

General Core

[Study Name/ID pre-filled]

Site Name:

Subject ID:

- 1) * Sex assigned at birth:
- Male Unknown
- Female Other, specify
- Intersex
- 2) Gender identity:
- Male
- Female
- Unknown
- Other, specify
- 3) *Date of birth (M M/D D/Y Y Y Y):
- 4) *Ethnicity(Choose one with which you MOST CLOSELY identify):
- Hispanic or Latino Unknown
- Not Hispanic or Latino Not Reported
- 5) *Race (Choose all those with which you identify):
- American Indian or Alaska Native White
- Asian Unknown
- Black or African-American Not reported
- Native Hawaiian or Other Pacific Islander
- 6) Language(s) fully fluent (Choose all that apply):
- English (eng) French/ Creole (cpf)
- Spanish (spa) German (ger)
- American Sign Language (sgn) Other, specify:
- Chinese languages (Chi)
- 7) Country of residence:
- USA (US) Mexico (MX)
- Canada (CA) Australia (AU)
- United Kingdom (GB) Other, specify:
- 8) First 3 digits of zip code:
- 9) Social security number:

ADDITIONAL PEDIATRIC-SPECIFIC ELEMENTS

These elements are recommended for pediatric stroke studies.

- 10) Maternal ethnicity (Choose one with which the mother MOST CLOSELY identifies):
- Hispanic or Latino Unknown
- Not Hispanic or Latino Not Reported
- 11) Maternal race (Choose all those with which the mother identifies):
- American Indian or Alaska Native White
- Asian Unknown
- Black or African-American Not reported
- Native Hawaiian or Other Pacific Islander
- 12) Paternal ethnicity (Choose one with which the father MOST CLOSELY identifies):
- Hispanic or Latino Unknown
- Not Hispanic or Latino Not Reported

Demographics

[Study Name/ID pre-filled]

Site Name:

Subject ID:

13) Paternal race (Choose all those with which the father identifies):

- American Indian or Alaska Native
 Asian
 Black or African-American
 Native Hawaiian or Other Pacific
 Islander

- White
 Unknown
 Not reported

*Element is classified as Core

GENERAL INSTRUCTIONS

This form contains data elements that are collected to describe the demographics of the study population. The items are used to compare baseline characteristics among study groups and to identify confounding variables.

The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 defines the minimum standard of basic racial and ethnic categories. (NIH Guideline on The Inclusion of Women and Minorities as Subjects in Clinical Research) NIH has chosen to continue the use of these definitions because they allow comparisons across many national data bases, especially national health data bases. Therefore, the racial and ethnic categories included on the CRF should be used as supplemental if a study requires that level of detail, otherwise the NIH standard should be used as the minimum standard.

Important note: The data elements noted with an asterisk on this CRF Module are classified as Core (i.e., required for all ALS studies to collect). The remaining data elements are classified as supplemental (i.e., non Core) and should only be collected if the research team considers them appropriate for their study. Please see the Data Dictionary for element classifications.

SPECIFIC INSTRUCTIONS

- Gender type – Self-reported gender of the participant/subject. Gender is the socially constructed identity of sex. Gender is equated with phenotypic sex. Gender may differ from the sex of an individual determined genetically.
 - Unspecified is defined as Undifferentiated/Indeterminant/Intersex
- Date of birth – Record the date of birth to the level of precision known (e.g., month/day/year, year, month/year, etc). The preferred format for recording date is MM/DD/YYYY. 99/99/9999 can be used to indicate an unknown date.
- Ethnicity – Choose only one with which the participant/ subject most closely identifies.
- Race – Choose all that apply. Response is obtained by report of the participant/subject or caretaker. Collecting information on race may not be allowed in some countries for concerns related to discrimination. In other countries, however, these concerns are considered a reason for recording race in order to guarantee equal access to care. Investigators receiving funding from the US National Institutes of Health (NIH) are required to report the number of subjects enrolled on an annual basis using the racial categories listed.

