AMERICAN OSTEOPATHIC ASSOCIATION
TREATING OUR FAMILY AND YOURS

PHYSICIANS IN TRAINING RESEARCH PROGRAM RESEARCH PLAN INSTRUCTIONS

Outline

Complete this section, on continuation pages, giving details following the outline below. The research proposed project plan should be self-contained and include sufficient information to evaluate the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies.

If this is a resubmission, one additional page should be included as an introduction, indicating how the previous critique(s) has (have) been addressed. Changes should be shown in bold type.

Begin each section of the research proposed project plan with a section header (e.g., Specific Aims, Background and Significance, etc.)

1. RESEARCH QUESTION AND SPECIFIC AIMS

Maximum One (1) Page: The broad, long-term objectives of the applicant's research program should be stated. These objectives should include the research proposed in the current application as well as that planned for subsequent research programs. Describe in a concise and realistic manner what the research the proposed project is intended to accomplish.

2. BACKGROUND & SIGNIFICANCE (May include Preliminary Studies, if applicable)

Maximum Three (3) Pages: Provide a clear, detailed background for this proposal. Critically evaluate existing knowledge. Specifically identify those gaps of knowledge that will be filled by the results of this proposal. Describe how the importance of the research in this proposal will relate to the long-term objectives stated in the Abstract and the Specific Aims of this proposal. Clearly identify the extent to which the proposed project has significance for osteopathic philosophy or practice and such significance should be described in detail. Be concise and select only those literature references pertinent to the propose research.

Discuss the status or results of any studies done by the applicant or mentor/sponsor that are pertinent to this proposal (if applicable). Include a list of any manuscripts or abstracts accepted for publication, in press, or previously published which resulted from those studies (if applicable). Include any other information that could help to establish the experience and competence of the applicant to pursue the proposed project or the mentor/sponsor to monitor the proposed project.

PARENT STUDIES ONLY

Maximum Two (2) Pages: If the proposed study is a supplemental project, include the parent study's research question, specific aim, research design and methods, power analysis (if applicable), and outcomes.

3. RESEARCH DESIGN & METHODS (including power analysis)

Maximum Seven (7) Pages: Provide a power analysis to justify the sample size you used for your proposed study to yield statistically significant findings. Please describe your ability to

recruit and retain the necessary number of individuals for the study.

Outline the design and the procedures to be used to test the hypotheses of the proposed project, including the expectations for all proposed studies. Describe conceptual models (frameworks), samples, experimental groups (if applicable), activities, data to be collected, and statistical design for analysis. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to test the hypotheses. Provide a tentative sequence and timetable for the proposed experiments.

If the proposed research will develop new methodologies, describe the advantages of those methodologies over existing methodologies. Discuss any procedures, situations, or material that may be hazardous to personnel and the precautions to be exercised.

4. HUMAN SUBJECTS *(if applicable)*

Maximum Two (2) Pages: For studies involving the use of human subjects, the following concerns must be addressed:

a. Provide a detailed description of the proposed involvement of human subjects in the work previously outlined in "Research Approach". Describe the characteristics of the subject population, including the sample size, age ranges, gender, racial/ethnic background, health status. Identify criteria for inclusion and exclusion.

b. ***Vulnerable Populations*:** Explain the rationale for the involvement of special classes of subjects, if any, such as fetuses, pregnant women, children, human in vitro fertilization, prisoners or other institutionalized individuals, or others who are likely to be vulnerable.

c. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be, make of existing specimens, records, or data.

d. Describe detailed plans for the recruitment of subjects and the consent procedures to be followed, including the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. State if the Institutional Review Board (IRB) has authorized a modification or waiver of the elements of consent or the requirement of document of consent.

e. The consent form must be included with the application. ***INCLUDE IN THE APPENDIX.***

f. Describe any potential risks - physical, psychological, social, legal, or other - and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

g. Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness. Where

appropriate, discuss provisions to ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects.

h. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

i. If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the food and drug administration.

j. In those studies where human research subjects will receive health care services including examination, diagnosis, or treatment, the principal investigator should be an osteopathic physician.

k. All applications that include human subjects must provide an IRB approval letter. ***NO FUNDS WILL BE RELEASED WITHOUT IRB APPROVAL. INCLUDE IN THE APPENDIX.***

    i. NOTE: If the PI is successful in securing an AOA grant award, but has not received and presented IRB approval to the AOA by the effective date of the grant contract, then no funds will be released until certification of IRB approval is filed with the AOA. If initial approval is not obtained within ninety (90) days of the effective date of the grant award, AOA will rescind the award.

