

Nurse-Family Partnership Research Standards

The primary mission of the Nurse-Family Partnership® (NFP) National Service Office (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 Implementing Agencies, NFP teams, and clients and therefore threaten implementation fidelity, the NFP NSO has developed the following research standards to ensure that the program goals are maintained.

Guiding Principles

- The primary mission of Nurse-Family Partnership National Service Office is to support the implementation of the NFP model in Implementing Agencies (IAs).
- The essential components of the NFP program are defined by the 18 model elements.
- Program implementation with fidelity is a prerequisite for IAs to participate in research.
- All potential NFP clients must be given the opportunity to participate in NFP without participating in research.
- The NFP NSO has the right and duty to regulate research conducted within NFP IAs 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 NHV in conducting research activities since this could compromise her ability to develop and maintain the therapeutic relationship with her client that is essential for good outcomes.
- **NHV as client advocate.** The NHV must be empowered to make decisions regarding research when she 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.

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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 must ensure that there is no coercion and that staff have the freedom to decline to participate without negative repercussions.
- **Compensation.** Subjects should be appropriately compensated by the research study when their participation in research requires extra time.

Agency Requirements

- **Program fidelity.** In order to ensure that research does not negatively affect program implementation, IAs are restricted from participating in research studies until they have met program development milestones indicating the presence of strong program implementation. 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 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 agency change or if a study is found to have negative impacts on the agency or its clients, the nurse supervisor is empowered to negotiate changes with the PI and, if necessary, to withdraw from the study.
- **Enrollment.** Most local agencies have enrollment targets that are tied to funding and fidelity. Research designs need to minimize negative effects on participant recruitment and retention.
- **Agency compensation.** Agencies 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 NFP NSO and IAs have a vested interest in how data are used, therefore both parties must agree in writing before data can be shared. In addition, third parties must complete Data Use Agreements with the NFP 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 is problematic to compare NFP data with other data sources when the populations, methods for data collection, and measurement differ.
- **Minimum necessary.** Data requests must include research questions and identify the specific data elements that are desired. Using this information, the NFP 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 NFP NSO.
- **Non-transferability.** Data that are shared with a third party may not be copied or shared with another entity.

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Research and Publications Communications Committee (RAPComm)

- **Research review.** All research must be reviewed and approved by NFP NSO's Research and Publications Communications Committee (RAPComm). RAPComm is not an Institutional Review Board (IRB). The purpose of RAPComm is to ensure that research conducted in NFP IAs is methodologically sound, coordinated, and complies with research guidelines.
- **Pre-grant/pre-IRB consultation.** Since NFP 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 NFP research standards.
- **Access to sites.** External researchers may not approach IAs about participating in research until RAPComm approval is obtained.

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 already 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 NFP NSO, research studies must accommodate those changes. RAPComm will mediate conflicts that may arise during the conduct of research.