Report of NCHS Research Ethics Review Board (ERB)
NCHS Protocol #2016-11 Transformed Healthy Start Program Evaluation Plan
Request for Initial Review
July 5, 2016

General Comments and ERB Actions

The NCHS Research ERB reviewed the request for approval of Protocol 2016-11 Transformed Healthy Start Program Evaluation Plan (submitted by the Health Resources and Services Administration, Maternal and Child Health Bureau (MCHB), using the full board review process based on 45 CFR 46. The protocol was tabled until the July 20, 2016 (or August 17, 2016 if necessary) ERB meeting pending responses from MCHB to the items listed below.

Protocol Issues

Response Required-Action Required

1. The Board is concerned about the scope of this protocol. The breadth and depth of the proposed "program evaluation" activities, particularly the content of the six client-level assessment forms to be administered to Healthy Start participants, suggest that this data collection will be extensive, similar to that of a national survey but collected under the framework of a program evaluation. Page 4 of the protocol states these client-level assessment forms will be used *"...for monitoring and evaluation purposes. The client data is the primary data source for the outcome evaluation. The client data provides information on individual-level socio-demographics, service needs, services received, and follow-up visits and enables DHSPS to understand the HS population and to track outcomes and progress at the participant level..... ...All HS grantees will administer the client-level assessment forms or collect the data contained in the forms during enrollment and throughout participation in the program. Once collected, data will be submitted to HRSA....The client-level data will be used to assess the reach of the program and services provided to HS participants*".

   Further, some of the questions in the participant questionnaires ask about personal, potentially sensitive subjects that are typically far beyond the scope of a traditional program evaluation. The proposed data collection as indicated per the client-level assessment forms would be appropriate for a new sample survey or census of Healthy Start participants. The investigators do not explicitly state that they will not publish their findings from this evaluation project (with almost 30,000 participants) in peer-reviewed journals.

   The client-level assessment forms do not constitute a survey or census of the HS program. Rather, HS is a national program and all HS grantees are participating in the program evaluation. The client-level assessment forms were created to serve both programmatic and evaluation purposes. The personal questions are included

so grantees can best assess client needs when providing case management services and to determine the appropriate type and level of services or resources for clients. Components of this information may also be used to help inform the outcomes assessed in the evaluation.

It is anticipated that findings from the evaluation will be published in peer-reviewed journals. These findings will include aggregated data only and will not include any identifiable data. Standard NCHS protocols of not reporting any tabulations with a numerator less than 10 and flagging any with a numerator 10-19 as unreliable will be followed.

2. Additional details are needed on the administration of these instruments, such as periodicity of administration, whom will administer the client-level assessment forms (and how they are trained), and what will happen if someone reports that they experienced (or are experiencing) a traumatic situation, such the questions on personal safety. Although a "follow up" box is indicated under these questions that the client was either "provided information/education about what to do if you have someone you know has a partner that hurts them physically" or "referred to local domestic violence program", this level of follow-up may not be sufficient if the client is in immediate danger (e.g., upon leaving the HS site). Further, the staff administering the survey may not be adequately trained on how to handle these situations, or if a client becomes unnerved by recalling past traumatic experiences (such as under "Stress and Discrimination". In some situations offering a telephone number or brochure may not be an adequate response. How will these clients be protected? Are procedures already in place? It is not clear if adequate safeguards are or will be in place at the time of data collection.

All HS grantees will administer the client-level assessment forms or collect the data contained in the forms during enrollment and throughout participation in the program. The assessment forms will be administered by Healthy Start program staff with various levels of training and education, including Family Services Managers, Home Visitors, High Risk Home Visiting Nurses, Public Health Assistants and Community Health Workers. The Demographic and Pregnancy History forms will be administered to all program participants upon enrollment in HS case management services following informed consent. The remaining assessment forms will be administered when relevant: Prenatal (from diagnosis of pregnancy to birth if the participant is or becomes pregnant), Postpartum (from birth to 6 months after delivery if the participant delivers a baby), and Interconception/Parenting (from 6 months to 2 years after delivery).

All HS program staff have received or will receive training on the use of the assessment forms and have access to additional training material through the HS EPIC Center (technical assistance contractor for the HS program). All program staff have been trained to handle clients in immediate danger and/or those

experiencing traumatic events. Each Healthy Start program has procedures in place to handle clients in immediate danger (see sample Depression Screening flowchart in Appendix B), which includes the following:

1. **Each Healthy Start program staff provides the client with instructions for handling medical and non-medical emergencies independent of program staff.**
2. **The Healthy Start program reviews options and resources for addressing non-medical emergencies with the client at the initial visit.**
3. **During the initial visit, the Healthy Start program instructs the client to contact their health care provider or call 911 for medical and non-medical emergencies.**
4. **The Healthy Start program documents the instructions given in the client's record.**
5. **The message on the Healthy Start program phones includes instructions for clients to hang up and dial 911 if they are dealing with an emergency situation during business hours. The message on Healthy Start program phones provides instructions for clients to hang up and dial 911 or go to the nearest emergency room, if the call is placed after hours or on weekends. The message also includes instructions for non-emergency care on the weekends and after hours.**
6. **HS program staff also have an Emergency Plan that provides instructions for clients to address non-emergencies and emergencies after hours or on weekends (see sample Violence Screening Decision Tree in Appendix C).**

Additionally, Healthy Start staff are trained in the Health Insurance Portability and Accountability Act (HIPPA) and Patient Privacy policies. Healthy Start staff adhere to HIPAA protocols regarding client information. Healthy Start clients complete an Acknowledgment and Receipt of Notice of Privacy Practices or Informed Consent if applicable. No data is shared unless there is a signed informed consent on file. Every effort is made to ensure confidentiality at multiple levels. The Healthy Start programs will continue to follow established Protected Health Information (PHI)/HIPPA policy. All local regulations for PHI and HIPPA compliance are adhered to including data storage, client identifiers, data transfer, and confidentiality within and outside of each agency.

3. The package includes a determination by Dr. Lydie A. Lebrun-Harris (Appendix 1, email dated December 3, 2015) that this project does not qualify as human subjects research because "you are proposing to study the implementation of the Healthy Start program and even though you are surveying PIs (principal investigators), you are not collecting information *about them*, but rather about the grantees' experiences. Since you're not collecting information about living individuals, it does not count as human subjects research so this does not need to go through the exemption process." (italicized emphasis in the original email).

   It appears that this determination was submitted as an overarching document to cover all activities under this protocol, and the Board interpreted it this way. Please clarify the

purpose and scope of this determination. Given the aforementioned sensitive, client-level questions mentioned in item 2, you are proposing to collect information about individual-level clients, and at least that portion would qualify as human subjects research.

The determination by Dr. Lydie A. Lebrun-Harris was in reference to only one survey, the National Healthy Start Program Survey (NHSPS). It was not intended to reflect any other aspects of the proposed evaluation.

4. The protocol states (page 4, under "Healthy Start Participant Survey" that "the HS participant survey will be developed, administered and analyzed by the contractor who will be hired (in July 2016) to provide support for the implementation of the evaluation plan, in consultation with the MCHB/HRSA evaluation team. The contractor will develop a new survey that will assess participants' experiences with the HS program and utilization of program services. MCHB/HRSA will submit the survey for OMB and IRB clearances." This participant survey will have to undergo a separate ERB review, as we cannot grant approval before an instrument is developed. If this is the case, it is unclear why the client-level instruments were submitted.

The client-level assessment forms are different from the HS Participant Survey. The client-level assessment forms are to be used for programmatic monitoring and evaluation. The HS Participant Survey, while it will be used in the evaluation, is intended to capture information on the clients' perspective/experience with the program and use of program services. To minimize confusion, the HS Participant Survey was removed from this proposal as it has not yet been developed. It will be submitted at a later date under separate ERB review.

5. The contact script states that information will be collected on the health of mothers and children up to age two. It is unclear if the program knows the outcome of all pregnancies of eligible participants. The Board is concerned about contacting the mother in cases where a live birth did not occur. This may be quite traumatic for the mother. Please provide additional detail, and how you might consider contacting these mothers in a more appropriate, sensitive and caring way.

Healthy Start programs provide grief support to clients that have had a loss (see sample procedures for fetal/infant death in Appendix D). The Healthy Start program also works with several other programs that offer grief support, as well as provide clients with a list of grief resources. Services are provided to assure the client and their families are linked to ongoing services for grief support. Healthy Start program staff build relationships with their participants before, during and after pregnancy. Their regular conduct is focused on caring for the mother and working with her to build resiliency and overcome life's challenges. In this regard, Healthy Start program staff meet with participants postpartum and into parenthood, and would reach out to offer support in the event of infant death. Staff have access to trained mental health therapists who are able to conduct appropriate

counseling to grieving clients. Additionally, staff receive ongoing training on client engagement, trauma, rapport/trust building, and handling sensitive issues.

6. On the "Participant Informed Consent" form for the PRAMS oversampling, the last bullet states "During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study". The Board is not sure what this means, and are unsure of how these participants would be contacted.

   The last bullet has been removed from both participant informed consent forms (please see Appendix E, pages E1-E6).

7. In the Consent form, under Risks and Benefits, there should be a statement that there are no direct benefits from participation in the study.

   This statement has been added to both participant informed consent forms (please see Appendix E, pages E1-E6).

8. We suggest rewording the final sentence of the "Agreement" section of the participant informed consent form, which currently reads "I agree that any information from this study may be used in any way that is helpful, as long as I am not identified and my name is not used". This language allows for too broad an interpretation and could allow for improper use of the data. Please adopt narrower language on how the data will be used.

   This statement was removed from both informed consent forms (please see Appendix E, pages E1-E6).

9. According to form 0.1250, approximately 20% of the study participants are estimated to be Hispanic. Will non-English speaking Hispanic mothers be allowed to enroll? Will the instruments and materials be translated into Spanish? If not, please justify why they are being excluded. Materials for any part of the evaluation that will be translated need to be submitted to the ERB for review as well.

   Non-English speaking Hispanic mothers are allowed to enroll in HS and the instruments and materials will be translated into Spanish. The client-level assessment forms are currently being piloted by the HS program, however. Thus, there may be some changes to the instruments. Translation of the instruments and related materials (e.g., contact script, informed consent) will be completed once the instruments have been finalized. Any revised instruments and any Spanish language instruments and materials will be submitted for ERB review at that time.

10. In the HS Pregnancy History Screening Tool, questions are asked about any children that were diagnosed with medical conditions at birth. Some of these conditions are rare (such as Spina Bifida), and could lead to unintended disclosure if published. Describe cell suppression mechanism to avoid this problem if you consider tabulating / publishing

these data.

We will follow standard NCHS protocol of not reporting any tabulations with a numerator less than 10 and flagging any with a numerator 10-19 as unreliable.

11. Question 22 of the preconception tool asks if the mother has ever been diagnosed with an autoimmune diseases, and HIV is listed as an example. This is an infectious disease, not an autoimmune disease.

    HIV was removed from the list of examples in question 22 (Appendix F, page F16) and question 22.2 (page F19) of the Preconception tool; in question 27 (Appendix F, page F42) and question 27.2 (pageF45) of the Prenatal tool; and question 39 (Appendix F, page F105) and question 39.2 (page F108) of the Parenting/Interconception tool.

Of Note (For information purposes only, no response required)

1. To facilitate review and discussion of this and future protocols, please add page numbers in the attachments. These can be handwritten to minimize your burden.

   Page numbers have been added to all attachments.

Date received by ERB:

NCHS Cover Sheet for Submitting Human Research Protocols and Related Documentation

The CDC Human Research Protection Office (HRPO) provides the forms for submitting and tracking human research protocols at CDC. Please see *HRPO Guide: Overview* for further details. Use this cover sheet when submitting HRPO forms to the NCHS Human Subjects Contact. When submitting materials with these forms, please consecutively number **ALL** pages beginning with the protocol title page and followed by consent form(s) and ancillary documents.

1 Protocol identifiers

Leave protocol ID blank if not yet assigned. Leave amendment number and amendment title blank if not requesting a review of changes to an ERB-approved protocol.

CDC protocol ID:

Protocol title: "Transformed Healthy Start Program Evaluation"

Amendment number:

Amendment title:

2 CDC primary contact

	Name and degrees (FirstName LastName, Degrees)	User ID	Telephone #	CDC unit
Primary contact	Jamelle Banks, MPH	jbanks@hrsa.gov	301-443-1726	

3 Forms submitted with this cover sheet

Check all that apply.

Requests for ERB review

- [X] 0.1250 Initial Review
- [ ] 0.1251 Continuing Review of Approved Protocol
- [ ] 0.1252 Review of Changes to Approved Protocol
- [ ] 0.1253 End of Human Research Review

Requests for exempted protocols

- [ ] 0.1250X Initial Review for Exemption
- [ ] 0.1251X Continuing Review of Exempted Protocol
- [ ] 0.1252X Review of Changes to Exempted Protocol
- [ ] 0.1253 End of Human Research Review

Tracking CDC's research partners

- [ ] 0.1370 CDC's Research Partners (supplement to 0.1250–0.1252X)

Managing incidents and adverse events

- [ ] 0.1254 Incident Report
- [ ] 0.1254S Supplemental Report on Adverse Events

Alternative review arrangements

- [ ] 0.1371 Request to Rely on a Non-CDC IRB

4 Additional comments

5 Approvals/Signatures

As principal investigator, I hereby accept responsibility for conducting this CDC-sponsored research project in an ethical manner, consistent with the policies and procedures contained in CDC's "Procedures for Protection of Human Research Participants" and to abide by the principles outlined in 45 CFR 46, "Protection of Human Subjects."

Signature	Date	Remarks
Principal Investigator: Jamelle L Banks	5/11/2016	

As a supervisor of the principal investigator, I hereby accept responsibility for ensuring that this CDC-sponsored research project is conducted in an ethical manner, consistent with the policies and procedures contained in CDC's "Procedures for Protection of Human Research Participants" and with the principles outlined in 45 CFR 46, "Protection of Human Subjects."

Signature	Date	Remarks
Branch Chief: N/A		Check if PI is Branch Chief: ☐
Division Director: Reem Ghandour	5/10/16	Check if PI is Division Director: ☐ none

I concur that this CDC-sponsored research project is consistent with the policies and procedures contained in CDC's "Procedures for Protection of Human Research Participants" and with other applicable CDC and NCHS policies.

Signature	Date	Remarks
Human Subjects Contact:		
NCHS Confidentiality Officer:		

6 OMB Reminder

Please note that the principal investigator is responsible for obtaining OMB clearance on federally sponsored information collections. Approval by or exemption from the NCHS Research ERB is unrelated to OMB clearance requirements under the Paperwork Reduction Act. For more information on whether your study requires OMB clearance, please contact your OMB coordinator or OPPE clearance staff.

Request for Initial Review by an Institutional Review Board

Use this form to submit a protocol for its first review by a CDC IRB or a non-CDC IRB. If seeking review by a non-CDC IRB, also include form 0.1371. See *HRPO Guide: IRB Review Cycle* for further details on how to complete this form.

1 Protocol identifiers

Leave protocol ID blank if not yet assigned.

CDC protocol ID:

Protocol version number _____ version date _____

Protocol title: "Transformed Healthy Start Program Evaluation Plan"

Suggested keywords (optional). Enter each term in a separate cell:

_____ _____ _____

_____ _____ _____

2 Key CDC personnel

	Name and degrees (FirstName LastName, Degrees)	User ID	SEV #	CDC NC/division
Primary contact (required)	Jamelle Banks, MPH	JBanks@hrsa.gov	_____	_____
Principal investigator (required)	Jamelle Banks, MPH	JBanks@hrsa.gov	_____	_____
Investigator 2	Reem Ghandour, DrPH, MPA	RGhandour@hrsa.gov	_____	_____
Investigator 3	Maura Dwyer, DrPH, MPH	MDwyer@hrsa.gov	_____	_____
Investigator 4	_____	_____	_____	_____
Investigator 5	_____	_____	_____	_____

SEV # is CDC's Scientific Ethics Verification Number. CDC NC/division is the national center (or equivalent) and division (or equivalent), or coordinating center or office if submitted at that level.

List all other CDC investigators, if any (name and degrees, user ID, SEV #, CDC NC/division):

_____

3 CDC's role in project

Check yes or no for each of the following.

☐y ☒n CDC employees or agents will obtain data by intervening or interacting with participants.

☐y ☒n CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens.

☐y ☒n CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens.

☐y ☒n CDC employees will provide substantial technical assistance or oversight.

☒y ☐n CDC employees will participate as co-authors in presentation(s) or publication(s).

"Agents" includes on-site contractors, fellows, and others appointed or retained to work at a CDC facility conducting activities under the auspices of CDC.

4 CDC's research partners

Research partners include *all* direct and indirect recipients of CDC funding (e.g., grants, cooperative agreements, contracts, subcontracts, purchase orders) and other CDC support (e.g., identifiable private information, supplies, products, drugs, or other tangible support) for this research activity, as well as collaborators who do not receive such support. See *HRPO Guide: CDC's Research Partners* for further details. Check one of the following.

☐ No research partners.

☒ Research partners are listed on form 0.1370, which accompanies this form.

5 Study participants—planned demographic frequencies

Report estimated counts (rather than percentages). Include participants at domestic and foreign sites. See *HRPO Guide: IRB Review Cycle* for definitions.

Number of participants	29,343
Location of participants	
Participating at domestic sites	29,343
Participating at foreign sites	0
Sex/Gender of participants	
Female	29,343
Male	0
Sex/gender not available	
Ethnicity of participants	
Hispanic or Latino	5,805
Not Hispanic or Latino	22,506
Ethnicity not available	
Race of participants	
American Indian or Alaska Native	578
Asian	306
Black or African American	19,279
Native Hawaiian or Other Pacific Islander	234
White	7,597
More than one race	1,111
Race not available	238

Comments on demographics

We will be identifying pregnant and postpartum Healthy Start (HS) enrollees (across all 100 HS grantees) who had a delivery in calendar year 2017, collecting HS client-level data, and linking the client-level data to vital records (birth and any subsequent death certificates). Additionally, in 15 randomly selected HS communities, we will be identifying pregnant and postpartum women who delivered between October 1, 2016 and September 30, 2017 and linking HS program data to both vital records and the Pregnancy Risk Assessment Monitoring System (PRAMS) to recruit the HS participants to complete the PRAMS survey.

For the linkage between HS and vital records, HS data files will include the universe of all pregnant and postpartum enrolled HS participants who delivered in calendar year 2017 for the following states/jurisdictions:

Alabama, Arkansas, Arizona, California, Colorado, Connecticut, Washington, DC, Florida, Georgia, Iowa, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Michigan, Minnesota, Missouri, Mississippi, North Carolina, Nebraska, New Jersey, New Mexico, Nevada, New York, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Virginia, Wisconsin, West Virginia.

For the linkage between HS, vital records and PRAMS, Healthy Start data files will include the universe of all pregnant and postpartum enrolled HS participants who delivered between October 1, 2016 and September 30, 2017 for the following states/jurisdictions:

Alabama, Connecticut, Iowa, Louisiana, Maryland, Missouri, New Mexico, New York, New York City, Michigan, Oregon, Pennsylvania, and South Carolina.

Vital Records Offices (VROs) and PRAMS will then transfer the linked data files to the Maternal and Child Health Bureau in the Health Resources and Services Administration (MCHB/HRSA) without personally identifiable information for all linked HS participants and non-participants to facilitate analytic comparison. MCHB/HRSA will use the unique HS client ID number to link the vital records data and vital records/PRAMS data to client-level data to identify the services received by HS participants.

6 Regulation and policy

6.1 Mode of IRB review on CDC's behalf

Location of IRB (check one):

☒ CDC IRB

☐ Non-CDC IRB through IRB authorization agreement [submit form 0.1371]

Institution or organization providing IRB review: _____

IRB registration number (if known): _____

Federalwide assurance number (if any): _____

Suggested level of risk to subjects (check one):

☒ Minimal

☐ Greater than minimal

Suggested level of IRB review (check one):

See *HRPO Worksheet for Expedited Review* for detailed assistance. If relying on a non-CDC IRB, please indicate the level of review that you think is appropriate under human research regulations.

☐ Convened-board review is suggested

- ☐ Not eligible for expedited review. For example, poses greater than minimal risk; involves use of drug, biologic, or device under IND or IDE; involves collection of large amount of blood; use of x-rays or microwaves; anesthesia; or physically invasive procedures
- ☐ Other specified reason: _____

☒ Expedited review is suggested, under the following categories (check all that apply):

- ☐ 1a Study of drugs not requiring Investigational New Drug exemption from FDA
- ☐ 1b Study of medical devices not requiring Investigational Device Exemption from FDA
- ☐ 2a Collection of blood from healthy, nonpregnant adults; below volume limit, minimally invasive
- ☐ 2b Collection of blood from other adults and children; below volume limit, minimally invasive
- ☐ 3 Prospective noninvasive collection of biological specimens for research purposes
- ☐ 4 Collection of data through routine, noninvasive procedures, involving no general anesthesia, sedation, x-rays, or microwaves
- ☐ 5 Research that uses previously collected materials
- ☐ 6 Collection of data from voice, video, digital, or image recordings made for research purposes
- ☒ 7 Research that uses interview, program evaluation, human factors, or quality assurance methods

6.2 Vulnerable populations

Characterize the intention to include each of the following vulnerable populations. Choose one option in each row, and indicate the page(s) where inclusion or exclusion is justified in the protocol.

	Targeted	Allowed	Excluded	NA	Page(s)
Pregnant women or fetuses	☒	☐	☐	☐	4-5, 7-8
Children (including viable neonates)	☒	☐	☐	☐	4-5, 7-8
Prisoners	☐	☐	☐	☒	

Describe other groups of potentially vulnerable subjects intended to be included or excluded, such as neonates of uncertain viability or nonviable neonates, persons with mental disabilities, or persons with economic or educational disadvantages.

A majority of Healthy Start participants are women and children with economic and educational disadvantages.

6.3 Free and informed consent

Characterize requested changes to required features of the informed consent process. If a waiver is requested, enter the page number of the protocol where the waiver is justified.

Which exceptions to the consent process are requested? Check all that apply:

- ☐ Waiver or alteration of elements of informed consent for adults — pg ____
- ☐ Waiver of assent for children capable of providing assent — pg ____
- ☐ Waiver of parental permission — pg ____

Which exceptions to documentation of informed consent are requested? Check all that apply:

- ☐ Waiver of documentation of informed consent for adults — pg ____
- ☐ Waiver of documentation of assent for children capable of providing assent — pg ____
- ☐ Waiver of documentation of parental permission — pg ____
- ☒ Waiver or alteration of authorization under HIPAA Privacy Rule — pg 11

How is it shown that the consent process is in understandable language? Check all that apply:

- ☒ Reading level has been estimated — pg 12
- ☐ Comprehension tool is provided — pg ____
- ☐ Short form is provided — pg ____
- ☐ Translation planned or performed
  - ☐ Certified translation/translator — pg ____
  - ☐ Translation and back-translation to/from target language(s) — pg ____
  - ☐ Other method (specify: ____) — pg ____

6.4 Other regulation and policy considerations

Check all that apply.

If requesting the exception to the PHS policy on informing those tested about HIV serostatus, enter the page number of the protocol where the waiver is justified.

☐ Exception is request to PHS informing those tested about HIV serostatus. pg .....

☐ Human genetic testing is planned now or in the future.

☐ This study includes a registrable clinical trial.

☐ This study involves long-term storage of identifiable biological specimens.

☐ This study involves a drug, biologic, or device.

See HRPO Worksheet to Determine FDA Regulatory Coverage for guidance on whether or not FDA regulations apply.

☐ This study will be conducted under an Investigational New Drug (IND) exemption or Investigational Device Exemption (IDE).

IND/IDE number(s): .....

6.5 Confidentiality protections

If at least one research site is within the US, then check either Granted, Pending, or No in each row. If no sites are within the US, then check NA in each row.

	Granted	Pending	No	NA
Certificate of Confidentiality (301(d))	☐	☐	☒	☐
Assurance of Confidentiality (308(d))	☐	☐	☒	☐

Describe any other formal confidentiality protections that are planned or are in place:

All agencies participating in the evaluation will sign strict data use agreements, including HS grantees, state Vital Records Offices (VROs), and PRAMS program offices. Further, PRAMS and vital records have their own IRB clearances and protocols that apply to their data and data linkage activities. The identifiable data will be securely stored at VROs and PRAMS program offices, and de-identified coded data will be stored at MCHB/HRSA.

The HS Monitoring and Evaluation System (HSMES) Database allows MCHB/HRSA to collect information on program participants and report on basic data components from all HS programs, including numbers served, number of new births, participation in prenatal care, etc. This database is maintained by a contractor (DSFederal) who will maintain secure storage of the HS program data and protect potentially personal identifiable information using standard HHS procedures (http://www.hhs.gov/ocio/securityprivacy/).

MCHB/HRSA will use a unique client ID to link the vital records data to the HS program data to identify the services received by HS participants. These data may still be potentially identifiable through a combination of demographic and medical characteristics, such as race/ethnicity, census tract of residence, and experience of infant death. Therefore, as an added level of precaution, MCHB/HRSA will maintain secure storage of vital records data and protect potentially personal identifiable information using standard HHS procedures.

For the PRAMS oversampling, MCHB/HRSA will receive the full PRAMS data file including de-identified data for all PRAMS participants in the selected states (both HS participants and non-participants) in a unified format. This file will also include linked vital records with census tract of residence for analytic purposes.

7 Material submitted with this form

Check all that apply. Describe additional material in the comments section.

- ☒ Complete protocol
- ☐ Peer reviewers' comments or division waiver (NIOSH)
- ☒ Consent, assent, and permission documents or scripts
- ☐ Other information for recruits or participants (e.g., ads, brochures, flyers, scripts)
- ☒ Data collection instruments (e.g., questionnaires, interview scripts, record abstraction tools)
- ☐ Certification of IRB approval or exemption for research partners

8 Additional comments

The proposed study is an analysis of some existing and some new HS client-level data linked to vital records (birth and death certificates) for all pregnant and postpartum HS enrollees who had a delivery in calendar year 2017, and analysis of some existing and some new Healthy Start client-level data linked to vital records and PRAMS for pregnant and postpartum women who had a delivery between October 1, 2016 and September 30, 2017 in 15 randomly selected HS communities. The data files contain some potentially identifiable information, such as mother and infant's date of birth, infant's date of death, and mother's zip code of residence, which could potentially be triangulated with other variables to identify individuals. However, as described in response to 6.5, the data will be securely stored at VROs and PRAMS program offices, and the study investigators at MCHB/HRSA will only have access to de-identified data.

CDC's Research Partners

Use this form to report current information on CDC's research partners whenever a partner institution or individual is added or information changes. Supply individual name and SEV number only for investigators collaborating with CDC under an individual investigator agreement (IIA). See *HRPO Guide: CDC's Research Partners* and either the *HRPO Worksheet for Basic Tracking of Research Partners* or the *HRPO Worksheet for Advanced Tracking of Research Partners* for details on how to complete this form.

Leave protocol ID blank if not yet assigned.

CDC protocol ID: _____ Protocol version number _____ version date _____

Protocol title: _____

Partner 1

Institution name: CDC/ONDIEH/NCCDPHP/DRH/ASB
Institution location: Atlanta, GA
Individual name (IIA only): Deborah Wettherhall
Reporting status: Initial report
Regulatory coverage: Engaged/non-exempt
Financial support: Other funding
Support award number: 16CC16017CUCJ
Support end date: 09302016
Nonfinancial support: No nonfinancial support
FWA number: FWA00001413
SEV number (IIA only): _____
IRB review status: Relying on CDC IRB
IRB approval expiration date: _____
Comments: _____

Partner 2

Institution name: NAPHSIS
Institution location: Silver Spring, MD
Individual name (IIA only): Makeva Rhoden
Reporting status: Initial report
Regulatory coverage: Not engaged
Financial support: Contract/subcontract
Support award number: UF5MC26845-01
Support end date: 5/31/2016
Nonfinancial support: No nonfinancial support
FWA number: _____
SEV number (IIA only): _____
IRB review status: Not applicable
IRB approval expiration date: _____
Comments: _____

Partner 3

Institution name: CDC/NCHS
Institution location: Atlanta, GA
Individual name (IIA only): Michael H. Sadagursky
Reporting status: Initial report
Regulatory coverage: Engaged/non-exempt
Financial support: Other funding
Support award number: 16HS165018CPCC
Support end date: 9/30/2016
Nonfinancial support: No nonfinancial support
FWA number: FWA00001413
SEV number (IIA only): _____
IRB review status: Relying on CDC IRB
IRB approval expiration date: _____
Comments: _____

Partner 4

Institution name: JSI
Institution location: Boston, MA
Individual name (IIA only): Makeva Rhoden
Reporting status: Initial report
Regulatory coverage: Not engaged
Financial support: Contract/subcontract
Support award number: _____
Support end date: _____
Nonfinancial support: No nonfinancial support
FWA number: FWA00000218
SEV number (IIA only): _____
IRB review status: Not applicable
IRB approval expiration date: _____
Comments: _____

Partner 5

Institution name: DSFederal
Institution location: Rockville, MD
Individual name (IIA only): Christopher Lim
Reporting status: Initial report
Regulatory coverage: Not engaged
Financial support: Contract/subcontract
Support award number:
Support end date:
Nonfinancial support: No nonfinancial support
FWA number:
SEV number (IIA only):
IRB review status: Not applicable
IRB approval expiration date:
Comments:

Partner 6

Institution name:
Institution location:
Individual name (IIA only):
Reporting status: Reporting status?
Regulatory coverage: Engaged? Exempt?
Financial support: Financial support?
Support award number:
Support end date:
Nonfinancial support: Nonfinancial support?
FWA number:
SEV number (IIA only):
IRB review status: IRB review status?
IRB approval expiration date:
Comments:

Partner 7

Institution name:
Institution location:
Individual name (IIA only):
Reporting status: Reporting status?
Regulatory coverage: Engaged? Exempt?
Financial support: Financial support?
Support award number:
Support end date:
Nonfinancial support: Nonfinancial support?
FWA number:
SEV number (IIA only):
IRB review status: IRB review status?
IRB approval expiration date:
Comments:

Partner 8

Institution name:
Institution location:
Individual name (IIA only):
Reporting status: Reporting status?
Regulatory coverage: Engaged? Exempt?
Financial support: Financial support?
Support award number:
Support end date:
Nonfinancial support: Nonfinancial support?
FWA number:
SEV number (IIA only):
IRB review status: IRB review status?
IRB approval expiration date:
Comments:

Partner 9

Institution name:
Institution location:
Individual name (IIA only):
Reporting status: Reporting status?
Regulatory coverage: Engaged? Exempt?
Financial support: Financial support?
Support award number:
Support end date:
Nonfinancial support: Nonfinancial support?
FWA number:
SEV number (IIA only):
IRB review status: IRB review status?
IRB approval expiration date:
Comments:

Partner 10

Institution name:
Institution location:
Individual name (IIA only):
Reporting status: Reporting status?
Regulatory coverage: Engaged? Exempt?
Financial support: Financial support?
Support award number:
Support end date:
Nonfinancial support: Nonfinancial support?
FWA number:
SEV number (IIA only):
IRB review status: IRB review status?
IRB approval expiration date:
Comments:

Transformed Healthy Start Program Evaluation Plan
Study Proposal

Purpose and Origins of Study

The overarching goal of this national Healthy Start (HS) evaluation is to determine the effect of the *transformed* HS program (which was initiated in 2014) on changes in participant-level characteristics (e.g. health services utilization, preventive behaviors, and health outcomes).