5. VERTEBRATE ANIMALS *(if applicable)*

Maximum Two (2) Pages: For studies involving the use of vertebrate animals, the following must be addressed:

a. Provide a detailed description of the proposed use of the animals in the work previously outlined in the Experimental Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.

b. Justify the use of animals, the choice of species, and the numbers used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and their numbers.

c. Provide information on the veterinary care of the animals involved.

d. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices where appropriate to minimize discomfort, distress, pain, and injury.

e. Describe any euthanasia method to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the panel on euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

f. All applications that include animal subjects must provide an IACUC approval letter. ***NO FUNDS WILL BE RESLEASED WITHOUT IACUC APPROVAL. INCLUDE IN THE APPENDIX.***

6. BIBLIOGRAPHY

Maximum Two (2) Pages: Provide a bibliography of any references cited in the proposed project plan. Each reference must include names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied upon in preparing any section of the application. The references should be limited to relevant and current literature. If available, provide a URL for references cited.

7. PROJECT TIMELINE

Prepare a proposed timeline for the project.

8. PROJECT MILESTONES

List significant events that demonstrate the accomplishments of the project's specific aims, (e.g., establishing advisory panels, meeting recruitment goals, completing initial and follow-up surveys/exams, implementing training programs, conducting analysis, etc.).

9. DISSEMINATION OF FINDINGS

Maximum half (1/2) Page: Provide the plan to dissemination the finding of the research project.

IF APPLICABLE, PLEASE CONSIDER THE FOLLOWING IN YOUR RESEARCH PLAN:

1. The type of Study Design (e.g., experimental, descriptive, cross-sectional, cohort, or other).
2. The goal, objectives and the full hypotheses are well stated.
3. The recruitment plan and how selection bias will be avoided.
4. The retention plan for participants to assure sufficient numbers is available to allow completion of the investigation.
5. The assurance of generalizability of this investigation to clinical practice (e.g., clinical relevance, university to community practice, US to other international sites, etc.).
6. The demographic description of the planned population/experimental group (e.g., age, gender,

race/ethic, educational level, socio-economic status).

7. The inclusion and exclusion eligibility recruitment criteria.
8. The outcome variables.
9. The charges and costs for patient outcome investigation and how those costs are calculated.
10. The assessment of participant comorbidities.
11. The stratification variables used (e.g., demographics, disease severity, educational level, work status, social supports, patient utilities, etc.)
12. The methods used to avoid the potential of non-random effects due to investigator bias ("gaming").
13. The process of a blinded study.
14. The description of the treatment to each group (experimental and control) with sufficient clarity such that reproducibility can reasonably be assured.
15. The complications that will be explored. How they will be identified. The structured tool that will be utilized. The definitions of individual complications used.
16. The statistical analysis used. The anticipated statistical power for the principal and alternative hypotheses of interest. The adjustment for multiple data analyses.
17. Other approaches that can be used to assure quality of this investigation (e.g., study oversight committee, blinding of the analyses, data completion, protocol violations, etc.).
18. The potential ethical concerns and how they will be reconciled.
19. The future investigations that will be based on this project.
20. Significance:
    a. The benefits of the study.
    b. Magnitude of the benefits.
    c. The validation measures that will be used for clinical studies that will capture the health status impact(s) of the planned intervention(s).
    d. The reduction of potential clinical complications.
    e. The potential economic impact of the planned research endeavor (to the individual and/or to society at large).
    f. The party or parties that will receive direct or indirect benefits from this investigation.
21. Confidentiality/Security - Who will have access to scientific data and what security safeguards exist in your data retrieval system.
22. ***APPENDIX:*** letters of support, IRB or IACUC approval letters, etc.
23. Plan for dissemination of findings.