Nurse-Family Partnership Expansion Evaluation Guide

A guide for the expansion and evaluation of Nurse-Family Partnership to serve individuals with previous live births (multips) and individuals who enroll after 28 weeks gestation but prior to the birth of the child (late registrants).

Mandy Allison, MD, MSPH
PREVENTION RESEARCH CENTER FOR FAMILY & CHILD HEALTH, UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS
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AUTHORS & CONTRIBUTORS

Mandy Allison, MD MSPH  
Prevention Research Center for Family & Child Health, Co-Director
Carol Franco-Rowe, MA  
Prevention Research Center for Family & Child Health, Research Analyst
Wendy Mazzuca, MPH BSN  
Prevention Research Center for Family & Child Health, NSO Liaison
Venice Ng Williams, PHD MPH  
Prevention Research Center for Family & Child Health, Associate Professor
Connie Lopez, MA BSN  
Prevention Research Center for Family & Child Health, Qualitative Analyst
Michael Knudtson, MS  
Prevention Research Center for Family & Child Health, Director of Biostatistics
Alain Glen, BSN  
NFP National Service Office, Manager of Nursing Practice
EXECUTIVE SUMMARY

This document provides guidance to communities considering evaluation of NFPx. NFPx is a change to two of the Nurse Family Partnership (NFP) model elements through the expansion of eligibility for NFP to individuals with previous live births (multiparous people or ‘multips’) and those who are referred to NFP after 28 weeks gestation but before the birth of the child (late registrants).

Since 2017, the team at the Prevention Research Center for Family and Child Health at the University of Colorado School of Medicine has been collaborating with partners at the National Service Office for NFP and Child First, local NFP teams from around the U.S., and other community-serving organizations to evaluate NFPx. This guide shares our learnings from this collaborative work. Important learnings include:

- defining key questions to be answered by an evaluation of NFPx,
- leveraging existing data to answer those key questions,
- developing and sustaining community partnerships to guide the evaluation,
- budget considerations,
- regulatory considerations including sample data sharing agreements, and
- planning for effective dissemination of findings from the evaluation.

New NFP network partners implementing NFPx are not expected to conduct an evaluation themselves. Instead, NFP network partners are expected to support an evaluation in the following ways: 1. Have existing relationships with health plans, and/or state-level partners such as departments of health or child welfare or early childhood, and/or evaluators with experience in evaluating home-visiting such as university partners. 2. Use those existing relationships to help an evaluation team develop an evaluation advisory committee and appropriate data use agreements or memoranda of understanding for data sharing. 3. Participate in meetings with an evaluation team on a monthly basis.

Our intent is for this guide to serve as a valuable resource to increase community partners' understanding of what an evaluation of NFPx may involve and to support evaluation teams in planning and conducting an evaluation. Questions or requests for additional information or resources can be directed to our team at the PRC at familychildprc@cuanschutz.edu or 303-724-7450.
INTRODUCTION
This document provides guidance to communities considering evaluation of NFPx. NFPx is a change to two of the Nurse Family Partnership (NFP) ‘model elements’ through the expansion of eligibility for NFP to individuals with previous live births (multiparous people or multips) and those who are referred to NFP after 28 weeks gestation but before the birth of the child (late registrants). New NFP network partners implementing NFPx are not expected to conduct an evaluation themselves. Instead, NFP network partners are expected to support an evaluation in the following ways:

1. Have existing relationships with health plans, and/or state-level partners such as departments of health or child welfare or early childhood, and/or evaluators with experience in evaluating home-visiting such as university partners.
2. Use those existing relationships to help an evaluation team develop an evaluation advisory committee and appropriate data use agreements or memoranda of understanding for data sharing.
3. Participate in meetings with an evaluation team on a monthly basis.

Expansion of NFP to serve Multiparous Clients. A formative study was conducted by the Prevention Research Center for Family and Child Health (PRC) from September 2017 to January 2021 in collaboration with 35 NFP network partners in 15 states. This formative study had 3 main objectives: 1) learn if formative study sites could get referrals for pregnant people with previous live births (multips), 2) determine if NFP could enroll and retain multips in the program, and 3) to identify the resources and modifications needed to serve multiparous clients well.

The results of the formative study revealed that the enrollment and retention rates for multips were similar or higher than the enrollment and retention rates for clients who were first-time parents. The formative study also confirmed that multip clients experienced more nurse-assessed risks, such as less social support and higher rates of smoking, and were referred to needed services more frequently than clients who were first-time parents. Through key informant interviews and discussions with NFP nurse supervisors, nurse home visitors, and clients, additional resources and training were developed to support nurses serving multip clients.

A randomized clinical trial (RCT) is being led by the PRC in collaboration with partners at Nationwide Children's Hospital and Ohio State University in Ohio to determine the effectiveness of NFP for people with previous live births. New network partners who choose to participate in NFPx and are not involved in the RCT will be asked to support ongoing evaluation of NFPx. More details about the Definition of an Evaluation and Measurement that may be used in an evaluation of NFPx are included below.

Expansion to NFP to serve Late Registrant Clients. The NFP nurse experience and data collected in the formative study showed that pregnant people with previous live births (multips) may access prenatal care and may be referred to support services later than first-time parents. Therefore, NFP network partners who participated in the formative study were granted permission to enroll clients after the 28th week of
pregnancy. After the completion of the formative study, an evaluation began in Florida. The objectives of the Florida NFP Expanded Eligibility Initiative Evaluation are to determine: 1) if expanding eligibility for NFP to include pregnant people who are referred after 28 weeks gestation (late registrants) allows NFP to reach more families with risks for poor health and life-course outcomes and 2) if NFP has a positive impact among late registrants. In addition to allowing for late registrants, some NFP network partners in Florida are also enrolling multips.

The initial findings from Florida suggest that about half of the pregnant people referred to NFP late have their first prenatal visit after the first trimester of pregnancy. Those referred to NFP after 28 weeks of pregnancy tend to have more physical and mental health concerns and social determinants of health that may negatively affect pregnancy outcomes and child and life-course development. So far, those referred to NFP after 28 weeks of pregnancy appear to enroll in NFP at similar or higher rates than those referred to NFP prior to 28 weeks of pregnancy. Interviews with selected NFP teams, referring partners, and late registrant clients have identified several reasons for late referrals to NFP including systems barriers (such as a person not being able to get access to early prenatal care) and personal barriers (such as a person not initially thinking they needed the support of NFP early in pregnancy and then realizing that they need additional support later). Interviews also revealed perceived benefits and challenges of serving late registrants. Once about 250 late registrants have enrolled in NFP, an evaluation of the impact of NFP for late registrants will be conducted.

The Role of the Prevention Research Center for Family & Child Health at the University of Colorado (PRC)

The PRC is an interdisciplinary research group housed within the Adult and Child Center for Outcomes Research and Delivery Science (https://medschool.cuanschutz.edu/accords) at the University of Colorado Anschutz Medical Campus. PRC research focuses on development of, adaptations to, and dissemination and implementation of interventions to promote optimal wellness for parents and children experiencing adversities and risks for poor mental and physical health.

The PRC works collaboratively with the National Service Office for NFP and Child First (NSO) to conduct research on adaptations to NFP model elements. NFP Model Element 2 states that individuals enrolled in NFP will be first time parents. Model Element 4 states that individuals will be enrolled in NFP prior to the completion of the 28th week of gestation. NFPx is an adaptation to these model elements allowing approved network partners to serve multips and late registrants. The PRC is currently conducting a randomized clinical trial (RCT) in partnership with Nationwide Children's Hospital, Ohio State University, and NFP network partners in Ohio to determine the effectiveness of NFP for people with previous live births. RCTs are the gold-standard for establishing evidence for the effectiveness of an intervention and were used to establish the effectiveness of the original NFP model for first-time parents enrolled before 28 weeks gestation. Other study designs to evaluate adaptations to NFP model elements that could be considered are described in the Study Design Considerations section of this document.
PURPOSE OF AN EVALUATION

What is the definition and purpose of an evaluation?

The Centers for Disease Control and Prevention differentiates evaluation, research, and monitoring as follows (https://www.cdc.gov/evaluation/index.htm):

**Evaluation**: Purpose is to determine effectiveness of a specific program or model and understand why a program may or may not be working. The goal is to improve programs.

**Research**: Purpose is theory testing and to produce generalizable knowledge. The goal is to contribute to knowledge base.

**Monitoring**: Purpose is to track implementation progress through periodic data collection. The goal is to provide early indications of progress (or lack thereof). There are also similarities: data collection methods and analyses are often similar between research and evaluation; monitoring and evaluation measure and assess performance to help improve performance and achieve results.”

NFP was originally designed by Dr. David Olds for people experiencing their first pregnancy and childbirth with the intervention beginning early in pregnancy because of evidence that this is a critical period when behavioral and biological changes occur. NFP effects found for first-time parents and their children may differ for people who already have other children. Any NFP network partner implementing NFPx will be required to support an evaluation. Continued evaluation of NFPx is necessary to determine if NFPx is having its desired effect of improving health and life course outcomes for a broader population of families than ‘traditional’ NFP serves. NFP was originally tested in three different RCTs with different populations in three different locations (Elmira, NY, Memphis, TN, and Denver, CO) before it was deemed effective and ready to be implemented broadly. Similarly, conducting evaluations of NFPx in a variety of communities with different community contexts and racial, ethnic, cultural, and linguistic backgrounds is important to determine if NFPx is ready for widespread implementation.

THEORETICAL FOUNDATIONS FOR NFP

Why does NFP serve individuals in their first pregnancy and those who are less than 28 weeks gestation?

Several theories are foundational to NFP: Human Ecology theory, Attachment theory, and Social Cognitive theory. Human Ecology theory emphasizes the importance of social contexts as influences on human development and having additional children in the home clearly alters the social context. Attachment Theory describes patterns of responses between caregiver-child dyads that begin to develop during pregnancy and predict child resiliency and social-emotional outcomes. People who previously birthed and parented a child have developed a parenting style which may be difficult to alter for subsequent children. As stress increases, adaptive parenting behaviors are more challenging. Social cognitive/self-efficacy theory suggests that one’s belief in their ability to accomplish tasks and their belief that accomplishing the tasks will lead to desired outcomes affect their ability to change their behaviors. Parents
with previous parenting experiences have established outcome expectations related to certain parenting behaviors that nurses may have difficulty influencing; therefore, these behaviors may be less amenable to change. In addition, people who have had previous pregnancies and live births have already experienced some of the neuroendocrine changes that accompany pregnancy, childbirth, and early caregiving and have developed a parenting style which may be difficult to alter for subsequent children.

