Nurse-Family Partnership Research Standards

The National Service Office (NSO) for Nurse-Family Partnership welcomes research directed toward evaluating the effectiveness of program implementation, gaining an increased understanding of clients' needs that can be addressed by home visiting, examining their responsiveness to home visiting practices, exploring improved means of implementation, or probing enhanced supports for home visiting providers. In support of such research, the NSO values principles of integrity in the conduct of such investigations, protection of participants' rights, transparency, and academic freedom, with attention in the design and interpretation of such research which minimizes sources of bias. Complementary to the effective implementation of NFP, the NSO shares with researchers the desire for well-designed, rigorous scientific inquiries aimed at the advancement of home visiting practice of potential benefit to the clients that we serve.

While valuing potential research opportunities, a primary purpose of the NSO is to support the implementation of the Nurse-Family Partnership program with quality and fidelity. Because fidelity is strongly associated with better program outcomes, it is imperative that research studies not interfere with program implementation.

Recognizing that certain research designs burden NFP Local Network Partners workforce, and clients, as well as the NSO, and therefore threaten implementation fidelity, the NSO has developed the following research standards to ensure that the program goals are maintained.

Guiding Principles

- The National Service Office supports the implementation of the NFP model by Local Network Partners (LNPs).
- The essential components of the NFP program are defined by the model elements.
- Program implementation with fidelity is a prerequisite for LNPs to participate in research.
- All potential NFP clients must be given the opportunity to participate in NFP without participating in research.
- The NSO has the right and duty to regulate research conducted within the NFP network to ensure that program fidelity is maintained.

Research Standards

Research cannot interfere with NFP Nurse Home Visitor (NHV) practice.

The primary mission of Nurse-Family Partnership is service delivery. Therefore, research designs may not compromise program implementation.

- **Role of the NHV.** The role of the NHV is exclusively clinical and therapeutic. Research designs should minimize the use of the NHVs in conducting research activities since this could compromise their ability to develop and maintain the therapeutic relationship with clients that is essential for good outcomes.
- **NHV as client advocate.** The NHV must be empowered to make decisions regarding research when she or he believes them to be in the best interest of the client (e.g., stopping a client's participation in research, or postponing research/data collection activities).
- **Clinical care.** Research protocols should not negatively impact delivery of clinical care.

- **Involvement of other specialists.** Research which involves service providers in addition to the NHV should ensure that the role of the extra provider does not interfere with the NHV's ability to establish and maintain therapeutic relationships with clients.
- **Research burden.** NHVs face many demands and have busy schedules. In addition to scheduling and conducting home visits, NHVs also must complete charting, outreach, referrals, recruitment, team and supervisor meetings, etc. Given these demands, research designs should not place extra burdens on their time. Researchers whose studies require more than minimal data collection should consider hiring research assistants to collect research data.

Study Subjects

- **Clients may decline research.** Research designs must allow NFP clients to decline to participate in research and still receive the NFP program.
- **NFP staff.** Research studies which involve consenting NFP staff at LNPs must ensure that there is no coercion and that staff have the freedom to decline to participate without negative repercussions.
- **Compensation.** Subjects (clients or LNP staff) should be appropriately compensated by the research study when their participation in research requires extra time.

LNP Requirements

- **Program fidelity.** To ensure that research does not negatively affect program implementation, LNPs are restricted from participating in research studies until they have met program development milestones indicating the presence of strong program implementation (as monitored by nursing consultation). Exceptions to this policy may be allowed if the research study has minimal burden or if it involves questions related to start-up or early implementation.
- **New nurses.** Depending on the design of research, new nurses (those with less than one year of experience in implementing NFP) may be barred from participating in certain studies until they have gained sufficient experience and are comfortable with the model.
- **Nurse Supervisor authority.** Studies must respect the Nurse Supervisor's authority over issues related to implementation of NFP at local sites. If conditions at the LNP change or if a study is found to have negative impacts on the LNP or its clients, the Nurse Supervisor is empowered to negotiate changes with the Principal Investigator (PI) and, if necessary, to withdraw from the study.
- **Enrollment.** Most LNPs have enrollment targets that are tied to funding and fidelity. Research designs need to minimize negative effects on participant recruitment and retention.
- **Compensation.** LNPs should be compensated for time spent doing research.

Data Standards

- **NFP data are proprietary.** NFP data are proprietary and may not be shared with third parties without appropriate approvals and signed agreements. Both the NSO and LNPs have a vested interest in how data are used, therefore the NSO (and LNPs, if the data are identifiable to specific LNPs) must agree in writing before data can be shared. In addition, third parties must complete Data Use Agreements with the NSO.
- **Uses of NFP data.** NFP data are collected for program evaluation and quality improvement purposes. This is the most appropriate use of this information. It may be problematic to compare NFP data with other data sources when the populations, methods for data

collection, or measurement differ.

- **Minimum necessary.** Data requests must include research questions and identify the specific data elements that are desired. Using this information, the NSO will construct data sets that are HIPAA-compliant.
- **Restricted use.** Data that are shared with a third party may only be used for the specific purpose for which the data request was granted. Data may not be used for additional purposes without specific approval from the NSO.
- **Non-transferability.** Data that are shared with a third party may not be copied or shared with another entity.

Research and Publications Communications Committee (RAPComm)

- **Research review.** All research, (including third party, research-related data requests), are reviewed and approved by the NSO's Research and Publications Communications Committee (RAPComm) for Nurse-Family Partnership. RAPComm is not an Institutional Review Board (IRB). The purpose of RAPComm is to ensure that research conducted in NFP LNPs or with NFP data is methodologically sound, coordinated, and complies with research guidelines. (Details on committee membership and review procedures are further described in the RAPComm Charter.)
- **Pre-grant/pre-IRB consultation.** Since the NSO has strict research standards, researchers should consult with a RAPComm representative prior to applying for funding or before submitting research proposals to IRB to ensure that proposed projects are consistent with these research standards.
- **Access to sites.** External researchers may not approach LNPs about participating in research until RAPComm approval is obtained.
- **Conditions of approval**. Implementation of research protocols, following RAPComm review and approval, is contingent upon acceptance of the following conditions:
  1. To notify the NSO of any unplanned developments that impact the conduct of the research with respect to the manner or the timeline described in the approved plan of research.
  2. To notify the NSO of any subsequent change in the research plan.
  3. To provide the NSO with documentation of Institutional Review Board (IRB) approval of the research plan and any subsequent IRB approval of modifications that are made to that plan.
  4. To notify the NSO of any breach in the protection of the confidentiality of the research participants.
  5. To provide the NSO with a summary of the findings and conclusions of the research.
  6. To provide the NSO, for non-binding review and comment prior to its public dissemination, any proposed paper or presentation arising from the research.
  7. To notify the NSO of the site and date of public dissemination of any paper arising from the research that has been accepted for publication or presentation.

IRB Approvals

- Prior to study implementation, researchers must submit their IRB Certificate of Approval (or IRB exemption, if applicable), a copy of the approved protocol, and a summary of changes made in the protocol since RAPComm approval.

Study Design Issues

- **Power.** Studies should be sufficiently powered to answer the research questions of interest.
- **Data collection.** Additional data gathering activities that are conducted must be appropriate to NFP and should not duplicate information that is already being collected by the program. In general, it is inappropriate to assess outcomes that NFP was not designed to achieve.

NFP Program or Policy Changes

- If there are program or policy changes within the NSO, research studies must accommodate those changes. RAPComm will mediate conflicts that may arise during the conduct of research.