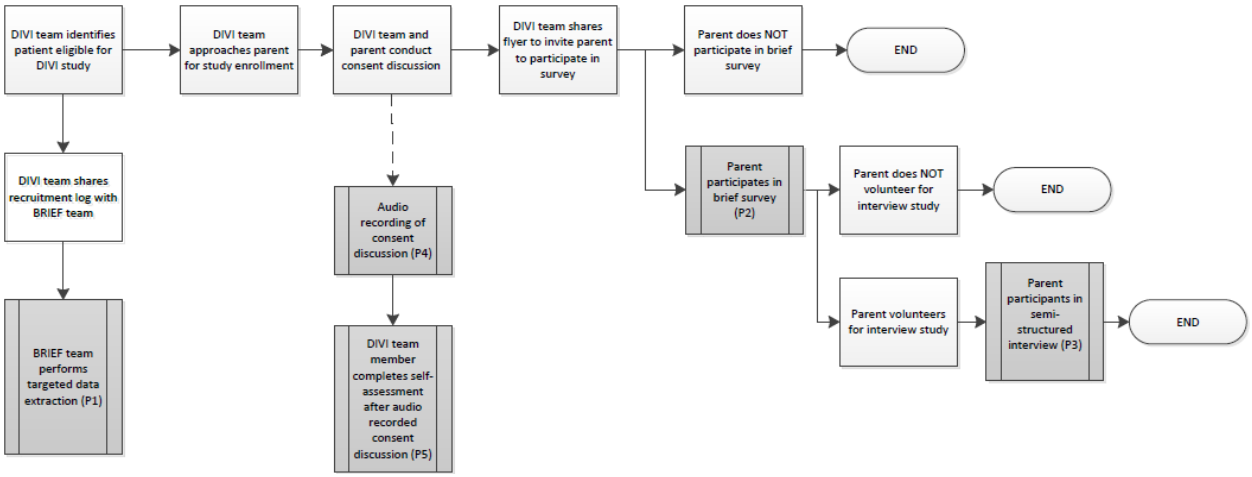

Figure 2. BRIEF Participant Timeline

5 Recruitment and Retention Plan Screening and Eligibility Criteria

5.1 Screening Log

A. See Screening Log [redacted]

5.2 Eligibility Criteria

A. Inclusion Criteria

- **a.** P1: Infants born between 24-0 and 31-6 weeks of gestation cared for in the UW NICU who are eligible for participation in the Darbe plus IV iron study.
- **b.** P2: English or Spanish speaking parents or legally authorized representatives (LARs) who were approached for participation in the Darbe plus IV iron study. Parents/LARs under age 18 will be excluded.
- **c.** P3: Parents/LARs who chose to participate in the survey in P2 and shared their contact information indicating interest in participating in an interview.
- **d.** P4: English or Spanish speaking parents/LARs who were approached for participation in the Darbe plus IV iron study.
- **e.** P5: Research team members who participate in recruitment procedures (e.g., tracking of potential participants, informed consent discussion) for the Darbe plus IV iron study.

6 Informed Consent

6.1 HIPAA Authorization

A. See HIPAA Authorization document [redacted]

7 Study Interventions

7.1 (P1) Infant Data Extraction

A. Data Extraction

- **a.** [Redacted] to collect data from DIVI study screening log and EMR and enter in *REDCap BRIEF P1. data extraction* (https://redcap.iths.org/surveys/?s=K37XKN4DCKWHFNY8)
  a. [redacted] to also collect at discharge—plan to cluster once monthly

7.2 (P2) Parent Survey

A. Survey Distribution

- **a.** DIVI study team to distribute BRIEF P2. survey flyer summary sheet [double sided English/Spanish] at time of recruitment
- **b.** REDCAP: emails full team with each entry of parent survey
  i. If completed, REDCap automated message notifying [redacted]/[redacted]/[redacted] for incentives and interviews
- **c.** [redacted] inform [redacted] and [redacted] if survey NOT completed at 7-10 days (postnatal only) → then [redacted] or [redacted] to bring BRIEF P2. survey flyer summary sheet to patient bedside

