



OFFICIAL POLICY

1. OVERARCHING GUIDELINES

- a) These principles will be applicable to all American Academy of Family Physicians National Research Network (AAFP NRN) sub-networks (eNQUIRENet, the Collaborative Care Research Network [CCRN], etc.).
- b) References to AAFP NRN will be assumed to include sub-networks.
- c) The research project must be relevant to family medicine, as determined by the AAFP NRN project vetting process through the AAFP NRN Leadership Group and/or the appropriate sub-network executive committee.
- d) The research project must be of interest to the AAFP NRN membership, as determined by the AAFP NRN project vetting process through the AAFP NRN Leadership Group and/or the appropriate sub-network executive committee.
- e) All research that involves human subjects must conform to the International Committee of Medical Journal Editors (ICMJE) registration guidelines.¹
- f) The AAFP NRN intends to conform to the National Institutes of Health (NIH) data sharing principles for all data that underlie and support publications arising from AAFP NRN research.²
- g) The conduct of a company-funded research project in no way constitutes an endorsement by the AAFP of the product or the funding company.
- h) The AAFP name may not be used in conjunction with the product or company without prior written authorization by the AAFP Executive Vice President/CEO or designee.

2. STATISTICAL ANALYSIS

- a) The AAFP NRN and its sub-contractors will perform or review all statistical analyses used for public reports, presentations, or publications that include any data derived from research in which the AAFP NRN is involved.

3. PUBLICATION

- a) It is the expectation of the AAFP NRN to publish research results in peer-reviewed medical journals.
- b) Publication of results should occur in a timely manner. In general, the primary paper is to be published within one year of the completion of data collection.
- c) Information deemed "confidential" by the funding company prior to commencing the research project may be withheld from publication, but all findings and

discoveries that are derived from the research project will be available for publication. New patentable discoveries may have publication delayed for up to 18 months. To invoke this clause, the company that funds the research must apply for a patent pertaining to the discovery within 12 months of the completion of data collection.

- d) Interpretation and publication of study findings by the AAFP NRN is the sole responsibility of the AAFP NRN. Any expectation of non-binding company review of a manuscript prior to publication must be clearly stated prior to the beginning of data collection for the research project. Manuscript review must be completed and comments must be returned to the AAFP NRN within 21 days of the date the manuscript is sent out for review by the AAFP NRN.
- e) The AAFP NRN will follow its written **Writing and Publication Policy**.

4. RESEARCH GRANTS

- a) The AAFP NRN is responsible for the development of research protocol(s).
- b) The AAFP NRN is responsible for conducting the research project.
- c) The AAFP NRN retains all raw data related to the research project and conducts all analyses.
- d) The AAFP NRN will provide timely interim and final reports on the research project to the funding company.
- e) The funding company is not expected to review presentations, abstracts, and manuscripts developed from the research project; however, the AAFP NRN may engage a non-binding company review at its discretion. This review will conform to the guidelines under #3 above.

5. COLLABORATIVE RESEARCH PROJECTS

- a) Collaborative research with industry is considered only when a research grant option is not practicable. In general, this falls within one of the following categories:
 - i) The project involves the use of the intellectual property of the funding company and such use can only be reasonably performed at the company site, such as a specific lab test only the company can perform; computer-based activities that are hosted by the company; or an analysis of clinical data that is integral to the project (Note: this analysis cannot be an outcome variable within the project).

OFFICIAL POLICY—PRINCIPLES FOR INDUSTRY-FUNDED RESEARCH

- ii) The project involves intellectual property that has not been made available for clinical use, whether through licensing, purchase, or public availability.
- iii) The project is highly likely to result in the development of new intellectual property that is patentable.
- b) All data collected during a collaborative research project must be made available to the AAFP NRN for independent analysis.
- c) The conduct of the research project, including practice, clinician, and patient recruitment, is managed by the AAFP NRN.
- d) The AAFP NRN must be the sole site of the project. With agreement of the funding company, the AAFP NRN site may include other affiliated research networks, network clinicians, and patients cared for within said affiliated networks.
- e) The statistical analysis guidelines outlined above apply to all research conducted by the AAFP NRN.
- f) The publication guidelines outlined above apply to all research conducted by the AAFP NRN.
- g) The AAFP NRN will utilize its contract template for all collaborative research projects.

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1. DeAngelis, C. et al., Clinical Trial Registration: a Statement from the International Committee of Medical Journal Editors, *N.Engl.J.Med.* 2004; 351:1250-51. This document basically states that all clinical trials that randomize treatments at any level must be registered prior to data collection to be accepted for publication. Registration is the system in place to keep companies from hiding unfavorable results.
 2. http://grants.nih.gov/grants/policy/data_sharing/
This policy basically states that study data, once de-identified and information that would reveal intellectual property removed should be shared on a public site for other researchers to use and analyze. Typically this occurs one to two years after closure of data collection.