Objectives

The national HS evaluation includes three components: 1) implementation; 2) utilization; and 3) outcome. The purpose of the implementation evaluation is to describe HS programs and strategies and to identify program factors that are associated with effective implementation. The purpose of the utilization evaluation is to examine the characteristics of participants and non-participants and factors that help explain differential penetration, or service rates. The purpose of the outcome evaluation is to assess the overall effectiveness of the program with regard to producing expected outcomes among the target population and factors that help explain variation in the program's impact on individual level outcomes. The outcome evaluation will employ a quasi-experimental method, which will include two types of comparisons:

1. A matched individual comparison analysis of linked vital records for HS participants and non-participants in the same general geographic service area for all 100 HS grantees, which maximizes generalizability and will allow for assessment of the key outcome of interest, infant mortality, with adequate statistical power.
2. A matched individual comparison analysis of HS participants and non-participants by oversampling of the Pregnancy Risk Assessment and Monitoring Survey (PRAMS) for a random sample of 15 HS grantees. This component of the evaluation data collection strategy will maximize internal validity with a broader set of outcomes and control or matching characteristics that can influence selection into the program.

Background

Improving pregnancy outcomes for women and children is one of the nation's top priorities. The infant mortality rate (IMR) is a widely used indicator of the nation's health. In 2013, the U.S. IMR was 5.96 infant deaths per 1,000 live births. However, racial-ethnic disparities persist and in the same year, the IMR for infants born to non-Hispanic black mothers was 11.11, more than double the non-Hispanic white IMR of 5.06 (Matthews, et al. 2015). The HS program was created to address factors that contribute to the high IMR, particularly among African-American and other minority groups. The program began in 1991 as a demonstration project with 15 grantees and has expanded over the past two decades to 100 grantees in 37 states and Washington, DC.

The HS program was transformed in 2014 to apply lessons from emerging research, past evaluation findings, and to act on national recommendations from the Report of Secretary's Advisory Committee on Infant Mortality (Secretary's Advisory Committee on Infant Mortality 2013). With an emphasis on standardized, evidence-based approaches, the goal of the redesigned HS program is to improve maternal and infant health and to reduce disparities in adverse perinatal outcomes in the US through evidence-based practices, community collaboration, organizational performance monitoring, and quality improvement. To achieve this

goal, the HS program employs five community-based approaches to service delivery and facilitates access to comprehensive health and social services for high-risk pregnant women, infants, children through their first two years, and their families in geographically, racially, ethnically, and linguistically diverse low-income communities with exceptionally high rates of infant mortality. The five approaches include: (1) improving women's health; (2) promoting quality services; (3) strengthening family resilience; (4) achieving collective impact; and (5) increasing accountability through quality improvement, performance monitoring, and evaluation.

Implementation of the program's approaches and subsequent activities is expected to result in a number of outcomes. Short-term outcomes include changes in knowledge, skills, motivation and health care utilization. Intermediate outcomes include changes in healthy behaviors, community, organizational, and systems capacity, quality, efficiency, effectiveness, active partnerships and networks. Long-term outcomes are related to changes in health status (for example, morbidity and mortality), policies, and environment.

To assess implementation and understand the overall impact of the newly transformed HS program, there is a need for a robust and comprehensive evaluation. Prior evaluations of HS (Devaney et al. 2000; Brand et al. 2010; Drayton et al. 2015; Health Resources and Services Administration 2006; Howell and Yemane 2006; Rosenbach et al. 2010) demonstrated some positive program impact on access to services, integration of services, maternal health care utilization, knowledge, and behaviors, as well as high participant satisfaction with the HS program. However, the evaluations showed mixed evidence with respect to an association with improved longer-term perinatal outcomes, such as rates of infant mortality, preterm birth, low birthweight and very low birthweight. These evaluations were limited by data quality issues, including inconsistency in the definition and source(s) of some measures; lack of verification of some measures; and missing and incomplete data. Further, the lack of a matched individual comparison analysis prevented strong inference regarding the impact of HS participation on perinatal outcomes.

Methodology

Evaluation Design

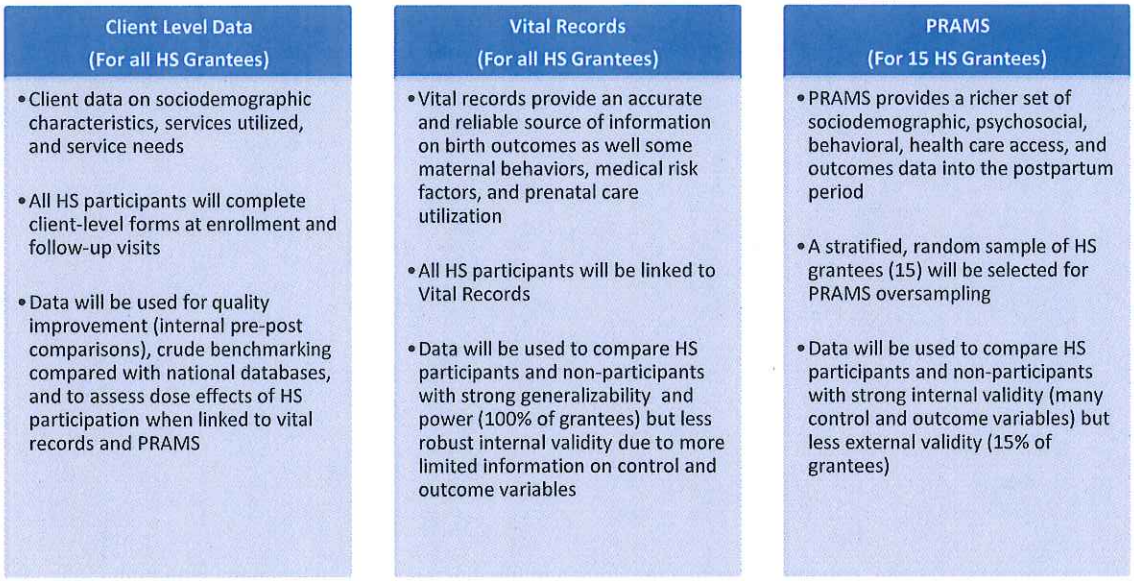
The implementation evaluation will be based on data from the National Healthy Start Program Survey (NHSPS) ~~and a HS participant survey (which is yet to be developed)~~ and will have both formative and summative purposes. Formative purposes include using the implementation evaluation findings to fine-tune the program. Summative uses include making a judgment about the extent to which the intervention was implemented as planned. This information can be used to interpret and explain program outcomes.

The utilization evaluation will link vital records (birth and death records) and client-level program data. It will assess how many women and children participated in the HS program and examine the characteristics of women and children who utilized the program, their level of participation, and the characteristics of women and children who did not utilize the program.

The outcome evaluation will link the PRAMS survey, vital records and client-level program data (see Figure 1). The primary outcome analysis will consist of the matched individual comparison analysis by oversampling the PRAMS for 15 randomly sampled grantees and will increase

internal validity with a quasi-experimental inference and rich set of outcomes and control characteristics that can influence selection into the program.

Figure 1. Linked Datasets for the Outcome Evaluation



Not all grantees will be part of the sampling frame of PRAMS states. Therefore, a secondary outcome analysis will consist of a vital records linkage and matched comparison for all HS grantees. A vital records analysis maximizes generalizability and will facilitate studying the ultimate outcome of infant mortality with adequate power. Further, the vital records analysis will enable multiple comparison groups to ensure robust results (e.g., within and outside of service areas, dose-response effect estimates among those with some level of HS participation, etc.).

For outcomes not available in vital records and PRAMS, benchmarking methods will also be utilized to compare individual level outcomes related to knowledge, behavior, risk, morbidity, and mortality among HS participants to data available from other sources or benchmarks. The benchmarking method compares the prevalence or incidence of an outcome among HS participants (such as smoking during pregnancy or use of a family planning method) to data available from other sources or benchmarks. However, the degree of consistency in the benchmark definition and study population can vary from HS depending on the data source. Therefore, an attempt will be made to choose data sources and populations most similar to HS but comparisons will be high-level performance comparisons relative to national data and thus crude and descriptive.

MCHB/HRSA is seeking IRB approval for the following:

1. Participating in the HS evaluation;
2. Completing the HS client-level assessment forms and providing the information to MCHB/HRSA;
3. Providing HS participant individual identifiers to state/jurisdiction Vital Records Offices (VROs);
4. Linking client-level data to vital records (e.g., infant birth and death certificates) for all 100 HS grantees;

5. Linking client-level data to other data sources such as PRAMS survey data for 15 randomly selected HS grantee sites; and
6. Sharing linked (e.g., vital records and PRAMS), de-identified data with MCHB/HRSA.

PRAMS and vital records have their own IRB clearances and protocols that apply to their data and data linkage activities. The data will be securely stored at VROs and PRAMS program offices.

Data Sources

National Healthy Start Program Survey (NHSPS)

The NHSPS is an OMB approved survey instrument designed to collect information about the implementation of the HS program across the five key approaches for monitoring and evaluation purposes. Survey data will be used to identify and describe program components and intervention models that may explain program outcomes. The information will be used to assess services offered and provided, intervention models used by projects, aggregated outcomes for the population served, and achievements at the grantee and national levels. HS grantees will be asked to complete the survey two times—at the end of the second and fourth grant years, and each time it will be open for a two-month period. The survey is designed to be self-administered through a web-based application by HS staff. Once they complete the survey, they will click on a submit button and MCHB/HRSA will be informed that the grantee completed the survey. JSI, Inc. was contracted to administer and analyze the NHSPS. JSI will monitor grantee response rates and conduct outreach to grantee sites to promote survey completion. JSI will also clean and analyze the survey data and provide the de-identified data and completed analysis (consistent with the HS evaluation analysis plan) to MCHB/HRSA. The NHSPS was reviewed by HRSA's Office of Research and Evaluation and received IRB exemption as it was determined to be non-research (please see email notification in Appendix A from Lydie A. Lebrun-Harris, PhD, MPH Office of Research and Evaluation, HRSA Office of Planning, Analysis and Evaluation. Dr. Lebrun-Harris's review pertained only to the NHSPS).

~~*Healthy Start Participant Survey*~~

~~The HS participant survey will be developed, administered and analyzed by the contractor who will be hired (in July 2016) to provide support for the implementation of the evaluation plan, in consultation with the MCHB/HRSA evaluation team. The contractor will develop a new survey that will assess participants' experiences with the HS program and utilization of program services. MCHB/HRSA will submit the survey for OMB and IRB clearance. The contractor will be responsible for administering the survey across HS sites. The survey may include both open-ended and close-ended questions. The evaluation support contractor shall use a standard database to clean and manage the participant survey data, and statistical software to analyze the survey data. The contractor will provide the de-identified data and completed analysis (consistent with the HS evaluation analysis plan) to MCHB/HRSA.~~

Client-level Assessment Forms

The client-level data provides uniform information at the individual level about HS participants, their children (up to age 2) and families for monitoring and evaluation purposes. The client data is the primary data source for the outcome evaluation. The client data provides information on individual-level socio-demographics, service needs, services received, and follow-up visits and

enables DHSPS to understand the HS population and to track outcomes and progress at the participant level. The client-level assessment forms do not constitute a survey or census of the HS program; rather, HS is a national program and all HS grantees are participating in the program evaluation. The client-level assessment forms were created to serve both programmatic and evaluation purposes. There are six (6) forms, including:

1. Demographic Intake Form
2. Pregnancy Status/History
3. Preconception
4. Prenatal
5. Postpartum; and
6. Interconception/ Parenting

All HS grantees will administer the client-level assessment forms or collect the data contained in the forms during enrollment and throughout participation in the program. The assessment forms will be administered by Healthy Start program staff with various levels of training and education, including Family Services Managers, Home Visitors, High Risk Home Visiting Nurses, Public Health Assistants and Community Health Workers. The Demographic and Pregnancy History forms will be administered to all program participants upon enrollment in HS case management services following informed consent. The remaining assessment forms will be administered when relevant: Prenatal (from diagnosis of pregnancy to birth if the participant is or becomes pregnant), Postpartum (from birth to 6 months after delivery if the participant delivers a baby), and Interconception/Parenting (from 6 months to 2 years after delivery).

All HS program staff have received or will receive training on the use of the assessment forms and have access to additional training material through the HS EPIC Center (technical assistance contractor for the HS program). All program staff have been trained to handle clients in immediate danger and/or those experiencing traumatic events. Each Healthy Start program has procedures in place to handle clients in immediate danger (see sample Depression Screening flowchart in Appendix B), which includes the following:

1. Each Healthy Start program staff provides the client with instructions for handling medical and non-medical emergencies independent of program staff.
2. The Healthy Start program reviews options and resources for addressing non-medical emergencies with the client at the initial visit.
3. During the initial visit, the Healthy Start program instructs the client to contact their health care provider or call 911 for medical and non-medical emergencies.
4. The Healthy Start program documents the instructions given in the client's record.
5. The message on the Healthy Start program phones includes instructions for clients to hang up and dial 911 if they are dealing with an emergency situation during business hours. The message on Healthy Start program phones provides instructions for clients to hang up and dial 911 or go to the nearest emergency room, if the call is placed after hours or on weekends. The message also includes instructions for non-emergency care on the weekends and after hours.
6. HS program staff also have an Emergency Plan that provides instructions for clients to address non-emergencies and emergencies after hours or on weekends (see sample

Violence Screening Decision Tree in Appendix C).

Additionally, Healthy Start staff are trained in the Health Insurance Portability and Accountability Act (HIPPA) and Patient Privacy policies. Healthy Start staff adhere to HIPAA protocols regarding client information. Healthy Start clients complete an Acknowledgment and Receipt of Notice of Privacy Practices or Informed Consent if applicable. No data is shared unless there is a signed informed consent on file. Every effort is made to ensure confidentiality at multiple levels. The Healthy Start programs will continue to follow established Protected Health Information (PHI)/HIPPA policy. All local regulations for PHI and HIPPA compliance are adhered to including data storage, client identifiers, data transfer, and confidentiality within and outside of each agency.

Healthy Start programs provide grief support to clients that have had a loss (see sample procedures for fetal/infant death in Appendix D). The Healthy Start program also works with several other programs that offer grief support, as well as provide clients with a list of grief resources. Services are provided to assure the client and their families are linked to ongoing services for grief support. Healthy Start program staff build relationships with their participants before, during, and after pregnancy. Their regular conduct is focused on caring for the mother and working with her to build resiliency and overcome life's challenges. In this regard, Healthy Start program staff meet with participants postpartum and into parenthood, and would reach out to offer support in the event of infant death. Staff have access to trained mental health therapists who are able to conduct appropriate counseling to grieving clients. Additionally, staff receive ongoing training on client engagement, trauma, rapport/trust building, and handling sensitive issues.

Once collected, data will be submitted to HRSA. The data are expected to be uploaded in batches (at yet-to-be-determined intervals) by HS grantees starting in October 2016[1]. The client-level data will be used to assess the reach of the program and services provided to HS participants. The client-level data will be collected and stored via the HS Monitoring and Evaluation System (HSMES) Database. This database is maintained by a contractor (DSFederal) who will ensure secure storage of the client-level data and protect potentially personal identifiable information using standard HHS procedures (http://www.hhs.gov/ocio/securityprivacy/).

Non-English speaking Hispanic mothers are allowed to enroll in HS. Thus the instruments and materials will be translated into Spanish. The client-level assessment forms are currently being piloted by the HS program and there may be subsequent changes to the instruments. Translation of the instruments and related materials (e.g., contact script, informed consent) will be completed once the instruments have been finalized. Any revised instruments and any Spanish language instruments and materials will be submitted for ERB review at that time.

Vital Records

U.S. vital statistics data are provided by the National Vital Statistics System (NVSS), through state and local collection and registration of birth and death events. The Centers for Disease

[1] Pending action by OMB.

Control and Prevention's (CDC) National Center for Health Statistics (NCHS) administers the NVSS through contracts with each jurisdiction. Over 99% of births in the U.S. are registered. Data are pulled directly from medical records, providing birth and mortality information, including socio-demographic and medical data. Data from vital records provide information on birth rates, infant mortality rates, leading causes of death, and risk factors for adverse pregnancy outcomes. Vital records data will be linked to HS client-level data (for all 100 HS grantees) and PRAMS (for 15 grantees only) for the utilization and outcome evaluations.

Pregnancy Risk Assessment Monitoring System (PRAMS)

The PRAMS program was initiated in 1987 by the CDC for the surveillance of low birth weight and infant mortality. PRAMS collects data 2-9 months after delivery by surveying or interviewing mothers on their attitudes and experiences before, during, and shortly after pregnancy, as well as multi-dimensional prenatal risk factors. The PRAMS questionnaire has two parts: core questions that are asked by all states and state-specific standard questions. The core portion of the questionnaire includes questions about the following:

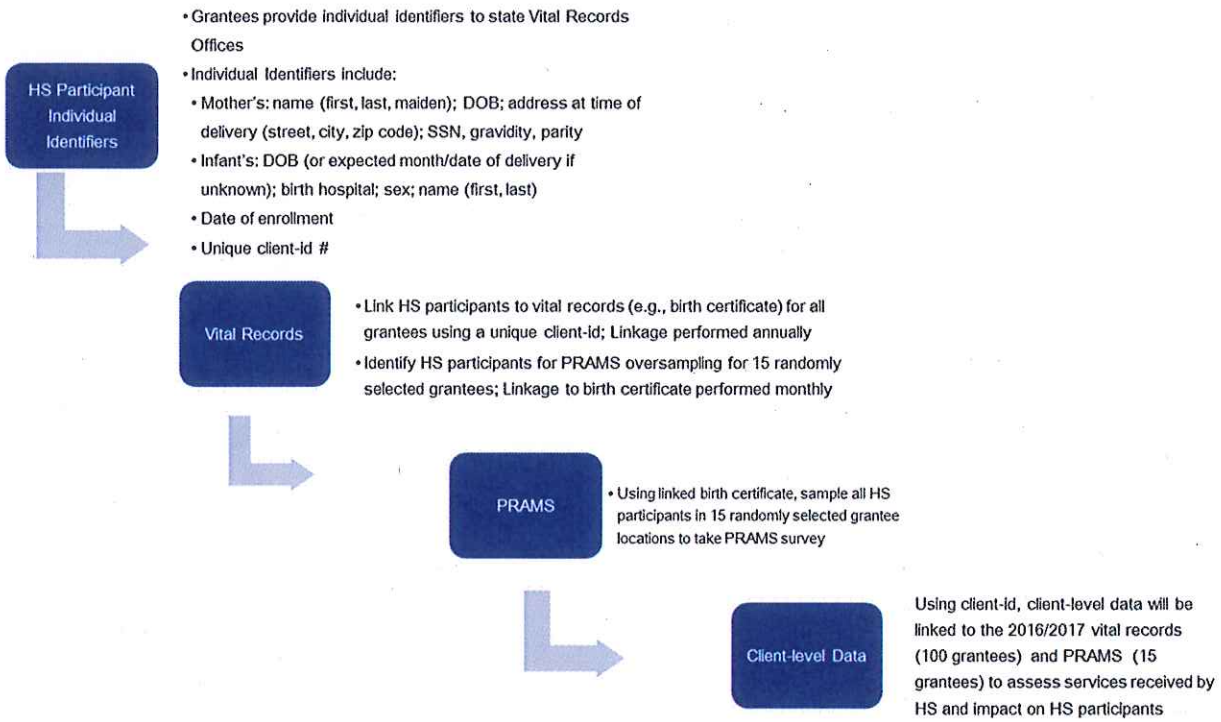
- Attitudes and feelings about the most recent pregnancy;
- Content and source of prenatal care;
- Maternal alcohol and tobacco consumption;
- Physical abuse before and during pregnancy;
- Pregnancy-related morbidity;
- Infant health care;
- Contraceptive use; and
- Mother's knowledge of pregnancy-related health issues, such as adverse effects of tobacco and alcohol; benefits of folic acid; and risks of HIV.

The second part of the questionnaire includes questions that are chosen from a pretested list of standard questions developed by the CDC or developed by states on their own. As a result, each state's PRAMS questionnaire is unique.

Data Linkages: Vital Records, PRAMS and Client-Level Program Data (Figure 2)

The HS program currently has 86 grantees located in states that conduct the PRAMS survey. To improve the chances of evaluating an operational HS program early in the grant cycle, the PRAMS oversampling was restricted to continuing grantees (75 of 100 total grantees). Similarly, CDC PRAMS recommended restricting the sample to grantees in states which currently field PRAMS (n=40) given the potential lack of capacity in new PRAMS Phase 8 states (up to 61 states/jurisdictions/tribes). Therefore, the HS Sampling Frame for the PRAMS oversampling included 63 of 75 continuing grantees that are located in current PRAMS states.

Figure 2. Data Linkage Process for HS Participant Individual Identifiers, Vital Records and PRAMS



Based on available funding and CDC support services, it was determined that 15 HS grantees could be selected for PRAMS oversampling. To ensure scientific integrity, the 15 HS grantees were randomly selected within strata determined to be of importance to the program. The strata include cells categorized by Grantee Level (1, 2, 3)[2], Service Area Focus (Urban, Rural, Border, AI/AN), and Region (Midwest, Northeast, South, West). Within the sampling frame, there were only 3 grantees located in the Western Region (all Level 1 grantees in NM and OR). Given that most Western HS grantees are Urban (7 of 12); a Western Urban Level-1 grantee was selected with certainty. To ensure geographic representation of the remaining regions, Level-2 and Level-3 grantees were selected in the general proportion of these grantees by region.

Beginning in fall 2016, the 15 randomly selected HS grantees will send linkage variables (Table 1) for pregnant and postpartum HS participants to their state/jurisdiction VROs. The VROs will link to the birth certificate and note which individuals are HS participants. The VROs will not retain the individual identifiers after the linkage is completed. PRAMS offices in the randomly selected states will sample these individuals to take part in the PRAMS survey (2 to 9 months postpartum). Oversampling via PRAMS will require ongoing monthly linkage to identify HS

[2] Level 1 Community-based HS programs serve a minimum of 500 participants per year and implement activities under the five approaches; Level 2 Enhanced Services grantees serve a minimum of 800 participants and engage in Level 1 activities as well as activities to stimulate community collaboration; Level 3 Leadership and Mentoring HS grantees serve a minimum 1,000 participants and engage in activities under Level 1 and 2, as well as activities to expand maternal and women's health services, develop place-based initiatives, and serve as centers to support other HS and similar programs.

participants for monthly batch sampling. The CDC will provide MCHB/HRSA with the full PRAMS file of all PRAMS participants in the selected states (both HS participants and non-participants), including linked vital records and geographic identifiers for analytic purposes. State/jurisdiction VROs will then transfer any subsequent infant death certificate data for the PRAMS sample to MCHB/HRSA. Finally, MCHB/HRSA will link client-level program information on service receipt within HS to PRAMS and vital records data, using the client ID number, to complete evaluation analyses. This will allow the evaluation team to fully assess the type, dose, and frequency of services HS participants received and the impact these services had on important benchmark and outcome measures. Further, oversampling via PRAMS will enable comparisons between HS participants and non-participants. The initial selection of 15 HS grantees includes 13 PRAMS States/Jurisdictions (AL, CT, IA, LA, MD, MO, NM, NY, NYC, MI, OR, PA, and SC).

Table 1. Proposed Individual Identifiers for Linkage to Vital Records

Mother's date of birth (or age in years but exact date of birth is preferred)
Mother's name
Mother's address at time of delivery (street, city, zip code, county)
Mother's social security number
Mother's race
Mother's ethnicity
Mother's Medicaid status (yes/no)
Mother's gravidity (# previous pregnancies)
Mother's parity (# previous live births)
Mother's date of enrollment
Mother's Unique Client ID # that can be used to anonymously identify the HS participant and subsequently link back to any client-level information that is provided to MCHB/HRSA
Infant date of birth* (or expected month or date of delivery if unknown)
Infant birth hospital*
Infant sex*
Infant name (first, last)*
Infant birth weight*
Bold = required elements

*May not be available if participant is lost to follow-up (e.g., participant moves, stops participating, etc.) or has not yet delivered; regardless of the number of available individual identifiers, annual linkage will be attempted for all pregnant and postpartum women with a known delivery in calendar year 2017 and all pregnant women with an expected delivery in 2017 or through March of 2018, in the possible event of early delivery occurring in 2017. The linkage may be repeated on an annual basis. The monthly PRAMS linkage will include any deliveries from October 2016 - September 2017.

Data Linkages: Vital Records and Client-Level Program Data

All 100 HS grantees will provide the required linkage variables (Table 1) for each pregnant and postpartum HS participant with a known or expected delivery during the evaluation study period. The VROs will complete the linkage of HS participants to birth certificates and will then transfer the data to MCHB/HRSA without personally identifiable information for all linked HS participants and non-participants in the same county/city to facilitate analytic comparison. These

data will include birth certificate data on linked participants with client ID number, date of enrollment as well as birth certificate data for non-participant controls from the same city or county with geographic identifiers (census tract or zip code). The VROs will not retain the individual identifiers after the linkage is completed. MCHB/HRSA will use the unique client ID to link the vital records data to the client-level assessment forms and identify the services received by HS participants, which will allow the evaluation team to fully assess the type, dose and frequency of services HS participants received, and the impact these services had on important benchmark and outcome measures. Finally, the VROs will update the linkage of HS participants and controls to include any subsequent infant death certificates and send the linked data file to MCHB/HRSA. Data received by MCHB/HRSA will not contain personal identifiers but may still be potentially identifiable through a combination of demographic and medical characteristics, such as race/ethnicity, census tract of residence, and experience of infant death. Therefore, as an added level of precaution, MCHB/HRSA will maintain secure storage of vital records data and protect potentially personal identifiable information using standard procedures. This linkage is expected to continue annually for all HS grantees.

Analysis

The HS program funding announcement includes several benchmarks through which the program's performance will be measured. The program also has several performance measures required for reporting by grantees. These benchmarks and performance measures are the key outcomes for assessment under the evaluation (Table 2). Benchmarks and performance measures indicate the progress of the program towards its objectives and the outcomes that the program should be impacting, such as low birthweight. Other outcomes may be examined, including those related to risk, health care access and utilization, health knowledge and behaviors, delivery and birth outcomes, and child health.

Table 2. Evaluation Metrics by Data Source

	Vitals	PRAMS Core Phase 8	Participant Level HS Data	HSPS	Other
Benchmarks					
Health insurance (preconception, pregnancy, postpartum)	Partial	X	X		
Well woman visit (preconception)		X	X	Track	NHIS; BRFSS
Postpartum visit		X	X	X	HEDIS
Safe sleep behaviors		X	X		
Ever breastfed	X	X	X	X	NIS
Cigarette smoking (preconception, pregnancy, postpartum)	Partial	X	X		
Interpregnancy interval <18 months	X	X	X		
Well child visits		X	X	Track	HEDIS
Perinatal depression screening (preconception, pregnancy, postpartum)		X	X		
Intimate partner violence screening (preconception, pregnancy)		X	X		
Additional outcomes and/or characteristics					
Infant mortality	X			X	
Low birth weight	X		X	X	
Preterm birth	X		X	X	
Current breastfeeding		X		Track	
Initiation of prenatal care	X	X	X	Track	
Adequacy of prenatal care	X				
Gestational weight gain	X	X	X	Track	
Weight management counseling (preconception, pregnancy, postpartum)		X	X		
Alcohol use screening		X	X		
Physical activity (preconception, pregnancy, postpartum)		X			
Maternal morbidity	X				
Pregnancy-related complications	X	X	X		
Cesarean section among low-risk first births	X				
Home visiting		X			
Screening or counseling for breastfeeding (pregnancy and postpartum)		X	X		
Screening or counseling for birth control (preconception, pregnancy, and postpartum)		X	X		
Screening for smoking (preconception, pregnancy, postpartum)		X	X		
Screening for drug use (pregnancy)		X	X		
Flu shot receipt and counseling		X	X	Track	
Dental visit		X	X		
Content of postpartum visit		X			
Benchmarks not covered by PRAMS-Core or VITALS	**Vitals**	**PRAMS Core Phase 8**	**Participant Level HS Data**	**HSPS**	**Other**
Breastfed at 6 months		Partial	X	X	NIS
Follow-up services for perinatal depression			X		
Read daily to child			X		NSCH
Documented reproductive life plan			X	X	
Father and/or partner involvement during pregnancy			X		
Father and/or partner involvement with child 0-24 months			X		
Fully implemented CAN				X	
At least 25% HS participant membership on their CAN membership			X		
QI and performance monitoring process				X	
Healthy Start Case Management Dosage					
Duration of enrollment (HS admit date, delivery date, discharge date)			X		
Breadth of interventions - visit type: phone, home, office, other			X		
Amount of contact time - Date of visit			X		
HS provider (RN, SW, MH counselor, paraprofessional)			X		
HS enrollment for a prior pregnancy			X		

Track = The HS Survey asked respondents if these items were tracked. BRFSS = Behavioral Risk Factor Surveillance System
DGIS = Discretionary Grant Information System
HEDIS = The Healthcare Effectiveness Data and Information Set NIS = National Immunization Survey
NSCH = National Survey of Children's Health

Analysis of the implementation evaluation will include descriptive analyses to test the statistical significance of bivariate associations between program and organization level factors and indicator(s) of effective program implementation. Program factors may include the size and scale of the program; outreach strategies employed; number and types of referrals provided; case management models utilized; caseloads maintained; the number and types of screenings provided; and promotion of male involvement, among others. Organization level factors may include the geographic service area or focus (urban, rural, border); the HS program level (1, 2 or 3); the lead agency type; age of the program; and staffing characteristics, among others.