**EXPANDED ELIGIBILITY CONSIDERATIONS**

When considering the expansion of eligibility for NFP, it is important to consider the following: 1) how will an expansion to multips and/or late registrants affect the current population that is being served by NFP? 2) is there a need to serve multips and/or late registrants in your community?; and 3) are administration and funders supportive of expanding eligibility for NFP to serve multips and/or late registrants?

*Implementation of NFPx risks diverting resources from first-time parents enrolled prior to 28 weeks of pregnancy for whom NFP is known to be effective.* NFP network partners should continue to work on identifying, enrolling, and retaining first-time parents who are facing adversity and structural inequity and are most likely to benefit from NFP. NFP must continue to prioritize families for whom we know we have an impact with this model based on existing scientific evidence.

*Funders and policy makers require evidence that NFP, and other home-visiting programs, can produce positive outcomes and is worth their investment of resources.* When funders and policy makers are in search of programs to implement in their community, they want to identify programs with empirical evidence that the intervention will have the desired outcome in their population. NFP is a program that demonstrates effectiveness in producing positive changes. Programs without this evidence base can result in a lack of changes in the desired outcomes, and therefore, a loss in investment.

*Identifying common outcome measures that are used across partners implementing NFPx allows for comparison of outcomes across communities and settings.* If positive outcomes of NFPx are consistent across diverse communities, then widespread implementation of NFPx may be indicated. If outcomes of NFPx differ between communities, for example, if NFP improves outcomes for multips in a large, urban city but not for multips in a rural area, we can investigate what is driving those differences and identify adaptations to the program to increase its effectiveness in rural populations.

**Logic Model**

*What is a logic model and why is it important for NFP?*

A logic model uses words and pictures to describe how an intervention or program is expected to work. It shows how the theory and/or principles behind the intervention and the activities of the intervention lead to the anticipated short and long-term outcomes. An evaluation plan should be guided by a logic model.
The NSO for NFP and ChildFirst has created a logic model for the ‘traditional’ NFP program. This version of the logic model is included in Appendix A and an interactive version of the logic model is located here: https://view.genial.ly/619bd13a09ac0e0d8c67b44c. Partners are encouraged to adapt this logic model for implementation of NFPx in their own settings and use the logic model to guide their evaluation plan.

**Tip:** There are many online resources on how to develop a logic model. Here are just a couple that can be used for guidance:
- Kellogg Foundation Logic Model Guide
- CDC Logic Model

**Key Questions to be Answered by an Evaluation**

*What should be considered when developing an evaluation plan?*

Evaluation plans for NFPx should consider the following questions:

1. Is NFPx reaching the intended population? This concept is sometimes called the ‘reach’ of the program. RE-AIM is a framework to guide the planning and evaluation of programs according to the 5 key RE-AIM outcomes: Reach, Effectiveness, Adoption, Implementation, and Maintenance (see RE-AIM.org for more resources). Consideration of the degree to which people who are most likely to benefit from the NFP intervention are being identified and enrolled in NFP is an important determinant of the effectiveness of NFP. Because public health interventions are addressed to large numbers of people, even small differences in risk levels between participants and nonparticipants can have a significant impact on the cost-effectiveness of the program.

2. Is NFPx being implemented with fidelity to the NFP model, i.e., is the program staying true to the model elements with the exception of serving people with previous live births and enrolling after 28 weeks of pregnancy but before the birth of the child?

3. How do the outcomes monitored for NFP differ between the expanded eligibility population and the ‘traditional’ population enrolled in NFP?

4. What modifications to NFP implementation are indicated to better serve the expanded eligibility population?

5. Does NFPx have the expected impact, i.e., is NFP effective for improving maternal and child health outcomes among the expanded population?

**A Note on Outcomes Versus Impact.** NFP program outcomes answer, ‘what happened?’ by showing the observed effects of the program on the participants. In NFP, impact answers the question, ‘was it the program that made it happen?’ by showing the degree to which the observed effect is attributable to the program or intervention. Measurement of impact requires a comparison group and refers to outcomes where a difference has been shown among people who receive NFP compared to similar people who did not receive NFP. The rate of preterm birth is a good example of why a comparison group of similar families is
needed to measure impact. We know that some people with previous live births who enrolled in NFP had complications, including preterm birth, with their previous pregnancies. Having a previous preterm birth is a risk factor for having another preterm birth. Therefore, comparing clients with previous births to clients who are pregnant for the first time for the outcome of preterm birth is not a fair comparison because the group with previous births was at higher risk to begin with. The appropriate comparison to determine if NFP can reduce preterm births among a group of people who had previous births would be to compare people with previous births with similar risk factors for preterm birth who did and did not receive NFP.

**STUDY DESIGN CONSIDERATIONS**

*What should be considered when designing an evaluation?*

Multiple study design options exist that can be used to determine the effectiveness of an intervention. Randomized clinical trials (RCTs) are considered the “gold standard” in this area. In an RCT, study participants are randomly assigned to either a comparison or intervention group. Researchers then compare the two groups for selected outcomes to learn about the effects of the intervention. Random assignment of people to receive one intervention or another can be challenging and may not always be feasible (for example, it may not be ethical to deprive a group of a specific intervention). In these cases, a quasi-experimental design (QED) may be the most appropriate study design to learn about the effects of an intervention. In a QED study, participants are not randomly assigned to a certain intervention, such as instances where a participant decides which group they want to be in. In a QED study, statistical methods are used to make the participants in each group as similar as possible. Despite using these statistical methods, QED studies have a risk of selection bias where those who are in the intervention group are different from those who are in the comparison group in ways that affect the outcomes outside of the effect of the intervention itself. For example, people who choose to participate in NFP may be more motivated to take care of their health than those who do not choose to participate in NFP.

Below are some important considerations when determining which study design is most appropriate:

- **Feasibility of the study design**
  - RCTs require randomization into either an intervention group or a comparison group,
  - RCTs might be deemed unethical,
  - There may be opposition to randomization by funders or relevant partners.

- **Appropriate pool of participants**
  - A statistician will need to determine if there are an adequate number of participants to reach statistical significance (i.e., statistical power),
  - QEDs require a matched group, meaning that the comparison group and intervention group need to be similar enough to create a statistical match.

- **Funding considerations**
Certain study designs may be more costly than others, for example RCTs tend to require more time and financial resources and thus may require more funding than a QED study.

Tip: To learn more about the differences between RCTs and QED study designs, you can visit several online resources

- Public Health Notes
- NIH
- Air Medical Journal

The Home Visiting Evidence of Effectiveness (HomVEE) project was launched by the U.S. Department of Health and Human Services to ‘provide an assessment of the evidence of effectiveness for early childhood home visiting models’ in a thorough and transparent manner (https://homvee.acf.hhs.gov/about-us/project-overview). HomVEE reviews the published literature to identify studies about home visiting effectiveness and prioritizes review of the home-visiting models and their associated studies based on criteria including study design, sample size, outcomes of interest, and population studied. Experimental study designs, such as RCTs, receive a higher priority rating than non-experimental comparison group designs, such as QED studies. Other criteria for receiving a higher priority rating include: 1) studies with a sample size of 250 or more families, 2) outcomes in one or more HomVEE priority domains (family economic self-sufficiency; linkages and referrals; reductions in child maltreatment; and reductions in juvenile delinquency, family violence, or crime), 3) and studies conducted with priority populations (indigenous communities, low-income, parents younger than 21 years, a history of child welfare involvement, a history of tobacco or substance use, children with developmental delays, and individuals in the Armed Forces). HomVEE prioritization may be considered when developing an evaluation plan.

In addition to considering HomVEE study prioritization criteria, evaluators can also consider what criteria Health and Human Services require for a home-visiting model to qualify as evidence-based. According to the 2021 HomVEE Handbook:

‘To meet HHS’ criteria for an “evidence-based early childhood home visiting service delivery model,” models must meet at least one of the following criteria: a) at least one high- or moderate-rated impact study of the model finds favorable (statistically significant) impacts in two or more of the eight outcome domains; b) At least two high- or moderate-rated impact studies of the model (using non-overlapping
**MEASUREMENT**

*What measures should be considered as part of an evaluation of NFPx?*

As part of the ongoing evaluation of NFPx, several measures are suggested to determine whether expansion of the NFP program is appropriate for the intended populations. The tables below summarize the measures and their data sources. Table 1 includes measures that can be obtained from analysis of data routinely collected by NFP teams that are part of NFP implementation. The NSO for NFP and Child First Research and Evaluation team has access to these data. The PRC also has access to these data with appropriate memoranda of understanding in place.