B. Incentives

- **a.** Within 3 days of completion of parent survey, [redacted] [or [redacted]/[redacted]] to send out incentives with thank you email to

parents who have completed *REDCap BRIEF P2. family survey* and *REDCap BRIEF P2. family survey Spanish*

i. Codes for $25 Amazon or Tango gift card can be found in [AmazonGiftCodes-111-8287595-4521800 – first 10 eGift Cards only]

ii. Track sent incentives using ORF-004-01 Research Participant Gift Card Tracking Log

1. Information needed includes Date (gift card dispensed), Participant's Full Name, Gift Card Amount Issued, type of Gift Card (i.e., Amazon or Tango)

C. Tracking

a. Note progress/completion in BRIEF Recruitment Logs

b. Track enrollment rates

7.3 (P3) Parent Interviews (N=40)

A. Recruitment

a. [redacted]/[redacted] to identify parents who volunteered to participate in *REDCap BRIEF P2. family survey* and *REDCap BRIEF P2. family survey Spanish*

i. Select participants for outreach based on purposive sampling criteria:

1. Equal proportion of enrollees (n=20) and decliners (n=20) in DIVI study
2. Equal proportion of parents approached pre- (n=20) and post-BRIEF (n=20) Intervention
3. Within each cohort, aim for at least 50% not non-Hispanic White
4. For Spanish interviews, aim to recruit at least 8, but as many as 12, out of the 40 total interviewees

ii. In order to reach the above goals, prioritize:

1. All decliners
2. All not non-Hispanic white participants
3. Parent/child on Medicaid

Parent Interview Cohorts		
	Pre-BRIEF Intervention	Post-BRIEF Intervention
Enrollees	10	10
Decliners	10	10

B. Scheduling

a. [redacted]/[redacted]/[redacted] to contact selected participants at least 3 days and up to no more than 4 months post-survey completion to participate in an interview; refer to participant's preferred method of contact

i. If by email:

1. Provide overview of interview
2. Attach BRIEF P3. parent interview information sheet
3. Provide potential dates and times for interview

ii. If by phone:
1. Provide overview of interview
2. Review BRIEF P3. parent interview information sheet, time permitting
3. Schedule interview
4. Email BRIEF P3. parent interview information sheet immediately after the call

iii. If by text:
1. Introduce self and BRIEF study
2. Remind participant about BRIEF P3. parent interview information sheet
3. Provide potential dates and times for interview

iv. Update the BRIEF Recruitment Logs spreadsheet with scheduled date and time

C. Reminders
- **a.** [redacted]/[redacted]/[redacted] to email/call/text participant to remind them of the interview the day before (confirm preferred method of contact during scheduling)
  - **i.** Send multiple reminders depending on how far out the interview is scheduled, or if the parent prefers multiple reminders

D. Interview
- **a.** Connect to Zoom call prior to scheduled interview time
- **b.** Request permission to record Zoom call
  - **i.** If yes, begin recording
  - **ii.** If no, take notes of participant's responses during interview
- **c.** Review information from BRIEF P3. parent interview information sheet; if necessary
- **d.** Begin interview
- **e.** Stop recording
- **f.** Collect information necessary to send interviewee incentive (i.e., interviewee's email)
- **g.** Note completion of the interview in BRIEF Recruitment Logs
- **h.** Upload interview audio to shared drive

E. Incentives
- **a.** [redacted]/[redacted] to send out incentives with thank you email to parents who have completed Parent Interview
  - **i.** Track sent incentives using ORF-004-01 Research Participant Gift Card Tracking Log
    1. Information needed includes Date (gift card dispensed), Participant's Full Name, Gift Card Amount Issued, type of Gift Card (i.e., Amazon or Tango)

7.4 (P4) Recruitment Discussion (N=100)