Analysis of the utilization evaluation will include descriptive analyses of HS participants in terms of a number of individual characteristics, including socio-demographic indicators, health behaviors, utilization of non-HS health services and health outcomes. Bivariate analyses will test for statistically significant differences in health behaviors, health service utilization patterns, and health outcomes between HS and non-HS participants and among HS participants, by level of utilization of HS services. Descriptive analyses will also examine service or penetration rates by intended target characteristics (e.g., % of uninsured or Medicaid-insured served) and summarize utilization levels among participants at the grantee level.

The outcome evaluation analysis will estimate the effect of program participation by comparing outcomes of HS participants and non-participants using multivariable techniques. Individual-level propensity score matching will ensure that outcome comparisons between participants and non-participants are balanced with respect to observed characteristics. Multiple comparison groups, including internal references among program participants, will be used to test the sensitivity of results and promote causal inference (e.g. postpartum versus prenatal enrollees, dose-response effects). Analyses will also examine variation in effects by program and organizational characteristics to identify critical practices that can be spread and scaled to maximize impact across grantees.

Data Use Agreement

Prior to HS client-level data, vital records and PRAMS data being linked, all agencies will be required to develop and sign a data sharing/transfer agreement. Through a subcontract with JSI, the National Association of Public Health Statistics and Information Systems (NAPHSIS) will develop a model data sharing/transfer agreement to be adapted and signed for each HS grantee, VRO, PRAMS program and MCHB/HRSA. The evaluation support contractor (to be awarded in ~~July~~ September 2016) will monitor the signing and receipt of data sharing/transfer agreements and provide assistance to all entities to modify the model data sharing agreement to fit the needs and requirements of all involved agencies. Data sharing/transfer agreements may include language pertaining to the tasks and responsibilities of each agency, how files are provided (e.g., format), and the timing of submissions. The contractor will also assist agencies in obtaining the appropriate signatures from agency representatives by following up on the status of the agreements and providing assistance when needed to obtain signatures. The contractor will ensure the receipt of the signed data sharing/transfer agreements for HS grantees, VROs, PRAMS programs, and MCHB/HRSA.

Request for Waiver of HIPAA Authorization

We request a waiver of HIPAA authorization for HS grantees (the 'providers' in this scenario) to send the data file containing protected health information from the client-level assessment forms (i.e. HS participant individual identifiers) to state/jurisdiction VROs, linking the HS participant individual identifiers to vital records and PRAMS, and sharing the linked, de-identified data with MCHB/HRSA. These data will contain personal identifiable information and protected health information about HS participants, including demographic information (e.g., zip code, date of birth, infant's date of death), health conditions, and utilization of health care services (including dates of service). Such data could be used to identify individuals, particularly if triangulated with other variables. However, the personal identifiable information will be collected and stored at the HS grantee locations, VROs and state PRAMS programs. MCHB/HRSA and its contractors will only receive de-identified coded information.

The protected health information included in the data files involves no more that minimal risk to the privacy of the individuals. HRSA has strong protections in place to protect any identifiers or potential identifiers from disclosure or improper use. VROs and PRAMS programs will transfer data to MCHB/HRSA without personally identifiable information for all linked HS participants and non-participants in the same geographic area to facilitate analytic comparison, including birth certificate data on linked participants with client ID number, date of enrollment, geographic identifiers (census tract or latitude/longitude) and birth certificate data for non-participant controls from the same city or county with geographic identifiers (census tract or latitude/longitude). MCHB/HRSA will use the unique client ID to link the data to client-level program data and identify the services received by HS participants. However, data may still be potentially identifiable through a combination of demographic and medical characteristics, such as race/ethnicity, census tract of residence, and experience of infant death. Therefore, as an added level of precaution, MCHB/HRSA will maintain secure storage of vital records data and protect potentially personal identifiable information using standard HHS procedures.

We will ask all agencies to follow the security guidelines and policies for HHS, as well as what they have to follow for their agencies. All of this information will be outlined in the data sharing and transfer agreement. The Vital Records offices will not hold onto the individual identifier data once they link it. It will only be used to link to the Vital Records (infant birth certificate and subsequent death certificates). From there, PRAMS programs will use the infant birth certificate as a sampling frame to identify HS participants to survey and the vital records and PRAMS data will be linked to program data using the HS participants' unique client-id/code. Further, the VROs and PRAMS programs have experience handling confidential data and will be careful to ensure the data they have from the Healthy Start grantees is kept confidential while in their possession. All agencies participating in the evaluation may also specify in the data sharing agreement that the VROs will not keep any data once they send the linked data to HRSA.

Informed Consent

Two separate informed consent forms and a participant contact script have been developed for this evaluation study (see Appendix E):

1. One for pregnant/postpartum women enrolled in HS case management services (during the study period), for participation in the vital records portion of the evaluation; and

2. One for pregnant/postpartum women enrolled in HS case management services (during the study period), for participation in the PRAMS oversampling portion of the evaluation.

Both consent forms also include consent for completion of the HS client-level assessment forms for any individual enrolled in HS case management services, and sending the de-identified client-level assessment information to MCHB/HRSA.

The informed consent forms have been tested for readability. The informed consent form for completion of the HS client-level assessment forms was determined to be at an 8th grade reading level. The informed consent forms for the vital records linkage and the PRAMS oversampling were determined to be at 9th grade reading levels. The form is above an 8th grade reading level due to the names of the agencies, data sets, and methods involved. Every effort was made to address literacy issues in the development of the informed consent forms.

Research Partners

MCHB/HRSA has/will establish a subcontract, two Interagency Agreements (IAAs), and an Indefinite Deliverable Indefinite Quantity (IDIQ) contract to support data collection and evaluation implementation activities. The subcontract is with NAPHSIS to develop model data sharing/transfer agreements between HS grantees, VROs, PRAMS programs, and MCHB/HRSA. The IAAs are with the CDC's NCHS and the CDC's Division of Reproductive Health (DRH) which oversees the PRAMS program. NCHS will ensure MCHB/HRSA receives calendar year vital records data (birth and death certificates) for HS participants and non-HS participants within the cities/counties from the 37 states, DC, and NYC that have currently funded HS projects. The IAA with DRH will support a new project coordinator as well as a limited amount of statistical support and technical assistance from existing PRAMS staff to PRAMS sites and HS grantees. The IDIQ contract is anticipated to be awarded in ~~July~~ September 2016. The IDIQ contract will support the implementation of the HS evaluation. Contract activities will include developing and administering a survey to HS participants; providing technical assistance to HS grantees, state/jurisdiction VROs, and PRAMS programs to support linkage processes; overseeing and monitoring the data collection, processing, cleaning, and management processes; analyzing evaluation data; preparing interim and final evaluation reports; coordinating the Technical Expert Panel (TEP) quarterly meetings (the external committee to guide the design and implementation of the evaluation); and providing administrative and coordination support to MCHB/HRSA staff managing previous established activities to support data collection processes and activities. Contractor support will also be provided for the process evaluation through DHSPS' current contractor, JSI. JSI will administer the NHSPS and conduct analysis of the responses. OER may also provide support for the survey analysis.

Publications

It is anticipated that findings from the evaluation will be published in peer-reviewed journals. These findings will include aggregated data only and will not include any identifiable data. Standard NCHS protocols of not reporting any tabulations with a numerator less than 10 and flagging any with a numerator 10-19 as unreliable will be followed.

REFERENCES

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Appendix A

Dwyer, Maura (HRSA) [C]

From: Banks, Jamelle (HRSA)
Sent: Thursday, December 03, 2015 2:47 PM
To: Harris, Lydie-Anne (HRSA)
Cc: Dwyer, Maura (HRSA) [C]; 'Maura Dwyer -DHMH-'; Ghandour, Reem (HRSA)
Subject: RE: HRSA Exemption Request Form for the Healthy Start Evaluation

Hi Lydie,

Thank you for your review and the determination. This email notice serves our purposes for the evaluation.

Thank you again,
Jamelle

From: Harris, Lydie-Anne (HRSA)
Sent: Thursday, December 03, 2015 12:09 PM
To: Banks, Jamelle (HRSA)
Cc: Dwyer, Maura (HRSA) [C]; 'Maura Dwyer -DHMH-'; Ghandour, Reem (HRSA)
Subject: RE: HRSA Exemption Request Form for the Healthy Start Evaluation

Hi Jamelle,

After reviewing the study description you provided, I actually think this does not qualify as human subjects research. You are proposing to study the implementation of the Healthy Start program and even though you are surveying PIs, you are not collecting information *about them,* but rather about the grantees' experiences. Since you're not collecting information *about* living individuals, it does not count has human subjects research so this does not need to go through the exemption process.

If you want a more formal documentation of this determination of non-research, I could prepare a memo to this effect (although it's not required by HHS regulations or HRSA policy). Please let me know if you'd like me to do this, or if this email notice serves your purposes.

Let me know if you have any other questions.
Thanks! Lydie

Lydie A. Lebrun-Harris, PhD, MPH
Office of Research and Evaluation
Office of Planning, Analysis and Evaluation
Health Resources and Services Administration
US Department of Health and Human Services
5600 Fishers Lane, Room 10C-16, Rockville, MD 20857
Tel: 301-443-2178
Email: LHarris2@hrsa.gov

From: Banks, Jamelle (HRSA)
Sent: Thursday, December 03, 2015 11:21 AM
To: Harris, Lydie-Anne (HRSA)
Cc: Dwyer, Maura (HRSA) [C]; 'Maura Dwyer -DHMH-'; Ghandour, Reem (HRSA)
Subject: HRSA Exemption Request Form for the Healthy Start Evaluation

Dear Lydie,

Please find attached the signed HRSA Exemption Request form for the Healthy Start evaluation. We are seeking exemption for administering the National Healthy Start Program Survey (NHSPS). Please let us know if you have any questions or need additional information.

Thank you,
Jamelle

Jamelle E. Banks, MPH
Chief Evaluation Officer
Division of Epidemiology | Office of Epidemiology and Research
Maternal and Child Health Bureau | Health Resources and Services Administration
5600 Fishers Lane, Rm 10C24, Rockville, MD 20857
Phone: 301-443-1726 | Fax: 301-480-0508 | Email: jbanks@hrsa.gov

Appendix B

Depression Screening

The Edinburgh Postnatal Depression Scale (EPDS) is to be properly administered to the client and scored by a staff member upon enrollment, at the first postpartum visit, at the three month postpartum visit, at annual assessment visits, upon exit from the program, and more often frequently if warranted.

EPDS ≤ 10

EPDS > 10

Positive results to question #10

Negative results to question #10

Administer Suicidal Ideation Questionnaire

Negative results to question #10

Discuss results with client.

Confirm that score matches client's feelings and your professional judgment.

If not, utilize interventions for "EPDS >10"

Positive for suicidal ideation, intent, plan, means, S/S PP psychosis

Suicidal thoughts, but denies ability and/or plan.

Develop suicide contract and/or safety plan

Assess and engage support system if appropriate and available

IMMEDIATE CRISIS INTERVENTION

Provide close supervision-do not leave client alone

With permission, assess and engage support system to accompany & transport client to Hospital Emergency Department or local Emergency Mental Health Access Center for assessment and treatment/hospitalization

If no outside support, call 911 or EMS for transport to Hospital Emergency Department

With permission, inform medical provider

REFER
to
Medical Provider
or
Mental Health Specialist/ Behavioral Health

EDUCATE

S/S of stress, depression and perinatal mood disorders

Common and treatable

Stress management & coping techniques

Effects of depression on ability to function at home, work, school, and in leisure activities

Importance of regular physical activity, proper nutrition and realistic expectations

Community resources and support services

EDUCATE

Treatment options and importance of follow-up care

Help/crisis intervention numbers

The National Suicide Prevention Lifeline (1-800-273-TALK)

Repeat the EPDS at intervals to monitor progress.

For ages 10-39, Native American and Alaska Natives have the highest suicide rates of all races and ethnicities.

Final 01/14

Appendix C

Violence/Abuse Flow Sheet

Violence screening will be done in a confidential setting using the Maternal, Infant Health Program (MIHP) Maternal Risk Identifier and the Infant Risk Identifier-Maternal Component enrollment forms, the program annual assessment forms and the program Exit form. Results will be entered into the electronic record by a program staff member.

Clients in a current abusive relationship will be reassessed for risk/safety at each visit.

Violence is NOT suspected and is NOT disclosed

Violence IS suspected, but NOT disclosed (visible injury; interview cues)

Past history of abuse Denies current abuse

Client self-discloses abuse/violence or positive assessment

Document that screening was conducted and that the patient did not disclose abuse

EDUCATE

Healthy relationships

Effects of domestic violence on children

Community resources and support services

If you suspect abuse, document reasons for concern

Reassess at another visit

Assess for safety concerns or any increase in violence risk

Assess for any concerns about past history of abuse

Discuss counseling to address abuse history

EDUCATE

The cycle of violence in domestic abuse

Importance of immediate crisis intervention if violence resumes or escalates

Community resources and support services including shelters, social services, legal service, support groups and help/crisis intervention numbers

National Domestic Violence Hotline
1-800-799-SAFE (7233)
To speak with crisis counselor or locate a shelter

Reassess risk each visit

Assess the environment for danger and evaluate for immediate threat and safety concerns

Imminent risk of physical harm

Assess readiness to address current abuse

REFER to local domestic violence organizations/ counseling

Assist client in accessing emergency services/shelter

Call 911 or EMS if necessry/appropriate

With permission notify medical care provider

Assist client in developing a safety and/or exit plan including alternate housing, economic supports and social supports. Keep copy in client record for review.

Reassure client that she is not alone-other women have experienced violence in their relationships

EDUCATE

Signs of escalating physical danger

Emergency escape kit

National Domestic Violence Hotline
1-800-799-SAFE (7233)
To speak with crisis counselor or locate a shelter

911 if imminent danger

Review safety plan each visit

Professional Resources

Michigan Coalition Against Domestic and Sexual Violence
(517) 347-7000 Phone/TTY
Website: www.mcadsv.org

http://www.bcbsm.com/pdf/DV_ReferenceGuide.pdf

http://mcedsv.org/images/Document/DVAM2012/DVFactSheet-Michigan.pdf

http://mcedsv.org/resources/parents_friends_and_family.html

http://www.michigan.gov/som/0,1607,7-192-29941_30586_240-2884--,00.html (Shelters)

http://www.michigan.gov/som/0,1607,7-192-29941_30586_240-2884--,00.html
http://www.mcadsv.org/help/locate.php
(Michigan domestic violence programs by county, city)

Final 01/14

Appendix D

Clients Experiencing Fetal/Infant Death

Once Healthy Start New Orleans (HSNO) is aware that a client has experienced a loss, the following steps should be taken:

1. Case Manager (CM) will initiate the HSNO Mortality Assessment form. He/She will also initiate the RTS program based on the gestational age of loss. (eg: 18 weeks gestational age loss would receive info on miscarriage)
2. If still hospitalized, the CM will visit the client in the hospital and review any plans that have been made with the client to assess what other assistance is needed. If at home, the CM will visit and assess what assistance is needed.
3. The CM will document on the HSNO Mortality Assessment form under "comments" any information obtained and will also include any concerns related to the client's coping mechanisms with the grieving process.
4. The CM will forward a copy of the assessment to the FIMR RN and to the Mental Health Associate.
5. The MHA will assess the need for further client intervention and follow up. This information will be documented on the Mortality Assessment Form.
6. If the death meets criteria for further review through the FIMR process, then appropriate follow up will be implemented through the FIMR RN. This information will also be documented on the Mortality Assessment Form.
7. The CM will be kept aware of all assessments by the MHA and the FIMR RN.
8. All fetal/infant deaths will be brought for discussion at the MDT meeting.
9. Follow up calls will be made to the client at 2 weeks post delivery, 6 weeks post delivery, 3 months post delivery, 6 months post delivery and first year anniversary. Info will be documented on the HSNO Mortality Assessment Form.

Appendix E

[Letterhead]

HEALTH RESOURCES AND SERVICES ADMINISTRATION
MATERNAL AND CHILD HEALTH BUREAU

Participant Informed Consent
Vital Records Linkage

Study Title: Evaluation of the National Healthy Start Program

Principal Investigator: Jamelle Banks, MPH
Chief Evaluation Officer
Division of Epidemiology | Office of Epidemiology and Research
Maternal and Child Health Bureau | Health Resources and Services Administration
5600 Fishers Lane, Rm 18N118, Rockville, MD 20857
jbanks@hrsa.gov
tel: 301-443-1726

IRB No.:

PI Version Date:

What you should know about this study:

- You are being asked to join an evaluation study.
- This form explains the study and your part in the study.
- Please read it carefully and take as much time as you need.
- You are a volunteer. You can choose not to take part and if you join, you may quit at any time. There will be no penalty if you decide to quit the study. Your decision will not affect the services you are receiving or will receive.
- ~~During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.~~

Purpose of the Healthy Start Program Evaluation:

The evaluation is being done by the federal government's Maternal and Child Health Bureau (MCHB) in the Health Resources and Services Administration (HRSA). We are doing an evaluation of the Healthy Start Program. We want to understand the experiences of women and children up to age two in the Healthy Start Program and the impact of the program on their health. This study will help us understand what parts of the program help improve the health of participants and why they are successful, so that we can grow the most successful parts of the program.

Why you are being asked to participate:

You were asked because you [will] participate in a Healthy Start Program's case management services. We ask you to join this study because you can provide information about your experiences with Healthy Start, your health and, if relevant, the health of your child[ren] up to age two. You do not have to participate. It is your choice. Your decision will not affect the services you are receiving or will receive.

Length of participation:

The Healthy Start Program Evaluation began in August 2016 and is expected to end in March 2019. You are being asked to share personal information about you and, if relevant, your child[ren] up to age two during the evaluation study.

Description of the process:

If you say yes, we will ask you to share information about you and, if relevant, your child[ren] up to age two, the care you receive, and about your participation in Healthy Start. Your information is confidential and will be kept in a secure place by the Healthy Start program.

Some of the information we will collect include the following:

- **Mother's name**
- **Mother's date of birth**
- Mother's address at time of delivery
- Mother's social security number
- Mother's race
- Mother's ethnicity
- Mother's Medicaid status
- Number of pregnancies
- Number of live births
- Mother's date of enrollment in HS
- **Mother's Healthy Start Client ID #** (this will be provided by your Healthy Start program)
- **Infant date of birth (or expected month or date of delivery if known)**
- Infant birth hospital
- Infant sex
- Infant name
- Infant birthweight

The items in **bold** are those we must have to include you in the evaluation study.

This information about you and your child[ren] will be provided to your state's Vital Records Office (VRO). Your state's VRO will link this information to your child[ren]'s vital records (birth certificate and death certificate, if any). The linked information, without any of your identifying information, will be sent to the Healthy Start office in MCHB/HRSA, where it will

be studied to assess the effects of Healthy Start on the health of you and your child[ren] up to age two.

Risks and Benefits:

There is minimal risk and no direct benefits related to participation in this study ~~related to this study~~. Your participation in this study is completely voluntary. ~~and~~ There is no penalty for not participating. The information collected will help the Healthy Start program(s) understand and improve the health of mothers and children up to age two.

Confidentiality:

Your identity will be kept confidential to the extent allowed by law. Your information will be given a code number that will keep your identity unknown to those other than your Healthy Start program and your state's Vital Records Office. No other personal information will be shared. Vital records will not keep your personal information after they have sent your linked data to MCHB/HRSA and the project has ended.

Whom to contact if you have questions:

You may have questions about your rights as a participant in this evaluation study. If so, please call the Research Ethics Review Board at the National Center for Health Statistics, toll-free at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol # _____. Your call will be returned as soon as possible.

Agreement:

I, _____, have read the process described above. I voluntarily agree to participate in the evaluation of the Healthy Start Program. I understand that all data collected will be kept confidential to the extent allowed by law and only shared with the Healthy Start program and my state's Vital Records Office, and that no identifiable data will be shared with the Healthy Start office in MCHB/HRSA. ~~I agree that any information from this study may be used in any way that is helpful, as long as I am not identified and my name is not used.~~

Participant Signature: _____ Date: _____

Witness Signature: _____ Date: _____

[Letterhead]

HEALTH RESOURCES AND SERVICES ADMINISTRATION
MATERNAL AND CHILD HEALTH BUREAU

Participant Informed Consent
PRAMS Oversampling

Study Title: Evaluation of the National Healthy Start Program

Principal Investigator: Jamelle Banks, MPH
Chief Evaluation Officer
Division of Epidemiology | Office of Epidemiology and Research
Maternal and Child Health Bureau | Health Resources and Services Administration
5600 Fishers Lane, Rm 18N118, Rockville, MD 20857
jbanks@hrsa.gov
tel: 301-443-1726

IRB No.:

PI Version Date:

What you should know about this study:

- You are being asked to join an evaluation study.
- This form explains the study and your part in the study.
- Please read it carefully and take as much time as you need.
- You are a volunteer. You can choose not to take part and if you join, you may quit at any time. There will be no penalty if you decide to quit the study. Your decision will not affect the services you are receiving or will receive.
- ~~During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.~~

Purpose of the Healthy Start Program Evaluation:

The evaluation is being done by the federal government's Maternal and Child Health Bureau (MCHB) in the Health Resources and Services Administration (HRSA). We are doing an evaluation study of the Healthy Start Program. We want to understand the experiences of women and children up to age two in the Healthy Start Program and the impact of the program on their health. This study will help us understand what parts of the program help improve the health of participants and why they are successful, so that we can grow the most successful parts of the program.

Why you are being asked to participate:

You were asked because you [will] participate in a Healthy Start Program's case management services. We ask you to join this study because you can provide information about your experiences with Healthy Start, your health and, if relevant, the health of your child[ren] up to age two. You do not have to participate. It is your choice. Your decision will not affect the services you are receiving or will receive.

Length of participation:

The Healthy Start Program Evaluation began in August 2016 and is expected to end in March 2019. You are being asked to share personal information about you and, if relevant, your child[ren] up to age two during the evaluation study.

Description of the process:

If you say yes, we will ask you to share information about you and, if relevant, your child[ren] up to age two, the care you receive, and about your participation in Healthy Start. Your information is confidential and will be kept in a secure place by the Healthy Start program.

Some of the information we will collect include the following:

- **Mother's name**
- **Mother's date of birth**
- Mother's address at time of delivery
- Mother's social security number
- Mother's race
- Mother's ethnicity
- Mother's Medicaid status
- Number of pregnancies
- Number of live births
- Mother's date of enrollment in HS
- **Mother's Healthy Start Client ID #** (this will be provided by your Healthy Start program)
- **Infant date of birth (or expected month or date of delivery if known)**
- Infant birth hospital
- Infant sex
- Infant name
- Infant birthweight

The items in **bold** are those we must have to include you in the evaluation study.

This information about you and your child[ren] up to age two will be sent to your state's Vital Records Office (VRO). Your state's VRO will link this information to your child[ren]'s vital records (birth certificate and death certificate, if any) and forward the information to your state's PRAMS (Pregnancy Risk Assessment Monitoring System) program. PRAMS collects

information from mothers 2-9 months after they have delivered a baby about their attitudes and experiences before, during, and shortly after pregnancy.

Your state's PRAMS program will contact you to complete the PRAMS survey. Your completed PRAMS survey will be sent to your state's PRAMS program. The vital records and PRAMS survey information, without any of your identifying information, will then be sent to the Healthy Start office in MCHB/HRSA, where it will be studied to assess the effects of Healthy Start on the health of you and your child[ren] up to age two.

Risks and Benefits:

There is minimal risk and no direct benefits related to participation in this study. ~~related to this study.~~ Your participation is completely voluntary. ~~and~~ There is no penalty for not participating. The information collected will help the Healthy Start program(s) understand and improve the health of mothers and children up to age two.

Confidentiality:

Your identity will be kept confidential to the extent allowed by law. Your information will be given a code number that will keep your identity unknown to those other than your Healthy Start program, your state's VRO, and your state's PRAMS program. No other personal information will be shared. Vital records will not keep your personal information after they have sent your linked data to MCHB/HRSA and the project has ended.

Whom to contact if you have questions:

You may have questions about your rights as a participant in this evaluation study. If so, please call the Research Ethics Review Board at the National Center for Health Statistics, toll-free at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol # _____. Your call will be returned as soon as possible.

Agreement:

I, _____, have read the process described above. I voluntarily agree to participate in the evaluation of the Healthy Start Program. I understand that all data collected will be kept confidential to the extent allowed by law and only shared with the Healthy Start program, my state's Vital Records Office, and PRAMS, and that no identifiable data will be shared with the Healthy Start office in MCHB/HRSA. ~~I agree that any information from this study may be used in any way that is helpful, as long as I am not identified and my name is not used.~~

Participant Signature: _____ Date: _____

Witness Signature: _____ Date: _____

[Letterhead]

Contact Script

Dear ,

You are being asked to join an evaluation study of the Healthy Start Program. We want to understand the experiences of women and children up to age two in the Healthy Start Program and the impact of the program on their health. This will help us understand what parts of the program help improve the health of participants and why they are successful, so that we can grow the most successful parts of the program. You can choose not to take part and if you join, you may quit at any time. There will be no penalty if you decide to quit the study. Your decision will not affect the services you are receiving or will receive.

You were asked to join the study because you [will] participate in a Healthy Start Program's case management services. The Healthy Start Program Evaluation study began in August 2016 and is expected to end in March 2019. You are being asked to share personal information about you and, if relevant, your child[ren] up to age two during the evaluation study.

If you choose to participate, you will be interviewed today and during future Healthy Start visits. The interviews will range from 15 minutes to 90 minutes, depending on whether or not you are pregnant. Any information you provide will be kept confidential to the extent allowed by law. You do not have to answer any question you do not want to, and you can end the interview at any time. The information collected will help the Healthy Start program(s) understand and improve the health of mothers and children up to age two.

Are you interested in participating?

If yes, thank you, we will now review and sign the informed consent form.

If no, is there anything I can do to make your participation in the evaluation study possible?

Appendix F

Healthy Start Demographic Screening Tool

May 2016

Name: _____

Completed by: _____ **Date of Administration:** _____

To be completed with each participant at intake.

1. What is your date of birth?

____/____/_____ (month/day/year)

2. What is the Zip Code where you live?

_____

- ☐ Don't Know
- ☐ Declined to answer

3. What is the highest grade or year of school you have completed?

Select one only.

- ☐ Less than high school
- ☐ High school graduate or GED completed
- ☐ Some college/ vocational school
- ☐ College graduate
- ☐ More than college
- ☐ Don't Know
- ☐ Declined to answer

4. Are you of Hispanic, Latino, or Spanish origin?

- ☐ No, not of Hispanic, Latino, or Spanish origin
- ☐ Yes, Mexican, Mexican Am., Chicano
- ☐ Yes, Puerto Rican Yes, Cuban
- ☐ Yes, another Hispanic, Latino, or Spanish origin — Print origin, for example, Argentinean, Colombian, Dominican, Nicaraguan, Salvadoran, Spaniard, and so on.

  _____

5. What is your race?

Select all that apply.

- ☐ Asian (i.e. Chinese, Thai, Pakistani, Korean, etc.)
- ☐ Native Hawaiian
- ☐ Other Pacific Islander (i.e. Samoan, Guamanian, Polynesia, etc.)
- ☐ Black/ African American
- ☐ American Indian/ Alaska native
- ☐ White
- ☐ Some other race

Last updated 5/10/2016 5:42 PM
Developed by the Healthy Start CoIIN, with technical support from the Healthy Start EPIC Center, JSI, and funding from the Health Resources and Services Administration, Maternal and Child Health Bureau grant #UF5MC268450103.

- ☐ More than one race
- ☐ Declined to answer

6. Were you born in the United States, including the Virgin Islands?

Select one only.

- ☐ Yes, born in the United States (Go to Question 7)
- ☐ No, not born in the United States (Go to Question 6.1)Don't know (Go to Question 7)
- ☐ Declined to answer (Go to Question 7)

6.1 What country were you born in?

COUNTRY:_____

- ☐ Don't know
- ☐ Declined to answer

6.2 When did you come to live in the United States?

Year_____

7. How well do you speak English?

- ☐ Very well
- ☐ Well
- ☐ Not well
- ☐ Not at all
- ☐ Don't know
- ☐ Declined to answer

8. Do you speak a language other than English at home?

- ☐ Yes (Go to question 8.1)
- ☐ No **[Screening Tool is complete]**
- ☐ Don't know **[Screening Tool is complete]**
- ☐ Declined to answer **[Screening Tool is complete]**

8.1 STAFF: If participant speaks a language other than English at home, ask:

What is this language?

Select one only.