Demographics CRF Module Instructions

GENERAL INSTRUCTIONS

This form contains data elements that are collected to describe the demographics of the study population. The items are used to compare baseline characteristics among study groups and to identify confounding variables.

The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 defines the minimum standard of basic racial and ethnic categories. (NIH Guideline on The Inclusion of Women and Minorities) NIH has chosen to continue the use of these definitions because they allow comparisons across many national data bases, especially national health data bases. Therefore, the racial and ethnic categories included on the CRF should be used as basic guidance, cognizant of the distinction based on cultural heritage.

Important note: Four of the data elements included on this CRF Module are considered Core (i.e., strongly recommended for all stroke clinical studies to collect). The remaining data elements (i.e., non Core) are supplemental and should only be collected if the research team considers them appropriate for their study.

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

Responses to the demographic elements should be obtained from self-report when possible.

- Gender type – Self-reported gender of the participant/subject. Gender is the socially constructed identity of sex. Gender is equated with phenotypic sex. Gender may differ from the sex of an individual determined genetically. The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 ([Click here for the NIH Guideline on The Inclusion of Women and Minorities](#))
 - Unspecified is defined as Undifferentiated/Indeterminant/Intersex
- Date of birth – Record the date of birth to the level of precision known (e.g., month/day/year, year, month/year, etc). The preferred format for recording date is MM/DD/YYYY. 99/99/9999 can be used to indicate an unknown date.
- Ethnicity – Choose only one with which the participant/subject most closely identifies.
- Race – Choose all that apply. Response is obtained by report of the participant/subject or caretaker. Collecting information on race may not be allowed in some countries for concerns related to discrimination. In other countries, however, these concerns are considered a reason for recording race in order to guarantee equal access to care. Investigators receiving funding from the US National Institutes of Health (NIH) are required to report the number of subjects enrolled on an annual basis using the racial categories listed.

The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 defines the minimum standard of basic racial and ethnic categories. ([Click here for the NIH Guideline on The Inclusion of Women and Minorities](#)). Collection of Race and Ethnicity Data in Clinical Trials (FDA, September 2005 - [Click here for FDA Guidance for Race and Ethnicity](#))
- Language(s) fully fluent – Choose all that apply. It may be easier to record the full name of the language and code the data later using the ISO 639-2 codes.
- Country of residence – Choose one. It may be easier to record the full name of the country and code the data later using the ISO 3166-1 alpha-2 codes.

Demographics CRF Module Instructions

- First 3 digits of zip code – This is an optional field, if this information is not provided enter 000.
- Social security number – Providing this information is entirely voluntary and the participant/ subject may refuse. This information must be kept confidential according to the Privacy Act of 1974, and must only be used for research purposes.
- Maternal ethnicity – Choose only one with which the mother most closely identifies. This element is recommended for pediatric stroke studies.
- Maternal race – Choose all those with which the mother identifies. This element is recommended for pediatric stroke studies.
- Paternal ethnicity – Choose only one with which the father most closely identifies. This element is recommended for pediatric stroke studies.
- Paternal race – Choose all those with which the father identifies. This element is recommended for pediatric stroke studies.