**Table 1. Measures for NFPx Evaluation from NFP Implementation Data**

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<tr>
<th>Concept and Measures</th>
<th>Potential Data Source(s)</th>
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<tr>
<td><strong>Population Served</strong></td>
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| For each population—a) ‘traditional’ NFP—first time parent enrolled prior to 28 weeks pregnancy, b) ‘late only’—first time parent enrolled after 28 weeks pregnancy, c) ‘multiparous only’—person with previous live birth enrolled prior to 28 weeks pregnancy, and d) ‘multiparous and late’—person with previous live birth enrolled after 28 weeks pregnancy. | NFP Demographic form  
NFP Maternal Health form  
NFP Health Habits form |
| - Race and ethnicity |                         |
| - Average client age at enrollment in years |                         |
| - Average estimated gestational age at time of enrollment in weeks |                         |
| - Marital/relationship status |                         |
| - Education level |                         |
| - Substance use at intake |                         |
|   - Tobacco past 24 hours |                         |
|   - Alcohol past 2 weeks |                         |
| - Marijuana past 2 weeks |                         |
| - Other substance use past 2 weeks |                         |
| - Body Mass Index |                         |
| - History of physical health concerns |                         |
| - History of mental health concerns |                         |
| **Program Implementation and Fidelity** | NFP Encounter form |
| - Average Caseload |                         |
| - Average % of caseload that is in each population. |                         |

• # completed visits for each population during the reporting period
  o #/% visits completed via telehealth
  o # Visits attempted
  o Average length of visits completed

Retention
• Average # of visits completed
• Average length of stay in program
• % of each client enrolled who were retained through pregnancy, infancy, and graduation

NFP Program Outcomes
• % babies born preterm
• % clients who initiated breastfeeding
• % clients who gained recommended weight based on BMI
• C-section incidence
• % babies screened with ASQ-3 at 10 and 18 months
• % Clients >=age 18 working at 12 mos
• % clients not-pregnant within 24 mos
• % index children who received up-to-date immunizations at 12 months
• % of clients with a positive change in education between enrollment and 12 mos post-partum
• % clients screened for depression or anxiety (ever)
• % clients screened that were referred for mental health treatment
• Average # of referrals for sibling per multip client (not applicable for first-time parents)
• % clients who reduced smoking during pregnancy

Table 2 includes measures of NFP program impact that require additional data sources outside of data collected as part of routine NFP implementation. These additional data sources include health plans and birth certificates and other state-level data sources. Access to these additional data sources requires ethics research review, data use agreements, and/or memoranda of understanding.

<p>| Table 2. Measures for NFPx Evaluation from Health Plan or State-Level Data Sources |</p>
<table>
<thead>
<tr>
<th>Concept and Measures</th>
<th>Potential Data Source(s)</th>
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</thead>
</table>
| Reach—requires data for people who are eligible and/or are referred but not enrolled in NFP | Centralized intake and referral
| % of people referred to NFP who enroll in NFP | Prenatal risk screen
| Characteristics of those who enroll in NFP compared to those who are referred but do not enroll | Birth certificates
| Comparison of people enrolled in NFP to entire potential eligible population based on birth certificates | NFP enrollment data
| Pregnancy and Birth Impact—requires a comparison group | Diagnostic codes from Medicaid or Health Plan OR birth certificate
| Incidence of gestational HTN | |
• Incidence of severe maternal morbidity (CDC definition/codes)  
  Diagnostic codes from Medicaid or Health Plan OR birth certificate (not as complete/does not meet CDC definition)

• Incidence of pre-term birth  
  Medicaid/Health Plan OR birth certificate

• Incidence of low birth weight  
  Medicaid/Health Plan OR birth certificate

• Incidence of c-section  
  Medicaid/Health Plan OR birth certificate

Maternal Impact—requires a comparison group

• Receipt of 6-week post-partum visit  
  Medicaid/Health Plan

• Receipt of long-acting contraception  
  Medicaid/Health Plan

Index Child Impact—requires a comparison group

• Receipt of recommended preventive care—6 well child visits in first 15 months  
  Diagnostic codes from Medicaid or Health Plan

• Emergency room visits for injuries or ingestions  
  Diagnostic codes and billing data from Medicaid or Health Plan

• Hospitalizations for injuries or ingestions  
  Diagnostic codes and billing data from Medicaid or Health Plan

Additional measures and their corresponding data sources that could be considered are included in Table 3. Different communities may choose to measure things that are important to them. As described in more detail below, an Evaluation Advisory Committee can help identify outcomes that are important to the community, and we encourage flexibility and creativity for measuring outcomes beyond those described in the tables in this document.

Table 3. Additional Measures and Data Sources to Consider

<table>
<thead>
<tr>
<th>Concept and Measures</th>
<th>Data Source(s)</th>
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<tbody>
<tr>
<td>NFP Program Outcomes</td>
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<tr>
<td>• Change in pregnancy outcomes for multips, i.e. a full term birth after a previous preterm birth</td>
<td>New forms</td>
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<tr>
<td>Maternal Impact—requires a comparison group</td>
<td></td>
</tr>
<tr>
<td>Child Impact—requires a comparison group</td>
<td></td>
</tr>
<tr>
<td>• NICU length-of-stay</td>
<td>Medicaid/Health Plan data</td>
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<tr>
<td>• Child receipt of Early Intervention services when referred</td>
<td>Early Intervention data</td>
</tr>
</tbody>
</table>
School readiness

Some states have state-level K readiness evaluations

Substantiated CPS report
Family preservation, e.g., placement in kinship care and family reunification

Child welfare data

EVALUATION ADVISORY COMMITTEE

What is the purpose of an advisory committee?

An evaluation advisory committee or evaluation team is critical to providing valuable insight when constructing the evaluation plan, implementing the evaluation, and providing feedback throughout the process. In general, an advisory committee should consist of members who are knowledgeable about and understand the NFP program.

Identifying Committee Members

Committee members can include a variety of individuals, coming from diverse professional and personal backgrounds, who are knowledgeable and interested in the NFP program and outcomes. Some suggested advisory committee members could include representatives from:

<table>
<thead>
<tr>
<th>Child Welfare</th>
<th>Early Childhood Programs</th>
<th>Department Of Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Health Plan or Key Health Care Partners in The Community</td>
<td>Other Partners Working in Early Childhood</td>
<td>Academic Programs at Local Universities or Colleges</td>
</tr>
<tr>
<td>Partners From Public Health Nursing</td>
<td>NFP Partners</td>
<td>Parents/Families, Such as Current or Previous NFP Clients And Other Parenting Individuals</td>
</tr>
</tbody>
</table>

Members should be able to commit to regular participation in committee meetings (as determined by the committee) and should be compensated for the time that they contribute (see Payment Considerations below).

Recruitment Of Committee Members can be done by leveraging existing partnerships with community organizations, healthcare partners, universities, government, or social services. Parent recruitment can be done by extending invitations to NFP clients who have graduated from the program (see Appendix B for Parent Advisory Committee Recruitment Flyer). A description of the role and compensation should be provided to all participants, though those representing an organization or government entity may not require payment and instead participate in a professional capacity (see Appendix C for Parent Advisory Committee Description). Below you will find additional information regarding payments for committee members.
Committee Charter and Agreements

A Committee Charter is a guideline on why the advisory board exists and how it will operate. This is a particularly useful tool for managing projects, committees, and advisory groups. They could be beneficial for outlining the objective and purpose of the project, scope, and roles and responsibilities of personnel and committee members. Committee Charters are dynamic documents that can be continuously revised to meet the needs of the committee.

A sample Evaluation Advisory Committee Charter can be found in Appendix D.

1. A charter should include the following key elements:
   a. Purpose and Mission Statement
   b. Membership composition
   c. Roles and responsibilities of committee members
   d. Standard Committee Procedures
   e. Term of Membership

Committee Member Agreements should also be used so committee participants are aware of their rights, responsibilities, and reimbursement as part of their involvement in an Evaluation Advisory Committees. These agreements are informal contracts between the Evaluation Team and committee members that explicitly state the expectations for committee members. Committee member agreements can be included in the committee charter or in a separate document. An example of these agreements is included in the Evaluation Advisory Committee Roles and Responsibilities section of Appendix D.

Advisory Committee Members Payment Considerations
Members of the evaluation advisory committee should be compensated for the time that they spend attending meetings, reviewing materials, and participating in the dissemination of evaluation findings. Some members may not be able to accept compensation due to the role they have in their organization. A sample payment structure can be found in Appendix E. Please note that payment amounts may vary depending on a variety of factors and samples should only be used for reference.

Role of Advisory Committee in Identifying Additional Measures and Prioritizing Outcomes
Advisory committee members can be vital in identifying and prioritizing outcomes to examine in an evaluation. When identifying outcomes to examine, committee members may have knowledge of additional data sources that could be used in evaluation. Appendix F includes a summary of priority setting methods that can be used.
EVALUATION TEAM

Who should be considered as part of an evaluation team?

When constructing an evaluation team, specific roles and responsibilities should be considered. Table 4 provides a list of examples of suggested roles with their corresponding responsibilities.

<table>
<thead>
<tr>
<th>Role</th>
<th>Duties and Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead Evaluator/ Principal Investigator</td>
<td>Project lead</td>
</tr>
<tr>
<td>Data Manager</td>
<td>Manages and cleans data for analysis, merges data sets</td>
</tr>
<tr>
<td>Data Analyst</td>
<td>Supports the statistician</td>
</tr>
<tr>
<td>Statistician</td>
<td>Conducts statistical analyses</td>
</tr>
<tr>
<td>Project Coordinator</td>
<td>Manages IRB, data sharing agreements, coordinates team meetings, prepares meeting agendas and minutes, maintains project charters and relevant documents, coordinates advisory committee meetings, maintains budgets and coordinates payments to members</td>
</tr>
<tr>
<td>Mixed Methods/Qualitative Analyst</td>
<td>Conducts surveys, qualitative interviews, and focus groups (not required, but nice to have)</td>
</tr>
<tr>
<td>Consultants</td>
<td>PRC consultant is required if evaluation team is outside of PRC or NSO for NFP and Child First, other methods consultants can be considered as needed.</td>
</tr>
</tbody>
</table>

REGULATORY CONSIDERATIONS

What should be considered in terms of regulatory compliance?

Regulatory compliance is the adherence to an organization’s rules and regulations, sometimes regulated by local, state, or federal agencies, and are typically designed to keep people safe. Depending on the network partner, you may need to obtain 1) approvals from ethics review boards, typically called Institutional Review Boards (IRB), approvals from compliance officers, and 2) Data Use Agreements (DUA), also called, Data Sharing Agreements. Some agencies may have other requirements in addition to or instead of IRBs and DUAs, such as approvals from compliance officers or memorandums of understanding (MOUs). Requirements may be different for each organization. These agreements are meant to ensure that no harm is being done to clients, patients and/or staff engaged in research or evaluation and to maintain confidentiality.