Staff: DO NOT READ OUT LOUD:

- ☐ African language (please specify):_____
- ☐ Arabic
- ☐ Chinese (please specify):_____
- ☐ Cape Verdean
- ☐ Creole

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F2

- ☐ English
- ☐ French
- ☐ German
- ☐ Greek
- ☐ Haitian Creole
- ☐ Hebrew
- ☐ Hindi
- ☐ Italian
- ☐ Japanese
- ☐ Korean
- ☐ Persian
- ☐ Polish
- ☐ Portuguese
- ☐ Russian
- ☐ Spanish
- ☐ Tagalog
- ☐ Vietnamese
- ☐ Urdu
- ☐ Other language (please specify):_____
- ☐ Declined to answer

The Healthy Start Demographic Screening Tool is Complete

Last updated 5/10/2016 5:42 PM
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F3

Health Start Pregnancy History Screening Tool

May 2016

Name: _____

Completed by: _____ **Date of Administration:** _____

This screening tool should be completed with all women seeking Healthy Start services.
Some key aims of this screening tool:

- **Assess woman's current pregnancy status**
- **Document previous pregnancy history**
- **Identify risks from previous pregnancy(s) which may impact future pregnancy**

---

1. Are you pregnant now?

- ☐ Yes (Go to question 1.1)
- ☐ No (Go to question 2)
- ☐ Don't know (Go to question 2)
- ☐ Declined to answer (Go to question 2)

1.1 How many weeks or months pregnant are you now?

_____Weeks OR
_____Months

- ☐ Don't know
- ☐ Declined to answer

1.2 Including this pregnancy, how many times have you been pregnant in your life? Include those that ended in live birth, miscarriage, stillbirth or fetal death, abortion, and ectopic or tubal pregnancy.

Staff: **DO NOT READ OUT LOUD**:

Live Birth: a birth at which a child is born alive
*Miscarriage: a loss of pregnancy before the 20th week of pregnancy
*Stillbirth or fetal death: a loss of pregnancy after the 20th week of pregnancy
*Abortion: a procedure to end a pregnancy
*Ectopic or tubal pregnancy: when a fertilized egg implants somewhere outside of the uterus, usually in the fallopian tube

_____PREGNANCIES (Go to question 3)

- ☐ Don't know (Go to question 3)
- ☐ Declined to answer (Go to question 3)

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FH

2. How many times have you been pregnant in your life? Include those that ended in live birth, miscarriage, stillbirth or fetal death, abortion, and ectopic or tubal pregnancy.

Staff: **DO NOT READ OUT LOUD:**

Live Birth: a birth at which a child is born alive
*Miscarriage: a loss of pregnancy before the 20th week of pregnancy
*Stillbirth or fetal death: a loss of pregnancy after the 20th week of pregnancy
*Abortion: a procedure to end a pregnancy
*Ectopic or tubal pregnancy: when a fertilized egg implants somewhere outside of the uterus, usually in the fallopian tube

_____PREGNANCIES

- ☐ Don't know
- ☐ Declined to answer

If participant has had no previous pregnancies, this screening tool is complete.

3. PLEASE READ OUT LOUD the following responses and write in the total number of each type of pregnancy outcome. Please write "0" if participant has not had that type of birth.

Please tell me how your previous pregnancies ended. How many of your pregnancies ended in a....?

- ☐ Live birth: _____ number of live births Date of last birth_____
- ☐ Miscarriage: _____ number of miscarriages
- ☐ Ectopic or tubal pregnancy: _____ number of ectopic or tubal pregnancies
- ☐ Abortion: _____ number of abortions
- ☐ Fetal death/stillbirth: _____ number of fetal deaths/stillbirths Date of most recent_____

DO NOT READ OUT LOUD:

- ☐ Declined to answer

4. How many of your children were delivered vaginally (naturally)?

_____children. IF NONE, ENTER "0"

- ☐ Declined to answer

5. How many of your children were delivered by Cesarean delivery (C-section)?

_____children. IF NONE, ENTER "0" AND go to question 6.1

- ☐ Declined to answer

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6. Did you have any problems or complications with any of your past pregnancies?

- ☐ Yes (Go to question 6.1)
- ☐ No (Go to question 7)
- ☐ Don't know (Go to question 7)
- ☐ Declined to answer (Go to question 7)

6.1 Which of the following problems did you have during your most recent pregnancy?

Select all that apply.

- ☐ Vaginal bleeding
- ☐ Kidney or bladder (urinary tract) infection (UTI)
- ☐ Severe nausea, vomiting, or dehydration that sent me to the doctor or hospital
- ☐ Cervix had to be sewn shut (cerclage for incompetent cervix)
- ☐ High blood pressure, hypertension (including pregnancy-induced hypertension [PIH]), preeclampsia, or toxemia
- ☐ Problems with the placenta (such as abruptio placentae or placenta previa)
- ☐ HIV, Herpes, or HPV
- ☐ Labor pains more than 3 weeks before my baby was due (preterm or early labor)
- ☐ Water broke more than 3 weeks before my baby was due (premature rupture of membranes [PROM])
- ☐ I had to have a blood transfusion
- ☐ I was hurt in a car accident
- ☐ Other: please specify:_____
- ☐ Declined to answer

7. Were any of your babies born more than 3 weeks before his or her due date?

- ☐ Yes, please specify how many: _____
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

8. Did any of your babies weigh less than 5 pounds, 8 ounces at birth?

- ☐ Yes, please specify how many: _____
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

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F6

9. Were any of your babies diagnosed with any medical conditions at birth?

- ☐ Yes (Go to question 9.1)
- ☐ No (Go to question 10)
- ☐ Don't know (Go to question 10)
- ☐ Declined to answer (Go to question 10)

9.1 What were they diagnosed with?

Select all that apply.

- ☐ Preterm (including Respiratory Distress Syndrome)
- ☐ Infection (e.g. Group B Strep, Herpes, HIV)
- ☐ NAS (Neonatal Abstinence Syndrome)
- ☐ Birth Defects (e.g. Congenital Heart Disease)
- ☐ Vision or Hearing problem
- ☐ Metabolic Disease (e.g. Phenylketonuria)
- ☐ Down Syndrome
- ☐ Cerebral Palsy
- ☐ Spina Bifida
- ☐ Other _____
- ☐ Don't know
- ☐ Declined to answer

10. Did any of your babies stay in the hospital after you came home?

Select one only.

- ☐ Yes
- ☐ No
- ☐ Declined to answer

11. How much weight in pounds did you gain during your last pregnancy?

_____ POUNDS (ENTER 0 IF PARTICIPANT'S WEIGHT DID NOT CHANGE)

- ☐ Lost weight during pregnancy: How much weight was lost? _____ pounds
- ☐ Don't know
- ☐ Declined to answer

12. Are all of your children living with you?

- ☐ Yes
- ☐ No
- ☐ Declined to answer

The Healthy Start Pregnancy History Screening Tool is Complete

Last updated 5/10/2016 5:42 PM
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F7

Healthy Start Preconception Screening Tool

May 2016

Name: _____

Completed by: _____ **Date of Administration:** _____

To be completed for women in the preconception period. This phase refers to the time period before becoming pregnant. During this phase, Healthy Start works with women (and sometimes partners) to improve their health, prepare their bodies for pregnancy if they desire it, and promote family planning.

Some key aims for HS grantees during this phase:

- *Optimize women's health, behaviors, and knowledge before pregnancy*
- *Enhance access to and quality of care for women before and between pregnancies*
- *Facilitate reproductive life planning (planning pregnancy, contraception, optimum birth spacing)*
- *Promote education, screening, referral, and treatment for women with high-risk conditions*

Demographics

1. Are you currently married or living with a partner, separated, divorced, widowed, or were you never married?

- ☐ Married or living with a partner
- ☐ Separated
- ☐ Divorced
- ☐ Widowed
- ☐ Never married
- ☐ Declined to answer

2. Are you currently...

Staff: **PLEASE READ OUT LOUD**:

- ☐ Employed for wages
- ☐ Self-employed
- ☐ Out of work for 1 year or more
- ☐ Out of work for less than 1 year
- ☐ A Homemaker
- ☐ A Student
- ☐ Retired
- ☐ Unable to work

DO NOT READ OUT LOUD

- ☐ Declined to answer

3. What is your yearly total household income before taxes? Include your income, your husband's or partner's income, and any other income you may have received. All information will be kept private and will not affect any services you are now getting.

- ☐ Less than $10,000
- ☐ $10,000 to less than $15,000
- ☐ $15,000 to less than $20,000
- ☐ $20,000 to less than $25,000
- ☐ $25,000 to less than $35,000
- ☐ $35,000 to less than $50,000

Last updated 7/19/2016 9:21 AM

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- ☐ $50,000 or more
- ☐ Don't know
- ☐ Declined to answer

4. How often has it been very hard to get by on your family's income, by this I mean to pay for food or housing?

- ☐ Never
- ☐ Rarely
- ☐ Somewhat often
- ☐ Very often
- ☐ Don't know
- ☐ Declined to answer

Social Determinants of Health

5. How often do you have transportation to or from your medical appointments?

- ☐ Never
- ☐ Sometimes
- ☐ Often
- ☐ Always
- ☐ Don't know
- ☐ Declined to answer

6. The next question is about whether you were able to afford the food you need. Which of these statements best describes the food situation in your household IN THE PAST 12 MONTHS?

- ☐ We could always afford to eat good nutritious meals.
- ☐ We could always afford enough to eat but not always the kinds of food we should eat.
- ☐ Sometimes we could not afford enough to eat.
- ☐ Often we could not afford enough to eat.
- ☐ Declined to answer

I would like to ask you about your current housing.

7. Do you own a place, rent a place, live in public housing, stay with a family member, or are you homeless?

- ☐ Owns or shares own home, condominium or apartment (Go to question 7.1)
- ☐ Rents or shares own home or apartment (Go to question 7.1)
- ☐ Lives in public housing (receives rental assistance, such as question 8) (Go to question 7.1)
- ☐ Lives with parent or family member (Go to question 7.1)
- ☐ Homeless (Go to question 7.2)
- ☐ Some other arrangement: _____ (Go to question 7.1)
- ☐ Declined to answer (Go to question 7.2)

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7.1. Is this place a regular place to stay? By "a regular place to stay" I am referring to a house, apartment, room, or other housing where you could stay 30 days in a row or more in the same place.

- ☐ Yes (Go to question 8)
- ☐ No (Go to question 8)
- ☐ Don't know (Go to question 8)
- ☐ Declined to answer (Go to question 8)

7.2. Do you share housing with someone, live in an emergency or transition shelter, or have some other living arrangement?

- ☐ Homeless and shares housing with someone
- ☐ Lives in an emergency or transition shelter
- ☐ Some other arrangement: _____
- ☐ Declined to answer

8. How do you feel about your current housing situation--do you feel very stable and secure, fairly stable and secure, just somewhat stable and secure, fairly unstable and insecure, or very unstable and insecure?

- ☐ Very stable and secure (Go to question 9)
- ☐ Fairly stable and secure (Go to question 9)
- ☐ Just somewhat stable and secure (Go to question 8.1)
- ☐ Fairly unstable and insecure (Go to question 8.1)
- ☐ Very unstable and insecure (Go to question 8.1)
- ☐ Not sure (Go to question 9)
- ☐ Declined to answer (Go to question 9)

8.1 What issues concern you about your housing situation?

- ☐ Received an eviction notice
- ☐ Non-payment of rent or past due rent
- ☐ Unable to pay future rent because lost housing subsidy, job, or other income source
- ☐ Non-payment of utilities or utility shut-off
- ☐ Housekeeping concerns (failure to maintain cleanliness of the unit)
- ☐ Housing is or will be condemned
- ☐ Friend or family member being evicted or threatened with eviction
- ☐ Threat of abuse by partner, family member, or other
- ☐ Being discharged or service is being terminated
- ☐ Personal conflict with others
- ☐ Other health or safety concerns
- ☐ Other lease violation(s) (please describe):_____
- ☐ Other (please describe):_____
- ☐ Don't know

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☐ Declined to answer

9. PLEASE READ OUT LOUD: I am going to read a list of services. Please tell me if you are receiving the service, if you have applied for the service and are waiting to find out if you will receive services, if you need services, or if you don't need services. I want to remind you that I ask these questions so we can provide the best services for your family.

	Receiving	Have applied for	Need	Do not need	Ineligible	Declined to answer
Childcare voucher						
Emergency Aid to the Elderly, Disabled, and Children (EAEDC)						
Food stamps/SNAP						
Heating assistance						
Immigration services						
Legal services						
Public housing						
Section 8 Voucher						
Social Security Disability Insurance (SSDI)						
Social Security Income (SSI)						
Transitional Aid to Families with Dependent Children (TAFDC)						
Temporary Assistance to Needy Families (TANF)						
Tribal Housing						
Utility Assistance						
Nutrition Supplemental Program for Women Infants and Children (WIC)						
Other (please specify)						

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FOLLOW UP	
Provided information/education about: ☐ Childcare voucher ☐ Emergency Aid to the Elderly, Disabled, and Children (EAEDC) ☐ Food stamps/SNAP ☐ Heating assistance ☐ Immigration services ☐ Legal services ☐ Public housing ☐ Section 8 Voucher ☐ Social Security Disability Insurance (SSDI) ☐ Social Security Income (SSI) ☐ Transitional Aid to Families with Dependent Children (TAFDC) ☐ Temporary Assistance to Needy Families (TANF) ☐ Tribal Housing ☐ Utility Assistance ☐ Nutrition Supplemental Program for Women Infants and Children (WIC) ☐ Other (please specify) **Date** _____	**Referral made for:** ☐ Childcare voucher ☐ Emergency Aid to the Elderly, Disabled, and Children (EAEDC) ☐ Food stamps/SNAP ☐ Heating assistance ☐ Immigration services ☐ Legal services ☐ Public housing ☐ Section 8 Voucher ☐ Social Security Disability Insurance (SSDI) ☐ Social Security Income (SSI) ☐ Transitional Aid to Families with Dependent Children (TAFDC) ☐ Temporary Assistance to Needy Families (TANF) ☐ Tribal Housing ☐ Utility Assistance ☐ Nutrition Supplemental Program for Women Infants and Children (WIC) ☐ Other (please specify) **Date** _____

10. Have you ever had a case with Child Protective Services?

☐ Yes (Go to question 10.1)
☐ No (Go to question 11)
☐ Don't know (Go to question 11)
☐ Declined to answer (Go to question 11)

10.1 Do you currently have an open case with Child Protective Services?

☐ Yes
☐ No
☐ Don't know
☐ Declined to answer

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Neighborhood and Community

11. Now I am going to ask you a few questions about your neighborhood or community. Please tell me if you agree or disagree with each of these statements.

Q#	Statement	Agree	Disagree	Don't know	Declined to answer
11.1	People in this neighborhood or community help each other out				
11.2	We watch out for each other's children in this neighborhood or community				
11.3	There are people I can count on in this neighborhood or community.				

12. How often do you feel safe in your community or neighborhood? Would you say never, sometimes, usually, or always?
Select one only.

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always
- ☐ Declined to answer

13. How often do you participate in school, community, or neighborhood activities? Would you say daily, weekly, monthly, a few times a year, less than once a year, or never?
Select one only.

- ☐ Daily
- ☐ Weekly
- ☐ Monthly
- ☐ A few times a year
- ☐ Less than once a year
- ☐ Never
- ☐ Declined to answer

14. How often do you get together or talk with family, friends or neighbors? Would you say daily, weekly, monthly, a few times a year, less than once a year or never?

Select one only.

- ☐ Daily
- ☐ Weekly
- ☐ Monthly
- ☐ A few times a year
- ☐ Less than once a year
- ☐ Never
- ☐ Declined to answer

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Medical Home / Access to Care/Health Insurance

15. A personal doctor or nurse is a health professional who knows you well and is familiar with your health history. This can be a general doctor, a specialist doctor, a nurse practitioner, or a physician's assistant. Do you have one or more persons you think of as your personal doctor or nurse?

- ☐ Yes (Go to question 15.1)
- ☐ No (Go to question 16)
- ☐ Don't know (Go to question 16)
- ☐ Declined to answer (Go to question 16)

15.1 Is there one person or more than one person?

- ☐ Yes, one person
- ☐ Yes, more than one person
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

16. Is there a place that you USUALLY go for care when you are sick or need advice about your health?

- ☐ Yes (Go to question 16.1)
- ☐ No (Go to question 17)
- ☐ There is more than one place (go to question 16.1)
- ☐ Don't know (Go to question 17)
- ☐ Declined to answer (Go to question 17)

16.1 What kind of place do you go to most often when you are sick or you need advice about your health? Is it a doctor's office, emergency room, hospital outpatient department, clinic or some other place?

- ☐ Doctor's Office
- ☐ Hospital Emergency Room
- ☐ Hospital Outpatient Department
- ☐ Clinic or Health Center
- ☐ Retail Store Clinic or "Minute Clinic"
- ☐ School (Nurse's Office, Athletic Trainer's Office)
- ☐ Does Not Go To One Place Most Often
- ☐ Some other place (Go to question 16.2)

16.2 **Please identify the usual place of care:**

- ☐ Friend/Relative
- ☐ Mexico/Other Locations Out Of Us
- ☐ Other _____

17. Please tell me what kind of health insurance you have:

- ☐ Private insurance through my job, or the job of my husband, partner or parents.
- ☐ Insurance purchased directly from an insurance company

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- ☐ Medicaid, Medical Assistance, or any kind of government assistance plan for those with low incomes or a disability
- ☐ TRICARE or other military health care
- ☐ Indian Health Service
- ☐ Other, specify: _____
- ☐ No insurance
- ☐ Don't know
- ☐ Declined to answer

18. During the past 12 months, did you see a doctor, nurse, or other health care worker for preventive medical care, such as a physical or well visit checkup?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to Answer

Health and Health History

19. In general, would you say that your overall health is excellent, very good, good, fair, or poor?

Select one only.

- ☐ Excellent
- ☐ Very good
- ☐ Good
- ☐ Fair
- ☐ Poor
- ☐ Don't know
- ☐ Declined to answer

20. In general, would you say that your mental and emotional health is excellent, very good, good, fair, or poor?

Select one only.

- ☐ Excellent
- ☐ Very good
- ☐ Good
- ☐ Fair
- ☐ Poor
- ☐ Don't know
- ☐ Declined to answer

21.1 How tall are you without shoes?

_____Feet _____ Inches

- ☐ Don't Know
- ☐ Declined to answer

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21.2 How much do you weigh?

_____ Pounds

☐ Don't Know
☐ Declined to answer

22. Has a healthcare provider ever told you that you have any of the following medical conditions?

Asthma (breathing problems/wheezing)

☐ Yes
☐ No
☐ Don't know
☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes
☐ No
☐ Don't know
☐ Declined to answer

Autoimmune disease[1] [Lupus (SLE), Rheumatoid Arthritis (RA), ~~HIV,~~ etc.]

☐ Yes
☐ No
☐ Don't know
☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes
☐ No
☐ Don't know
☐ Declined to answer

Cancer

☐ Yes
☐ No
☐ Don't know
☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes
☐ No
☐ Don't know
☐ Declined to answer

Cardiovascular disease (heart problems)

☐ Yes
☐ No
☐ Don't know
☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes
☐ No
☐ Don't know
☐ Declined to answer

Depression or other mental health conditions (anxiety, bipolar)

☐ Yes
☐ No
☐ Don't know
☐ Declined to answer

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If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

Diabetes (high blood sugar)

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

Eating disorders (anorexia/bulimia)

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

Gestational Diabetes

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

High blood pressure

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

PKU (phenylketonuria)[2]

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

Renal disease (kidney problems)

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

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If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

Seizure disorders (Epilepsy)

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

Sickle Cell

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

Thrombophilia (blood clots)

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

Thyroid disease – hypo/hyper (overactive or underactive thyroid)

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

Other_____

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

22.1 STAFF: If participant currently has any of the above conditions, ask: Have you been seen in the emergency room or hospitalized for any of these conditions within the past 6 months?

- ☐ Yes (Got to question 22.2)
- ☐ No (Go to question 23)
- ☐ Declined to answer (Go to question 23)

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22.2 Please tell me which condition or conditions you were seen for in the past 6 months:

- ☐ Asthma (Breathing problems/wheezing)
- ☐ Autoimmune disease (such as lupus (SLE), Rheumatoid Arthritis (RA~~), HIV~~)
- ☐ Cancer
- ☐ Cardiovascular disease (Heart problems)
- ☐ Depression or other mental health conditions (anxiety, bipolar)
- ☐ Diabetes (High blood sugar)
- ☐ Eating disorders (Anorexia/bulimia)
- ☐ Gestational diabetes
- ☐ High Blood Pressure
- ☐ PKU (phenylketonuria)
- ☐ Renal disease (Kidney problems)
- ☐ Seizure disorders (Epilepsy)
- ☐ Sickle Cell
- ☐ Thrombophilia (Blood Clots)
- ☐ Thyroid disease—(Hypo/hyper—overactive or underactive thyroid)

23. Are you currently having any pain?

- ☐ Yes
- ☐ No
- ☐ Declined to answer

24. Are you taking any prescription medications?

- ☐ Yes (Go to question 24.1)
- ☐ No (Go to question 25)
- ☐ Don't know (Go to question 25)
- ☐ Declined to answer (Go to question 25)

24.1 STAFF: ask participant specifically each one below.

Are you taking any:	**Yes**	**No**	**Don't know**	**Declined to answer**
Pain medications (such as morphine, codeine, oxycodone, Vicodin, or methadone)				
Blood Thinners (such as Coumadin, heparin, or Lovenox)				
Male Hormones (such as testosterone)				
Antibiotics (such as tetracycline, doxycycline, Flagyl or streptomycin, trimethoprim, Bactrim, Septra)				
Seizures or Epilepsy medications (such as valproate, Dilantin or Depakote)				
Acne medications (such as Accutane, Retin-A)				
High Blood Pressure medications (ace inhibitors such as Capoten, Vasotec,Lotensin)				
High Cholesterol medications (statins, such as Lipitor, Pravachol, Zocor, Mevacor)				
Antidepressants (such as lithium, Paxil)				

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24.2 STAFF: If participant is currently taking any of the above medications, ask:

Are you taking these medications as prescribed?

- ☐ Yes
- ☐ No
- ☐ Declined to answer

24.3 STAFF: If participant <u>is not</u> taking medication as prescribed, ask:

Please specify which medications:

- ☐ Pain medications (such as morphine, codeine, oxycodone, vicodin, or methadone)
- ☐ Blood Thinners (such as Coumadin, heparin, or lovenox)
- ☐ Male Hormones (such as testosterone)
- ☐ Antibiotics(such as tetracycline, doxycycline, Flagyl or streptomycin,trimethoprim, Bactrim, Septra)
- ☐ Seizures Or Epilepsy medications(such asvalproate, Dilantin or Depakote)
- ☐ Acne medications (such as Accutane, Retin-A)
- ☐ High Blood Pressure medications(ace inhibitors such as Capoten, Vasotec,Lotensin)
- ☐ High Cholesterol medications s (statins, such as Lipitor, Pravachol, Zocor, Mevacor)
- ☐ Antidepressants (such as lithium, Paxil)

25. During the past month, how many times a week did you take a multivitamin, a prenatal vitamin, or a folic acid vitamin?

- ☐ I did not take a multivitamin, prenatal vitamin or folic acid vitamin at all
- ☐ 1 to 3 times a week
- ☐ 4 to 6 times a week
- ☐ Every day of the week
- ☐ Don't Know
- ☐ Declined to answer

26. How long ago did you last have a flu vaccination? Would you say less than six months ago, six months to a year ago, more than a year ago, or never?

Select one only.

- ☐ Less than six months ago
- ☐ Six months to one year ago
- ☐ More than one year ago
- ☐ Never
- ☐ Don't know
- ☐ Declined to answer

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27. Have you ever received the following vaccines?

Q#	Vaccine	Yes	No	Don't know	Declined to answer
27.1	MMR (measles, mumps, rubella) vaccine				
27.1.1	If not, have you been tested for immunity to rubella?				
27.2	Hepatitis B vaccine (3 doses)				
27.3	All 3 shots of the Gardasil (HPV virus) vaccine				
27.4	Have you ever had chicken pox or shingles?				
27.4.1	If not, have you received 2 doses of the varicella vaccine?				
27.5	In the last 10 years, have you received Tdap (tetanus, diphtheria, and pertussis)?				

28. Have you ever been diagnosed with any of the following?

	Yes	No	Don't know	Declined to answer
Toxoplasmosis				
Tuberculosis				
Cytomegalovirus				
Hepatitis B or C				
Zika				
Chlamydia				
Gonorrhea				
Herpes Simplex				
HIV				
Syphilis				
Other:				

29. When was the last time you were tested for sexually transmitted diseases or sexually transmitted infections?

	Less than 6 months ago	6 months to 1 year ago	More than 1 year ago	Never
Chlamydia				
Gonorrhea				
Herpes Simplex				
HIV				
Syphilis				
Other:				

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30. Thinking back over the past 12 months would you say you used a condom with your partner or partners for sexual intercourse every time, most of the time, about half the time, some of the time, or none of the time?

- ☐ Every time
- ☐ Most of the time
- ☐ About half of the time
- ☐ Some of the time
- ☐ None of the time
- ☐ Not applicable
- ☐ Don't know
- ☐ Declined to answer

31. How long ago did you last have your teeth cleaned by a dentist/hygienist? Would you say less than six months ago, six months to a year ago, more than a year ago, or never?

Select one only.

- ☐ Less than six months ago
- ☐ Six months to one year ago
- ☐ More than one year ago
- ☐ Never
- ☐ Don't know
- ☐ Declined to answer

FOLLOW UP

Provided information/education about:

- ☐ Keeping a healthy weight such as through diet and exercise
- ☐ Health risks during pregnancy
- ☐ Getting vaccines
- ☐ Getting flu shot
- ☐ Travel advisory
- ☐ Sexually transmitted infections
- ☐ Keeping teeth healthy

Date _____

Provided:

- ☐ Nutritional counseling
- ☐ Immunizations: Please specify_____
- ☐ **Pain assessment**

Date _____

Referred to:

- ☐ Primary Care Provider
- ☐ Nutritionist
- ☐ Dentist
- ☐ Other: Please specify_____

Date_____

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Mental Health

32. Over the past two weeks, how often have you experienced any of the following?

Q#	Problem	Not at all	Several Days	More than half the days	Nearly every day	Score
32.1	Little interest or pleasure in doing things	0	1	2	3	
32.2	Feeling down, depressed, or hopeless	0	1	2	3	
	Total Score					

NOTE: Circle the number that matches the participant's answer, and add the answers for both together to get the final score. If the final score is more than 3, further assessment is needed.

FOLLOW UP

☐ **Provided information/ education about resources for depression**

Date_____

☐ **Provided further assessment using evidence-based tool such as PHQ-9 or Edinburgh Postnatal Depression Screening Tool.**

Date_____

☐ **Provided counseling**

Date_____

Referred to:

☐ Mental Health Center
☐ Primary Care Provider
☐ Other: Please specify_____

Date_____

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Substance Use

33. If it's okay with you, I'd like to ask you a few questions that will help me give you better care. The questions relate to your experience with alcohol, cigarettes, and other drugs. Some of the substances we'll talk about are prescribed by a doctor (like pain medications). But I will only record those if you have taken them for reasons or in doses other than prescribed. I'll also ask you about illicit or illegal drug use.

In the past year, how often have you used the following?

Substance	Never	Once or Twice Monthly	Weekly	Daily or Almost Daily	Declined to answer
Alcohol (4 or more drinks per day)					
Tobacco Products (including cigarettes, chewing tobacco, snuff, iqmik, or other tobacco products like snus Camel Snus, orbs, e-cigarettes, lozenges, cigars, or hookah)					
Mood-altering Drugs (including marijuana)					
Prescription Drugs for Non-Medical Reasons					
Illegal Drugs (marijuana, cocaine, crack, heroin, uppers/crank/meth, PCP, diet pills, LSD)					

34. Which of the following statements best describes the rules about smoking inside your home now?

- ☐ No one is allowed to smoke anywhere inside my home
- ☐ Smoking is allowed in some rooms or at some times
- ☐ Smoking is permitted anywhere inside my home

Staff: DO NOT READ OUT LOUD:

- ☐ Declined to answer

35. On average, about how many hours per day are you in the same room or vehicle with another person who is smoking?

_____Number of hours per day (enter 1 hour through 24 hours)

- ☐ I spend less than one hour per day in a room or vehicle with somebody who is smoking
- ☐ I am never in a room or vehicle with someone who is smoking
- ☐ Declined to answer

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FOLLOW UP		
Provided information/education about: ☐ Potential effects on pregnancy of tobacco ☐ Potential effects on pregnancy of alcohol ☐ Potential effects on pregnancy of drug use ☐ Tobacco cessation **Date**_____	**Provided further assessment:** ☐ Assess, Advise and Assist for Alcohol Use Disorders (for "Yes" to 1 or more days of heavy drinking [for women, 4 or more drinks per day]) ☐ NIDA-Modified ASSIST (for any use of illegal or prescription drug use for non-medical reasons) ☐ Provided Brief Intervention Date_____	**Referred to:** ☐ Tobacco Quit Line ☐ Behavioral Health Provider ☐ Primary Care Provider ☐ Substance abuse treatment program ☐ Other: Please specify_____ **Date**_____

Personal Safety

36. We are concerned about the safety of all participants. Please answer the following questions so that we can help you if needed.

Q#	During the past 12 months...	Yes	No	Declined to Answer
36.1	Did your husband or partner threaten or make you feel unsafe in some way?			
36.2	Were you frightened for your safety or your family's safety because of the anger or threats of your husband or partner?			
36.3	Did your husband or partner try to control your daily activities, for example, control who you could talk to or where you could go?			
36.4	Did your husband or partner push, hit, slap, kick, choke, or physically hurt you in any other way?			
36.5	Did your husband or partner force you to take part in touching or any sexual activity when you did not want to?			
36.6	Did anyone else physically hurt you in any way?			

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FOLLOW UP
☐ Provided information/ education about what to do if you have or someone you know has a partner that hurts them physically Date _____ ☐ Referred to local domestic violence program. List name of program here: _____ Date _____

Stress and Discrimination

37. STAFF: PLEASE READ OUT LOUD:

Stress is something we've all felt, and is often part of our daily lives. If you experience stress over a prolonged period of time however, it can be harmful to both your mind and body. Stress influences our moods, sense of well-being, behavior and overall health. We ask the following questions to learn what stressors you have in your life and to better understand how to help reduce the stress in your life.

This question is about things that may have happened during the past twelve months. For each item, check "no" if it did not happen or "yes" if it did. (It may help to look at the calendar when you answer these questions).

