

Attachment 1b

National Health and Nutrition Examination Survey (NHANES) Blood Draw – Infants (0 to less than 12 months) Pilot Study

Form Approved
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This attachment represents the burden for the blood draws for participants 0 to less than 12 months and/or the time to complete the venipuncture refusal questionnaire.

Safety Exclusion and Fasting Questionnaire

Question 1: Does your infant have a bleeding disorder such as hemophilia or von Willebrand Disease, or a blood disorder such as aplastic anemia or leukemia?

Record the response by typing [Y] for “Yes,” [N] for “No,” [R] if he or she refuses, or [D] for “Don’t know.”

Q1: This question asks whether the SP (Survey Participant) has a bleeding disorder such as hemophilia or a blood disorder such as aplastic anemia or leukemia, which is an exclusion criterion for this procedure.	Explain to parent or guardian that we cannot perform phlebotomy on participants who have hemophilia or a known blood disorder. Hemophilia is a rare disease where an individual’s blood does not clot normally. If a relative has hemophilia or a blood disorder but the infant does not, the infant is not excluded. If the infant is excluded, the Blood Draw Exclusion box displays. Read the text in the box to the parent or guardian and escort the infant and parent/guardian SP back to the coordinator area.
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Question 2: Is your infant currently participating in a chemotherapy protocol or received cancer chemotherapy in the past 4 weeks? Record the response by typing Y for “Yes, N for “No,” R if he or she refuses, or D for “Don’t know.”

Q2: This question asks whether the SP is currently receiving cancer chemotherapy or received cancer chemotherapy in the past 4 weeks. This situation excludes the SP from this procedure.	Explain that we cannot perform phlebotomy on participants who are currently receiving cancer chemotherapy or have received cancer chemotherapy within the past 4 weeks. If the infant is excluded, the Blood Draw Exclusion box is displayed. Read the text in the box to the parent or guardian and escort parent/guardian and infant back to the coordinator area.
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Question 3: Has your infant had blood drawn in the past 30 days? Record the response by typing Y for “Yes, N for “No,” R if he or she refuses, or D for “Don’t know.”

Q2: This question asks whether the SP has had blood drawn in the past 30 days. This situation excludes the SP from this procedure.	Explain that we cannot perform phlebotomy on participants who have had recent blood draws. If the infant is excluded, the Blood Draw Exclusion box is displayed. Read the text in the box to the parent or guardian and escort parent/guardian and infant back to the coordinator area.
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Fasting Questionnaire

Q1: When was the last time your infant ate or drank anything other than plain water?

Record date and time of response

Q1: This question elicits the last time the SP ate or drank anything and determines fasting time.	Record the last time the infant has had anything to eat or drink.
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Q2: Has your infant had any of the following since (time from question 1 inserted here)?

Record date and time of response

Milk, juice or soda	Do not include diet soda.
Cough or cold remedies?	Ask the SP to describe the activity, item consumed, and the correct time.
Antacids, laxatives, or anti-diarrheal medications?	Antacids neutralize stomach acids. Laxatives stimulate evacuation of the bowels. Anti-diarrheals relieve diarrhea and cramping. Include all over-the-counter antacids, laxatives, and anti-diarrheals. If the answer is "Yes," clarify the response. Ask the SP to describe the activity, item consumed, and the correct time.
Dietary supplements such as vitamins? [Include multivitamins and single nutrient supplements.]	Vitamins refer to various relatively complex organic substances occurring naturally in plant and animal tissue. They are essential in small amounts for the control of metabolic processes. Many are available over the counter as liquid multivitamins or single-nutrient supplements like Vitamin D. Include all of these when clarifying the response to this question. If the answer is "Yes," clarify the response. Ask the SP to describe the supplement, item consumed, and the correct time.

Blood Draw Exclusion Box – Example Text

The following responses will be read to the participant if they answer “yes”, refused or don’t know to the safety exclusion questions in the infant blood pilot.

Blood drawn in 30 days:

(Yes): Because your infant has had blood collected in the past 30 days, we will not be able to draw blood for this study. However, I would like to thank you very much for answering my questions and for cooperating with our research.

(Ref): Because you refused to answer if your infant has had blood collected in the past 30 days, we will not be able to draw blood for this study. However, I would like to thank you very much for answering my questions and for cooperating with our research.

(DK): Because you do not know if your infant has had blood collected in the past 30 days, we will not be able to draw blood for this study. However, I would like to thank you very much for answering my questions and for cooperating with our research.

Hemophilia:

(Yes): Because your infant has hemophilia or other blood disorder, we will not be able to draw blood for this study. However, I would like to thank you very much for answering my questions and for cooperating with our research.

(Ref): Because you refused to answer if your infant has hemophilia or other blood disorder, we will not be able to draw blood for this study. However, I would like to thank you very much for answering my questions and for cooperating with our research.

(DK): Because you do not know if your infant has hemophilia or other blood disorder, we will not be able to draw blood for this study. However, I would like to thank you very much for answering my questions and for cooperating with our research.

Chemotherapy:

(Yes): Because your infant had recent chemotherapy or is currently undergoing chemotherapy, we will not be able to draw blood for this study. However, I would like to thank you very much for answering my questions and for cooperating with our research.

(Ref): Because you refused to answer if your infant had recent chemotherapy or is currently undergoing chemotherapy, we will not be able to draw blood for this study. However, I would like to thank you very much for answering my questions and for cooperating with our research.

(DK): Because you do not know if your infant had recent chemotherapy or is currently undergoing chemotherapy, we will not be able to draw blood for this study. However, I would like to thank you very much for answering my questions and for cooperating with our research.

Follow-Up Questionnaire for Venipuncture Refusal

NHANES recommends administering a follow-up questionnaire to the parents/guardians that have refused the venipuncture to gain insight about the reasons for refusal.

It is common for parents to not permit a blood draw on their newborn or infant. To help us better understand why parents may decide not to allow us to draw blood on their infant, we appreciate if you could answer the following one question.

1. What is the reason you chose not to have your infant's blood drawn today? Please check all that apply.

- Baby is too young
- Do not want to hurt the baby or fear of sticking child/hurting child
- Fear of child crying
- Too much blood
- It is not important enough to justify the pain
- Afraid of complications if the baby moves
- Afraid of multiple attempts for a successful blood draw
- Other specify (add parent or guardian's reason)

2. Is there anything that would have changed your mind?
3. Is there anything the staff could have done to make you feel more comfortable?