Institutional Review Board (IRB)

Institutional Review Boards (IRBs) are a committee of professionals that provide scientific and ethical review to proposed research studies and evaluations. Organizations such as major hospital systems or public health departments may have their own IRB offices, while some smaller agencies may outsource their approvals to neighboring universities, larger hospitals, or government agencies. Organizational leadership should be able to help identify the appropriate representatives for their IRB.
**Research or quality improvement?**

The IRB representative will help in determining if an evaluation is considered “research”, “non-human subjects research”, “quality improvement”, or “program evaluation”. These categories vary by IRBs but generally are determined by the type of data collected, who participates, the level of risk to participants, and/or whether you intend to share findings with broader audiences. A determination is made by the reviewers of IRB on which category the evaluation falls under and has implications for how findings are shared. An example of an IRB determination checklist can be found in Appendix G.

**Tip:** IRBs usually have a checklist on their website to determine. These checklists are helpful in putting together an IRB submission or determining which category the evaluation falls under (see Appendix 6, COMIRB Comparison of The Characteristics of Research, Quality Improvement, and Program Evaluation Activities).

---

**Data Use Agreements**

Data use agreements (DUAs) are contractual agreements between two or more parties outlining the terms of an exchange of data. DUAs are usually required any time there is an exchange of patient, client, or participant data and are meant to prevent any breach in confidentiality. DUAs outline the terms of the exchange, how the data will be protected, and any expectations from the providers and receivers of the data. Organizations may have specific steps in developing and signing off on a DUA, such as requiring signatures from organizational leadership. IRBs may also require that a DUA be in place as part of their approval process. Each party involved in a data exchange should confirm requirements with their organizational contacts, such as a compliance officer. For example, obtaining birth certificate data may require both a DUA and an IRB approval from a local or state government agency before data can be exchanged. Table 5 lists examples of what may be required as part of a DUA. An example of a DUA is listed in Appendix H. A Memorandum of Understand (MOU) is an agreement or informal contract between two or more parties jointly participating in research activities that outlines the responsibilities of each party. Though not a legally binding contract, MOUs can be useful alongside DUAs to confirm all parties understand their commitments and ensure that their obligations are met to successfully conduct an evaluation.

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**Tip:** Several online resources are available to learn more about IRB. The American Psychological Association’s website provides more information about what an IRB is and how they function to protect study participants.

- APA IRB FAQ
### Table 5. Elements of a DUA

<table>
<thead>
<tr>
<th>Element</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limitations on use</td>
<td>Explanation of how the data will be used</td>
</tr>
<tr>
<td>Use of Sensitive Information</td>
<td>Explain whether the requested data set includes HIPAA-protected information, such as being de-identified data set, limited data sets, or containing Protected Health Information (PHI), such as names, geographic locations, phone numbers, social security numbers, medical records numbers, or any other unique identifying number, characteristics, or codes</td>
</tr>
<tr>
<td>Safeguards</td>
<td>Protections in place to safeguard data, such as being stored on password protected devices with access only to authorized personnel</td>
</tr>
<tr>
<td>Risks and Protections</td>
<td>Explanation of possible risks with receipt of data, such as access to unauthorized individuals, and steps to protect against any intended risks</td>
</tr>
<tr>
<td>Authorized access</td>
<td>List of individuals with access to data and what their role is</td>
</tr>
<tr>
<td>Data transfer</td>
<td>How the data will be transferred between organizations, such as the use of secure file transfer protocol (SFTP). Most IT departments can help with creating a SFTP for file exchanges</td>
</tr>
<tr>
<td>Publication</td>
<td>Explanation of how the data will be shared to internal or public audiences</td>
</tr>
</tbody>
</table>

### DISSEMINATION

An important aspect of conducting an evaluation is creating products for dissemination and identifying the appropriate partners with whom to share learnings. Disseminating findings from an evaluation is helpful for soliciting guidance and feedback from partners (such as NSO), receiving appropriate approvals from leadership, and/or documenting processes.

#### Dissemination Audiences

When considering the appropriate audiences for dissemination, it is important to consider partners who would benefit from the learnings of the evaluation. Mandatory audiences include: 1) NFP NSO, 2) local NFP teams, 3) invested partners or parties in the community, and 4) clients and families. Identifying additional audiences can be done with the support of the Advisory Committee.

#### Dissemination Products and Methods of Sharing

In constructing products for dissemination, the team should identify which product would be most appropriate for the intended audience. For example, academic audiences require scientific rigor in their product, and therefore an article for peer review to an academic journal would be most appropriate. Meanwhile, families and community partners tend to prefer products that highlight the main take-aways or

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**Tip:** One meeting should be held with the Evaluation Advisory Committee as a brainstorming session for identifying potential audiences and dissemination products.

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**Tip:** Evaluation Advisory Committee members may be helpful in providing their expertise regarding data sharing requirements.
learnings from the evaluation, and therefore, a one-page information sheet or an infographic may be an appropriate product.

Any evaluation funded by the NSO for NFP and Child First requires a standardized report to be completed at the conclusion of the funding period. The report should include the following components:

1. Objectives/specific evaluation questions
2. Summary of evaluation advisory committee membership and input (if applicable)
3. Data sources and measures
4. Methods
5. Results
6. Summary of implications

We recommend that evaluation teams should track their dissemination products in any format. See Appendix I for an example of a dissemination tracker. Table 6 includes other types of dissemination products and methods of sharing.

| Table 6. Examples of Dissemination Products, Methods of Dissemination, & Audiences |
|-------------------------------|--------------------------------------------------|
| **Product** | **Sharing Method & Audience** |
| Posters | Emails of PDF posters to stakeholders and relevant audiences, poster presentations in academic meetings and forums, local public health or nursing meetings |
| One-Page Information Sheet | Email of PDF document to stakeholders and relevant audiences, families |
| Infographics | Email of PDF document to stakeholders and relevant audiences, community audiences, families |
| Videos | YouTube, public or community audiences, families |
| Presentations | Local or national academic meetings or forums, local or national public health or nursing meetings, local colleges or universities, stakeholder team meetings, community audiences, PRC, NSO |
| Publications | Academic peer-reviewed journals with PRC consultation |

Tip: Inviting Evaluation Advisory Committee members to participate in brainstorming, participation, and presentation of dissemination products is a great way to involve them in the process. The research team at the PRC has previously invited committee members to co-author peer-reviewed publications and presentation findings to local and national Maternal Child Health conferences.
LIST OF TABLES
1. Table 1. Measures for NFPx Evaluation from NFP Implementation Data
2. Table 2. Measures for NFPx Evaluation from Health Plan or State-Level Data Sources
3. Table 3. Additional Measures and Data Sources to Consider
4. Table 4. Roles and Responsibilities of Evaluation Team members
5. Table 5. Elements of a DUA
6. Table 6. Examples of Dissemination Products, Methods of Dissemination, & Audiences

LIST OF APPENDICES
A. NFP Logic Model
B. Parent Advisory Committee Recruitment Flyer
C. Sample Parent Advisory Committee Description
D. Sample Committee Charter
E. Summary of Priority Setting Methods
F. COMIRB Comparison of The Characteristics of Research, Quality Improvement, and Program Evaluation Activities
G. Example of Data Use Agreement
H. Example of Dissemination Tracker
APPENDIX A. NFP LOGIC MODEL
An interactive version of the logic model is located here: https://view.genial.ly/619bd13a09ac0e0d8c67b44c

NURSE-FAMILY PARTNERSHIP LOGIC MODEL

Inputs
- Community Advisory Board
- Collaboration with other community service providers
- Outreach to Nurse-Family Partnership referral partners
- Conduct in-person and telehealth visits from early in pregnancy through child age 2 years tailoring intervention using nursing process and informed by the pregnant clients' centered principles

Activities
- Nursing Workforce Development and Ongoing Support
  - Reflective Practice
  - Nursing Practice Management
  - Assessment of quantitative and qualitative data for continuous quality improvement

Nurse-Client Interaction
- Improve pregnancy outcomes by monitoring pregnant client's physical and mental health, promoting use of prenatal care, addressing social determinants of health, and developing client understanding of topics in the following domains: Personal Health, Life Course Development, Maternal Role, and Health & Human Services.
- Improve child health and development by monitoring child health and development, promoting use of well-child care, addressing social determinants of health, promoting child safety and sensitive parent-child interactions, and developing client understanding of topics in the following domains: Environmental Health, Maternal Role: Friends & Family and Health & Human Services.
- Improve life course outcomes by promoting use of preventive care, supporting family planning and achievement of realistic goals for education and work, assessing and addressing parental experiences of trauma and associated outcomes, and developing client understanding of a range of topics in the following domains: Personal Health, Life Course Development: Friends & Family, and Health & Human Services.

Outputs
- Enrollment of population most likely to benefit
- Program fidelity
- Retention of empathetic and prepared nursing workforce
- Client engagement and retention
- Client satisfaction
- Client knowledge, self-efficacy and resources
- Child lives in a safe environment where secure attachment can occur

Outcomes
- Improve pregnancy outcomes
- Improve child health and development
- Improve the health and economic self-sufficiency of the family

Contextual Factors
- Systemic oppression
- Community perception
- Federal/state/local policy
- Availability of other community services
- Funding sources
- Environmental/national/global events
APPENDIX B. PARENT ADVISORY COMMITTEE RECRUITMENT FLYER

We need your help

We are recruiting clients who are currently in Nurse Family Partnership (NFP) or were previously in NFP as well as other caregivers to participate in the Parent Engagement Committee for the Ohio Expanded Eligibility Initiative Evaluation.

What does participating mean? You would attend monthly meetings beginning in June, at a time that will be determined by the group, to provide your thoughts and input on a research project meant to determine the effectiveness of NFP on clients who have had a previous live birth. A few examples of what you might help with are giving input on forms that are completed during home visits, interview questions for participants, and how the overall research process affects clients.

Who is eligible? A parent is anyone who is the primary caregiver for a child. Primary caregivers can include a biological, adoptive, or foster mother or father, or relatives, such as grandparents, aunts, and uncles. Those eligible can include individuals who have been in NFP before, currently enrolled or individuals who have never been in NFP before.

What is the time commitment? The Ohio Parent Advisory Committee will meet monthly for approximately one hour. The meeting is led by the University of Colorado virtually via Zoom meeting. Meeting materials will be sent to you by email before the meeting each month. Meetings will begin in June of 2022 and continue until June of 2027. You do not need to participate for all 5 years unless you choose to do so. At the end of each year, we will ask if you would like to continue to participate.