DRAFT

Social History

- 1) What is the highest grade or level of school you have completed or the highest degree you have received?
- | | |
|--|---|
| <input type="checkbox"/> Never attended/ Kindergarten only | <input type="checkbox"/> High school graduate |
| <input type="checkbox"/> 1st Grade | <input type="checkbox"/> GED or equivalent |
| <input type="checkbox"/> 2nd Grade | <input type="checkbox"/> Some college, no degree |
| <input type="checkbox"/> 3rd Grade | <input type="checkbox"/> Associate degree: occupational, technical, or vocational program |
| <input type="checkbox"/> 4th Grade | <input type="checkbox"/> Associate degree: academic program |
| <input type="checkbox"/> 5th Grade | <input type="checkbox"/> Bachelor's degree (e.g., BA, AB, BS, BBA) |
| <input type="checkbox"/> 6th Grade | <input type="checkbox"/> Master's degree (e.g., MA, MS, MEng, MEd, MBA) |
| <input type="checkbox"/> 7th Grade | <input type="checkbox"/> Professional school degree (e.g., MD, DDS, DVM, JD) |
| <input type="checkbox"/> 8th Grade | <input checked="" type="checkbox"/> Doctoral degree (e.g., PhD, EdD) |
| <input type="checkbox"/> 9th Grade | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> 10th Grade | |
| <input type="checkbox"/> 11th Grade | |
| <input type="checkbox"/> 12th Grade, no diploma | |
- 2) *Years of education (0-30):
- 3) Current employment status:
- | | |
|---|---|
| <input type="checkbox"/> Working now | <input type="checkbox"/> Disabled, permanently or temporarily |
| <input type="checkbox"/> Only temporarily laid off, sick leave or maternity leave | <input type="checkbox"/> Keeping house |
| <input type="checkbox"/> Looking for work, unemployed | <input type="checkbox"/> Student |
| <input type="checkbox"/> Retired | <input type="checkbox"/> Other, specify: |
| | <input type="checkbox"/> Unknown |
| a. If working now, do you usually work 35 hours or more per week? | |
| <input type="checkbox"/> Yes | <input type="checkbox"/> Hours vary |
| <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
- 4) Marital/ Partner status:
- | | |
|---|------------------------------------|
| <input type="checkbox"/> Never married | <input type="checkbox"/> Divorced |
| <input type="checkbox"/> Married | <input type="checkbox"/> Separated |
| <input type="checkbox"/> Domestic partnership | <input type="checkbox"/> Widowed |
- 5) Number of people living with:
- a. If one or more people, describe the individual(s) with whom you live (Choose all that apply):
- | | |
|---|--|
| <input type="checkbox"/> Spouse | <input type="checkbox"/> Stepson or stepdaughter |
| <input type="checkbox"/> Biological son or daughter | <input type="checkbox"/> Brother or sister |
| <input type="checkbox"/> Adopted son or daughter | <input type="checkbox"/> Father or mother |

- Stepfather or stepmother
- Grandchild
- Grandparent
- Parent-in-law
- Son-in-law or daughter-in-law
- Other relative
- Roomer or boarder
- Housemate or roommate
- Unmarried partner
- Foster child
- Other patient/resident in care facility
- Personal care attendant
- Military unit member
- Other non-relative
- N/A – Homeless
- N/A – Alone
- Unknown

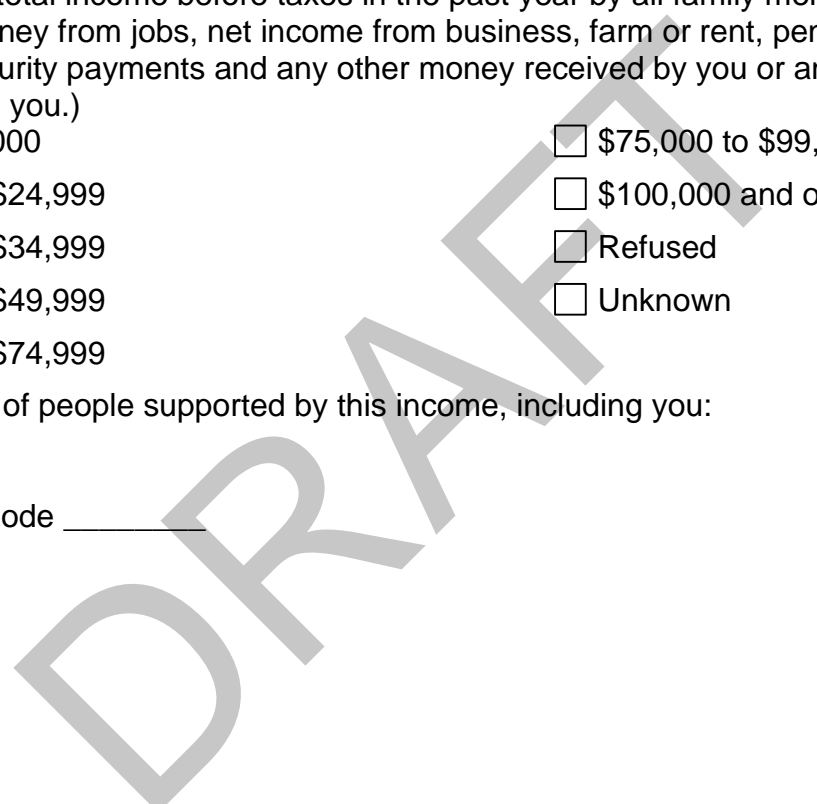
6) Income group that best represents your total combined family income for the past 12 months: (This includes the total income before taxes in the past year by all family members living with you. Please include money from jobs, net income from business, farm or rent, pensions, dividends, welfare, social security payments and any other money received by you or any other family member living with you.)