Q#	Event	Yes	No
37.1	A close family member was very sick and had to go into the hospital		
37.2	I got separated or divorced from my husband or partner		
37.3	I moved to a new address		
37.4	I was homeless or had to sleep outside, in a car, or in a shelter		
37.5	My husband or partner lost his job		
37.6	I lost my job even though I wanted to go on working		
37.7	My husband, partner, or I had a cut in work hours or pay.		
37.8	I was apart from my husband or partner due to military deployment or extended work-related travel		
37.9	I argued with my husband or partner more than usual		
37.10	My husband or partner said he didn't want me to be pregnant		
37.11	I had problems paying the rent, mortgage, or other bills		
37.12	My husband, partner, or I went to jail		
37.13	Someone very close to me had a problem with drinking or drugs		
37.14	Someone very close to me died		

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38. The next set of questions asks you about how other people have treated you. In your day-to-day life, how often have any of the following things happened to you?

Q#	Treatment	Almost every day	At least once a week	A few times a month	A few times a year	Less than once a year	Never	Declined to answer
38.1	You are treated with less courtesy or respect than other people.							
38.2	You receive poorer service than other people at restaurants or stores.							
38.3	People act as if they think you are not smart.							
38.4	People act as if they are afraid of you.							
38.5	You are threatened or harassed.							

If participant answers "**a few times a month**" or more frequently to any of the above, please go to question 39.

If participant answers "**less than once a year**", "**never**", or **declines to answer**, go to question 40.

39. What do you think is the main reason for these experiences?

- ☐ Your ancestry or national origins
- ☐ Your gender
- ☐ Your race
- ☐ Your age
- ☐ Your religion
- ☐ Your height
- ☐ Your weight
- ☐ Some other aspect of your physical appearance
- ☐ Your sexual orientation
- ☐ Your education or income level
- ☐ Your shade of skin color
- ☐ Physical Disability
- ☐ Other, please specify:

  _____

  _____
- ☐ Don't know
- ☐ Declined to answer

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40. The following statements are about the way you handle life events. Please tell me which are true for you most of the time.

Select all that apply.

- ☐ I tend to bounce back quickly after hard times
- ☐ I have a hard time making it through stressful events
- ☐ It does not take me long to recover from a stressful event
- ☐ It is hard for me to snap back when something bad happens
- ☐ I usually come through a difficult time with little trouble
- ☐ I tend to take a long time to get over set-backs in my life
- ☐ Don't know
- ☐ Declined to answer

Partner Involvement / Social Support

41. People sometimes look to others for companionship, assistance, or other types of support. These questions ask you about the types of support that would be available to you if you needed it. If you are not sure which answer to select, please choose the one answer that comes closest to describing it.

For the following questions your response options are the following; None of the time, a little of the time, some of the time, most of the time or all of the time; If you needed it, how often is someone available...

Q#	Support Task	All of the time	Most of the time	Some of the time	A little of the time	None of the time
41.1	To provide temporary financial support?					
41.2	To do something enjoyable with you?					
41.3	To help with daily chores if you were sick					
41.4	To turn to for suggestions about how to deal with a personal problem?					

42. Who do you count on for support?

Select all that apply.

- ☐ Current Partner
- ☐ Ex- partner

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- ☐ Parents
- ☐ Other child or children
- ☐ Other relative(s)
- ☐ Friend(s)
- ☐ Neighbor(s)
- ☐ Other _____

FOLLOW UP
☐ **Provided information/education about importance of social supports**
Date_____
Referral made to: ☐ Social Worker ☐ Parent help line ☐ Parent support group ☐ Other: Please specify_____
Date_____

Reproductive Life Planning

We have a few questions about your thoughts about having more children. This information will help us support you in making decisions about whether and when you might have more children.

43. Do you plan to have any children at any time in your future?

- ☐ Yes (Go to question 43.1)
- ☐ No (Go to question 44)
- ☐ Unable to get pregnant **[Survey is Complete]**
- ☐ Don't know (Go to question 44)
- ☐ Declined to answer(Go to question 44)

43.1 How many children would you like to have?

_____Children

- ☐ Don't know
- ☐ Declined to answer

43.2 Would you like to become pregnant in the next year?

- ☐ Yes (Go to question 44)
- ☐ No (Go to question 43.3)
- ☐ I am okay either say (Go to question 43.3)

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- ☐ Don't know (Go to question 43.3)
- ☐ Declined to answer (Go to question 43.3)

43.3 How long would you like to wait until you or your partner becomes pregnant?

- ☐ 1 year -17 months
- ☐ 18 months to 2 years
- ☐ More than 2 years
- ☐ Don't know
- ☐ Declined to answer

44. Are you currently using any form of contraception or birth control to either prevent pregnancy or prevent sexually transmitted infections?

- ☐ Yes (Go to question 44.1)
- ☐ No (Go to question 45)
- ☐ Declined to answer (Go to question 45)

44.1. What kind of birth control are you or your husband or partner using now to keep from getting pregnant or to prevent sexually transmitted diseases?

Select all that apply.

- ☐ Implant (such as Nexplanon)
- ☐ IUD (intrauterine device such as Mirena or ParaGard or Liletta)
- ☐ Female sterilization (Hysterectomy or Tubal Ligation)
- ☐ Male sterilization (Vasectomy)
- ☐ Injectable (Depo-Provera®)
- ☐ Birth control pill
- ☐ Patch (such as OrthoEvra®)
- ☐ Vaginal ring (NuvaRing®)
- ☐ Diaphragm
- ☐ Male condoms
- ☐ Female condoms
- ☐ Withdrawal
- ☐ Natural family planning methods (such as rhythm or cervical mucus testing)
- ☐ Foam/Jelly/Spermicide
- ☐ Lactational Amenorrhea Method (LAM) –i.e., breastfeeding
- ☐ Emergency contraception (Plan B – the "morning after pill")
- ☐ Periodic abstinence
- ☐ Other:_____
  _____
  _____
- ☐ I don't plan to use any birth control or contraceptive methods
- ☐ Don't know
- ☐ Declined to answer

44.2. Are you satisfied with your birth control method?

- ☐ Yes **[Screening Tool is Complete]**
- ☐ No (Go to question 45)
- ☐ Don't know (Go to question 45)
- ☐ Declined to answer (Go to question 45)

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45. What family planning method do you plan to use to avoid pregnancy?

Select all that apply.

- ☐ Implant (such as Nexplanon)
- ☐ IUD (intrauterine device such as Mirena or ParaGard or Liletta)
- ☐ Female sterilization (Hysterectomy or Tubal Ligation)
- ☐ Male sterilization (Vasectomy)
- ☐ Injectable (Depo-Provera®)
- ☐ Birth control pill
- ☐ Patch (such as OrthoEvra®)
- ☐ Vaginal ring (NuvaRing®)
- ☐ Diaphragm
- ☐ Male condoms
- ☐ Female condoms
- ☐ Withdrawal
- ☐ Natural family planning methods (such as rhythm or cervical mucus testing)
- ☐ Foam/Jelly/Spermicide
- ☐ Lactational Amenorrhea Method (LAM) –i.e., breastfeeding
- ☐ Emergency contraception (Plan B – the "morning after pill")
- ☐ Periodic abstinence
- ☐ Other:_____
  _____
  _____
- ☐ I don't plan to use any birth control or contraceptive methods
- ☐ Don't know
- ☐ Declined to answer

45.1 How sure are you that you will be able to use this method without any problems- not at all confident, somewhat confident, or very confident?

- ☐ Not at all confident
- ☐ Somewhat confident
- ☐ Very Confident
- ☐ Don't know
- ☐ Declined to answer

FOLLOW UP

- ☐ **Provided information/education about family planning or birth control**

Date _____

Provided birth control:

- ☐ Referred for birth control
- ☐ Primary Care Provider
- ☐ Planned Parenthood
- ☐ Other: please specify _____

Date _____

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The Healthy Start Preconception Screening Tool is Complete

Last updated 7/19/2016 9:21 AM
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Healthy Start Prenatal Screening Tool

May 2016

Name: _____

Completed by: _____ **Date of Administration:** _____

To be completed for women in prenatal period. This phase refers to the time period from diagnosis of pregnancy to birth.

Some key aims during this phase:

- *Improve health risk screening for all pregnant women*
- *Provide evidence-based tobacco cessation counseling*
- *Refer and treat women with substance abuse and mental health disorders*
- *Increase access to and quality of prenatal care*
- *Support comprehensive home visiting programs.*

Prenatal Care

Let's start off by asking some questions about your pregnancy.

1. How many weeks or months pregnant are you?

_____ Weeks OR _____Months

☐ Don't know
☐ Declined to answer

2. What is your baby's due date?

Due Date: _____

☐ Don't know
☐ Declined to answer

3. How many weeks or months pregnant were you when you had your first visit for prenatal care? Do not count a visit that was only for a pregnancy test or only for WIC (the Special Supplemental Nutrition Program for Women, Infants, and Children).

_____ Weeks OR _____ Months

☐ Don't know
☐ Declined to answer

☐ I didn't go for prenatal care (Go to question 6)

4. Are you currently receiving prenatal care?

☐ Yes (Go to question 5)
☐ No (Go to question 6)

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☐ Declined to answer (Go to question 6)

5. When was your last prenatal care visit?

Month_____ Year_____

☐ Declined to answer

6. Have you had any difficulty getting the prenatal care you want or need?

☐ Yes (Go to question 6.1)
☐ No (Go to question 7)
☐ Declined to answer (Go to question 7)

6.1 Please tell me the reasons it has been difficult to get prenatal care?

Staff: DO NOT READ OUT LOUD

Select all that apply.

☐ OB provider won't schedule an appointment until the end of the first trimester
☐ OB provider refused to schedule an appointment because my pregnancy is advanced
☐ If advanced pregnancy, # of weeks
☐ I couldn't get an appointment when I wanted one
☐ I couldn't find a doctor or clinic that accepted Medicaid
☐ It is hard to communicate with the doctor or clinic staff
☐ It is hard to understand the information the doctor or clinic gives me
☐ I haven't had enough money or insurance to pay for my visits
☐ I didn't have my Medicaid (or state Medicaid name) card
☐ I didn't have any transportation to get to the clinic or doctor's office
☐ I couldn't take time off work
☐ I had no one to take care of my children
☐ I have had too many other things going on in my life
☐ I didn't know I was pregnant
☐ I didn't want anyone to know I was pregnant
☐ I didn't want prenatal care
☐ Other
_____
_____
_____

7. A personal doctor or nurse is a health professional who knows you well and is familiar with your health history. This can be a general doctor, a specialist doctor, a nurse practitioner, or a physician's assistant. Do you have one or more persons you think of as your personal doctor or nurse?

☐ Yes (Go to question 7.1)
☐ No (Go to question 8)
☐ Don't know (Go to question 8)
☐ Declined to answer (Go to question 8)

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7.1 Is there one person or more than one person?

- ☐ Yes, one person
- ☐ Yes, more than one person
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

8. Is there a place that you USUALLY go for care when you are sick or need advice about your health?

- ☐ Yes (Go to question 8.1)
- ☐ No (Go to question 9)
- ☐ There is more than one place (Go to question 8.1)
- ☐ Don't know (Go to question 9)
- ☐ Declined to answer (Go to question 9)

8.1 What kind of place do you go to most often when you are sick or you need advice about your health? Is it a doctor's office, emergency room, hospital outpatient department, clinic or some other place?

Staff: DO NOT READ OUT LOUD.
Select one answer.

- ☐ Doctor's Office
- ☐ Hospital Emergency Room
- ☐ Hospital Outpatient Department
- ☐ Clinic or Health Center
- ☐ Retail Store Clinic or "Minute Clinic"
- ☐ School (Nurse's Office, Athletic Trainer's Office)
- ☐ Does Not Go To One Place Most Often
- ☐ Some other place (Go to question 16.2)

8.2 Please identify the usual place of care:

- ☐ Friend/Relative
- ☐ Mexico/Other Locations Out Of Us
- ☐ Other _____

9. Please tell me what kind of health insurance you have:

- ☐ Private health insurance through my job, or the job of my husband, partner or parents
- ☐ Insurance purchased directly from an insurance company
- ☐ Medicaid, Medical Assistance, or any kind of government assistance plan for those with low incomes or a disability
- ☐ TRICARE or other military health care
- ☐ Indian Health Service
- ☐ Other, specify: _____
- ☐ No insurance
- ☐ Don't know
- ☐ Declined to answer

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FOLLOW UP
Provided information/education about: ☐ Importance of regular prenatal care ☐ Importance of having a regular provider/medical home ☐ Medicaid eligibility ☐ Birth spacing **Date** _____ **Provided Service:** ☐ Enrolled in Medicaid **Date** _____ **Referred for:** ☐ Medicaid enrollment ☐ OB/GYN provider ☐ Primary Care Provider **Date**_____

Demographics

10. Are you currently married or living with a partner, separated, divorced, widowed, or were you never married?

- ☐ Married or living with a partner
- ☐ Separated
- ☐ Divorced
- ☐ Widowed
- ☐ Never married
- ☐ Declined to answer

11. Are you currently...

STAFF: Please read out loud:

- ☐ Employed for wages
- ☐ Self-employed
- ☐ Out of work for 1 year or more
- ☐ Out of work for less than 1 year
- ☐ A Homemaker
- ☐ A Student
- ☐ Retired
- ☐ Unable to work

DO NOT READ OUT LOUD

- ☐ Declined to answer

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12. What is your yearly total household income before taxes? Include your income, your husband's or partner's income, and any other income you may have received. All information will be kept private and will not affect any services you are now getting.

- ☐ Less than $10,000
- ☐ $10,000 to less than $15,000
- ☐ $15,000 to less than $20,000
- ☐ $20,000 to less than $25,000
- ☐ $25,000 to less than $35,000
- ☐ $35,000 to less than $50,000
- ☐ $50,000 or more
- ☐ Don't know
- ☐ Declined to answer

13. How often has it been very hard to get by on your family's income, by this I mean to pay for food or housing?

- ☐ Never
- ☐ Rarely
- ☐ Somewhat often
- ☐ Very often
- ☐ Don't know
- ☐ Declined to answer

Social Determinants of Health

14. How often do you have transportation to or from your medical appointments?

- ☐ Never
- ☐ Sometimes
- ☐ Often
- ☐ Always
- ☐ Don't know
- ☐ Declined to answer

15. The next question is about whether you were able to afford the food you need. Which of these statements best describes the food situation in your household IN THE PAST 12 MONTHS?

- ☐ We could always afford to eat good nutritious meals.
- ☐ We could always afford enough to eat but not always the kinds of food we should eat.
- ☐ Sometimes we could not afford enough to eat.
- ☐ Often we could not afford enough to eat.
- ☐ Declined to answer

16. Do you own as place, rent a place, live in public housing, stay with a family member, or are you homeless?

- ☐ Owns or shares own home, condominium or apartment (Go to question 16.1)
- ☐ Rents or shares own home or apartment (Go to question 16.1)
- ☐ Lives in public housing (receives rental assistance, such as Section 8) (Go to question 16.1)
- ☐ Lives with parent or family member (Go to question 16.1)

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- ☐ Homeless (Go to question 16.2)
- ☐ Some other arrangement: _____ (Go to question 16.1)
- ☐ Declined to answer (Go to question 16.2)

16.1 Is this place a regular place to stay? By "a regular place to stay" I am referring to a house, apartment, room, or other housing where you could stay 30 days in a row or more in the same place.

- ☐ Yes (Go to question 17)
- ☐ No (Go to question 17)
- ☐ Don't know (Go to question 17)
- ☐ Declined to answer (Go to question 17)

16.2. Do you share housing with someone, live in an emergency or transition shelter, or have some other living arrangement?

- ☐ Homeless and shares housing with someone
- ☐ Lives in an emergency or transition shelter
- ☐ Some other arrangement: _____
- ☐ Declined to answer

17. How do you feel about your current housing situation--do you feel very stable and secure, fairly stable and secure, just somewhat stable and secure, fairly unstable and insecure, or very unstable and insecure?

- ☐ Very stable and secure (Go to question 18)
- ☐ Fairly stable and secure (Go to question 18)
- ☐ Just somewhat stable and secure (Go to question 17.1)
- ☐ Fairly unstable and insecure (Go to question 17.1)
- ☐ Very unstable and insecure (Go to question 17.1)
- ☐ Not sure (Go to question 18)
- ☐ Declined to answer (Go to question 18)

17.1 What issues concern you about your housing situation?

- ☐ Received an eviction notice
- ☐ Non-payment of rent or past due rent
- ☐ Unable to pay future rent because lost housing subsidy, job, or other income source
- ☐ Non-payment of utilities or utility shut-off
- ☐ Housekeeping concerns (failure to maintain cleanliness of the unit)
- ☐ Housing is or will be condemned
- ☐ Friend or family member being evicted or threatened with eviction
- ☐ Threat of abuse by partner, family member, or other
- ☐ Being discharged or service is being terminated
- ☐ Personal conflict with others
- ☐ Other health or safety concerns
- ☐ Other lease violation(s) (please describe):_____

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☐ Other (please describe):_____
_____

☐ Don't know
☐ Declined to answer

18. I am going to read a list of services. Please tell me if you are receiving the service, if you have applied for the service and are waiting to find out if you will receive services, if you need services, or if you don't need services. I want to remind you that I ask these questions so we can provide the best services for your family.

STAFF: Please read the following services out loud:

	Receiving	Have applied for	Need	Do not need	Ineligible	Declined to answer
Childcare voucher						
Emergency Aid to the Elderly, Disabled, and Children (EAEDC)						
Food stamps/SNAP						
Heating assistance						
Immigration services						
Legal services						
Public housing						
Section 8 Voucher						
Social Security Disability Insurance (SSDI)						
Social Security Income (SSI)						
Transitional Aid to Families with Dependent Children (TAFDC)						
Temporary Assistance to Needy Families (TANF)						
Tribal Housing						
Utility Assistance						
Nutrition Supplemental Program for Women Infants and Children (WIC)						
Other (please specify)						

19. Have you ever had a case with Child Protective Services?

☐ Yes (Go to question19.1)
☐ No (Go to question 20)
☐ Don't know (Go to question 20)
☐ Declined to answer (Go to question 20)

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19.1 Do you currently have an open case with Child Protective Services?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

FOLLOW UP	
Provided information/education about: ☐ Childcare voucher ☐ Emergency Aid to the Elderly, Disabled, and Children (EAEDC) ☐ Food stamps/SNAP ☐ Heating assistance ☐ Immigration services ☐ Legal services ☐ Public housing ☐ Section 8 Voucher ☐ Social Security Disability Insurance (SSDI) ☐ Social Security Income (SSI) ☐ Transitional Aid to Families with Dependent Children (TAFDC) ☐ Temporary Assistance to Needy Families (TANF) ☐ Tribal Housing ☐ Utility Assistance ☐ Nutrition Supplemental Program for Women Infants and Children (WIC) ☐ Other (please specify) **Date** _____	**Referral made for:** ☐ Childcare voucher ☐ Emergency Aid to the Elderly, Disabled, and Children (EAEDC) ☐ Food stamps/SNAP ☐ Heating assistance ☐ Immigration services ☐ Legal services ☐ Public housing ☐ Section 8 Voucher ☐ Social Security Disability Insurance (SSDI) ☐ Social Security Income (SSI) ☐ Transitional Aid to Families with Dependent Children (TAFDC) ☐ Temporary Assistance to Needy Families (TANF) ☐ Tribal Housing ☐ Utility Assistance ☐ Nutrition Supplemental Program for Women Infants and Children (WIC) ☐ Other (please specify) **Date** _____

Neighborhood and Community

20. Now I am going to ask you a few questions about your neighborhood or community. Please tell me if you agree or disagree with each of these statements.

Q#	Statement	Agree	Disagree	Don't know	Declined to answer
20.1	People in this neighborhood or community help each other out				
20.2	We watch out for each other's children in this neighborhood or community				
20.3	There are people I can count on in this neighborhood or community.				

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21. How often do you feel safe in your community or neighborhood? Would you say never, sometimes, usually, or always?
Select one only.

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always
- ☐ Declined to answer

22. How often do you participate in school, community, or neighborhood activities? Would you say daily, weekly, monthly, a few times a year, less than once a year, or never?
Select one only.

- ☐ Daily
- ☐ Weekly
- ☐ Monthly
- ☐ A few times a year
- ☐ Less than once a year
- ☐ Never
- ☐ Declined to answer

23. How often do you get together or talk with family, friends or neighbors? Would you say daily, weekly, monthly, a few times a year, less than once a year or never?

Select one only.

- ☐ Daily
- ☐ Weekly
- ☐ Monthly
- ☐ A few times a year
- ☐ Less than once a year
- ☐ Never
- ☐ Declined to answer

Health and Health History

24. In general, would you say that your overall health is excellent, very good, good, fair, or poor?

Select one only.

- ☐ Excellent
- ☐ Very good
- ☐ Good
- ☐ Fair
- ☐ Poor
- ☐ Don't know
- ☐ Declined to answer

25. In general, would you say that your mental and emotional health is excellent, very good, good, fair, or poor?

Select one only.

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- ☐ Excellent
- ☐ Very good
- ☐ Good
- ☐ Fair
- ☐ Poor
- ☐ Don't know
- ☐ Declined to answer

26.1 How tall are you without shoes?

_____Feet _____ Inches

- ☐ Don't Know
- ☐ Declined to answer

26.2 Just before you got pregnant with your new baby, how much did you weigh?

_____ Pounds

- ☐ Don't Know
- ☐ Declined to answer

26.3 How much do you weigh now?

_____ pounds

- ☐ Don't Know
- ☐ Declined to answer

27. Has a healthcare provider ever told you that you have any of the following medical conditions?

Asthma (breathing problems/wheezing)

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

Autoimmune disease[1] [Lupus (SLE), Rheumatoid Arthritis (RA), ~~HIV,~~ etc.]

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

Cancer

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No

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☐ Don't know ☐ Declined to answer

Cardiovascular disease (heart problems)

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

Depression or other mental health conditions (anxiety, bipolar)

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

Diabetes (high blood sugar)

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

Eating disorders (anorexia/bulimia)

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

Gestational Diabetes

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

High blood pressure

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes ☐ No

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☐ Don't know ☐ Declined to answer

PKU (phenylketonuria)[2]

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

Renal disease (kidney problems)

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

Seizure disorders (Epilepsy)

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

Sickle Cell

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

Thrombophilia (blood clots)

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

Thyroid disease – hypo/hyper (overactive or underactive thyroid)

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes ☐ No

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☐ Don't know
☐ Declined to answer

Other_____

If **yes**, ask: Is this something you have currently?

☐ Yes
☐ No
☐ Don't know
☐ Declined to answer

27.1 STAFF: If participant currently has any of the above conditions, ask:

Have you been seen in the emergency room or hospitalized for any of these conditions within the last 6 months?

☐ Yes
☐ No
☐ Declined to answer

27.2 Which condition or conditions were you seen for in the past 6 months.

☐ Asthma (Breathing problems/wheezing)
☐ Autoimmune disease (such as lupus (SLE), Rheumatoid Arthritis (RA~~), HIV~~)
☐ Cancer
☐ Cardiovascular disease (Heart problems)
☐ Depression or other mental health conditions (anxiety, bipolar)
☐ Diabetes (High blood sugar)
☐ Eating disorders (Anorexia/bulimia)
☐ Gestational diabetes
☐ High Blood Pressure
☐ PKU (phenylketonuria)
☐ Renal disease (Kidney problems)
☐ Seizure disorders (Epilepsy)
☐ Sickle Cell
☐ Thrombophilia (Blood Clots)
☐ Thyroid disease—(Hypo/hyper—overactive or underactive thyroid)

28. Are you currently having any pain?

☐ Yes
☐ No
☐ Declined to answer

29. Are you taking any prescription medications?

☐ Yes (go to question 29.1)
☐ No (go to question 30)
☐ Don't know (go to question 30)
☐ Declined to answer (go to question 30)

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29.1 STAFF: ask participant specifically about each medication below.

Are you taking any:	Yes	No	Don't know	Declined to answer
Pain medications (such as morphine, codeine, oxycodone, Vicodin, or methadone)				
Blood Thinners (such as Coumadin, heparin, or Lovenox)				
Male Hormones (such as testosterone)				
Antibiotics (such as tetracycline, doxycycline, Flagyl or streptomycin, trimethoprim, Bactrim, Septra)				
Seizures or Epilepsy medications (such as valproate, Dilantin or Depakote)				
Acne medications (such as Accutane, Retin-A)				
High Blood Pressure medications (ace inhibitors such as Capoten, Vasotec,Lotensin)				
High Cholesterol medications (statins, such as Lipitor, Pravachol, Zocor, Mevacor)				
Antidepressants (such as lithium, Paxil)				

29.2 STAFF: If participant is currently taking any of the above medications, ask:

Are you taking these medications as prescribed?

- ☐ Yes (Go to question 30)
- ☐ No (Go to question 29.3)
- ☐ Declined to answer (Go to question 30)

29.3 Please specify which medications:

- ☐ Pain medications (such as morphine, codeine, oxycodone, vicodin, or methadone)
- ☐ Blood Thinners (such as Coumadin, heparin, or lovenox)
- ☐ Male Hormones (such as testosterone)
- ☐ Antibiotics(such as tetracycline, doxycycline, Flagyl or streptomycin,trimethoprim, Bactrim, Septra)
- ☐ Seizures Or Epilepsy medications(such asvalproate, Dilantin or Depakote)
- ☐ Acne medications (such as Accutane, Retin-A)
- ☐ High Blood Pressure medications(ace inhibitors such as Capoten, Vasotec,Lotensin)
- ☐ High Cholesterol medications s (statins, such as Lipitor, Pravachol, Zocor, Mevacor)
- ☐ Antidepressants (such as lithium, Paxil)

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30. During the past month, how many times a week did you take a multivitamin, a prenatal vitamin, or a folic acid vitamin?

- ☐ I did not take a multivitamin, prenatal vitamin or folic acid vitamin at all
- ☐ 1 to 3 times a week
- ☐ 4 to 6 times a week
- ☐ Every day of the week
- ☐ Don't Know
- ☐ Declined to answer

31. How long ago did you last have a flu vaccination? Would you say less than six months ago, six months to a year ago, more than a year ago, or never?

Select one only.

- ☐ Less than six months ago
- ☐ Six months to one year ago
- ☐ More than one year ago
- ☐ Never
- ☐ Don't know
- ☐ Declined to answer

32. Have you received a Tdap (tetanus, diphtheria, pertussis) and/or Hepatitis B shot since you became pregnant?

- ☐ Yes, Tdap **only**
- ☐ Yes, Hep B **only**
- ☐ Yes, **both** Tdap and Hep B
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

33. Have you been tested for Hepatitis C since you became pregnant?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

34. Have you ever been diagnosed with any of the following?

	Yes	No	Don't know	Declined to answer
Toxoplasmosis				
Tuberculosis				
Cytomegalovirus				
Hepatitis B or C				
Zika				
Chlamydia				
Gonorrhea				
Herpes Simplex				
HIV				
Syphilis				
Other:				

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35. When was the last time you were tested for sexually transmitted diseases or sexually transmitted infections?

	Less than 6 months ago	6 months to 1 year ago	More than 1 year ago	Never
Chlamydia				
Gonorrhea				
Herpes Simplex				
HIV				
Syphilis				
Other:				

36. How long ago did you last have your teeth cleaned by a dentist/hygienist? Would you say less than six months ago, six months to a year ago, more than a year ago, or never?

Select one only.

- ☐ Less than six months ago
- ☐ Six months to one year ago
- ☐ More than one year ago
- ☐ Never
- ☐ Don't know
- ☐ Declined to answer

37. How often do you wear a seatbelt when you ride in a car, truck or van?

- ☐ Never
- ☐ Seldom
- ☐ Always
- ☐ Not applicable (doesn't ride in car, truck or van)
- ☐ Don't know
- ☐ Declined to answer

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FOLLOW UP

Provided information/education about:

- ☐ Keeping a healthy pregnancy weight including how much weight to gain during pregnancy
- ☐ Nutrition
- ☐ Exercise
- ☐ Getting vaccines
- ☐ Getting flu shot
- ☐ Travel advisory
- ☐ Sexually transmitted infections
- ☐ Keeping teeth healthy
- ☐ Health risks during pregnancy
- ☐ Seat belt use during pregnancy

Date _____

Provided:

- ☐ Nutritional counseling
- ☐ Immunizations: Please specify_____
- ☐ Pain assessment

Date _____

Referred to:

- ☐ Primary Care Provider
- ☐ Nutritionist
- ☐ Dentist
- ☐ Other: Please specify_____

Date _____

Mental Health

38. Over the past two weeks, how often have you experienced any of the following?

Q#	Problem	Not at all	Several Days	More than half the days	Nearly every day	Score
38.1	Little interest or pleasure in doing things	0	1	2	3	
38.2	Feeling down, depressed, or hopeless	0	1	2	3	
	Total Score					

NOTE: Circle the number that matches the participant's answer, and add the answers for both together to get the final score. If the final score is more than 3, further assessment is needed.

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FOLLOW UP
☐ **Provided information/ education about resources for depression** Date _____ ☐ **Provided further assessment using evidence-based tool such as PHQ-9 or Edinburgh Postnatal Depression Screen** Date _____ ☐ **Provided counseling** Date _____ **Referred to:** ☐ Mental health center ☐ Primary Care Provider ☐ Other: Please specify_____ Date _____

Substance Use

39. If it's okay with you, I'd like to ask you a few questions that will help me give you better care. The questions relate to your experience with alcohol, cigarettes, and other drugs. Some of the substances we'll talk about are prescribed by a doctor (like pain medications). But I will only record those if you have taken them for reasons or in doses other than prescribed. I'll also ask you about illicit or illegal drug use.

In the past year, how often have you used the following?

Substance	Never	Once or Twice Monthly	Weekly	Daily or Almost Daily	Declined to answer
Alcohol (4 or more drinks per day)					
Tobacco Products (including cigarettes, chewing tobacco, snuff, iqmik, or other tobacco products like snus Camel Snus, orbs, e-cigarettes, lozenges, cigars, or hookah)					
Mood-altering Drugs (including marijuana)					
Prescription Drugs for Non-Medical Reasons					
Illegal Drugs (marijuana, cocaine,					

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crack, heroin, uppers/crank/meth, PCP, diet pills, LSD)					

40. Do you currently smoke any cigarettes or use any tobacco products?

Select one only.