How will I be compensated? Each parent will receive a monthly stipend of up to $110, which includes a $25/hour honorarium, $25/hour childcare support, and $10/month data internet support. Additional technological support in the form of a tablet will be provided if needed. You will receive $245 for the initial training that we will provide.

What are the minimum expectations? Parents are expected to attend a minimum of six meetings per year and are encouraged to attend as many meetings as possible. Parents will be paid as indicated above for each meeting they attend and participate in. You would not be paid for meetings that you cannot attend.

Will I receive training? The University of Colorado will offer a 1 hour-long training for parent representatives to explain the NFP Expanded Eligibility Initiative, basic evaluation and research concepts, their rights and responsibilities as a parent participant in the evaluation and how the Advisory Committee will function. Additional online training will be offered, and participants will be paid for their time to complete all training as noted above.

Questions? If you are interested or have further questions about this opportunity, please email Wendy Mazzuca, RN at wendy.mazzuca@cuanschutz.edu
The University of Colorado (CU) Prevention Research Center (PRC) will:

- Set a rate for parent honorarium of $25/hour x 2 hours = $50/month
- Set a rate for childcare reimbursement of $25/hour x 2 hours = $50/month
- Set a rate for travel/travel-related expenses of mileage reimbursement at CU rate of 52 cents per mile OR gas cards of $25? per travel event plus per diem costs.
- Provide technology support such as providing tablets (~$600 each x tablets. $xxx total) and covering up to 30 GB internet per year/data costs at $120 per parent x 8 parents = $960 total annually. Data support for the initial onboarding will be $20 per parent.
- Be transparent with parents and explain the process for reimbursement. The steps for this process are as follows:
  1. Wendy creates scope of work.
  2. Parents must share their full name, email, phone number and complete mailing address with Wendy Mazzuca. Wendy will share this information with Marlene Davis at the PRC
  3. Marlene will submit paperwork for individual accounts to be set up with the University for payment.
  4. Each parent will receive an email from the University (CUSupplier@cu.edu) with instructions for setting up an account for payment. The information necessary for this form includes:
    A. First and Last Name
    B. Email Address
    C. Phone Number
  D. Social security number or tax id
  5. Once the account is set up, Wendy will notify Marlene of parent participants who attend each meeting and training. Marlene completes the request for payment and Wendy signs the request. If Wendy is not available to sign, Ben or Natalie will sign and if they are not available, Mandy will sign.
  6. Payment occurs within 30 Days from the Invoice Date
  7. Remind parent participants that if they receive $600 or more in payments, they will be required to report this for tax purposes.

Parent Leadership Option for Participation
Graduating, graduated clients or other caregivers actively participate in the NFP Expanded Eligibility Initiative (NFPx) Ohio Parent Advisory Committee. (e.g., NFPx Ohio Parent Advisory Committee)

**Involvement:** The Ohio Parent Advisory Committee meets monthly for approximately one hour. The meeting is led by the PRC virtually via Zoom meeting. Meeting materials will be provided in advance.

**Time Commitment:** About 2 hours per month for meeting attendance and review of materials provided. Participants must agree to attend at least 6 meetings per year.

**Compensation:** Each parent will receive a monthly stipend of $100 plus $10 for internet support for a total of $110 monthly X 8 parents. Each participant will also receive payment for attending approximately 3 hours of onboarding education. Each parent will receive $245 for the initial onboarding with covers stipend and internet support. Parent participants will have the option to renew annually for up to 72 months (about 5 years). To see the monthly, annual and 5-year cost for each participant, see https://olucdenver.sharepoint.com/:x:/r/sites/NFPMultipsRCT/Shared%20Documents/Parent-Family%20Engagement/Budget%20for%20Parent%20Advisory%20Committee%20Ohio.xlsx?d=woc4b6eqc623d4305b04e4c0110b426fc&csf=1&web=1&e=3gHce2

**Recruitment:** PRC will recruit up to 8 parents for the Advisory Committee, ideally 4 from the Dayton service area and 4 from the Columbus service area. PRC will ask for recommendations from the Dayton and Columbus NFP network partners. PRC will also ask other stakeholders for suggestions (To be identified)

**Training:** PRC will lead a 1 hour-long training for up to 8 parents regarding the current NFP Expanded Eligibility Initiative, basic evaluation and research concepts, their rights and responsibilities as a parent participant, Advisory Committee functioning, etc. Fyreworks online training will also be offered. FYRE stands for Family/Youth/Researcher Education. Fyreworks is designed to help researchers, teens, and families work together to answer questions about children’s health. https://fyreworkstraining.com/
APPENDIX D. SAMPLE EVALUATION ADVISORY COMMITTEE CHARTER

Florida NFP Expanded Eligibility Initiative
Evaluation Advisory Committee Charter

**Purpose.** The purpose of this charter is to describe the composition, roles, and responsibilities of the Evaluation Advisory Committee for the Florida Nurse-Family Partnership (NFP) Expanded Eligibility Initiative. This charter is intended to be an evolving, living document that will be updated as needed based on input from members of the evaluation team or the Evaluation Advisory Committee.

I. **Project Overview.** The broad, long-term objective of the Florida NFP Expanded Eligibility Initiative Evaluation is to determine: 1) if expanding eligibility for NFP to include women who are referred after 28 weeks gestation (late registrants) and women with previous live births (multiparous women) allows NFP to reach more families with risks for poor health and life-course outcomes and 2) if NFP has a positive impact among late registrants and multiparous women and their children. This evaluation is funded by the NFP National Service Office (NSO) and conducted by the Prevention Research Center for Family and Child Health (PRC) at the University of Colorado. The Principal Investigators are Mandy Allison and Venice Williams. The primary aims of the evaluation we are currently undertaking are:
   - Describe the characteristics of pregnant women referred to NFP after 28 weeks gestation, reasons for 'late' referral, women’s rates of enrollment in NFP, and women’s reasons for not enrolling.
   - Determine how women enrolled in NFP after 28 weeks gestation may differ from women enrolled prior to 28 weeks.
   - Explore use of existing data sources for measuring program impact.

II. **Evaluation Advisory Committee Composition.** The committee consists of individuals representing agencies who are invested in maternal and child health; NFP and NSO staff; and individuals that provide a ‘family voice’, including former NFP clients and parents of young children in Florida. The committee will include representatives from each of the following groups:
   - Parents/clients
   - Florida Department of Health
   - Florida Department of Children and Families (child welfare)
   - Florida Association of Healthy Start Coalitions
   - Florida Maternal Infant and Early Childhood Home Visiting Initiative (MIECHV)
   - Florida Perinatal Quality Collaborative – no current representative
   - Florida Department of Education – no current representative
   - Agency for Health Care Administration (Florida Medicaid) – no current representative
   - Nurse home visitors – no current representative
   - NFP National Service Office

III. **Evaluation Advisory Committee Roles and Responsibilities.** Over the course of the project, committee members will be asked to actively engage in committee activities and provide input on defining outcomes of importance, identifying data sources that could be used to measure those shared outcomes, developing data use agreements, providing feedback on evaluation findings, and assisting with dissemination of evaluation findings.
The responsibility of all members of the evaluation team is to ensure that principles of stakeholder engagement (reciprocity, respect, co-learning, transparency, honesty, and trust) are upheld. Evaluation Advisory Committee members will serve as project collaborators providing input on key decisions and advice on the course and conduct of the evaluation. Their input and contributions will be recognized.

All members of the evaluation team and Evaluation Advisory Committee will agree to the following Agreements:

- We agree to clearly communicate the purpose of each meeting with agendas emailed at least one week ahead of time and agreed upon actions after each meeting.
- We agree to start and end meetings on time.
- We agree to allot time at the beginning of meetings to get to know one another and sharing experiences.
- We agree to take care of our needs during meetings as needed.
- We agree to actively participate in meetings by asking questions, sharing perspectives, and acknowledging others' contributions. Actively participate means to...
  - Ask questions for clarification.
  - Respect one another and alternative perspectives through practicing humility.
  - Listen to one another, where each person gets a turn to speak, and others acknowledge what they have heard.
- We agree to confidentiality and anonymity when needed of what is shared in meetings.
- We agree to stay focused on shared goals and tasks to create solutions, with flexibility to pivot due to new priorities.

IV. **Project Funding.** The project is funded by the NFP National Service Office through December 2021, with a no cost extension through March 2022. The evaluation team is working to secure additional funding to support evaluation of the impact of the NFP Expanded Eligibility Initiative and continued engagement of the Evaluation Advisory Committee through December 2024.

V. **Evaluation Advisory Committee Participation and Compensation.** Committee members will participate in evaluation activities based on their interests and availability, as well as their knowledge, experience, and perspective. They will be provided with appropriate information in a timely manner to maintain their meaningful engagement and are expected to collaborate in decision-making at critical phases and help to resolve challenges that arise.

a. **Duration.** The period of performance for the current project is January 2020 through March 2022. We are working to obtain funding through December 2024.

b. **Compensation and expenses.** All committee members will be compensated $50 per hour for each meeting. Parent leaders will receive an additional $50 per hour for meeting preparation and $10 per month to cover data usage to participate in meetings.

c. **Estimated number and frequency of project meetings/activities:**
   - Monthly meetings via Zoom video conference
   - Review of meeting materials
   - Intermittent e-mails requiring response.
   - Ad hoc meetings and workgroups as members' time and interest align.
APPENDIX E. SAMPLE EVALUATION BUDGET AND COSTS

Below are samples budgets with estimated annual costs related to conducting an evaluation (as of 2023). Costs will vary depending on a variety of factors including state, local, and organizational requirements and these should only be used for reference.