- Under \$15,000
- \$15,000 to \$24,999
- \$25,000 to \$34,999
- \$35,000 to \$49,999
- \$50,000 to \$74,999
- \$75,000 to \$99,999
- \$100,000 and over
- Refused
- Unknown

a. Number of people supported by this income, including you:

Region:

7) Indicate your zip Code _____





Data Collection Worksheet

Please Note: The Data Collection Worksheet (DCW) is a tool to aid integration of a PhenX protocol into a study. The PhenX DCW is not designed to be a data collection instrument. Investigators will need to decide the best way to collect data for the PhenX protocol in their study. Variables captured in the DCW, along with variable names and unique PhenX variable identifiers, are included in the PhenX Data Dictionary (DD) files.

BABY HUG Part VII: EDUCATION - SCHOOL QUESTIONNAIRE

1. What is your child's current grade? _____
2. What is your child's current age? _____ years _____ months
3. Has your child ever been held back or repeated a grade?

1 Yes

2 No

A. How many grades?

1

2

3 or more

B. Which grade(s)? (List up to 3 most recent grades) _____

4. Does your child have any accommodations because of learning differences?
Check all that apply:

A. Special Education Services

B. 504 plan

C. IEP-individualized education plan

D. Special tutoring or classes not available to regular students

E. Other

1. Describe: _____

F. My child does not receive any accommodation for learning differences

Protocol source: <https://www.phenxtoolkit.org/protocols/view/840201>

DRAFT

SDH Screener

[Study Name/ID pre-filled]

Site Name:

Subject ID:

1. Are you worried that in the next 2 months you may not have a safe or stable place to live? (eviction, being kicked out, homelessness)
 Yes
 No
2. Are you worried that the place you are living now is making you sick? (has mold, bugs/rodents, water leaks, not enough heat)
 Yes
 No
3. In the last 12 months, did you worry that your food could run out before you got money to buy more?
 Yes
 No
4. In the last 3 months, has the electric gas, oil or water company threatened to shut off services to you home?
 Yes
 No
5. In the last 3 months, has lack of transportation kept you from medical appointments or getting your medications?
 Yes
 No
6. In the last 3 months, did you have to skip buying medications or going to doctor's appointments to save money?
 Yes
 No
7. Do you need help getting child care or care for an elderly or sick adult?
 Yes
 No
8. Do you need legal help? (child/family services, immigration, housing discrimination, domestic issues, etc.)
 Yes
 No
9. Are you finding it so hard to get along with a partner, spouse, or family members that it is causing you stress?
 Yes
 No
10. Does anyone in your life hurt you, threaten you, frighten you or make you feel unsafe?
 Yes
 No

Do you need help?

- Yes
 No

Phone Number:

For patients 1 -17 years old

Montefiore



Dear Parent,

At Montefiore we care about your child's health, both physical and emotional, and we want to make sure that your child receives the best quality of care.

Studies have shown that the more stressful events you experience as a kid the more likely you are to have long-term physical health problems as an adult such as diabetes, high blood pressure, heart disease, etc. As the number of the stressful events your child is exposed to increases, your child's risk for these health problems increases as well. At Montefiore, we have the opportunity to identify these risks so that we can help prevent or lower the risk for health problems for your child.

