

AOA Research Handbook

The Research Handbook of the American Osteopathic Association



AMERICAN OSTEOPATHIC ASSOCIATION

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2010 AOA RESEARCH HANDBOOK

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I. GENERAL INFORMATION AND PROCEDURES

A. INTRODUCTION

The American Osteopathic Association (AOA) recognizes that support and encouragement of quality scientific research is a critical part of its overall mission to improving American health care through the promotion of osteopathic medicine. The Council on Research (Council) is responsible to the AOA Board of Trustees (Board) to provide oversight and development of the research activities of the profession. The Council implements AOA policy on CLINICALLY RELEVANT research at the direction of the Board. The Council reports to the Bureau of Osteopathic Clinical Education and Research (Bureau) and receives STAFF support from the Division of Research Development in the AOA Department of Quality and Research.

The Council accepts and evaluates all applications for funding described in this document and makes recommendations for funding to the Bureau and to the Board. The Council also provides oversight and management of these funded programs, provides research grant and fellowship evaluation and oversight, and makes recommendations to the Bureau and the Board on research policy, procedures and strategic direction. The Council works to provide advocacy for research training, political advocacy for osteopathic research and research leadership.

Forms are available for downloading on the AOA Website www.DO-Online.org under “Research and Grants”, “Grant and Fellowship Application Forms”.

Address for All Applications and Submissions

Division of Research Development
American Osteopathic Association
142 East Ontario Street
Chicago, IL 60611-2864
research@osteopathic.org
(312) 202-8102 or Toll Free (800) 621-1773, Ext. 8102; Fax (312) 202-8402

B. ROLE AND SCOPE OF OSTEOPATHIC RESEARCH

1. The purposes of the research programs administered by the Council are to:
 - a) Investigate problems that will lead to a better understanding and a more effective application of the philosophy and concepts of Osteopathic Manipulative Medicine (OMM) and Osteopathic Principles and Practice (OPP);
 - b) Develop the research capacity of the osteopathic profession by supporting the training and research of career track investigators.
 - c) For purposes of osteopathic sponsorship of research projects, the priority of research will focus on that done under osteopathic sponsorship that is directed toward answering questions traditionally or currently associated with the osteopathic profession and its particular philosophy or practice. The questions associated with osteopathic medicine arise primarily from a clinical base, and the Council is particularly interested in clinical and basic science projects that deal with reasonable directness to further knowledge in osteopathic medicine.

2. Research Priorities:

The AOA recognizes the value of all areas of biomedical research. However the resources and facilities of the profession are limited and direct research funding must focus exclusively on those areas of research that investigate the unique aspects of osteopathic medicine with an emphasis on OMM/OPP. The breadth of this research focus may include, but is not limited to:

- a) Mechanisms of action of OMM
- b) Clinical Efficacy of OMM
- c) Inter- and Intra-rater reliability of palpatory assessment
- d) Cost effectiveness of osteopathic health care
- e) Osteopathic physician and patient interactions
- f) Methods of teaching palpation and OMM.

The AOA also recognizes the need for seed funding for pilot grants for uniquely osteopathic research projects. Seed funding will enable researchers to acquire the pilot data that will enable a particular research project to secure significant funding from resources outside of the AOA grants program. Such funding will also be available to emerging researchers to develop their skills and credentials and increase their eligibility for external funding. Grants from the AOA are specifically targeted to researchers and projects that have a high likelihood of advancing to significant external funding and clinically relevant findings.

THE AOA COUNCIL ON RESEARCH WILL NOT FUND GRANTS THAT WILL BE USED TO DEVELOP AND/OR ENGINEER EQUIPMENT.

The AOA is interested in high quality scientific investigation and limits its approval of applications to those projects that have reasonable promise of revealing important scientific knowledge. In years where insufficient quality applications are available, funds will not be disbursed. In addition, researchers and institutions are accountable for conducting research and publishing results from projects funded through this program.