### Sample Evaluation Costs

#### PERSONNEL

<table>
<thead>
<tr>
<th>Role</th>
<th>Annual Salary Estimate including benefits</th>
<th>Time Required Annually</th>
<th>Estimated Annual Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead Evaluator/ Principal Investigator</td>
<td>$200,000.00</td>
<td>10% FTE (about 4 hours/week)</td>
<td>$20,000.00</td>
</tr>
<tr>
<td>Project Coordinator</td>
<td>$105,000.00</td>
<td>20% FTE (about 8 hours/week)</td>
<td>$21,000.00</td>
</tr>
<tr>
<td>Statistician</td>
<td>$166,000.00</td>
<td>10% FTE (about 4 hours/week)</td>
<td>$16,600.00</td>
</tr>
<tr>
<td>Data Analyst (support to Statistician for data matching and cleaning)</td>
<td>$120,000.00</td>
<td>20% FTE (about 8 hours/week)</td>
<td>$24,000.00</td>
</tr>
<tr>
<td><strong>Total Personnel Annually</strong></td>
<td></td>
<td></td>
<td><strong>$81,600.00</strong></td>
</tr>
</tbody>
</table>

#### Additional Costs

- **Research Review costs (for example, Florida Department of Health Charges for research review to obtain birth certificates)**
  - Annual review $200.00

- **Data pull from health plan (this is based on our recent QED study; pays for analyst at health plan)**
  - Per one time data pull $75,000.00

- **Data pull from other state-based data source**
  - Per one time data pull $75,000.00

**Total Additional Costs/Project** $150,200.00

(Notes that the cost of data pulls can be very variable, and that more than one data pull could be needed during a project)

### Sample Total Estimate

- **TOTAL ANNUAL DIRECT COST ESTIMATE** $231,800.00
- **INDIRECT COSTS (10%)** $23,180.00
- **TOTAL ANNUAL COSTS** $254,980.00
### Sample Evaluation Advisory Committee Costs

<table>
<thead>
<tr>
<th>Description</th>
<th>Notes</th>
<th>Unit cost</th>
<th>Monthly cost</th>
<th>Annual cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Training</td>
<td>$25/hour for time and $25/hour for child care and other costs; estimated 4 hours of training</td>
<td>$200</td>
<td>n/a</td>
<td>$200</td>
</tr>
<tr>
<td>Hourly Compensation</td>
<td>$25/hour for time and $25/hour for child care and other costs at board member’s discretion; assuming one meeting of one hour per month with one hour preparation/review time</td>
<td>$50</td>
<td>$100</td>
<td>$1,200</td>
</tr>
<tr>
<td>Internet Stipend</td>
<td>Based on 2 GB data per meeting; assuming one meeting per month</td>
<td>$10</td>
<td>$10</td>
<td>$120</td>
</tr>
<tr>
<td>Tablet (for accessing online meetings, e-mail, document review)</td>
<td>Tablet provided if needed by Committee Member; typically must be returned at end of project if grant-funded</td>
<td>$600</td>
<td>n/a</td>
<td>$600</td>
</tr>
<tr>
<td>Food for meetings</td>
<td>If in person; food and drink per person; assuming one meeting per month</td>
<td>$15</td>
<td>$15</td>
<td>$180</td>
</tr>
<tr>
<td>Travel</td>
<td>Assuming local travel; consider adding additional $2000/national meeting if Committee Member may present at national meeting</td>
<td>$20</td>
<td>$20</td>
<td>$240</td>
</tr>
<tr>
<td>Appreciation gift</td>
<td>Annual gift to show appreciation for contributions (ideas include gift box with food or succulent plant)</td>
<td>$30</td>
<td>n/a</td>
<td>$30</td>
</tr>
</tbody>
</table>

**TOTAL ANNUAL COST PER COMMITTEE MEMBER** $2,970

(Note that inclusion of Committee Members who speak different languages may require additional funding to support interpretation.)
APPENDIX F. SUMMARY OF PRIORITY SETTING METHODS
This Summary was written by Venice Williams, PhD, MPH

Priority Setting Methods

1. Dot Voting: Give each member a certain number of "votes" using colored adhesive dots. The rule of thumb is each person gets a number of dots equal to 1/4 the number of items. Sorting and combining like ideas can be postponed until after voting, so time is not spent discussing low priority items. Re-voting can be done several times as ideas are sorted and clarified. Or, you invest time initial to clarifying and sorting the ideas, and vote later.

   **Advantage:** Highly visual and simple.

   **Disadvantages:** Takes up majority opinion, and may alienate a minority group that could damage future group interaction.

2. Weighted Voting: Points are assigned to individual rankings. For example, if the members is to rank the top five choices, 5 votes would be given to the first choice, 4 votes to the second, 3 votes to the third and so on. All individual scores for each item are then tallied and items can be ranked by total group score.

   **Advantage:** More accurate than straight voting in measuring member preferences. Weighted voting can also be conducted and tallied between meetings, so that group time is not spent on this task.

   **Disadvantage:** Doesn’t explicitly involve discussions.

3. Consensus Decision: This is the most time-consuming method, but important where implementation of the decision will require the acceptance and commitment of all members. Ground rules for building consensus are:

   - Solicit all members in discussion.
   - Avoid arguments.
   - State all concerns (especially minority views).
   - Listen to all concerns - Ask clarifying questions, paraphrase concerns.
   - List pros and cons of each position on chart.
   - If two positions conflict, look for a third which will reconcile differences.
   - Get expression of support from all members before making decisions final.

   **Advantage:** Incorporates discussion, ensuring clarity and resolving concerns or questions. More likely for minority voices to be heard.

   **Disadvantage:** Time consuming, resource intensive.
Specific consensus building method: Delphi (involves 1-on-1 interviews) and Modified Delphi Method

1. Phase 1 – open-ended questionnaire with qualitative assessment (we’ve done this already). Once all the questionnaires were received, we compiled the responses and reviewed the responses to generate a list of proposed outcomes. The list of proposed outcomes was shared and discussed with members.

2. Phase 2 – ranking evaluation through close-ended questionnaire. Ask each member to rank the outcomes 5-point Likert scale for a range of criteria, i.e. significance, innovation, relevance, feasibility. Using predetermined consensus thresholds (see below), we will decide which research questions will be brought forward to the consensus meeting for review. Research questions that meet the inclusion or non-consensus thresholds will progress to phase III for review. Research questions that meet the exclusion consensus threshold will not be brought forward for review.

Consensus thresholds
Inclusion >75% of respondents provide a positive result (four or five) on the Likert scale for all criteria.
Exclusion >75% of respondents provide a negative result (one or two) on the Likert scale for all criteria.
Non-consensus When the proposed priority research question has met neither the inclusion nor exclusion consensus thresholds.

3. Phase 3 – in person/virtual consensus meeting. A semi-structured agenda will be provided to minimize time constraints, and to ensure that all individual participants are allowed a period of uninterrupted time to voice their opinions for each outcome discussed. Each proposed outcome will be individually discussed by the group, thereby providing an opportunity for members to reconsider their initial ratings in light of other members' views. Following these discussions, the members will be asked to anonymously assign a score from 1 to 9 for each outcome (see below)

Phase 3 scoring scale

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Should not be studied</td>
<td>Lowest priority</td>
<td>Very low priority</td>
<td>Low priority</td>
<td>Medium priority</td>
<td>Slightly high priority</td>
<td>Moderately high priority</td>
<td>High priority</td>
<td>Highest priority</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Once the scores have been compiled, outcomes meeting one of the following predetermined criteria will be brought forward for final ranking:

- 100% of respondents scored the outcome as either a seven, eight or nine; or
- At least 10% of respondents scored the outcome as a nine.

If none of the outcomes meet these criteria, the top 10 scoring outcomes will be brought forward for final ranking.

These highest ranked outcomes will once again be discussed by the group. The members will then be asked to rank their top XX (5?) outcomes.

Prevention Research Center for Family & Child Health
NFPx Evaluation Guide
JUNE 2023
APPENDIX G. COMIRB COMPARISON OF THE CHARACTERISTICS OF RESEARCH, QUALITY IMPROVEMENT, AND PROGRAM EVALUATION ACTIVITIES

University of Colorado
Denver | Janssatz Medical Campus
Colorado Multiple Institutional Review Board (COMIRB)

COMPARISON OF THE CHARACTERISTICS OF RESEARCH, QUALITY IMPROVEMENT, AND PROGRAM EVALUATION ACTIVITIES

Use the chart below if you have questions whether your project should be considered a Research, Quality Improvement activity, or Program Evaluation. If your project satisfies any of the conditions in the Research column, it should be submitted to COMIRB for review prior to implementation. COMIRB cannot provide retrospective approval after your research project commences. If you would like assistance in evaluating your project, contact COMIRB@ucdenver.edu. Additional information on what constitutes human subjects research is available here.