- ☐ Yes
- ☐ No
- ☐ Declined to answer

41. Which of the following statements best describes the rules about smoking inside your home now?

STAFF: Please read out loud:

- ☐ No one is allowed to smoke anywhere inside my home
- ☐ Smoking is allowed in some rooms or at some times
- ☐ Smoking is permitted anywhere inside my home

DO NOT READ OUT LOUD:

- ☐ Declined to answer

42. On average, about how many hours per day are you in the same room or vehicle with another person who is smoking?

_____Number of hours per day (enter 1 hour through 24 hours)

- ☐ I spend less than one hour per day in a room or vehicle with somebody who is smoking
- ☐ I am never in a room or vehicle with someone who is smoking
- ☐ Declined to answer

43. Which of the following statements would you say best describes your alcohol consumption, INCLUDING beer and wine coolers? Please read the following responses out loud.

- ☐ I drink alcohol regularly now – about the same as before finding out I was pregnant
- ☐ I drink alcohol regularly now but I've cut down since I found out I was pregnant
- ☐ I drink alcohol every once in a while
- ☐ I have quit drinking alcohol since I found out I was pregnant
- ☐ I wasn't drinking alcohol around the time I found out I was pregnant and I don't currently drink

Staff: DO NOT READ OUT LOUD:

- ☐ Don't know
- ☐ Declined to answer

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FOLLOW UP		
Provided information/education about: ☐ Potential effects on pregnancy of tobacco ☐ Potential effects on pregnancy of alcohol ☐ Potential effects on pregnancy of drug use ☐ Tobacco cessation **Date**_____	**Provided further screening/assessment:** ☐ TWEAK, T-ACE, or 4 Ps (for "Yes" to 1 or more days of heavy drinking [for women, 4 or more drinks per day]) ☐ NIDA-Modified ASSIST (for any use of illegal or prescription drug use for non-medical reasons) ☐ **Provided Brief Intervention** Date_____	**Referred to:** ☐ Tobacco Quit Line ☐ Behavioral Health Provider ☐ Primary Care Provider ☐ Substance abuse treatment program ☐ Other: Please specify_____ **Date**_____

Personal Safety

44. We are concerned about the safety of all participants. Please answer the following questions so that we can help you if needed.

Q#	During the past 12 months...	Yes	No	Declined to Answer
44.1	Did your husband or partner threaten or make you feel unsafe in some way?			
44.2	Were you frightened for your safety or your family's safety because of the anger or threats of your husband or partner?			
44.3	Did your husband or partner try to control your daily activities, for example, control who you could talk to or where you could go?			
44.4	Did your husband or partner push, hit, slap, kick, choke, or physically hurt you in any other way?			
44.5	Did your husband or partner force you to take part in touching or any sexual activity when you did not want to?			
44.6	Did anyone else physically hurt you in any way?			

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FOLLOW UP
☐ Provided information/ education about what to do if you have or someone you know has a partner that hurts them physically Date_____ ☐ Referred to local domestic violence program _____ Date _____

Readiness for Motherhood

45. When you got pregnant with this baby, were you trying to get pregnant?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

46. How do you feel about being pregnant?

STAFF: Please read out loud:

- ☐ Very unhappy to be pregnant
- ☐ Unhappy to be pregnant
- ☐ Not Sure
- ☐ Happy to be pregnant
- ☐ Very happy to be pregnant

DO NOT READ OUT LOUD:

- ☐ Don't know
- ☐ Declined to answer

47. What method do you plan to use to feed your new baby in the first few weeks?

- ☐ Breastfeed only (baby will not be given formula)
- ☐ Formula feed only
- ☐ Both breast and formula feed
- ☐ Don't know yet
- ☐ Declined to answer

48. Where are you planning to deliver your baby? _____

- ☐ Don't know
- ☐ Declined to answer

49. Do you have a Cesarean section scheduled?

- ☐ Yes: Date_____
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

FOLLOW UP

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Provided information/education about:

- ☐ Breastfeeding
- ☐ Feeding your newborn
- ☐ Labor and delivery, including premature labor , preparation for C-section

Date _____

Referred to:

- ☐ Prenatal classes

Date _____

Stress and Discrimination

50. Stress is something we've all felt, and is often part of our daily lives. If you experience stress over a prolonged period of time however, it can be harmful to both your mind and body. Stress influences our moods, sense of well-being, behavior and overall health. We ask the following questions to learn what stressors you have in your life and to better understand how to help reduce the stress in your life.

This question is about things that may have happened during the past twelve months. For each item, please tell me "no" if it did not happen or "yes" if it did. (It may help to look at the calendar when you answer these questions).

Q#	Event	Yes	No
50.1	A close family member was very sick and had to go into the hospital		
50.2	I got separated or divorced from my husband or partner		
50.3	I moved to a new address		
50.4	I was homeless or had to sleep outside, in a car, or in a shelter		
50.5	My husband or partner lost his job		
50.6	I lost my job even though I wanted to go on working		
50.7	My husband, partner, or I had a cut in work hours or pay.		
50.8	I was apart from my husband or partner due to military deployment or extended work-related travel		
50.9	I argued with my husband or partner more than usual		
50.10	My husband or partner said he didn't want me to be pregnant		
50.11	I had problems paying the rent, mortgage, or other bills		
50.12	My husband, partner, or I went to jail		
50.13	Someone very close to me had a problem with drinking or drugs		
50.14	Someone very close to me died		

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51. The next set of questions asks you about how other people have treated you. In your day-to-day life, how often have any of the following things happened to you?

Q#	Treatment	Almost every day	At least once a week	A few times a month	A few times a year	Less than once a year	Never	Declined to answer
51.1	You are treated with less courtesy or respect than other people.							
51.2	You receive poorer service than other people at restaurants or stores.							
51.3	People act as if they think you are not smart.							
51.4	People act as if they are afraid of you.							
51.5	You are threatened or harassed.							

If participant answers "**a few times a year**" or **more frequently** to any of the above, go to question 52.

If participant answers "**less than once a year**", "**never**", or **declines to answer**, go to question 53.

52. What do you think is the main reason for these experiences?

- ☐ Your ancestry or national origins
- ☐ Your gender
- ☐ Your race
- ☐ Your age
- ☐ Your religion
- ☐ Your height
- ☐ Your weight
- ☐ Some other aspect of your physical appearance
- ☐ Your sexual orientation
- ☐ Your education or income level
- ☐ Your shade of skin color
- ☐ Physical Disability
- ☐ Other, please specify:

  _____

  _____
- ☐ Don't know
- ☐ Declined to answer

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53. The following statements are about the way you handle life events. Please tell me which are true for you most of the time.

STAFF: Please read out loud:
Select all that apply.

- ☐ I tend to bounce back quickly after hard times
- ☐ I have a hard time making it through stressful events
- ☐ It does not take me long to recover from a stressful event
- ☐ It is hard for me to snap back when something bad happens
- ☐ I usually come through a difficult time with little trouble
- ☐ I tend to take a long time to get over set-backs in my life
- ☐ Don't know
- ☐ Declined to answer

FOLLOW UP

☐ **Provided information/ education about resources for stress management**

Date _____

☐ **Provided counseling on stress management**

Date _____

Referred to:

- ☐ Mental Health Center
- ☐ Primary Care Provider
- ☐ Other: Please specify_____

Date _____

Social Support / Father Involvement

54. People sometimes look to others for companionship, assistance, or other types of support. These questions ask you about the types of support that would be available to you if you needed it. If you are not sure which answer to select, please choose the one answer that comes closest to describing it.

For the following questions your response options are the following; none of the time, a little of the time, some of the time, most of the time or all of the time; If you needed it, how often is someone available...

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Q#	Support Task	All of the time	Most of the time	Some of the time	A little of the time	None of the time
54.1	To provide temporary financial support?					
54.2	To do something enjoyable with you?					
54.3	To help with daily chores if you were sick					
54.4	To turn to for suggestions about how to deal with a personal problem?					

55. What is your baby's father's role in your life?

Check all that apply.

Staff: DO NOT READ OUT LOUD

- ☐ Partner is deceased (Go to question 56)
- ☐ Partner is incarcerated (Go to question 56)
- ☐ Assists with housework and/or runs errands (ex: grocery shopping) (Go to question 55.1)
- ☐ Attends prenatal appointments and/or childbirth classes (Go to question 55.1)
- ☐ Provides emotional support (Go to question 55.1)
- ☐ Provides financial support (Go to question 55.1)
- ☐ Partner plays no role / is not involved (Go to question 55.1)
- ☐ Other (please specify):_____ _____ (Go to question 55.1)
- ☐ Declined to answer (Go to question 55.1)

55.1 Would you describe the father of this baby as:

- ☐ Involved in my pregnancy and supportive of me
- ☐ Involved but not supportive of me
- ☐ Aware that I'm pregnant but not involved
- ☐ Not aware that I'm pregnant
- ☐ Declined to answer

56. Is there someone you can count on to help you during this pregnancy and with your new baby?

- ☐ Yes (Go on to question 57)
- ☐ No (Go on to question 58)
- ☐ Don't know (Go on to question 58)
- ☐ Declined to answer (Go on to question 58)

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57. Who do you count on for support?

Select all that apply.

- ☐ Current Partner
- ☐ Ex- partner
- ☐ Baby's father
- ☐ Parents
- ☐ Other child or children
- ☐ Other relative(s)
- ☐ Friend(s)
- ☐ Neighbor(s)
- ☐ Clergy
- ☐ Other _____

FOLLOW UP

- ☐ **Provided information/education about importance of social supports**

Date_____

Referral made to:

- ☐ Social Worker
- ☐ Parent help line
- ☐ Parent support group
- ☐ Other: Please specify_____

Date_____

Reproductive Life Planning

We have a few questions about your thoughts about having more children. This information will help us support you in making decisions about whether and when you might have more children.

58. Do you plan to have any more children after this baby is born?

- ☐ Yes (Go to question 58.1)
- ☐ No (Go to question 59)
- ☐ Don't know (Go to question 59)
- ☐ Declined to answer(Go to question 59)

58.1 How many children would you like to have?

_____Children (Go to question 58.2)

- ☐ Don't know (Go to question 58.2)
- ☐ Declined to answer

58.2 How long would you like to wait until you or your partner becomes pregnant?

- ☐ 1 year -17 months
- ☐ 18 months to 2 years
- ☐ More than 2 years
- ☐ Don't know
- ☐ Declined to answer

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59. What family planning method(s) do you plan to use until you or your partner are ready to become pregnant again?

Select all that apply.

- ☐ Implant (such as Nexplanon)
- ☐ IUD (intrauterine device such as Mirena or ParaGard or Liletta)
- ☐ Female sterilization (Hysterectomy or Tubal Ligation)
- ☐ Male sterilization (Vasectomy)
- ☐ Injectable (Depo-Provera®)
- ☐ Birth control pill
- ☐ Patch (such as OrthoEvra®)
- ☐ Vaginal ring (NuvaRing®)
- ☐ Diaphragm
- ☐ Male condoms
- ☐ Female condoms
- ☐ Withdrawal
- ☐ Natural family planning methods (such as rhythm or cervical mucus testing)
- ☐ Foam/Jelly/Spermicide
- ☐ Lactational Amenorrhea Method (LAM) –i.e., breastfeeding
- ☐ Emergency contraception (Plan B – the "morning after pill")
- ☐ Periodic abstinence
- ☐ Other:_____
  _____
  _____
- ☐ I don't plan to use any birth control or contraceptive methods
- ☐ Don't know
- ☐ Declined to answer

59.1 How sure are you that you will be able to use this method without any problems- not at all confident, somewhat confident, or very confident?

- ☐ Not at all confident
- ☐ Somewhat confident
- ☐ Very Confident
- ☐ Don't know
- ☐ Declined to answer

FOLLOW UP

- ☐ **Provided information/education about family planning or birth control**

Date _____

- ☐ **Provided counseling about family planning**
- ☐ **Provided birth control**
- ☐ **Referred for birth control**
  - ○ **Primary Care Provider**
  - ○ **Planned Parenthood**
  - ○ **Other: please specify** _____

Date _____

The Healthy Start Prenatal Screening Tool is Complete

Last updated 7/19/2016 9:21 AM

Developed by the Healthy Start CoIIN, with technical support from the Healthy Start EPIC Center, JSI, and funding from the Health Resources and Services Administration, Maternal and Child Health Bureau grant #UF5MC268450103.

Healthy Start Postpartum Screening Tool

May 2016

Name: _____

Completed by: _____ **Date of Administration:** _____

To be completed for women in postpartum period. This phase refers to the time period from birth to six months after the baby is born. During this phase, Healthy Start works with mothers, infants and families to optimize maternal and newborn health. The optimal time to administer this tool is 4-6 weeks post-partum.

Some key aims during this phase:

- *Ensure quality of care for newborns*
- *Ensure access to quality postpartum care*
- *Assess for and manage mood disorders/screen for postpartum depression*
- *Facilitate reproductive life planning*
- *Provide lactation counseling and support*
- *Promote safe sleep*

Pregnancy Outcome

First, we'll start with questions about your pregnancy.

1. Please tell me what the outcome was of your pregnancy.

Select one only.

- ☐ Live birth- single baby (Go to question 1.1)
- ☐ Live birth- multiples (twins, triplets, etc.) Please indicate _____(Go to question 1.1)
- ☐ Miscarriage (Go to question 13)
- ☐ Ectopic or tubal pregnancy (Go to question 13)
- ☐ Abortion (Go to question 13)
- ☐ Fetal death/stillbirth (Go to question 1.1)
- ☐ Declined to answer(Go to question 13)

1.1 When was your baby born?

Date: _____

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1.2 Where was your baby born? Was it at a hospital, birthing center, home, or some other place?

Select one only.

- ☐ Hospital
- ☐ Birthing center
- ☐ Home
- ☐ Other place: _____
- ☐ Declined to answer

1.3 Was your labor induced?

Select one only.

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

1.4 Was your baby born vaginally or by C-section?

Select one only.

- ☐ Vaginally
- ☐ C-section (Go to question 1.4.1)
- ☐ Declined to answer

1.4.1 If baby was delivered by C-section: What were the reasons you had a cesarean section (C-section)? Was it because...

Select all that apply.

- ☐ You had a C-section before
- ☐ The baby was in the wrong position
- ☐ The baby was past the due date
- ☐ Your doctor was worried that the baby was too big
- ☐ You had a medical condition that made going into labor dangerous
- ☐ Your doctor or nurse tried to induce labor, but it didn't work
- ☐ Your labor was taking too long
- ☐ The fetal monitor showed that the baby was having problems during labor
- ☐ You wanted to schedule your delivery
- ☐ You didn't want to have the baby vaginally
- ☐ Some other reason(s): _____
- ☐ Don't know
- ☐ Declined to answer

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1.5 Were you diagnosed with gestational diabetes during your last pregnancy? Gestational diabetes is when you have high blood sugar when you didn't have it before you got pregnant.

Select one only.

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

1.6 Did your baby stay in the hospital after you came home?

Select one only.

- ☐ Yes
- ☐ No
- ☐ Declined to answer

1.7 How many weeks pregnant were you when your baby was born?

_____weeks

- ☐ Don't know
- ☐ Declined to answer

1.8 How much did your baby weigh at birth?

_____pounds _____ounces

- ☐ Don't know
- ☐ Declined to answer

Infant Care

The next few questions are about your baby's food and eating habits.

2. Did you ever breast feed or pump breast milk to feed your new baby after delivery, even for a short period of time?

Select one only.

- ☐ Yes (Go to question 2.1)
- ☐ No (Go to question 3)
- ☐ Declined to answer (Go to question 3)

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2.1 How many days, weeks or months did you breastfeed or pump breast milk for your child?

_____ Number of **days** OR **weeks** OR **months** (please write in the number provided by the participant and circle days, weeks or months)

- ☐ Still/Currently breastfeeding
- ☐ Don't know
- ☐ Declined to answer

3. What are you currently feeding your baby?

Select all that apply.

- ☐ Breastmilk
- ☐ Formula
- ☐ Cereal
- ☐ Other solids: Please indicate
  _____
  _____
  _____
- ☐ Declined to answer

4. Do you have any concerns about your baby's feeding?

- ☐ Yes (Go to question 4.1)
- ☐ No (Go to question 5)
- ☐ Don't know (Go to question 5)
- ☐ Declined to answer (Go to question 5)

4.1. What is your concern?

Select all that apply

- ☐ Baby is having trouble latching
- ☐ Baby is distracted
- ☐ Constipation
- ☐ Baby is too sleepy to eat
- ☐ Baby refuses to feed
- ☐ I worry that I may not have enough milk
- ☐ Baby is not gaining weight
- ☐ Baby is spitting up a lot after feeding
- ☐ Other
- ☐ Don't know
- ☐ Declined to answer

FOLLOW UP
Provided information/education about: ☐ Breastfeeding ☐ Baby nutrition ☐ Parenting ☐ Infant care

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Date _____

Provided:

- ☐ Breastfeeding support
- ☐ Counseling about parenting

Date _____

Referred to:

- ☐ Breastfeeding support
- ☐ Nutritionist
- ☐ Parent Information Resource Center
- ☐ Parent support group
- ☐ Parenting classes
- ☐ Other: Please specify _____

Date _____

Safe Sleep & Car Safety

Good sleep habits are important to your child's physical health and emotional well-being. An important part of safe sleep is the place where your baby sleeps, his sleeping position, the kind of crib or bed, and type of mattress.

5. In which one position do you most often lie your baby down to sleep now? Check ONE answer.

- ☐ On his or her side
- ☐ On his or her back
- ☐ On his or her stomach
- ☐ Declined to answer

6. In the past 2 weeks, how often has your new baby slept alone in his or her own crib or bed?

- ☐ Always
- ☐ Often
- ☐ Sometimes
- ☐ Rarely
- ☐ Never
- ☐ Don't know
- ☐ Declined to answer

7. STAFF: PLEASE READ OUT LOUD and ask participant to say "no" if it doesn't usually apply to her child or "yes" if it does.

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Please tell us how your new child most often slept in the past 2 weeks.

Sleeping Location	Yes	No
In a crib, bassinet, or pack and play		
On a twin or larger mattress or bed		
On a couch, sofa, or armchair		
In an infant car seat or swing		
With a blanket		
With toys, cushions, or pillows, including nursing pillows		
With crib bumper pads (mesh or non-mesh		
In a sleeping sack or wearable blanket		

8. When your baby rides in a car, truck, or van, how often does he or she ride in an infant car seat? Would you say always, often, sometimes, rarely, or never?

- ☐ Always
- ☐ Often
- ☐ Sometimes
- ☐ Rarely
- ☐ Never
- ☐ Declined to answer

FOLLOW UP

Provided information/education about:

- ☐ Safe sleep positions, safe sleep environment
- ☐ Car seat safety (installation, placement in car, rear facing, checking weight and height limits)

Date _____

Provided:

- ☐ Crib
- ☐ Car seat

Date _____

Referred for:

- ☐ Crib
- ☐ Crib assembly
- ☐ Car seat
- ☐ Car seat installation
- ☐ Car seat installment education

Name of local organization(s) providing services_____

Date _____

Last updated 5/10/2016 5:42 PM
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Baby Insurance / Access to Care

A personal doctor or nurse is a health professional who knows your baby well and is familiar with your baby's health history. This can be a general doctor, a pediatrician, a specialist doctor, a nurse practitioner, or a physician's assistant.

9. Do you have one or more persons you think of as your baby's personal doctor or nurse?

- ☐ Yes (Go to question 9.1)
- ☐ No (Go to question 10)
- ☐ Don't know (Go to question 10)
- ☐ Declined to answer (Go to question 10)

9.1 Is there one person or more than one person?

Select one only.

- ☐ Yes, one person
- ☐ Yes, more than one person
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

10. Is there a place that your baby USUALLY goes for care when he or she is sick or when you or another caregiver need advice about your baby's health?

- ☐ Yes (Go to question 10.1)
- ☐ No (Go to question 11)
- ☐ There is more than one place (Go to question 10.1)
- ☐ Declined to answer (Go to question 11)

10.1 What kind of place does your baby go to most often when he/she is sick or you need advice about his/her health? Is it a doctor's office, emergency room, hospital outpatient department, clinic or some other place?

Select one only.

- ☐ Doctor's Office
- ☐ Hospital Emergency Room
- ☐ Hospital Outpatient Department
- ☐ Clinic or Health Center
- ☐ Retail Store Clinic or "Minute Clinic"
- ☐ School (Nurse's Office, Athletic Trainer's Office)
- ☐ Does Not Go To One Place Most Often
- ☐ Some other place (Go to question 10.2)

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10.2 **Please identify the usual place of care:**

- ☐ Friend/Relative
- ☐ Mexico/Other Locations Out Of Us
- ☐ Other _____

11. When was your baby's last visit to a doctor, nurse, or other health provider for a well-child check-up?

Month_____ Year_____

- ☐ Don't know
- ☐ Declined to answer

11.1 Did your child receive vaccines during this visit?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

12. Please tell me what kind of health insurance your baby has:

- ☐ Private health insurance through my job, or the job of my husband, partner or parents
- ☐ Insurance purchased directly from an insurance company
- ☐ Medicaid, Medical Assistance, or any kind of government assistance plan for those with low incomes or a disability
- ☐ TRICARE or other military health care
- ☐ Indian Health Service
- ☐ Other, specify: _____
- ☐ No insurance
- ☐ Don't know
- ☐ Declined to answer

FOLLOW UP
Provided information/education about: ☐ Importance of regular visits to primary care provider ☐ Importance of receiving vaccines on schedule ☐ Medicaid eligibility **Date** _____ **Provided Service:** ☐ Enrolled in Medicaid **Date** _____ **Provided vaccines:**

Last updated 5/10/2016 5:42 PM
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- ☐ Hepatitis B
- ☐ Diphtheria, Tetanus, Pertussis (DTaP)
- ☐ Haemophilus influenzae Type B (Hib)
- ☐ Pneumococcal
- ☐ Inactivated Poliovirus (IPV)
- ☐ Influenza (Flu)
- ☐ Measles, Mumps, Rubella (MMR)
- ☐ Varicella
- ☐ Hepatitis A

Date _____

Referred for:

- ☐ Medicaid enrollment
- ☐ Primary Care Provider
- ☐ Pediatrician

Date_____

Reproductive Life Planning

We have a few questions about your thoughts about having more children. This information will help us support you in making decisions about whether and when you might have more children.

13. Do you plan to have any children at any time in your future?

- ☐ Yes (Go to question 13.1)
- ☐ No (Go to question 14)
- ☐ Unable to get pregnant (Go to question 16)
- ☐ Don't know (Go to question 14)
- ☐ Declined to answer (Go to question 14)

13.1 How many children would you like to have?

_____Children

- ☐ Don't know
- ☐ Declined to answer

13.2 Would you like to become pregnant in the next year?

- ☐ Yes (Go to question 14)
- ☐ No (Go to question 13.3)
- ☐ I am okay either way (Go to question 13.3)
- ☐ Don't know (Go to question 14)
- ☐ Declined to answer (Go to question 14)

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13.3 How long would you like to wait until you or your partner becomes pregnant?

- ☐ 1 year -17 months
- ☐ 18 months to 2 years
- ☐ More than 2 years
- ☐ Don't know
- ☐ Declined to answer

14. Are you currently using any form of contraception or birth control to either prevent pregnancy or prevent sexually transmitted infections?

- ☐ Yes (Go to question 14.1)
- ☐ No (Go to question 15)
- ☐ Declined to answer (Go to question 15)

14.1. What kind of birth control are you or your husband or partner using now to keep from getting pregnant or to prevent sexually transmitted diseases?

Select all that apply.

- ☐ Implant (such as Nexplanon)
- ☐ IUD (intrauterine device such as Mirena or ParaGard or Liletta)
- ☐ Female sterilization (Hysterectomy or Tubal Ligation)
- ☐ Male sterilization (Vasectomy)
- ☐ Injectable (Depo-Provera®)
- ☐ Birth control pill
- ☐ Patch (such as OrthoEvra®)
- ☐ Vaginal ring (NuvaRing®)
- ☐ Diaphragm
- ☐ Male condoms
- ☐ Female condoms
- ☐ Withdrawal
- ☐ Natural family planning methods (such as rhythm or cervical mucus testing)
- ☐ Foam/Jelly/Spermicide
- ☐ Lactational Amenorrhea Method (LAM) –i.e., breastfeeding
- ☐ Emergency contraception (Plan B – the "morning after pill")
- ☐ Periodic abstinence
- ☐ Other:_____
- ☐ I don't plan to use any birth control or contraceptive methods
- ☐ Don't know
- ☐ Declined to answer

14.2. Are you satisfied with your birth control method?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

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15. What family planning method do you plan to use to avoid pregnancy?

Select all that apply.

- ☐ Implant (such as Nexplanon)
- ☐ IUD (intrauterine device such as Mirena or ParaGard or Liletta)
- ☐ Female sterilization (Hysterectomy or Tubal Ligation)
- ☐ Male sterilization (Vasectomy)
- ☐ Injectable (Depo-Provera®)
- ☐ Birth control pill
- ☐ Patch (such as OrthoEvra®)
- ☐ Vaginal ring (NuvaRing®)
- ☐ Diaphragm
- ☐ Male condoms
- ☐ Female condoms
- ☐ Withdrawal
- ☐ Natural family planning methods (such as rhythm or cervical mucus testing)
- ☐ Foam/Jelly/Spermicide
- ☐ Lactational Amenorrhea Method (LAM) –i.e., breastfeeding
- ☐ Emergency contraception (Plan B – the "morning after pill")
- ☐ Periodic abstinence
- ☐ Other:_____ _____ _____
- ☐ I don't plan to use any birth control or contraceptive methods
- ☐ Don't know
- ☐ Declined to answer

15.1. How sure are you that you will be able to use this method without any problems- not at all confident, somewhat confident, or very confident?

- ☐ Not at all confident
- ☐ Somewhat confident
- ☐ Very Confident
- ☐ Don't know
- ☐ Declined to answer

FOLLOW UP
☐ **Provided information/education about family planning or birth control** **Date** _____ ☐ **Provided counseling about family planning** ☐ **Provided birth control** ☐ **Referred for birth control** o **Primary Care Provider** o **Planned Parenthood** o **Other: please specify** _____ **Date** _____

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Demographics

Now, I would like to ask a few questions to provide us with some background information.

16. Are you currently married or living with a partner, separated, divorced, widowed, or were you never married?

- ☐ Married or living with a partner
- ☐ Separated
- ☐ Divorced
- ☐ Widowed
- ☐ Never married
- ☐ Declined to answer

17. Are you currently...

STAFF: Please read out loud:

- ☐ Employed for wages
- ☐ Self-employed
- ☐ Out of work for 1 year or more
- ☐ Out of work for less than 1 year
- ☐ A Homemaker
- ☐ A Student
- ☐ Retired
- ☐ Unable to work

Staff: DO NOT READ OUT LOUD

- ☐ Declined to answer

18. What is your yearly total household income before taxes? Include your income, your husband's or partner's income, and any other income you may have received. All information will be kept private and will not affect any services you are now getting.

- ☐ Less than $10,000
- ☐ $10,000 to less than $15,000
- ☐ $15,000 to less than $20,000
- ☐ $20,000 to less than $25,000
- ☐ $25,000 to less than $35,000
- ☐ $35,000 to less than $50,000
- ☐ $50,000 or more
- ☐ Don't know
- ☐ Declined to answer

19. How often has it been very hard to get by on your family's income, by this I mean to pay for food or housing?

- ☐ Never
- ☐ Rarely
- ☐ Somewhat often
- ☐ Very often
- ☐ Don't know
- ☐ Declined to answer

Social Determinants of Health

20. How often do you have transportation to or from your medical appointments?

- ☐ Never
- ☐ Sometimes

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- ☐ Often
- ☐ Always
- ☐ Don't know
- ☐ Declined to answer

21. The next question is about whether you were able to afford the food you need. Which of these statements best describes the food situation in your household IN THE PAST 12 MONTHS?

- ☐ We could always afford to eat good nutritious meals.
- ☐ We could always afford enough to eat but not always the kinds of food we should eat.
- ☐ Sometimes we could not afford enough to eat.
- ☐ Often we could not afford enough to eat.
- ☐ Declined to answer

Now I would like to ask you about your current housing.

22. Do you own a place, rent a place, live in public housing, stay with a family member, or are you homeless?

- ☐ Owns or shares own home, condominium or apartment (Go to question 22.1)
- ☐ Rents or shares own home or apartment (Go to question 22.1)
- ☐ Lives in public housing (receives rental assistance, such as Section 8) (Go to question 22.1)
- ☐ Lives with parent or family member (Go to question 22.1)
- ☐ Homeless (Go to question 22.2)
- ☐ Some other arrangement: _____ (Go to question 22.1)
- ☐ Declined to answer (Go to question 22.2)

22.1 Is this place a regular place to stay? By "a regular place to stay" I am referring to a house, apartment, room, or other housing where you could stay 30 days in a row or more in the same place.

- ☐ Yes (Go to question 23)
- ☐ No (Go to question 23)
- ☐ Don't know (Go to question 23)
- ☐ Declined to answer (Go to question 23)

22.2 Do you share housing with someone, live in an emergency or transition shelter, or have some other living arrangement?

- ☐ Homeless and shares housing with someone
- ☐ Lives in an emergency or transition shelter
- ☐ Some other arrangement: _____
- ☐ Declined to answer

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23. How do you feel about your current housing situation--do you feel very stable and secure, fairly stable and secure, just somewhat stable and secure, fairly unstable and insecure, or very unstable and insecure?

