
OFFICIAL POLICY

The American Academy of Family Physicians National Research Network and its sub-networks (collectively known as the AAFP NRN) engage external collaborators and investigators in AAFP NRN research studies. Each individual brings unique insights and experience, and plays a central role in creating and disseminating credible and innovative research in support of better patient care.

To ensure the best possible environment and to facilitate collaboration between the AAFP NRN and external investigators, we have outlined all roles and responsibilities. The information below explains the expectations for external investigators involved in research within the AAFP NRN, either entirely or in part. All investigators wishing to collaborate with the AAFP NRN will be asked to review and acknowledge receipt of the outlined guidelines.

AAFP NRN MISSION AND PROJECT SELECTION

Projects proposed by external investigators must be consistent with the mission of the AAFP NRN. The interest and dedication of the member physicians is crucial to the success of our research projects, so their opinions are regularly solicited prior to embarking on specific research projects. The AAFP NRN's mission statement can be found on our website at <http://www.aafp.org/nrn>. The total body of work undertaken by the AAFP NRN will be consistent with the following principles.

Projects are expected to:

- Be designed and implemented collaboratively with the AAFP NRN.
- Have a senior member of the AAFP NRN listed as a member of the research team.
- Have a potential clinical and/or financial impact for members.
- Have practical value that is sustainable after the project.
- Be in line with the AAFP NRN's mission statement and the code of federal regulations from the U.S. Department of Health and Human Services. (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>)
- Have the support and interest of the physician members of the AAFP NRN.

Additionally, for projects to be viable within the AAFP NRN they must:

- Have adequate funding, as determined by the AAFP NRN.
- Have a solid study design.
- Be led by a qualified principal investigator (PI) or co-investigator with a solid reputation and track record.
- Have an experienced team.

The decision to conduct a study within the AAFP NRN will be made by the AAFP NRN director in consultation with the AAFP NRN Leadership Group.

GUIDELINES FOR STUDY DEVELOPMENT AND SUPERVISION

Policies to enhance the collaboration between external investigators and the AAFP NRN are detailed below. These apply to all projects conducted within the AAFP NRN, both when the AAFP NRN is the lead and when the AAFP NRN is a subcontractor.

Budget Development & Guidance

The PI must work with the AAFP NRN director, or designated representative, in developing a budget at the earliest possible point in the project proposal process. Development of the project budget will be guided by the following policies:

For projects where the AAFP NRN is the lead:

1. Each individual with responsibility for a portion of the budget will be accountable to the AAFP NRN director or designated representative for proper management of that budget in accordance with the AAFP NRN policies and appropriate federal regulations.
2. Modifications and reallocations within a project budget that affect total direct amount of dollars available to the AAFP NRN or subcontractor will be documented in writing and provided to all relevant parties as outlined by the AAFP grants management office.
3. Modification in the budget that moves funds from one project component (as defined in the implementation plan) to another project component must be approved by the AAFP NRN director, or designated representative.

For projects where the AAFP NRN is being subcontracted:

1. Budgets for the AAFP NRN's projects must be developed with recognition for the need to support, in part, a reasonable portion of the AAFP NRN's infrastructure through the proper apportionment of facilities and administrative fees associated with the project. In general, the AAFP NRN does not waive facilities and administrative fees, but will accept lower fees than our recognized standard fees for federal and non-federal projects per the written policies of the original funder of the project.
2. Budgets for the AAFP NRN's projects must be developed with clear delineation between budget lines managed by the external PI and those managed by the AAFP NRN.
3. All project budgets, relevant to the AAFP NRN's involvement, must be approved by the AAFP NRN director or designated representative prior to submission of the proposal for funding and/or approval. The AAFP NRN's budget must also be viewed with the total budget for feasibility.

OFFICIAL POLICY—EXTERNAL INVESTIGATOR COLLABORATING GUIDELINES

4. Modifications and reallocations within a project budget that affect total direct amount of dollars available to the AAFP NRN or subcontractor will be documented in writing and provided to all relevant parties as outlined by the AAFP grants management office.

Study Development and Guidance

Clear lines of authority and responsibility are necessary to facilitate communication among all members of the project team. This is particularly important when the project principals are geographically separated. Day-to-day operations of an AAFP NRN project will be guided by the following policies:

1. AAFP NRN projects must be developed with clear delineation between study responsibilities and scope of work managed by the external PI and those managed by the AAFP NRN.
2. For each funded project, the PI and designated AAFP NRN Leadership Group representative will jointly develop a specific implementation plan, and the PI will work closely with appropriate AAFP NRN staff to follow the said implementation plan.
3. Any external team members working with the investigator on a project must first be deemed to have the necessary expertise in conducting practice-based research studies with a solid track record. In addition, the external investigator and all external team members must provide a current copy of their Human Subject Training Certificates if they are to be covered by the AAFP institutional review board (IRB).
4. All studies conducted in the AAFP NRN must be reviewed and approved or ceded by the AAFP IRB. The principal investigator also agrees to have the study reviewed and approved by other IRBs identified as relevant. This guideline also applies to all modifications and annual reviews.
5. Any modification(s) made to the study protocol that impacts the AAFP NRN or subcontractor must be collaboratively developed by the AAFP NRN and subcontractor.
6. When the AAFP NRN is the lead, each co-investigator with responsibility for a portion of the study will be accountable to the AAFP NRN PI for proper management of that portion of the project in accordance with the AAFP NRN policies and appropriate federal and IRB regulations. Subcontractor staff will be responsible to the local co-investigator.

7. The AAFP NRN director or designated representative has the authority to establish and enforce administrative procedures that minimize the vulnerability of the AAFP NRN in the financial and administrative management of research grants. Furthermore, if the study is not meeting expectations, the AAFP NRN director or designated representative reserves the right to re-examine budgeting of AAFP NRN staff.
8. At the close of a project, the external PI will work with the appropriate AAFP NRN staff to develop and submit a final progress report, including budget information as required by the funding agency and AAFP IRB.

PUBLIC DISSEMINATION OF RESEARCH FINDINGS

The AAFP NRN expects all research to result in publishable reports in the academic press. All collaborating investigators must adhere to the AAFP NRN's Writing and Publication Guidelines, which contains specific timelines for publication. Please see this document for details.

CONDUCT

A collaborative process is only successful when all parties are allowed the opportunity to contribute in a non-threatening environment. Therefore, all investigators are expected to conduct themselves in a professional, respectful, and considerate manner while fulfilling their responsibilities on AAFP NRN projects.

Any disrespectful or inappropriate behavior is to be reported immediately to the designated AAFP NRN Leadership Group representative for the study, who will consult with the AAFP NRN director regarding suitable next steps. Ongoing disrespectful or inappropriate behavior among any member of the research team could impact the decision to collaborate in the future.

CONFLICT RESOLUTION

Effective conflict management requires an honest and open exchange of information between the persons who are experiencing the conflict. If at any time a conflict arises from the above mentioned policies, it is recommended that the team member who has the concern first address it with the party involved.

If an adequate resolution cannot be reached, it is recommended that both parties contact the designated AAFP NRN Leadership Group representative for the study, who will consult with the AAFP NRN director regarding suitable next steps.

In addition, the external investigator has the right to appeal any decision of the AAFP NRN director in writing to the director of the Health of the Public and Science (HOPS) Division.