Investigators are encouraged to identify areas that need exploration under osteopathic auspices and to seek out the best possible application of their own talents, skills, and interests to that exploration. They are invited to discuss proposed projects with the Council or its designated consultant while in the planning stages. Though the Council neither helps prospective grantees write applications nor assumes responsibility for prospective grantees who have asked for consultation, such conversations can be of help in eliminating areas of duplication or identifying general problems needing osteopathic research.

C. AOA RESEARCH HANDBOOK

The research programs of the AOA are administered by the Council in accordance with the guidelines and policies set forth in the *AOA Research Handbook (Handbook)*. The *Handbook* is available on the AOA website at www.Do-Online.org, under “Research and Grants”. It incorporates policy and changes in policy as approved by the Board. Applicants for grants and fellowships shall follow procedures described in the *Handbook*.

The Council is responsible for maintaining the *Handbook* and will review no less than bi-annually.

D. FUNDING RESOURCES

Research grants and fellowships are funded through resources of the AOA Osteopathic Research and Development Fund (ORDF) and the A. T. Still Foundation and Research Institute.

Osteopathic Research and Development Fund: The Council (then the Bureau of Research), with the support of the AOA Board of Trustees, began a capital campaign in 1988 to develop a source of monies for research. The goal of this initiative was to create an endowment, to be called the Osteopathic Research and Development Fund (ORDF). The fund is administered by the Council under published guidelines. ORDF funds are used to support such activities as osteopathic research grants and fellowships, manpower development and education programs, and for research resources development.

A.T. Still Osteopathic Foundation: The Foundation supports osteopathic research and will, on application by the Council, provide selective and direct funding for Council administered programs and projects.

II. ANNUAL RESEARCH CONFERENCE

The AOA through the Council sponsors an annual Research Conference, held in conjunction with the AOA Annual Convention and Scientific Seminar. The primary purpose of the Conference is to provide a national forum for osteopathic physicians, scientific researchers, residents and interns, as well as students, who are involved in, support and/or are interested in research. The Conference serves to promote research within the osteopathic profession and to allow the profession to demonstrate its research interests and strengths. It is the goal of the Conference to disseminate research findings and to create a forum for osteopathic scientists to discuss their mutual interests concerning funding, administrative policies and research interest topics that may lead to collaboration.

The Council determines the agenda for each conference, frequently by issuing a Call for Proposals two years in advance of the Conference date. A Call for Proposals may be general or specific. The full Council reviews the proposals and approves the agenda that best meets the needs of the research community at that time. Proposals of merit may be held by the Council for consideration for a later conference.

Investigators are invited to present their research and findings to colleagues in a series of didactic sessions, and to participate in discussion and critical analysis. Researchers and student researchers are also invited to submit abstracts, which are published in the Research Conference Program and in the *JAOA—The Journal of the American Osteopathic Association*. Abstracts are presented at the Conference in a Poster Session. Students of osteopathic medicine are especially encouraged to participate in the Poster Session, and the Council sponsors a Student Poster Competition, a judged event.

A. RESEARCH ABSTRACTS AND POSTER PRESENTATION SESSION

The Poster Session is an integral part of the Research Conference. A Call for Abstracts is issued early in the year and the submission deadline is on or near April 30 of each year.

Members of the Council, or their designees, review the abstract submissions, and those that are approved are published in the JAOA—The Journal of the American Osteopathic Association prior to the conference. Abstracts are submitted in four categories:

- OPP=Osteopathic Manipulative Medicine/Osteopathic Principles and Practice
- C=Clinical Studies
- B=Basic Sciences
- M/HP=Medical Education/Health Policy

The formal Poster Session takes place on the first or second day of the conference and presenters should be available with their posters during that time. The time is published each year in the Research Conference schedule and is posted at DO-Online (www.do-online.org) under “Research and Grants”. Students may elect to enter the Student Poster Competition at the time of abstract submission (See Section C below). Posters should be exhibited on each day that the exhibit halls are open.