<table>
<thead>
<tr>
<th>RESEARCH</th>
<th>QUALITY IMPROVEMENT</th>
<th>PROGRAM EVALUATION</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FUNDING</strong></td>
<td>Funded by a research grant, award, or contract, or unfunded. If funded as research, all activities supported by the funding must be considered research.</td>
<td>Typically unfunded. May be funded by awards specifically for quality improvement; confirm IRB requirements, if any, with funder.</td>
<td>Often funded by a grant, award, or contract for the purpose of developing or improving a service program. If the funding specifically requires evaluation of the program, the evaluation component may be considered research; confirm with funder. May also be unfunded.</td>
</tr>
<tr>
<td><strong>INTENT</strong></td>
<td>To develop or contribute to generalizable knowledge.</td>
<td>To improve a specific business practice. In a hospital, this may include improving the quality and/or consistency of care in a specific unit or the entire hospital.</td>
<td>To evaluate the effectiveness of a specific program in meeting the intended goals of the program.</td>
</tr>
<tr>
<td><strong>DESIGN</strong></td>
<td>The methodologies for conducting Research, Quality Improvement, and Program Evaluation projects are similar and are all systematic. Differential aspects are provided below as a guideline.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PUBLICATION</strong></td>
<td>Publication alone does not define an activity as research. Differential aspects are provided below as a guideline.</td>
<td>Project results will be disseminated informally (e.g., within the institution, department, or practice) soon after project completion to determine if the change improved delivery of care or another business practice, and to inform business decisions and operations. If methodology or results are interesting, results may be published. Publication must note that the project was carried out as CQI, and did not meet the definition of research per DHHS regulations. The project may not be described as research.</td>
<td>Intent to publish or present results generally presumed at the onset of the project. Evaluation results will be provided to the program owner and stakeholders, and to the funder. Unless the evaluation was carried out as research with IRB approval, any publication should note that the project was carried out as Program Evaluation, and did not meet the definition of research per DHHS regulations. The project may not be described as research.</td>
</tr>
<tr>
<td><strong>Mandate or Endorsement</strong></td>
<td>Activities conducted to fulfill academic obligations to conduct and publish research, to complete a research project as graduation requirements, or as defined by a funding award.</td>
<td>Project is endorsed or mandated by the institution or clinic as part of CQI operations. Project may be mandated by educational requirements (e.g., requirement to design and complete a CQI project). To document endorsement, COMIRB may ask for a letter of support from the head of the involved clinic or department, acknowledging the project as CQI.</td>
<td>Activity endorsed or mandated by program owner and funder.</td>
</tr>
<tr>
<td><strong>IMPACT</strong></td>
<td>Findings of the study are not expected to immediately and directly affect institutional or programmatic practice.</td>
<td>Findings of the project are expected to immediately and directly improve an institutional practice.</td>
<td>Findings of the evaluation are expected to immediately and directly demonstrate the success and/or shortcomings of the program.</td>
</tr>
<tr>
<td><strong>POPULATION</strong></td>
<td>Carefully defined through individual inclusion and exclusion criteria in the research protocol. Participation is voluntary.</td>
<td>Generally includes all participants of the program in which improvements are being implemented (e.g., all patients and providers in a specific practice). Participation may or may not be voluntary.</td>
<td>Generally includes all stakeholders of the program (e.g., all program clients, staff, and leaders). Participation in the evaluation may be voluntary for some but mandatory for others.</td>
</tr>
</tbody>
</table>

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This table may also be used as a tool to conduct and document a self-evaluation of the project. In that case, the project leader should indicate above where the project fits on each row. If any of the boxes in the research column are checked then the project must be submitted to COMIRB for review and approval. If the tool indicates that this is quality improvement (QI) or program evaluation (PE) only, complete the rest of this form, obtain any necessary signatures, and keep this in your project records.

Acknowledgement
I have appropriately used this tool to evaluate my project entitled: _______________________

By my signature below, I affirm that this project meets the definition of:

Circle the appropriate term: Quality Improvement Program Evaluation

I certify that I will conduct my project in compliance with all federal, state and local laws and policies. If during the course of the project it is amended in such a way as to meet the definition of human subject research under 45 CFR 46 or 21 CFR 56 then I understand that I must submit to COMIRB for review prior to continuing the project.

Signature of Project Leader Date Signature of Mentor (if applicable) Date

I have reviewed this project proposal and determine that meets the criteria for quality improvement or program evaluation as outlined above and is an appropriate project to be conducted within this Division/Department/School:

Signature of Appropriate Authority (or their designee) Title Position Date

QA Program Evaluation Research Tool CF-195, Effective 6-5-20
APPENDIX H. SAMPLE DATA USE AGREEMENT

Note: These will vary in content depending on the requirements specified by participating entities.

Bureau of Family Health Services
Prenatal and Infant Risk Screen and Healthy Start Services
Data Use Agreement

Background and Purpose

The Bureau of Family Health Services at the Florida Department of Health (DOH) may release prenatal and infant risk screen and Healthy Start Services data to entities with an approved Bureau of Family Health Services Prenatal and Infant Risk Screen and Healthy Start Services Data Use Agreement (Data Use Agreement) for purposes authorized by section 382.025, Florida Statutes. All persons with data access must sign the Data Use Agreement outlining the terms and conditions for using prenatal and infant risk screen data. A data use agreement is specific to the individual project and all projects require annual review.

The Bureau of Family Health Services at the DOH conducts a detailed review of every application for access to prenatal and infant risk screen and Healthy Start Services data and makes a determination on a case by case basis. Requests for confidential data will be granted only if the project meets the statutory criteria, the criteria above, and the project cannot be reasonably completed with de-identified information.

Approved applicants are held to the highest ethical standards and must agree to the stipulations detailed in the Data Use Agreement.

Return application to:
Florida Department of Health
Kelly Rogers
Maternal and Child Health Section Program Administrator
Division of Community Health Promotion
Bureau of Family Health Services
Florida Department of Health
4052 Bald Cypress Way, Bin A-13
Tallahassee, FL 32399-1723
Bureau of Family Health Services
Prenatal and Infant Risk Screen and Healthy Start
Services Data Use Agreement

Date: 6/17/2022

I. Project Director Information
Name of Requestor: Dr. Mandy Allison
Title: Pediatrician, Associate Professor in the Department of Pediatrics at the University of Colorado, and Co-Director of the Prevention Research Center for Family and Child Health
Requestor’s Organization/Agency: University of Colorado School of Medicine, Department of Pediatrics
Mailing Address: University of Colorado School of Medicine, 1890 North Revere Court, Mailstop F443, Aurora, CO 80045
Telephone Number: 303.724.7450
Fax Number: n/a
Contact Person (if different from Project Director): Dr. Venice Williams
Contact Person’s Telephone Number: 303.724.3646
Contact Person’s E-Mail Address: venice.williams@cuanschutz.edu

Does this application update a previous Data Use Agreement?  ☒ Yes  ☐ No

II. Project Summary
Project Title: Evaluating Late Enrollment in Florida’s Nurse-Family Partnership

Purpose of the Project:
Selected Florida Nurse-Family Partnership (NFP) sites are participating in a pilot project for expanded enrollment. In particular, these NFP sites can enroll first-time low-income mothers after 28 weeks estimated gestational age (EGA), as well as women with previous live births (multiporous or multiplo). This evaluation has two components: i. Evaluating late enrollment and aims to describe 1) the characteristics of pregnant women referred to NFP after 28 weeks EGA, 2) reasons for ‘late’ referral, 3) women’s rates of enrollment in NFP, and 4) women’s reasons for not enrolling; ii. Evaluating preliminary impact of expanded enrollment for late enrollees and multiplo.

Intended Use of the Data: This data will help us describe the characteristics of pregnant women referred to Nurse-Family Partnership (NFP) after 28 weeks EGA, and these women’s rates of enrollment into the home-visiting program. We will assess preliminary impact of NFP for late enrollees and multiplos. Data from the Florida Prenatal Risk Screen will be matched to other datasets to accomplish this aim.

Will the study results be used for publication and/or presentation?  ☒ Yes  ☐ No
If yes, then please provide publication and presentation information. Study results will be included for possible presentation at national public health or health services research conferences like the American Public Health Association Annual Meeting as well as internal presentations with the NFP National Service Office (NSO). In terms of publication, the study results will be result in a report that will be shared with the NSO and will be used to inform decisions regarding late registrants. The findings will also result in at least one manuscript to be published in the peer-reviewed health services research literature.

The Project Director is the Data Custodian for this project; however, there are some circumstances which may allow another person to be the Data Custodian.

Are you the Data Custodian for this project?  □ Yes  □ No [The Data Custodian is responsible for observance of all conditions of use and for establishment and maintenance of physical and electronic security arrangements to prevent unauthorized use. This individual must have the legal authority to keep the information confidential and maintain confidentiality. If the custodian is changed, the organization must promptly notify the Bureau of Family Health Services Maternal and Child Health Section]

If no, please indicate the name of the Data Custodian and their relationship to the requestor’s organization: Michael Knadtson, MS - Director of Data Operations and Biostatistics at the University of Colorado’s Prevention Research Center

Is the requested data needed for work being performed under contract with the DOH?  □ Yes  □ No

If yes, then please provide the DOH contract manager’s name:

III. Data Requested and Specifications:

<table>
<thead>
<tr>
<th>Data Requested</th>
<th>Data Specifications</th>
<th>Data Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑ Prenatal Risk Screen</td>
<td>☑ Years (Specify) yearly 2018-2023</td>
<td>☑ Photocopies</td>
</tr>
<tr>
<td>☑ Infant Risk Screen</td>
<td></td>
<td>☑ Electronic Transfer (Secure FTP)</td>
</tr>
<tr>
<td>☑ Healthy Start Services</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Our current DUA includes data through July 2021. We would like an updated data pull for 2021 data and then yearly after that.

☒ Statewide Data
☐ County Only (Specify)

IV. Linkage

Describe in detail any linkage of requested information. Please specify the data sources, the variables which will be used for linking, and which variables will be kept in the linked file.

We request all available variables in the Prenatal Risk Screen dataset. This data will be linked to data from the Florida Association of Healthy Start Coalitions, Inc. on central intake, referral and enrollment to prenatal and postpartum services, as well as Birth Certificate data (with Infant Risk Screen data) from Vital Statistics, and data from the Florida Department of Children and Families (DCF). We will match data on mother’s first and last name, mother’s date of birth, and/or mother’s social security number. Once linked, we will assign participant IDs to each unique mother and remove personal identifiers including names, date of birth, and social security number.
V. Security and Confidentiality

The release of information that may lead to the identification of individuals or be traced back to an individual record is prohibited. However, statistical and research results based on the data provided by the Bureau of Family Health Services pursuant to this Agreement may be released. Any person(s) who access, disclose or use personally identifiable information in a manner or for a purpose not authorized by this agreement may be subject to civil and criminal sanctions contained in applicable federal and state statues.

Only the listed Data Custodian or authorized users listed on this agreement may access data. Describe where data will be stored and how data will be accessed by authorized users.

Do you agree to each of the following requirements?
1) The files will be used only to accomplish the research project described in this agreement. Yes No
2) These files, or any files extracted or derived from them, will not be released to other organizations or individuals who have not been named in this agreement. Yes No
3) No attempt will be made to link information from any other source to records for specific individuals for whom records are included in these files, unless authorized by this agreement. Yes No
4) No listing of information from individual records, with or without identifiers, will be published or otherwise released. Yes No
5) No statistical tabulations or research results will be released which reveal information about identifiable individuals. Yes No
6) Statistical and research results derived from these files may be published. However, no results may be copyrighted by the author without the permission of the Bureau of Family Health Services. Yes No

VI. Data Destruction Schedule

Consistent with Florida law, applicants must make provisions for the destruction of records at the conclusion of their project, or when the data is no longer required. Maintaining the privacy of the individuals whose personal information is included in vital records is required to preserve the integrity of the data sharing process.