- ☐ Very stable and secure (Go to question 24)
- ☐ Fairly stable and secure (Go to question 24)
- ☐ Just somewhat stable and secure (Go to question 23.1)
- ☐ Fairly unstable and insecure (Go to question 23.1)
- ☐ Very unstable and insecure (Go to question 23.1)
- ☐ Not sure (Go to question 23.1)
- ☐ Declined to answer (Go to question 24)

23.1 What issues concern you about your housing situation?

- ☐ Received an eviction notice
- ☐ Non-payment of rent or past due rent
- ☐ Unable to pay future rent because lost housing subsidy, job, or other income source
- ☐ Non-payment of utilities or utility shut-off
- ☐ Housekeeping concerns (failure to maintain cleanliness of the unit)
- ☐ Housing is or will be condemned
- ☐ Friend or family member being evicted or threatened with eviction
- ☐ Threat of abuse by partner, family member, or other
- ☐ Being discharged or service is being terminated
- ☐ Personal conflict with others
- ☐ Other health or safety concerns
- ☐ Other lease violation(s) (please describe):_____
- ☐ Other (please describe):_____
  _____
- ☐ Don't know
- ☐ Declined to answer

24. I am going to read a list of services. Please tell me if you are receiving the service, if you have applied for the service and are waiting to find out if you will receive services, if you need services, or if you don't need services. I want to remind you that I ask these questions so we can provide the best services for your family.

	Receiving	Have applied for	Need	Do not need	Ineligible	Declined to answer
Childcare voucher						
Emergency Aid to the Elderly, Disabled, and Children (EAEDC)						
Food stamps/SNAP						
Heating assistance						
Immigration services						
Legal services						
Public housing						

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Section 8 Voucher						
Social Security Disability Insurance (SSDI)						
Social Security Income (SSI)						
Transitional Aid to Families with Dependent Children (TAFDC)						
Temporary Assistance to Needy Families (TANF)						
Tribal Housing						
Utility Assistance						
Nutrition Supplemental Program for Women Infants and Children (WIC)						
Other (please specify)						

25. Have you ever had a case with Child Protective Services?

- ☐ Yes (Go to question 25.1)
- ☐ No (Go to question 26)
- ☐ Don't know (Go to question 26)
- ☐ Declined to answer(Go to question 26)

25.1 If yes, ask: Do you currently have an open case with Child Protective Services?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

FOLLOW UP	
Provided information/education about:	**Referral made for:**
☐ Childcare voucher	☐ Childcare voucher
☐ Emergency Aid to the Elderly, Disabled, and Children (EAEDC)	☐ Emergency Aid to the Elderly, Disabled, and Children (EAEDC)
☐ Food stamps/SNAP	☐ Food stamps/SNAP
☐ Heating assistance	☐ Heating assistance
☐ Immigration services	☐ Immigration services
☐ Legal services	☐ Legal services
☐ Public housing	☐ Public housing
☐ Section 8 Voucher	☐ Section 8 Voucher
☐ Social Security Disability Insurance (SSDI)	☐ Social Security Disability Insurance (SSDI)
☐ Social Security Income (SSI)	☐ Social Security Income (SSI)
☐ Transitional Aid to Families with Dependent Children (TAFDC)	☐ Transitional Aid to Families with Dependent Children (TAFDC)
☐ Temporary Assistance to Needy Families (TANF)	☐ Temporary Assistance to Needy Families (TANF)
☐ Tribal Housing	☐ Tribal Housing
☐ Utility Assistance	☐ Utility Assistance
☐ Nutrition Supplemental Program for Women Infants and Children (WIC)	☐ Nutrition Supplemental Program for Women Infants and Children (WIC)
☐ Other (please specify)	☐ Other (please specify)

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Date _____	Date _____

Neighborhood and Community

26. Now I am going to ask you a few questions about your neighborhood or community. Please tell me if you agree or disagree with each of these statements.

Q#	Statement	Agree	Disagree	Don't know	Declined to answer
26.1	People in this neighborhood or community help each other out				
26.2	We watch out for each other's children in this neighborhood or community				
26.3	There are people I can count on in this neighborhood or community.				

27. How often do you feel safe in your community or neighborhood? Would you say never, sometimes, usually, or always?
Select one only.

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always
- ☐ Declined to answer

28. How often do you participate in school, community, or neighborhood activities? Would you say daily, weekly, monthly, a few times a year, less than once a year, or never?
Select one only.

- ☐ Daily
- ☐ Weekly
- ☐ Monthly
- ☐ A few times a year
- ☐ Less than once a year
- ☐ Never
- ☐ Declined to answer

29. How often do you get together or talk with family, friends or neighbors? Would you say daily, weekly, monthly, a few times a year, less than once a year or never?

Select one only.

- ☐ Daily
- ☐ Weekly
- ☐ Monthly
- ☐ A few times a year
- ☐ Less than once a year
- ☐ Never

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☐ Declined to answer

Medical Home / Access to Care/Health Insurance

A personal doctor or nurse is a health professional who knows you well and is familiar with your health history. This can be a general doctor, a specialist doctor, a nurse practitioner, or a physician's assistant.

30. Do you have one or more persons you think of as your personal doctor or nurse?

☐ Yes (Go to question 30.1)
☐ No (Go to question 31)
☐ Don't know (Go to question 31)
☐ Declined to answer(Go to question 31)

30.1 Is there one person or more than one person?

☐ Yes, one person
☐ Yes, more than one person
☐ No
☐ Don't know
☐ Declined to answer

31. Is there a place that you USUALLY go for care when you are sick or need advice about your health?

☐ Yes (Go to question 31.1)
☐ No (Go to question 32)
☐ There is more than one place (go to question 31.1)
☐ Don't know (Go to question 32)
☐ Declined to answer (Go to question 32)

31.1 What kind of place do you go to most often when you are sick or you need advice about your health? Is it a doctor's office, emergency room, hospital outpatient department, clinic or some other place?

☐ Doctor's Office
☐ Hospital Emergency Room
☐ Hospital Outpatient Department
☐ Clinic or Health Center
☐ Retail Store Clinic or "Minute Clinic"
☐ School (Nurse's Office, Athletic Trainer's Office)
☐ Some other place _____

32. Please tell me what kind of health insurance you have:

☐ Private health insurance through my job, or the job of my husband, partner or parents
☐ Insurance purchased directly from an insurance company
☐ Medicaid, Medical Assistance, or any kind of government assistance plan for those with low incomes or a disability
☐ TRICARE or other military health care
☐ Indian Health Service
☐ Other, specify: _____

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- ☐ No insurance
- ☐ Don't know
- ☐ Declined to answer

33. Since your child was born, have you had a postpartum checkup for yourself? A postpartum checkup is the regular checkup a woman has 4-6 weeks after she gives birth.

- ☐ Yes (Go to question 33.1)
- ☐ No (Go to question 33.2)
- ☐ Don't know (Go to question 34)

33.1 When?

(Date) _____

33.2 Do you have one scheduled?

- ☐ Yes: Please indicate when_____
- ☐ No
- ☐ Declined to answer

FOLLOW UP

Provided information/education about:

- ☐ Importance of regular postpartum care
- ☐ Importance of having a regular provider/medical home
- ☐ Medicaid eligibility
- ☐ Birth spacing

Date _____

Provided Service:

- ☐ Enrolled in Medicaid

Date _____

Referred for:

- ☐ Medicaid enrollment
- ☐ OB/GYN provider
- ☐ Primary Care Provider

Date _____

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Maternal Health

34. In general, would you say that your overall health is excellent, very good, good, fair, or poor?

Select one only.

- ☐ Excellent
- ☐ Very good
- ☐ Good
- ☐ Fair
- ☐ Poor
- ☐ Don't know
- ☐ Declined to answer

35. In general, would you say that your mental and emotional health is excellent, very good, good, fair, or poor?

Select one only.

- ☐ Excellent
- ☐ Very good
- ☐ Good
- ☐ Fair
- ☐ Poor
- ☐ Don't know
- ☐ Declined to answer

36.1 How tall are you without shoes?

_____Feet _____ Inches

- ☐ Don't Know
- ☐ Declined to answer

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36.2 Just before you got pregnant with your new baby, how much did you weigh?

_____ Pounds

- ☐ Don't Know
- ☐ Declined to answer

36.3 How much do you weigh now?

_____ Pounds

- ☐ Don't Know
- ☐ Declined to answer

37. During the past month, how many times a week did you take a multivitamin, a prenatal vitamin, or a folic acid vitamin?

- ☐ I did not take a multivitamin, prenatal vitamin or folic acid vitamin at all
- ☐ 1 to 3 times a week
- ☐ 4 to 6 times a week
- ☐ Every day of the week
- ☐ Don't Know
- ☐ Declined to answer

38. How long ago did you last have a flu vaccination? Would you say less than six months ago, six months to a year ago, more than a year ago, or never?

Select one only.

- ☐ Less than six months ago
- ☐ Six months to one year ago
- ☐ More than one year ago
- ☐ Never
- ☐ Don't know
- ☐ Declined to answer

39. How long ago did you last have your teeth cleaned by a dentist/hygienist? Would you say less than six months ago, six months to a year ago, more than a year ago, or never?

Select one only.

- ☐ Less than six months ago
- ☐ Six months to one year ago
- ☐ More than one year ago
- ☐ Never
- ☐ Don't know
- ☐ Declined to answer

FOLLOW UP

Provided information/education about:

- ☐ Keeping a healthy weight such as through diet and exercise
- ☐ Getting flu shot
- ☐ Keeping teeth healthy

Date _____

Provided:

- ☐ Nutritional counseling
- ☐ Flu vaccines

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Date _____

Referred to:

- ☐ Primary Care Provider
- ☐ Nutritionist
- ☐ Dentist
- ☐ Other: Please specify_____

Date _____

Mental Health

40. Over the past two weeks, how often have you experienced any of the following?

Q#	Problem	Not at all	Several Days	More than half the days	Nearly every day	Score
40.1	Little interest or pleasure in doing things	0	1	2	3	
40.2	Feeling down, depressed, or hopeless	0	1	2	3	
	Total Score					

NOTE: Circle the number that matches the participant's answer, and add the answers for both together to get the final score. If the final score is more than 3, further assessment is needed.

FOLLOW UP

Provided information/ education about:

- ☐ Postpartum depression or "Baby Blues"
- ☐ Local resources for depression

Date_____

Provided:

- ☐ Further assessment using evidence-based tool such as the Edinburgh Postnatal Depression Scale (EPDS)
- ☐ Counseling

Date_____

Referred to:

- ☐ **Mental health center**
- ☐ **Primary Care Provider**
- ☐ **Other: Please specify**_____

Date_____

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Substance Use

41. If it's okay with you, I'd like to ask you a few questions that will help me give you better care. The questions relate to your experience with alcohol, cigarettes, and other drugs. Some of the substances we'll talk about are prescribed by a doctor (like pain medications). But I will only record those if you have taken them for reasons or in doses other than prescribed. I'll also ask you about illicit or illegal drug use.

In the past year, how often have you used the following?

Substance	Never	Once or Twice Monthly	Weekly	Daily or Almost Daily	Declined to answer
Alcohol (4 or more drinks per day)					
Tobacco Products (including cigarettes, chewing tobacco, snuff, iqmik, or other tobacco products like snus Camel Snus, orbs, e-cigarettes, lozenges, cigars, or hookah)					
Mood-altering Drugs (including marijuana)					
Prescription Drugs for Non-Medical Reasons					
Illegal Drugs (marijuana, cocaine, crack, heroin, uppers/crank/meth, PCP, diet pills, LSD)					

41.1 Did you smoke any cigarettes or use any tobacco products during the last 3 months of your pregnancy?

- ☐ Yes (Go to question 41.2)
- ☐ No (Go to question 42)
- ☐ Don't know (Go to question 42)
- ☐ Declined to answer (Go to question 42)

41.2 During the last 3 months of your pregnancy, how many cigarettes did you smoke on an average day?

- ☐ 41 cigarettes or more
- ☐ 21 to 40 cigarettes
- ☐ 11 to 20 cigarettes
- ☐ 6 to 10 cigarettes
- ☐ 1 to 5 cigarettes
- ☐ Less than 1 cigarette
- ☐ Declined to answer

42. Which of the following statements best describes the rules about smoking inside your home now?

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- ☐ No one is allowed to smoke anywhere inside my home
- ☐ Smoking is allowed in some rooms or at some times
- ☐ Smoking is permitted anywhere inside my home

Staff: DO NOT READ OUT LOUD:

- ☐ Declined to answer

43. On average, about how many hours per day are <u>you</u> in the same room or vehicle with another person who is smoking?

_____Number of hours per day (enter 1 hour through 24 hours)

- ☐ I spend less than one hour per day in a room or vehicle with somebody who is smoking
- ☐ I am never in a room or vehicle with someone who is smoking
- ☐ Declined to answer

44. On average, how many hours per day is <u>your baby</u> in the same room or vehicle with another person who is smoking?

_____Number of hours per day (enter 1 hour through 24 hours)

- ☐ My baby spends less than one hour per day in a room or vehicle with somebody who is smoking
- ☐ My baby is never in a room or vehicle with someone who is smoking
- ☐ Declined to answer

FOLLOW UP		
Provided information/education about: ☐ Potential effects on pregnancy of tobacco ☐ Potential effects on pregnancy of alcohol ☐ Potential effects on pregnancy of drug use ☐ Tobacco cessation **Date**_____	**Provided further assessment:** ☐ Assess, Advise and Assist for Alcohol Use Disorders (for "Yes" to 1 or more days of heavy drinking [for women, 4 or more drinks per day]) ☐ NIDA-Modified ASSIST (for any use of illegal or prescription drug use for non-medical reasons) ☐ **Provided Brief Intervention** Date_____	**Referred to:** ☐ Tobacco Quit Line ☐ Behavioral Health Provider ☐ Primary Care Provider ☐ Substance abuse treatment program ☐ Other: Please specify_____ **Date**_____

Personal Safety

45. We are concerned about the safety of all participants. Please answer the following questions so that we can help you if needed.

Q#	During the past 12 months...	Yes	No	Declined to Answer
45.1	Did your husband or partner threaten or			

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	make you feel unsafe in some way?			
45.2	Were you frightened for your safety or your family's safety because of the anger or threats of your husband or partner?			
45.3	Did your husband or partner try to control your daily activities, for example, control who you could talk to or where you could go?			
45.4	Did your husband or partner push, hit, slap, kick, choke, or physically hurt you in any other way?			
45.5	Did your husband or partner force you to take part in touching or any sexual activity when you did not want to?			
45.6	Did anyone else physically hurt you in any way?			

FOLLOW UP
☐ **Provided information / education about what to do if you have or someone you know has a partner that hurts them physically**
Date _____
☐ **Referred to local domestic violence program** _____
Date _____

Stress and Discrimination

46. Stress is something we've all felt, and is often part of our daily lives. If you experience stress over a prolonged period of time however, it can be harmful to both your mind and body. Stress influences our moods, sense of well-being, behavior and overall health. We ask the following questions to learn what stressors you have in your life and to better understand how to help reduce the stress in your life.

This question is about things that may have happened during the past twelve months. For each item, tell me "no" if it did not happen or "yes" if it did. (It may help to look at the calendar when you answer these questions).

Q#	Event	Yes	No
46.1	A close family member was very sick and had to go into the hospital		

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46.2	I got separated or divorced from my husband or partner		
46.3	I moved to a new address		
46.4	I was homeless or had to sleep outside, in a car, or in a shelter		
46.5	My husband or partner lost his job		
46.6	I lost my job even though I wanted to go on working		
46.7	My husband, partner, or I had a cut in work hours or pay.		
46.8	I was apart from my husband or partner due to military deployment or extended work-related travel		
46.9	I argued with my husband or partner more than usual		
46.10	My husband or partner said he didn't want me to be pregnant		
46.11	I had problems paying the rent, mortgage, or other bills		
46.12	My husband, partner, or I went to jail		
46.13	Someone very close to me had a problem with drinking or drugs		
46.14	Someone very close to me died		

47. The next set of questions asks you about how other people have treated you. In your day-to-day life, how often have any of the following things happened to you?

Q#	Treatment	Almost every day	At least once a week	A few times a month	A few times a year	Less than once a year	Never	Declined to answer
47.1	You are treated with less courtesy or respect than other people.							
47.2	You receive poorer service than other people at restaurants or stores.							
47.3	People act as if they think you are not smart.							
47.4	People act as if they are afraid of you.							
47.5	You are threatened or harassed.							

If participant answers "**a few times a year**" or **more frequently** for any of the above, go to question 48.

If participant answers **"less than once a year"** or **"never"** to all of the above, go to question 49.

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48. What do you think is the main reason for these experiences?

- ☐ Your ancestry or national origins
- ☐ Your gender
- ☐ Your race
- ☐ Your age
- ☐ Your religion
- ☐ Your height
- ☐ Your weight
- ☐ Some other aspect of your physical appearance
- ☐ Your sexual orientation
- ☐ Your education or income level
- ☐ Your shade of skin color
- ☐ Physical Disability
- ☐ Other, please specify:

  _____

  _____
- ☐ Don't know

Staff: DO NOT READ OUT LOUD:

- ☐ Declined to answer

Developed by the Healthy Start CoIIN, with technical support from the Healthy Start EPIC Center, JSI, and funding from the Health Resources and Services Administration, Maternal and Child Health Bureau grant #UF5MC268450103.

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49. The following statements are about the way you handle life events. Please tell me which are true for you most of the time.

Select all that apply.

- ☐ I tend to bounce back quickly after hard times
- ☐ I have a hard time making it through stressful events
- ☐ It does not take me long to recover from a stressful event
- ☐ It is hard for me to snap back when something bad happens
- ☐ I usually come through a difficult time with little trouble
- ☐ I tend to take a long time to get over set-backs in my life

FOLLOW UP
☐ **Provided information/ education about resources for stress management**
Date_____
☐ **Provided counseling on stress management**
Date_____
Referred to: ☐ Mental health center ☐ Primary Care Provider ☐ Other: Please specify_____
Date_____

Father Involvement / Social Support

50. People sometimes look to others for companionship, assistance, or other types of support. These questions ask you about the types of support that would be available to you if you needed it. If you are not sure which answer to select, please choose the one answer that comes closest to describing it.

For the following questions your response options are the following; none of the time, a little of the time, some of the time, most of the time or all of the time; If you needed it, how often is someone available...

Q#	Support Task	All of the time	Most of the time	Some of the time	A little of the time	None of the time
50.1	To provide temporary financial support?					

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50.2	To do something enjoyable with you?					
50.3	To help with daily chores if you were sick?					
50.4	To turn to for suggestions about how to deal with a personal problem?					
50.5	To watch your baby for you?					

51. What is the baby's father's role in your life?

Check all that apply.

Staff: DO NOT READ OUT LOUD:

- ☐ Baby's father is deceased (Go to question 52)
- ☐ Baby's father is incarcerated (Go to question 52)
- ☐ Cares for baby (feeding, bathing, etc.) (Go to question 55.1)
- ☐ Assists with housework and/or runs errands (ex: grocery shopping) (Go to question 55.1)
- ☐ Attends medical appointments (Go to question 55.1)
- ☐ Provides emotional support (Go to question 55.1)
- ☐ Provides financial support (Go to question 55.1)
- ☐ Baby's father plays no role/is not involved (Go to question 55.1)
- ☐ Other (please specify):_____ (Go to question 55.1)
- ☐ Declined to answer (Go to question 55.1)

51.1 Would you describe the father of your baby as:

- ☐ Involved and supportive of me and my baby
- ☐ Involved but not supportive of me or my baby
- ☐ Not involved

Staff: DO NOT READ OUT LOUD:

- ☐ Declined to answer

52. Is there someone you can count on to help you with your baby?

- ☐ Yes
- ☐ No
- ☐ Declined to answer

53. Who do you count on for support?

Select all that apply.

- ☐ Current Partner
- ☐ Ex- partner

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- ☐ Baby's father
- ☐ Parents
- ☐ Other child or children
- ☐ Other relative(s)
- ☐ Friend(s)
- ☐ Neighbor(s)
- ☐ Clergy
- ☐ Other _____

FOLLOW UP
☐ **Provided information/education about importance of social supports**
Date_____
Referral made to: ☐ Social Worker ☐ Parent help line ☐ Parent support group ☐ Other: Please specify_____
Date_____

The Healthy Start Postpartum Screening Tool is Complete

Developed by the Healthy Start CoIIN, with technical support from the Healthy Start EPIC Center, JSI, and funding from the Health Resources and Services Administration, Maternal and Child Health Bureau grant #UF5MC268450103.

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Name: _____

Completed by: _____ **Date of Administration:** _____

To be completed with women and babies in the period beyond the immediate postpartum phase. This phase refers to the time period from age 6 months to two years after delivery. During this phase, Healthy Start works with mothers, babies and families to strengthen family resilience, creating a foundation for optimal child health and development.

Administer this tool at 6 months after delivery, 1 year after delivery and just prior to the completion of the program at 2 years *(to ensure child and Mom are ready to leave program with supports in place).*

Child Health and Safety

I am going to start off by asking some questions about your child.

1. What is the date of birth of your youngest child? _____

2. Did you ever breastfeed or pump breast milk to feed your child after delivery, even for a short period of time?

- ☐ Yes (Go to question 2.1)
- ☐ No (Go to question 3)
- ☐ Declined to answer (Go to question 3)

2.1 How many days, weeks or months did you breastfeed or pump breast milk for your child?

_____ Number of **days** OR **weeks** OR **months** (please write in the number provided by the participant and circle days, weeks or months)

- ☐ Don't know
- ☐ Declined to answer

3. Please indicate the number of days you or a family member read to your child during the past week.

Reading includes books with words or pictures but not books read by an audio tape, record, CD, or computer.

STAFF: Record the total number of days, from 0 days (no days) to 7 days (everyday).

____0 DAYS ____1 DAY____2 DAYS____3 DAYS____4 DAYS____5 DAYS____6 DAYS____7 DAYS

- ☐ Don't know
- ☐ Declined to answer

4. Your child's development is important. I have some questions about your child's development.

Q#	Are you or anyone else concerned about:	Yes	No	Don't know	Declined to answer
4.1	How your child talks, makes speech sounds, or understands?				
4.2	How your child uses his or her arms or legs?				
4.3	How your child uses his or her hands or fingers to do things?				
4.4	How your child is learning to do things for himself or herself?				
4.5	How your child behaves or gets along with others?				

FOLLOW UP

- ☐ **Provided information/education about child development**
- ☐ **Provided information/education about parenting**

Date _____

- ☐ **Provided counseling about parenting**

Date _____

Referred to:

- ☐ Parent Information Resource Center
- ☐ Parent support group
- ☐ Parenting classes
- ☐ Other: Please specify _____

Date _____

Safe Sleep

STAFF: Ask the questions in this section for children less than 12 months old.

Good sleep habits are important to your child's physical health and emotional well-being. An important part of safe sleep is the place where your baby sleeps, his sleeping position, the kind of crib or bed, and type of mattress.

5. In which one position do you most often lie your child down to sleep now?

Select one only.

- ☐ On his or her side

- ☐ On his or her back
- ☐ On his or her stomach

6. In the past 2 weeks, how often has your new child slept alone in his or her own crib or bed?

- ☐ Always
- ☐ Often
- ☐ Sometimes
- ☐ Rarely
- ☐ Never
- ☐ Don't know
- ☐ Declined to answer

7. Please tell us how your new child most often slept in the past 2 weeks.

STAFF: PLEASE READ the choices out loud and ask participant to say "no" if it doesn't usually apply to her child or "yes" if it does.

Sleeping Location	Yes	No
In a crib, bassinet, or pack and play		
On a twin or larger mattress or bed		
On a couch, sofa, or armchair		
In an infant car seat or swing		
With a blanket		
With toys, cushions, or pillows, including nursing pillows		
With crib bumper pads (mesh or non-mesh		
In a sleeping sack or wearable blanket		

8. When your child rides in a car, truck, or van, how often does he or she ride in an infant car seat? Would you say always, often, sometimes, rarely, or never?

- ☐ Always
- ☐ Often
- ☐ Sometimes
- ☐ Rarely
- ☐ Never
- ☐ Declined to answer

9. Has your child been tested for lead?

- ☐ Yes (Go to question 9.1)
- ☐ No (Go to question 10)
- ☐ Don't know (Go to question 10)
- ☐ Declined to answer (Go to question 10)

9.1 Did your child's lead levels concern the doctor?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

FOLLOW UP

Provided information/education about:

- ☐ Safe sleep positions
- ☐ Car seat safety (installation, placement in car, rear facing, checking weight and height limits)
- ☐ Lead poisoning

Date _____

Provided:

- ☐ Crib
- ☐ Car seat
- ☐ Lead testing

Date _____

Referred for:

- ☐ Crib
- ☐ Crib assembly
- ☐ Car seat
- ☐ Car seat installation
- ☐ Car seat installment education

Name of local organization(s) providing services_____

Primary care provider for lead testing_____

Date _____

Child Insurance / Access to Care / Medical Home

A personal doctor or nurse is a health professional who knows your child well and is familiar with your child's health history. This can be a general doctor, a pediatrician, a specialist doctor, a nurse practitioner, or a physician's assistant.

10. Do you have one or more persons you think of as your child's personal doctor or nurse?

- ☐ Yes (Go to question 10.1)
- ☐ No (Go to question 11)
- ☐ Don't know (Go to question 11)
- ☐ Declined to answer (Go to question 11)

10.1 Is there one person or more than one person?

Select one only.

- ☐ Yes, one person
- ☐ Yes, more than one person
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

11. Is there a place that you USUALLY go for care when your child is sick or you need advice about your child's health?

- ☐ Yes (Go to question 11.1)
- ☐ No (Go to question 12)
- ☐ There is more than one place (Go to question 11.1)
- ☐ Declined to answer (Go to question 12)

11.1 What kind of place does your child go to most often when he/she is sick or you need advice about his/her health? Is it a doctor's office, emergency room, hospital outpatient department, clinic or some other place?

- ☐ Doctor's Office
- ☐ Hospital Emergency Room
- ☐ Hospital Outpatient Department
- ☐ Clinic or Health Center
- ☐ Retail Store Clinic or "Minute Clinic"
- ☐ School (Nurse's Office, Athletic Trainer's Office)
- ☐ Does Not Go To One Place Most Often
- ☐ Some other place (Go to question 11.2)

11.2 Please identify the usual place of care:

- ☐ Friend/Relative
- ☐ Mexico/Other Locations Out Of Us
- ☐ Other _____

12. Please tell me what kind of health insurance your child has:

- ☐ Private insurance through my job, or the job of my husband, partner or parents.
- ☐ Insurance purchased directly from an insurance company
- ☐ Medicaid, Medical Assistance, or any kind of government assistance plan for those with low incomes or a disability
- ☐ TRICARE or other military health care
- ☐ Indian Health Service
- ☐ Other, specify: _____
- ☐ No insurance
- ☐ Don't know
- ☐ Declined to answer

13. When was your child's last visit to a doctor, nurse, or other health provider for a well-child check-up?

Month_____ Year_____

- ☐ Don't know
- ☐ Declined to answer

13.1 Did your child receive vaccines during this visit?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

FOLLOW UP

Provided information/education about:

- ☐ Importance of regular visits to primary care provider
- ☐ Importance of receiving vaccines on schedule
- ☐ Medicaid eligibility

Date _____

- ☐ **Enrolled in Medicaid**

Date _____

Provided vaccines:

- ☐ Hepatitis B
- ☐ Diphtheria, Tetanus, Pertussis (DTaP)
- ☐ Haemophilus influenzae Type B (Hib)
- ☐ Pneumococcal
- ☐ Inactivated Poliovirus (IPV)
- ☐ Influenza (Flu)
- ☐ Measles, Mumps, Rubella (MMR)
- ☐ Varicella
- ☐ Hepatitis A

Date _____

Referred for:

- ☐ Medicaid enrollment
- ☐ Primary Care Provider
- ☐ Pediatrician

Date_____

Reproductive Life Planning

We have a few questions about your thoughts about having more children. This information will help us support you in making decisions about whether and when you might have more children.

14. Do you plan to have any children at any time in your future?

- ☐ Yes (Go to question 14.1)
- ☐ No (Go to question 15)
- ☐ Unable to get pregnant (Go to question 17)
- ☐ Don't know (Go to question 15)
- ☐ Declined to answer (Go to question 15)

14.1 How many children would you like to have?

_____Children

- ☐ Don't know
- ☐ Declined to answer

14.2 Would you like to become pregnant in the next year?

- ☐ Yes (Go to question 15)
- ☐ No (Go to question 14.3)
- ☐ I am okay either way (Go to question 14.3)
- ☐ Don't know (Go to question 15)
- ☐ Declined to answer (Go to question 15)

14.3 How long would you like to wait until you or your partner becomes pregnant?

- ☐ 1 year -17 months
- ☐ 18 months to 2 years
- ☐ More than 2 years
- ☐ Don't know
- ☐ Declined to answer

15. Are you currently using any form of contraception or birth control to either prevent pregnancy or prevent sexually transmitted infections?

- ☐ Yes (Go to question 15.1)
- ☐ No (Go to question 16)
- ☐ Declined to answer (Go to question 16)

15.1. What kind of birth control are you or your husband or partner using now to keep from getting pregnant or to prevent sexually transmitted diseases?

Select all that apply.

- ☐ Implant (such as Nexplanon)
- ☐ IUD (intrauterine device such as Mirena or ParaGard or Liletta)
- ☐ Female sterilization (Hysterectomy or Tubal Ligation)
- ☐ Male sterilization (Vasectomy)
- ☐ Injectable (Depo-Provera®)
- ☐ Birth control pill
- ☐ Patch (such as OrthoEvra®)
- ☐ Vaginal ring (NuvaRing®)
- ☐ Diaphragm
- ☐ Male condoms
- ☐ Female condoms
- ☐ Withdrawal
- ☐ Natural family planning methods (such as rhythm or cervical mucus testing)
- ☐ Foam/Jelly/Spermicide
- ☐ Lactational Amenorrhea Method (LAM) –i.e., breastfeeding
- ☐ Emergency contraception (Plan B – the "morning after pill")
- ☐ Periodic abstinence
- ☐ Other:_____
- ☐ I don't use any birth control or contraceptive methods
- ☐ Don't know
- ☐ Declined to answer

15.2. Are you satisfied with your birth control method?

- ☐ Yes (Go to question 17)
- ☐ No (Go to question 16)
- ☐ Don't know (Go to question 16)
- ☐ Declined to answer(Go to question 16)

16. What family planning method do you plan to use to avoid pregnancy?

Select all that apply.