A. Audio-recording and upload (N=100)
- **a.** DIVI team has script for consent to audio-record consent discussion
- **b.** DIVI team member to retrieve iPad from [redacted]
  - **i.** iPad will be passcode protected
  - **ii.** Passcode will be provided to consenting DIVI study team members only
- **c.** Once the tablet is unlocked, two icons will be present on the home screen
  - **i.** Voice Memos app
  - **ii.** Link to REDCap
- **d.** Using the Voice Memos app
  - **i.** Open Voice Memos app
  - **ii.** Tap the record button (red circle) to begin recording
  - **iii.** Tap the pause button (two vertical red bars) to stop recording
  - **iv.** Tap “Done” to save the recording
  - **v.** Renaming the recording
    1. Tap the name at the top of the screen (the default name is typically “New Recording X”)
    2. Enter the [DIVI screening ID]
    3. Tap “return” on the keyboard
    4. Tap “Done” on the bottom right corner of the screen
  - **vi.** Tap the more options button at the top of the screen (Circle with three dots)
  - **vii.** Tap “Share…”
  - **viii.** Tap “Save to files”
  - **ix.** Tap “On My iPad”
  - **x.** Select “BRIEF Consent Audio”
  - **xi.** Tap “Save”
- **e.** Return to home screen and open link to REDCap survey
  - **i.** Enter DIVI screening ID
  - **ii.** Select your name from the list of DIVI Team Members
  - **iii.** If the Consent Discussion was recorded, select “Yes”
  - **iv.** Tap “Upload file”
  - **v.** Tap “Choose File”, tap “Choose File” again
  - **vi.** Navigate to the “BRIEF Consent Audio” folder
    1. If not in the BRIEF Consent Audio folder already, tap “Browse” in the upper left-hand corner
    2. Tap “On My iPad”
    3. Tap the “BRIEF Consent Audio” file
    4. Tap the recording
  - **vii.** Tap “Upload file”
  - **viii.** Complete short milestones format survey about consent discussion that just took place
- **f.** Close both the Voice Memos and the REDCap link and turn off the tablet
- **g.** Return tablet to [redacted]

B. Milestone self-assessments (N=100)

a. Complete the Likert Scale questions for each of the 11 milestones
b. Close survey
c. [Automated REDCAP step]—share with BRIEF team with each completion
d. Close both the recording app and the REDCap link and turn off the tablet
e. Return tablet to [redacted]

7.5 (P5) Research Team Member Interviews (N=8)

F. Scheduling
- **a.** [Redacted] to invite NICU team members to complete a scheduling poll
- **b.** [Redacted] to schedule NICU team members based on responses to scheduling poll

G. Reminders
- **a.** [Redacted] to email NICU team member to remind them of the interview the day before
  - **i.** Send multiple reminders depending on how far out the interview is scheduled, or if the NICU team member prefers multiple reminders

H. Interview
- **a.** Connect to Microsoft teams call prior to scheduled interview time
- **b.** Request permission to record Microsoft teams call
  - **i.** If yes, begin recording
  - **ii.** If no, take notes of participant's responses during interview
- **c.** Begin interview
- **d.** Stop recording
- **e.** Collect information necessary to send interviewee incentive (i.e., interviewee's email)
- **f.** Note completion of the interview in BRIEF Logs
- **g.** Upload interview audio to shared drive

I. Incentives
- **a.** Upon completion of interview send out incentive via Tango
  - **i.** Track sent incentives using ORF-004-01 Research Participant Gift Card Tracking Log
    1. Information needed includes Date (gift card dispensed), Participant's Full Name, Gift Card Amount Issued, type of Gift Card (i.e., Amazon or Tango)

8 Study Compliance

A. See study compliance doc [redacted]

9 Data Collection and Study Forms

9.1 Participant Binder

A. See BRIEF Recruitment Logs

9.2 Study Forms

A. See Aim 3. BRIEF Intervention shared drive for study forms

9.3 General Instructions for Completing Forms

9.4 Data Flow

A. See analysis plan

9.5 Administrative Forms

A. See Aim 3. BRIEF Intervention shared drive for administrative forms

A. Data Security
    a. Level 3: Could cause risk of material harm to individuals if disclosed.
        i. Description: These data could result in harm that can have genuine impact, but the magnitude and/or duration are generally not serious, long-lasting, and/or irreversible.
    b. See GUIDANCE_Data_Security_Protections_1.31_2021.06.24 for additional details

A. To be developed upon completion of analysis