That's why it's so important to answer this questionnaire honestly, even though these are personal questions. Answering this questionnaire is completely **optional**.

We would like you to **answer the following questions based on your child's experiences before the age of 18.**

Your answers will be kept confidential. Please feel free to ask any questions.

Thank you,

The Montefiore Medical Group Team

Please read the questions below. We want to know the TOTAL number of times you answer YES, but we don't need to know which questions you answered YES to. Each time you answer YES, place a line through one of the circles below. When the questionnaire is complete, count up the number of circles you have crossed out.

Since your CHILD was born:

1. Have you and your partner separated or divorced?
2. Has your child lived with anyone who was depressed or mentally ill, or who attempted suicide?
3. Has your child lived with anyone who was a problem drinker or used street drugs?
4. Has your child lived with anyone who has been to prison?
5. Has your child ever witnessed anyone in the home (parents or adults) push, grab, slap, or throw things at each other and/or witnessed anyone kick, bite, hit with a fist, or hit each other with something hard, or ever witness people threatening each other with a weapon, such as a knife or a gun?
6. Since your child was born, have there been times when your child has not had enough to eat, has not had anyone take him/her to the doctor, or have any of his/her caregivers been too drunk or high to take care of him/her?
7. Since your child was born, has a parent or other adult in your home sworn at, insulted, or put your child down or acted in a way that made your child afraid that he/she might be physically hurt?
8. Did a parent or other adult in your home push, grab, slap, or throw something at your child, or ever hit him/her so hard that she /he had marks or was injured?
9. Did a parent, adult, or someone at least 5 years older than your child ever touch your child sexually or try to make your child touch them sexually?
10. Since your child was born, do you feel as if there has NOT been anyone in his/her family who makes him/her feel special, or that you or his other caregivers have NOT been able to be a source of strength, support or protection for your child?



Total Number of Child "YES" Answers Here: _____

For patients 18 years old & up

Montefiore



Dear Valued Patient of Montefiore:

At Montefiore, we care about your physical and emotional health, and we want to make sure that you receive the best quality of care.

Studies have shown that the more stressful events you experience as a kid the more likely you are to have long-term physical health problems as an adult such as diabetes, high blood pressure, heart disease, etc.

That's why it's so important to answer this questionnaire honestly, even though these are personal questions. Answering this questionnaire is completely **optional**.

We would like you to **answer the following questions based on your life experiences before the age of 18**. Your answers will be kept confidential. Please feel free to ask any questions.

Thank you,

The Montefiore Medical Group Team

Please read the questions below. We want to know the TOTAL number of times you answer YES, but we don't need to know which questions you answered YES to. Each time you answer YES, place a line through one of the circles below. When the questionnaire is complete, count up the number of circles you have crossed out.

While YOU were growing up, during your first 18 years of life:

1. Were your parents ever separated or divorced?
2. Was anyone you lived with depressed or mentally ill, or did they attempt suicide?
3. Did you live with anyone who was a problem drinker, alcoholic or used street drugs?
4. Did anyone you lived with go to prison?
5. Was your mother or step-mother pushed, grabbed, slapped, kicked, bitten, hit with a fist or something hard, had something thrown at her, repeatedly hit for at least a few minutes, or ever threatened or hurt by a knife or a gun?
6. While you were growing up, did you sometimes not have enough to eat, wear dirty clothes, not have anyone take you to the doctor, or were your parents too drunk or high to take care of you?
7. Did a parent or adult in your home swear at you, insult you, or put you down or act in a way that made you afraid you might be physically hurt?
8. Did a parent or other adult in your home push, grab, slap, or throw something at you, or ever hit you so hard that you had marks or were injured?
9. Did a parent, adult, or someone at least 5 years older than you ever touch you sexually or try to make you touch them sexually?
10. While you were growing up, did you feel as if there was NO ONE who made you feel special or loved, or that your family was NOT a source of strength, support and protection for you?



Total Number of "YES" Answers Here: _____