- ☐ Implant (such as Nexplanon)
- ☐ IUD (intrauterine device such as Mirena or ParaGard or Liletta)
- ☐ Female sterilization (Hysterectomy or Tubal Ligation)
- ☐ Male sterilization (Vasectomy)
- ☐ Injectable (Depo-Provera®)
- ☐ Birth control pill
- ☐ Patch (such as OrthoEvra®)
- ☐ Vaginal ring (NuvaRing®)
- ☐ Diaphragm
- ☐ Male condoms
- ☐ Female condoms
- ☐ Withdrawal
- ☐ Natural family planning methods (such as rhythm or cervical mucus testing)
- ☐ Foam/Jelly/Spermicide
- ☐ Lactational Amenorrhea Method (LAM) –i.e., breastfeeding
- ☐ Emergency contraception (Plan B – the "morning after pill")
- ☐ Periodic abstinence
- ☐ Other:_____
- ☐ I don't plan to use any birth control or contraceptive methods
- ☐ Don't know
- ☐ Declined to answer

16.1 How sure are you that you will be able to use this method without any problems- not at all confident, somewhat confident, or very confident?

- ☐ Not at all confident
- ☐ Somewhat confident
- ☐ Very Confident
- ☐ Don't know
- ☐ Declined to answer

FOLLOW UP
☐ **Provided information/education about family planning or birth control**
Date _____
☐ **Provided counseling about family planning**
☐ **Provided birth control**
☐ **Referred for birth control**
○ **Primary Care Provider**
○ **Planned Parenthood**
○ **Other: please specify** _____
Date _____

Demographics

Now, I would like to ask a few questions to provide us with some background information.

17. Are you currently married or living with a partner, separated, divorced, widowed, or were you never married?

- ☐ Married or living with a partner
- ☐ Separated
- ☐ Divorced
- ☐ Widowed
- ☐ Never married
- ☐ Declined to answer

18. Are you currently...

STAFF: Please read out loud:

- ☐ Employed for wages
- ☐ Self-employed
- ☐ Out of work for 1 year or more
- ☐ Out of work for less than 1 year
- ☐ A Homemaker
- ☐ A Student
- ☐ Retired
- ☐ Unable to work

Staff: DO NOT READ OUT LOUD

- ☐ Declined to answer

19. What is your yearly total household income before taxes? Include your income, your husband's or partner's income, and any other income you may have received. All information will be kept private and will not affect any services you are now getting.

- ☐ Less than $10,000
- ☐ $10,000 to less than $15,000
- ☐ $15,000 to less than $20,000
- ☐ $20,000 to less than $25,000
- ☐ $25,000 to less than $35,000
- ☐ $35,000 to less than $50,000
- ☐ $50,000 or more
- ☐ Don't know
- ☐ Declined to answer

20. How often has it been very hard to get by on your family's income, by this I mean to pay for food or housing?

- ☐ Never
- ☐ Rarely
- ☐ Somewhat often
- ☐ Very often
- ☐ Don't know
- ☐ Declined to answer
- ☐ Don't know
- ☐ Declined to answer

Social Determinants of Health

21. How often do you have transportation to or from your medical appointments?

- ☐ Never
- ☐ Sometimes
- ☐ Often
- ☐ Always
- ☐ Don't know
- ☐ Declined to answer

22. The next question is about whether you were able to afford the food you need. Which of these statements best describes the food situation in your household IN THE PAST 12 MONTHS?

- ☐ We could always afford to eat good nutritious meals.
- ☐ We could always afford enough to eat but not always the kinds of food we should eat.
- ☐ Sometimes we could not afford enough to eat.
- ☐ Often we could not afford enough to eat.
- ☐ Declined to answer

Now I would like to ask you about your current housing.

23. Do you own a place, rent a place, live in public housing, stay with a family member, or are you homeless?

- ☐ Owns or shares own home, condominium or apartment (Go to question 23.1)
- ☐ Rents or shares own home or apartment (Go to question 23.1)
- ☐ Lives in public housing (receives rental assistance, such as Section 8) (Go to question 23.1)
- ☐ Lives with parent or family member (Go to question 23.1)
- ☐ Homeless (Go to question 23.2)
- ☐ Some other arrangement: _____ (Go to question 23.1)
- ☐ Declined to answer (Go to question 23.2)

23.1 Is this place a regular place to stay? By "a regular place to stay" I am referring to a house, apartment, room, or other housing where you could stay 30 days in a row or more in the same place.

- ☐ Yes (Go to question 24)
- ☐ No (Go to question 24)
- ☐ Don't know (Go to question 24)
- ☐ Declined to answer (Go to question 24)

23.2 Do you share housing with someone, live in an emergency or transition shelter, or have some other living arrangement?

- ☐ Homeless and shares housing with someone
- ☐ Lives in an emergency or transition shelter
- ☐ Some other arrangement: _____
- ☐ Declined to answer

24. How do you feel about your current housing situation--do you feel very stable and secure, fairly stable and secure, just somewhat stable and secure, fairly unstable and insecure, or very unstable and insecure?

- ☐ Very stable and secure (Go to question 25)
- ☐ Fairly stable and secure (Go to question 25)
- ☐ Just somewhat stable and secure (Go to question 24.1)
- ☐ Fairly unstable and insecure (Go to question 24.1)
- ☐ Very unstable and insecure (Go to question 24.1)
- ☐ Not sure (Go to question 25)
- ☐ Declined to answer

(Go to question 25)

24.1 What issues concern you about your housing situation?

- ☐ Received an eviction notice
- ☐ Non-payment of rent or past due rent
- ☐ Unable to pay future rent because lost housing subsidy, job, or other income source
- ☐ Non-payment of utilities or utility shut-off
- ☐ Housekeeping concerns (failure to maintain cleanliness of the unit)
- ☐ Housing is or will be condemned
- ☐ Friend or family member being evicted or threatened with eviction
- ☐ Threat of abuse by partner, family member, or other
- ☐ Being discharged or service is being terminated
- ☐ Personal conflict with others
- ☐ Other health or safety concerns
- ☐ Other lease violation(s) (please describe):_____
- ☐ Other (please describe):_____
- ☐ Don't know
- ☐ Declined to answer

25. I am going to read a list of services. Please tell me if you are receiving the service, if you have applied for the service and are waiting to find out if you will receive services, if you need services, or if you don't need services. I want to remind you that I ask these questions so we can provide the best services for your family.

	Receiving	Have applied for	Need	Do not need	Ineligible	Declined to answer
Childcare voucher						
Emergency Aid to the Elderly, Disabled, and Children (EAEDC)						
Food stamps/SNAP						
Heating assistance						
Immigration services						
Legal services						
Public housing						
Section 8 Voucher						
Social Security Disability Insurance (SSDI)						
Social Security Income (SSI)						
Transitional Aid to Families with Dependent Children (TAFDC)						
Temporary Assistance to Needy Families (TANF)						
Tribal Housing						
Utility Assistance						
Nutrition Supplemental Program for Women Infants and Children (WIC)						
Other (please specify)						

26. Have you ever had a case with Child Protective Services?

- ☐ Yes (Go to question 26.1)
- ☐ No (Go to question 27)
- ☐ Don't know (Go to question 27)
- ☐ Declined to answer (Go to question 27)

26.1 If yes, ask: Do you currently have an open case with Child Protective Services?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

FOLLOW UP	
Provided information/education about: ☐ Childcare voucher ☐ Emergency Aid to the Elderly, Disabled, and Children (EAEDC) ☐ Food stamps/SNAP ☐ Heating assistance ☐ Immigration services ☐ Legal services ☐ Public housing ☐ Section 8 Voucher ☐ Social Security Disability Insurance (SSDI) ☐ Social Security Income (SSI) ☐ Transitional Aid to Families with Dependent Children (TAFDC) ☐ Temporary Assistance to Needy Families (TANF) ☐ Tribal Housing ☐ Utility Assistance ☐ Nutrition Supplemental Program for Women Infants and Children (WIC) ☐ Other (please specify) **Date** _____	**Referral made for:** ☐ Childcare voucher ☐ Emergency Aid to the Elderly, Disabled, and Children (EAEDC) ☐ Food stamps/SNAP ☐ Heating assistance ☐ Immigration services ☐ Legal services ☐ Public housing ☐ Section 8 Voucher ☐ Social Security Disability Insurance (SSDI) ☐ Social Security Income (SSI) ☐ Transitional Aid to Families with Dependent Children (TAFDC) ☐ Temporary Assistance to Needy Families (TANF) ☐ Tribal Housing ☐ Utility Assistance ☐ Nutrition Supplemental Program for Women Infants and Children (WIC) ☐ Other (please specify) **Date** _____

Neighborhood and Community

27. Now I am going to ask you a few questions about your neighborhood or community. Please tell me if you agree or disagree with each of these statements.

Q#	Statement	Agree	Disagree	Don't know	Declined to answer
27.1	People in this neighborhood or community help each				

	other out				
27.2	We watch out for each other's children in this neighborhood or community				
27.3	There are people I can count on in this neighborhood or community.				
27.4	If my child was outside playing and got hurt or scared, there are adults nearby who I trust to help my child.				
27.5	I feel comfortable letting my child play outside alone.				

28. How often do you feel safe in your community or neighborhood? Would you say never, sometimes, usually, or always?
Select one only.

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always
- ☐ Declined to answer

29. How often do you participate in school, community, or neighborhood activities? Would you say daily, weekly, monthly, a few times a year, less than once a year, or never?
Select one only.

- ☐ Daily
- ☐ Weekly
- ☐ Monthly
- ☐ A few times a year
- ☐ Less than once a year
- ☐ Never
- ☐ Declined to answer

30. How often do you get together or talk with family, friends or neighbors? Would you say daily, weekly, monthly, a few times a year, less than once a year or never?
Select one only.

- ☐ Daily
- ☐ Weekly
- ☐ Monthly
- ☐ A few times a year
- ☐ Less than once a year
- ☐ Never
- ☐ Declined to answer

Medical Home / Access to Care

A personal doctor or nurse is a health professional who knows you well and is familiar with your health history. This can be a general doctor, a specialist doctor, a nurse practitioner, or a physician's assistant.

31. Do you have one or more persons you think of as your personal doctor or nurse?

- ☐ Yes (Go to question 31.1)
- ☐ No (Go to question 32)
- ☐ Don't know (Go to question 32)
- ☐ Declined to answer (Go to question 32)

31.1 Is there one person or more than one person?

- ☐ Yes, one person
- ☐ Yes, more than one person
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

32. Is there a place that you USUALLY go for care when you are sick or need advice about your health?

- ☐ Yes (Go to question 32.1)
- ☐ No (Go to question 33)
- ☐ There is more than one place (go to question 32.1)
- ☐ Don't know (Go to question 33)
- ☐ Declined to answer (Go to question 33)

32.1 What kind of place do you go to most often when you are sick or you need advice about your health? Is it a doctor's office, emergency room, hospital outpatient department, clinic or some other place?

Select one only.

Staff: DO NOT READ OUT LOUD

- ☐ Doctor's Office
- ☐ Hospital Emergency Room
- ☐ Hospital Outpatient Department
- ☐ Clinic or Health Center
- ☐ Retail Store Clinic or "Minute Clinic"
- ☐ School (Nurse's Office, Athletic Trainer's Office)
- ☐ Some other place _____(

33. Please tell me what kind of health insurance you have:

- ☐ Private health insurance through my job, or the job of my husband, partner or parents
- ☐ Insurance purchased directly from an insurance company
- ☐ Medicaid, Medical Assistance, or any kind of government assistance plan for those with low incomes or a disability
- ☐ TRICARE or other military health care
- ☐ Indian Health Service
- ☐ Other, specify: _____

34. During the past 12 months, did you see a doctor, nurse, or other health care worker for preventive medical care, such as a physical or well visit checkup?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to Answer

FOLLOW UP

Provided information/education about:

- ☐ Importance of regular preventative care
- ☐ Importance of having a regular provider/medical home
- ☐ Medicaid eligibility
- ☐ Birth spacing

Date _____

Provided Service:

- ☐ Enrolled in Medicaid

Date _____

Referred for:

- ☐ Medicaid enrollment
- ☐ OB/GYN provider
- ☐ Primary Care Provider

Date _____

Maternal Health

35. In general, would you say that your overall health is excellent, very good, good, fair, or poor?

Select one only.

- ☐ Excellent
- ☐ Very good
- ☐ Good
- ☐ Fair
- ☐ Poor
- ☐ Don't know
- ☐ Declined to answer

36. In general, would you say that your mental and emotional health is excellent, very good, good, fair, or poor?

Select one only.

- ☐ Excellent
- ☐ Very good
- ☐ Good
- ☐ Fair

- ☐ Poor
- ☐ Don't know
- ☐ Declined to answer

37.1 How tall are you without shoes?

_____Feet _____ Inches

- ☐ Don't Know
- ☐ Declined to answer

37.2 How much do you weigh?

_____ Pounds

- ☐ Don't Know
- ☐ Declined to answer

38. Did you have a postpartum checkup after your child was born?

- ☐ Yes (Go to question 38.1)
- ☐ No (Go to question 39)
- ☐ Declined to answer (Go to question 39)

38.1. Approximately how many weeks postpartum did you have your postpartum checkup?

_____Weeks

39. Has a healthcare provider ever told you that you have any of the following medical conditions?

Asthma (breathing problems/wheezing)

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

Autoimmune disease[1] [Lupus (SLE), Rheumatoid Arthritis (RA), ~~HIV,~~ etc.]

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

Cancer

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No

☐ Don't know ☐ Declined to answer

Cardiovascular disease (heart problems)

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

Depression or other mental health conditions (anxiety, bipolar)

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

Diabetes (high blood sugar)

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

Eating disorders (anorexia/bulimia)

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

Gestational Diabetes

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

High blood pressure

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

☐ Yes ☐ Don't know
☐ No ☐ Declined to answer

PKU (phenylketonuria)[2]

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

Renal disease (kidney problems)

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

Seizure disorders (Epilepsy)

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

Sickle Cell

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

Thrombophilia (blood clots)

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

Thyroid disease – hypo/hyper (overactive or underactive thyroid)

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

If **yes**, ask: Is this something you have currently?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined to answer

Other_____

If **yes**, ask: Is this something you have currently?

- ☐ Yes (Go to question 39.1)
- ☐ No (Go to question 40)
- ☐ Don't know (Go to question 40)
- ☐ Declined to answer (Go to question 40)

39.1 STAFF: If participant currently has any of the above conditions, ask:

Have you been seen in the emergency room or hospitalized for any of these conditions within the last 6 months?

- ☐ Yes (Go to question 39.2)
- ☐ No (Go to question 40)
- ☐ Declined to answer (Go to question 40)

39.2 Please tell me which condition or conditions you have been seen for in the emergency room hospital within the past 6 months.

- ☐ Asthma (Breathing problems/wheezing)
- ☐ Autoimmune disease (such as lupus (SLE), Rheumatoid Arthritis (RA~~), HIV~~)
- ☐ Cancer
- ☐ Cardiovascular disease (Heart problems)
- ☐ Depression or other mental health conditions (anxiety, bipolar)
- ☐ Diabetes (High blood sugar)
- ☐ Eating disorders (Anorexia/bulimia)
- ☐ Gestational diabetes
- ☐ High Blood Pressure
- ☐ PKU (phenylketonuria)
- ☐ Renal disease (Kidney problems)
- ☐ Seizure disorders (Epilepsy)
- ☐ Sickle Cell
- ☐ Thrombophilia (Blood Clots)
- ☐ Thyroid disease—(Hypo/hyper—overactive or underactive thyroid)

40. Are you currently having any pain?

- ☐ Yes
- ☐ No
- ☐ Declined to answer

41. Are you taking any prescription medications?

- ☐ Yes (Go to question 41.1)
- ☐ No (Go to question 42)
- ☐ Don't know (Go to question 42)
- ☐ Declined to answer (Go to question 42)

41.1 STAFF: Ask participant specifically about each medication .

Are you taking any:	Yes	No	Don't know	Declined to answer
Pain medications (such as morphine, codeine, oxycodone, Vicodin, or methadone)				
Blood Thinners (such as Coumadin, heparin, or Lovenox)				
Male Hormones (such as testosterone)				
Antibiotics (such as tetracycline, doxycycline, Flagyl or streptomycin, trimethoprim, Bactrim, Septra)				
Seizures or Epilepsy medications (such as valproate, Dilantin or Depakote)				
Acne medications (such as Accutane, Retin-A)				
High Blood Pressure medications (ace inhibitors such as Capoten, Vasotec,Lotensin)				
High Cholesterol medications (statins, such as Lipitor, Pravachol, Zocor, Mevacor)				
Antidepressants (such as lithium, Paxil)				

41.2 STAFF: if participant is currently taking any of the above medications, ask:

Are you taking these medications as prescribed?

- ☐ Yes (Go to question 42)
- ☐ No (Go to question 41.3)
- ☐ Declined to answer (Go to question 42)

41.3 Please specify which medications:

- ☐ Pain medications (such as morphine, codeine, oxycodone, vicodin, or methadone)
- ☐ Blood Thinners (such as Coumadin, heparin, or lovenox)
- ☐ Male Hormones (such as testosterone)
- ☐ Antibiotics(such as tetracycline, doxycycline, Flagyl or streptomycin,trimethoprim, Bactrim, Septra)
- ☐ Seizures Or Epilepsy medications(such asvalproate, Dilantin or Depakote)
- ☐ Acne medications (such as Accutane, Retin-A)
- ☐ High Blood Pressure medications(ace inhibitors such as Capoten, Vasotec,Lotensin)
- ☐ High Cholesterol medications s (statins, such as Lipitor, Pravachol, Zocor, Mevacor)
- ☐ Antidepressants (such as lithium, Paxil)

42. During the past month, how many times a week did you take a multivitamin, a prenatal vitamin, or a folic acid vitamin?

- ☐ I did not take a multivitamin, prenatal vitamin or folic acid vitamin at all
- ☐ 1 to 3 times a week
- ☐ 4 to 6 times a week
- ☐ Every day of the week
- ☐ Don't Know
- ☐ Declined to answer

43. How long ago did you last have a flu vaccination? Would you say less than six months ago, six months to a year ago, more than a year ago, or never?

Select one only.

- ☐ Less than six months ago
- ☐ Six months to one year ago
- ☐ More than one year ago
- ☐ Never
- ☐ Don't know
- ☐ Declined to answer

44. Have you ever received the following vaccines?

Q#	Vaccine	Yes	No	Don't know	Declined to answer
44.1	MMR (measles, mumps, rubella) vaccine				
44.1.1	If not, have you been tested for immunity to rubella?				
44.2	Hepatitis B vaccine (3 doses)				
44.3	All 3 shots of the Gardasil (HPV virus) vaccine				
44.4	Have you ever had chicken pox or shingles?				
44.4.1	If not, have you received 2 doses of the varicella vaccine?				
44.5	In the last 10 years, have you received Tdap (tetanus, diphtheria, and pertussis)?				

45. Have you ever been diagnosed with any of the following?

	Yes	No	Don't know	Declined to answer
Toxoplasmosis				
Tuberculosis				
Cytomegalovirus				
Hepatitis B or C				
Zika				
Chlamydia				
Gonorrhea				
Herpes Simplex				
HIV				
Syphilis				
Other:				

46. When was the last time you were tested for sexually transmitted diseases or sexually transmitted infections?

	Less than 6 months ago	6 months to 1 year ago	More than 1 year ago	Never
Chlamydia				
Gonorrhea				
Herpes Simplex				
HIV				
Syphilis				
Other:				

47. How long ago did you last have your teeth cleaned by a dentist/hygienist? Would you say less than six months ago, six months to a year ago, more than a year ago, or never?

Select one only.

- ☐ Less than six months ago
- ☐ Six months to one year ago
- ☐ More than one year ago
- ☐ Never
- ☐ Don't know
- ☐ Declined to answer

FOLLOW UP

Provided information/education about:

- ☐ Keeping a healthy weight such as through diet and exercise
- ☐ Getting vaccines
- ☐ Getting flu shot
- ☐ Sexually transmitted infections
- ☐ Keeping teeth healthy
- ☐ Health risks during pregnancy

Date _____

Provided:

- ☐ Nutritional counseling
- ☐ Immunizations: Please specify_____
- ☐ Pain assessment

Date _____

Referred to:

- ☐ Primary Care Provider
- ☐ Nutritionist
- ☐ Dentist
- ☐ Other: Please specify_____

Date _____

Mental Health

48. Over the past two weeks, how often have you experienced any of the following?

Q#	Problem	Not at all	Several Days	More than half the days	Nearly every day	Score
48.1	Little interest or pleasure in doing things	0	1	2	3	
48.2	Feeling down, depressed, or hopeless	0	1	2	3	
	Total Score					

NOTE: Circle the number that matches the participant's answer, and add the answers for both together to get the final score. If the final score is more than 3, further assessment is needed.

FOLLOW UP

☐ **Provided information/education about resources for depression**

Date_____

Provided Servic:

☐ Further assessment using evidence-based tool such as PHQ-9 Counseling

Date_____
Referred to:

☐ Mental health center
☐ Primary Care Provider
☐ Other: Please specify_____

Date_____

Substance Use

49. If it's okay with you, I'd like to ask you a few questions that will help me give you better care. The questions relate to your experience with alcohol, cigarettes, and other drugs. Some of the substances we'll talk about are prescribed by a doctor (like pain medications). But I will only record those if you have taken them for reasons or in doses other than prescribed. I'll also ask you about illicit or illegal drug use.

In the past year, how often have you used the following?

Substance	Never	Once or Twice Monthly	Weekly	Daily or Almost Daily	Declined to answer
Alcohol (4 or more drinks per day)					
Tobacco Products (including cigarettes, chewing tobacco, snuff, iqmik, or other tobacco products like snus Camel Snus, orbs, e-cigarettes, lozenges, cigars, or hookah)					
Mood-altering Drugs (including marijuana)					
Prescription Drugs for Non-Medical Reasons					
Illegal Drugs (marijuana, cocaine, crack, heroin, uppers/crank/meth, PCP, diet pills, LSD)					

50. Which of the following statements best describes the rules about smoking inside your home now?

- ☐ No one is allowed to smoke anywhere inside my home
- ☐ Smoking is allowed in some rooms or at some times
- ☐ Smoking is permitted anywhere inside my home

DO NOT READ OUT LOUD:

- ☐ Declined to answer

51. On average, about how many hours per day are you in the same room or vehicle with another person who is smoking?

_____Number of hours per day (enter 1 hour through 24 hours)

- ☐ I spend less than one hour per day in a room or vehicle with somebody who is smoking
- ☐ I am never in a room or vehicle with someone who is smoking
- ☐ Declined to answer

52. On average, about how many hours a day is your child in the same room or vehicle with someone who is smoking?

Select one only.

_____ Number of hours per day (enter 1 hour through 24 hours)

- ☐ My child is never in a room or vehicle with someone who is smoking
- ☐ My child spends less than one hour per day in a room or vehicle with someone who is smoking
- ☐ My child is never in a room or vehicle with someone who is smoking
- ☐ Don't know
- ☐ Declined to answer

FOLLOW UP		
Provided information/education about: ☐ Potential effects on pregnancy of tobacco ☐ Potential effects on pregnancy of alcohol ☐ Potential effects on pregnancy of drug use ☐ Tobacco cessation **Date**_____	**Provided further assessment:** ☐ Assess, Advise and Assist for Alcohol Use Disorders (for "Yes" to 1 or more days of heavy drinking [for women, 4 or more drinks per day]) ☐ NIDA-Modified ASSIST (for any use of illegal or prescription drug use for non-medical reasons) ☐ **Provided Brief Intervention** Date_____	**Referred to:** ☐ Tobacco Quit Line ☐ Behavioral Health Provider ☐ Primary Care Provider ☐ Substance abuse treatment program ☐ Other: Please specify_____ **Date**_____

Personal Safety

53. We are concerned about the safety of all participants. Please answer the following questions so that we can help you if needed.

Q#	During the past 12 months...	Yes	No	Declined to Answer
53.1	Did your husband or partner threaten or make you feel unsafe in some way?			
53.2	Were you frightened for your safety or your family's safety because of the anger or threats of your husband or partner?			
53.3	Did your husband or partner try to control your daily activities, for example, control who you could talk to or where you could go?			
53.4	Did your husband or partner push, hit, slap, kick, choke, or physically hurt you in any other way?			
53.5	Did your husband or partner force you to take part in touching or any sexual activity when you did not want to?			
53.6	Did anyone else physically hurt you in any way?			

FOLLOW UP

☐ Provided information/ education about what to do if you have or someone you know has a partner that hurts them physically

Date _____

☐ Referred to local domestic violence program _____

Date _____

Stress and Discrimination

54. Stress is something we've all felt, and is often part of our daily lives. If you experience stress over a prolonged period of time however, it can be harmful to both your mind and body. Stress influences our moods, sense of well-being, behavior and overall health. We ask the following questions to learn what stressors you have in your life and to better understand how to help reduce the stress in your life.

This question is about things that may have happened during the past twelve months. For each item, please tell me "no" if it did not happen or "yes" if it did. (It may help to look at the calendar when you answer these questions).

Q#	Event	Yes	No
54.1	A close family member was very sick and had to go into the hospital		
54.2	I got separated or divorced from my husband or partner		
54.3	I moved to a new address		
54.4	I was homeless or had to sleep outside, in a car, or in a shelter		
54.5	My husband or partner lost his job		
54.6	I lost my job even though I wanted to go on working		
54.7	My husband, partner, or I had a cut in work hours or pay.		
54.8	I was apart from my husband or partner due to military deployment or extended work-related travel		
54.9	I argued with my husband or partner more than usual		
54.10	My husband or partner said he didn't want me to be pregnant		
54.11	I had problems paying the rent, mortgage, or other bills		
54.12	My husband, partner, or I went to jail		
54.13	Someone very close to me had a problem with drinking or drugs		
54.14	Someone very close to me died		

55. The next set of questions asks you about how other people have treated you. In your day-to-day life, how often have any of the following things happened to you?

Q#	Treatment	Almost every day	At least once a week	A few times a month	A few times a year	Less than once a year	Never	Declined to answer

55.1	You are treated with less courtesy or respect than other people.							
55.2	You receive poorer service than other people at restaurants or stores.							
55.3	People act as if they think you are not smart.							
55.4	People act as if they are afraid of you.							
55.5	You are threatened or harassed.							

STAFF: If participant answers "**a few times a year**" or **more frequently** to any of the above, go to question 56.

If participant answers "**less than once a year**", "**never**" or declines to answer, go to question 57.

56. What do you think is the main reason for these experiences?

- ☐ Your ancestry or national origins
- ☐ Your gender
- ☐ Your race
- ☐ Your age
- ☐ Your religion
- ☐ Your height
- ☐ Your weight
- ☐ Some other aspect of your physical appearance
- ☐ Your sexual orientation
- ☐ Your education or income level
- ☐ Your shade of skin color
- ☐ Physical Disability
- ☐ Other, please specify: _____
- ☐ Don't know
- ☐ Declined to answer

57. The following statements are about the way you handle life events. Please tell me which are true for you <u>most of the time</u>.

Select all that apply.

- ☐ I tend to bounce back quickly after hard times
- ☐ I have a hard time making it through stressful events

- ☐ It does not take me long to recover from a stressful event
- ☐ It is hard for me to snap back when something bad happens
- ☐ I usually come through a difficult time with little trouble
- ☐ I tend to take a long time to get over set-backs in my life
- ☐ Don't know
- ☐ Declined to answer

FOLLOW UP

☐ **Provided information/ education about resources for stress management**

Date_____

☐ **Provided counseling on stress management**

Date_____

Referred to:

- ☐ Mental health center
- ☐ Primary Care Provider
- ☐ Other: Please specify_____

Date_____

Social Support / Father Involvement

58. People sometimes look to others for companionship, assistance, or other types of support. These questions ask you about the types of support that would be available to you if you needed it. If you are not sure which answer to select, please choose the one answer that comes closest to describing it.

For the following questions your response options are the following; none of the time, a little of the time, some of the time, most of the time or all of the time; If you needed it, how often is someone available…

Q#	Support Task	All of the time	Most of the time	Some of the time	A little of the time	None of the time
58.1	To provide temporary financial support?					
58.2	To do something enjoyable with you?					
58.3	To help with daily chores if you were sick					
58.4	To turn to for suggestions about how to deal with a personal problem?					
58.5	To watch your child for you?					

59. What is the baby's father's role in your life?

Select all that apply.

Staff: DO NOT READ OUT LOUD:

- ☐ Baby's father is deceased (Go to question 60)
- ☐ Baby's father is incarcerated (Go to question 60)
- ☐ Cares for child (feeding, bathing, reading to child, etc.) (Go to question 59.1)
- ☐ Assists with housework and/or runs errands (ex: grocery shopping)
- ☐ Attends medical appointments (Go to question 59.1)
- ☐ Provides emotional support (Go to question 59.1)
- ☐ Provides financial support (Go to question 59.1)
- ☐ Baby's father plays no role/is not involved (Go to question 59.1)
- ☐ Other (please specify):_____ (Go to question 59.1)
- ☐ Declined to answer (Go to question 59.1)

59.1 Would you describe the father of your child as:

- ☐ Involved and supportive of me and my child
- ☐ Involved but not supportive of me or my child
- ☐ Not involved
- ☐ Declined to answer

60. Is there someone you can count on to help you with your child?

- ☐ Yes
- ☐ No
- ☐ Declined to answer

61. Who do you count on for support?

Select all that apply.

- ☐ Current Partner
- ☐ Ex- partner
- ☐ Child's father
- ☐ Parents
- ☐ Other child or children
- ☐ Other relative(s)
- ☐ Friend(s)
- ☐ Neighbor(s)
- ☐ Clergy
- ☐ Other _____

FOLLOW UP

☐ **Provided information/education about importance of social supports:**

Date_____

Referral made to:

- ☐ Social Worker
- ☐ Parent help line
- ☐ Parent support group
- ☐ Other: Please specify_____

Date_____

The Healthy Start Interconception/Parenting Screening Tool is Complete