

The Federation of State Physician Health Programs Research Guidelines for Investigators

Introduction:

These guidelines were developed by the FSPHP to help investigators interested in working with Physician Health Programs (PHPs) or with data generated by PHPs, in order to inform prospective investigators, standardize procedures, and facilitate research collaboration. The guidelines are meant to promote and facilitate research excellence in the field of physician health. In addition, these guidelines aim to clarify the role of FSPHP Member PHPs in research endeavors and encourage their participation in the same. One central focus of the FSPHP Research Committee is to review the scientific value of the prospective research in the field and develop a collaborative partnership with a broad array of experienced investigators. The FSPHP in general and the Research Committee in specific are committed to evidenced based practice and seek to encourage the rigorous collection of the highest quality data to best inform and direct current and emerging practices.

Proposed Research to Be Evaluated Based on the Following Components:

1. Significance

The description of the proposed research must include the value and importance of the project and research questions to the field of physician health and/or to the FSPHP.

2. Investigators

The research committee will consider past publications, history of grant funding, and experience as scientists. Previous research in the field of physician health or PHP research collaboration are desired but not required. Junior investigators should describe their mentorship plan.

3. Innovation

The FSPHP is committed to continuous improvement in the care of physicians with mental health and substance use conditions and research is the central element of that commitment. Thus, applications that challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions are encouraged.

4. Approach

The proposed research should summarize the methodology. Explain if the research is associated with a grant application to a major research-funding institution (e.g., one of the National Institutes). The FSPHP research committee or an ad hoc subcommittee of the research committee may review the methodology. It is anticipated that the membership of the subcommittee will be determined by the member's expertise.

5. Environment/Collaboration

A collaborative relationship between the FSPHP, especially members of the research committee, and

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researchers in a proposed project is considered important, and essential in many cases. Evidence of collaborative spirit or intention may include early involvement of the FSPHP research committee on the part of the researchers. We encourage researchers to include the FSPHP in early discussions of the project, its importance, design, and practicality. Early collaboration with the federation will benefit researchers by providing the PHP perspective on the issues to be researched, which could help in proposal development. Chairpersons of the research committee would welcome preliminary discussions and may refer interested researchers to members who have experience or expertise that could prove helpful. For each research project to be evaluated for approval by the FSPHP, a written proposal is to be submitted for review by the FSPHP Research committee. The Research Committee will designate a point person to liaison with the researchers during the course of the research and in the writing of papers based on the work. Matters pertaining to the review and authorship of papers for publication are considered collaborative issues yet will be determined ahead and described ahead of time in the proposal.

6. Study Timeline

The research proposal should include a description of the proposed study time.

7. Protection for Human Subjects – IRB

Researchers should include plans for the IRB to review and approve of the study. The IRB serves as an objective third party, an oversight committee, governed by Federal Regulations with the purpose of protecting and managing risk to human participants involved in research. FSPHP anticipates that all research meets IRB standards. Following is a short list of specific goals of the IRB:

- > To promote the safety and well-being of human participants
- > To ensure adherence to the ethical values and principles underlying research
- > To ensure that only ethical and scientifically valid research is implemented
- > To allay concerns by the general public about the responsible conduct of research

8. Impact on Member PHPs

Whereas individual PHP's have limited resources – time, personnel, money – for conducting or participating in research, proposed researchers should be specific on the anticipated commitment of individual PHP's and/or resources to assist with data needs.

9. Collaboration

The extent to which proposed research will provide some funding for personnel to conduct the work at the PHP level is considered important. A document that defines the relationship between the FSPHP and the researchers may be required. It is anticipated that when a project receives the endorsement of the research committee of the FSPHP, the proposal will then be presented to the Board of Directors of

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the FSPHP for approval. If approved, the Board or its designee (e.g., the research committee) will communicate with member states of the FSPHP concerning its endorsement and will encourage individual PHP's to participate in the project.

Contacting FSPHP

Interested investigators may contact one of the co-chairs of the Research Committee of the FSPHP to begin discussion of a research idea and background. Further steps will be developed and discussed at that time.

Summary of information to include in a proposal for research to partner with FSPHP:

- Investigators and individuals Involved/ Provide bio's, background, and role.
- Project Title
- Abstract (500 words or less)
- Specific Aims
- Relevant Brief Background/Literature
- Proposed Study Population (inclusion/exclusion criteria, number of participants by groups, etc.)
- Recruitment Plan (When/how do you plan to access participants? What help will you need to do this, participant stipends.)
- Proposed Methodology (include study visit schedule, frequency and duration of study visits, information about follow-up(s), plan to re-contact, etc.)
- Proposed Measures
- Plan Comparisons/Data Analysis Plan
- Proposed start-date
- Proposed recruitment completion date
- Proposed study end-date
- Study milestones
- IRB Training Plans, and IRB Plans
- Status of IRB Submission
- Proposed Partnership /Collaboration with FSPHP:
- Funding Type and Plans
- Draft or completed protocol and consent forms

<u>Click here</u> to submit a Research Proposal Planning Sheet to FSPHP.

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