Please detail the manner and timeline for destruction. If you are following a data destruction policy set by your organization or agency, please attach that policy to your application.

VII. Data Use by Others

Will any sub-contractors affiliated with this project use the data during the course of the project?
Yes No

If yes, each sub-contractor or other individual will need to complete a separate Data Use Agreement. Please identify the individuals of the sub-contractor who will have access or be using the data and describe the work they will perform.

VIII. Fees:

Prior to generating the data, the DOH will provide an estimate of the costs incurred in its preparation. Once the request is approved and payment received, the data will be provided. A waiver or reduction of the fees authorized by section 382.0255(1), Florida Statutes, will be considered only if the intended use of the data will have a direct benefit to the Bureau of Family Health Services.
health-related benefit to Florida citizens. If a waiver or reduction of the fees is requested, describe how use of the data is a direct benefit to Florida citizens.

IX. Contact with Human Subject:

No contacts of any kind can be made with any person named on a certificate or data file or related persons without the written permission of the Bureau of Family Health Services and review by the DOH Institutional Review Board (IRB). If the project requires DOH IRB review, applicants must first submit a signed and notarized Data Use Agreement along with the protocol for review to the Bureau of Family Health Services. A Data Use Agreement may be rejected if the research protocol involves intrusive follow-back of research subjects.

Will the project involve direct contact with individuals or establishments mentioned on the record?

☐ Yes  ☑ No

If so, describe the need for such activity and the types of individuals or establishments who will be contacted.

X. All Staff Accessing the Information

List name, title, affiliation and role in this project for each authorized user:

Venice Ng Williams, PhD, MPH, Assistant Professor at University of Colorado’s Prevention Research Center, serves as Co-Investigator of this project.

Wendy Gehring, Data Analyst at the University of Colorado’s Prevention Research Center, serves as data manager in this project.

Bridget Mosley, Sr. Data Analyst at the University of Colorado, serves as data analyst in this project.

Laura Helmkamp, Sr. Data Analyst at the University of Colorado, serves as data analyst in this project.

Jacob Thomas, Sr. Data Analyst at the University of Colorado, serves as data analyst in this project.

XI. Use and Consent of the Data

Prenatal and infant risk screen and Healthy Start services data may only be used for the specific purpose(s) described in this agreement. All persons with data access must maintain the confidentiality of the data and prevent release to unauthorized parties. All publications, tabular presentations, maps or depictions of cartographic information must aggregate results to protect the identity of individuals and comply with applicable state and federal laws. The Division of Community Health Promotion, Bureau of Family Health Services, Maternal and Child Health Section shall be notified immediately by phone (850-245-4103) after discovery of any use or disclosure of the data not provided for by this agreement.

As the signatory for this agreement as the Data Custodian, the Data Custodian bears full responsibility for adhering to all data confidentiality, security policies, and the terms of this agreement. The Data Custodian serves as the point of contact for receiving, maintaining, protecting, and ultimately destroying the data provided by DOH. Data may be used by the custodian only for the purpose stated in this agreement and may not be used for any other purpose. No entity with data access may link prenatal and infant risk screen and Healthy Start Services data with any other source of information without the written authorization of the Bureau of Family Health Services. Additionally, proper physical, computer and system security safeguards will be maintained by the signatory’s requestor’s organization/agency pursuant of the agreement.

Bureau of Family Health Services 04/06/2021 -5 -

CHP37
Physical Security

The requestor’s organization shall ensure that DOH data are used and stored in an area that is physically safe from access by unauthorized persons during working hours and non-working hours. The requestor’s organization agrees to safeguard DOH data from loss, theft, or inadvertent disclosure and, therefore, agrees to:

1. Secure all areas of the organization’s facilities where employees assist in the administration of the program’s use or disclose DOH data. Ensure that authorized individuals only access these secure areas with properly coded key cards, authorized door keys or access authorization, and access to premises is by official identification.

2. Issue identification badges to workers who assist in the administration of the organization’s programs and require the organization’s workers to wear these badges at organization’s facilities where DOH data are stored and used.

3. Store paper records with DOH data in locked spaces, such as locked file cabinets, locked file rooms, locked desks, or locked office in facilities which are multi-use, meaning that where the requestor’s organization and non-requestor’s organization functions in one building in work areas that are not securely segregated from each other.

4. Use all reasonable measures to prevent non-authorized personnel and visitors from having access to, control of, or viewing DOH data.

Computer Security Safeguards

The requestor’s organization agrees to comply with the general computer security safeguards, system security controls, and audit controls in this section.

General Computer Security Safeguards:

1. Encrypt portable computer devices, such as but not limited to, laptops and notebook computers, that process and/or store DOH data with an encryption solution that is full-disk utilizing a minimum algorithm of 256 bit AES or 3DES (Triple DES) if AES is unavailable.

2. Encrypt workstations where DOH data are stored using an encryption product that utilizes a minimum algorithm of 256 bit AES, or 3DES (Triple DES) if AES is unavailable, and is recognized as an industry leader in meeting the needs for the intended solution.

3. Ensure that only the minimum necessary amount of DOH data is downloaded to a laptop or hard drive when absolutely necessary for current business purposes.

4. Encrypt all electronic files that contain DOH data when the file is stored on any removable media type device (i.e., USB thumb drives, floppies, CD/DVD, portable hard drive, etc.) using an encryption product that utilizes a minimum algorithm of 256 bit AES, or 3DES (Triple DES) if AES is unavailable, and is recognized as an industry leader in meeting the needs for the intended solution.

5. Ensure that all emails sent outside the requestor’s organization’s e-mail environment that include DOH data are sent via an encrypted method using an encryption product that is recognized as an industry leader in meeting the needs for the intended solution.

6. Ensure that all workstations, laptops and other systems that process and/or store DOH data have a commercial third-party anti-virus software solution and are automatically updated when a new anti-virus definition/software release is available.
7. Ensure that all workstations, laptops, and other systems that process and/or store DOH data have current security patches applied and are up-to-date.

8. Ensure that all DOH data are wiped from all systems and backups when the data is no longer legally required. The requestor's organization shall ensure in writing that the wipe method conforms to the US Department of Defense standards for data destruction.

9. Ensure that any remote access to DOH data are established over an encrypted session protocol using an encryption product that is recognized as an industry leader in meeting the needs of the intended solution. The requestor's organization shall ensure all remote access is limited to the minimum necessary and maintains the principles of least privilege.

System Security Controls:

In order to comply with the following system security controls, requestor's organization agrees to:

1. Ensure that all systems containing DOH data provide an automatic timeout after no more than 15 minutes of inactivity.

2. Ensure that all systems containing DOH data display a warning banner stating that data is confidential, systems are logged, and system use is for business purposes only. Users shall be directed to log off the system if they do not agree with these requirements.

3. Ensure that all systems containing DOH data log successes and failures of user authentication and authorizations granted. The system shall log all data changes and system accesses conducted by all users (including all levels of users, system administrators, developers, and auditors). The system shall have the capability to record data access for specified users when requested by authorized management personnel. A log of all system changes shall be maintained and be available for review by authorized management personnel.

4. Ensure that all systems containing DOH data use role-based access controls for all user authentications, enforcing the principle of least privileges.

5. Ensure that all data transmissions over networks outside of the requestor's organization's control are encrypted end-to-end using an encryption product that is recognized as an industry leader in meeting the needs for the intended solution when transmitting DOH data. Encrypt DOH data at the minimum of 256 bit AES or 3DES (Triple DES) if AES is unavailable.

6. Ensure that all systems that are accessible via the Internet or store DOH data interactively use a comprehensive third-party real-time host-based intrusion detection and prevention program or are protected at the perimeter by a network-based IDS/IPS solution.

Any failure of persons listed in this agreement to abide by the terms of this agreement constitutes a breach and may result in legal action and/or the demand for immediate return of all data obtained hereunder and the destruction under the supervision of the DOH of all copies of the data in the requestor's, the organization's, employees, agents, assigns, or subcontractor's possession. All actions brought under this agreement will be in the State of Florida. In any action brought by the DOH under this agreement in which the DOH prevails, the DOH shall be entitled to its attorney's fees and court costs.

*** All persons who come in direct contact with prenatal/infant screen data are required to sign this agreement. If additional signatures are required, please provide them on the last page of this agreement.
Project Director and Data Custodian’s Name (Please Print): Mandy Allison and Michael Knudson

Project Director Signature:

[Signature]

8/1/2022

Data Custodian’s Signature:

[Signature]

7/24/2022

FOR OFFICE USE ONLY

Fees Waived: Yes ☑ No ☐  Fees Reduced: Yes ☐ No ☑
DOH IRB Recommendation: Yes ☑ No ☐

Florida Department of Health Reviewers:

[Signature]

(Reviewer 1)

Angel Watson

[Signature]

(Reviewer 2)

Kelly Rogers

Florida Department of Health Authorization:

[Signature]

Anna Simmons

Date:

8/10/2022

Bureau Chief

Bureau of Family Health Services

This agreement shall expire three years from the date above. If the agreement is not renewed, all prenatal and infant risk screen and Healthy Start services data must be handled in accordance with the Data Destruction Plan.
APPENDIX I. SAMPLE DISSEMINATION TRACKER

Note: Adjust to meet the needs of the Evaluation Team, Evaluation Advisory Committee, and relevant partners.

<table>
<thead>
<tr>
<th>Peer-reviewed publications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Author</strong></td>
</tr>
<tr>
<td>Venice Williams</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Presentations (including conference sessions, webinars, community events)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Venue or Conference</strong></td>
</tr>
<tr>
<td>Presentation for AB</td>
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</table>

<table>
<thead>
<tr>
<th>Other products (e.g., policy briefs, infographics, research briefs, reports, tools)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Authors</strong></td>
</tr>
<tr>
<td>One pager of qual findings for NFPX sites</td>
</tr>
</tbody>
</table>