The Poster Session is held in collaboration with the National Student Osteopathic Medical Association (SOMA). Abstracts submitted separately through SOMA must meet the AOA criteria and may be entered in the Student Poster Competition, have a later submission date, and are not included in the JAOA—The Journal of the American Osteopathic Association (JAOA) abstract issue but are published in a later issue of the JAOA. Students interested in SOMA submission should consult the SOMA website for further information.

B. AOA RESEARCH ABSTRACT CRITERIA

The following criteria are for structured abstracts in which authors summarize their research under several short headings (see #7 below). Descriptive abstracts and informative abstracts, i.e. reviews or case reports, are not accepted for the research conference.

1. Please review the abstract category before submission. If an incorrect category is made, please submit the abstract to the correct category before the deadline.
2. The information presented in the abstract must be original, not a duplicate and not previously published in a peer-reviewed journal.
 - a.) Abstracts that appear to be replicate versions of a single study will be rejected. Submissions will be checked for duplication and replicated versions will be rejected.
 - b.) Abstracts are not eligible for consideration if the paper has been presented at a U.S. National or international meeting held in North America before the AOA research conference.
 - c.) Abstracts are not eligible for consideration if the manuscript of the abstract has been published before the AOA research conference.
3. Abstract text is limited to 2500 characters including spaces.
4. Abstracts must be free of typographical and other errors. If the author finds any errors, the abstract may be withdrawn or, if the abstract is accepted and the author discovers errors, the errors may be indicated during the presentation.

5. After your completed abstract has been submitted, revision will be possible until the deadline. An email should be sent to the AOA division of research development of the changes needed. Abstract authors may not be added, deleted, or the order of the authors' names be revised after the deadline.
6. Do not use abbreviations, unless spelled out first, acronyms, footnotes, or references in the abstract.
7. All abstracts should have a clearly stated hypothesis, overview of the research design, materials and methods, results, and conclusion.
8. The abstract should summarize what is included in the poster.
9. The abstract must be authored by:
 - a.) At least one osteopathic physician, or faculty member from one of the colleges of osteopathic medicine, or a student at a recognized college of osteopathic medicine; or
 - b.) A student or faculty member at an international osteopathic college; or
 - c.) Individuals in other areas of scientific research.
10. The abstract must be submitted through:
 - a.) A medical organization or other AOA recognized organization; or
 - b.) An International Osteopathic School Or Organization; Or
 - b.) Other professional organization at the discretion of the council on research.
11. The first-named author should be the individual who conducted the majority of research. Co-authors should be listed in direct relation to the amount of research they contributed.
12. Where applicable, institutional review board (IRB) approval must be noted.
13. Authors are invited to indicate if they would like to enter the student poster competition. If the abstract is entered in the student poster competition, the first author must be a medical student at a college of osteopathic medicine at the time the research is conducted, and at the time that the abstract is submitted.
14. If the abstract is accepted:
 - a.) The first author must register to attend the AOA Research Conference and must remit the appropriate registration fee.
 - b.) Online registration is available at www.do-online.org.
15. The abstract will be published in the JAOA—the Journal of the American Osteopathic Association (JAOA). Abstracts not accepted for presentation are not published and will not be disclosed outside of AOA and persons associated with the selection process (e.g., the peer review committee).

- a.) Proofread abstracts carefully to avoid errors before they are submitted. The JAOA will make any needed typographical changes to the abstract.
16. If an emergency arises and the presenter is unable to attend, he/she must notify the division of research development in writing prior to the research conference that he/she will be withdrawing the abstract or naming a substitute presenter. The first author should contact the AOA Division Of Research Development.

- a.) Primary responsibility for compliance with any disclosure or nondisclosure requirements resides solely with researchers and/or research sponsors.
- b.) In the event that an author's/presenter's work will be published in a major peer reviewed medical journal concurrent with the timing of the research conference, it is the responsibility of the abstract author/presenter to notify the JAOA of the publication name and date as soon as possible. Doing so will allow JAOA to work with the publication to coordinate embargo of the material.

17. ASSIGNMENT OF COPYRIGHT

- a.) In submitting an abstract, the author transfers to the American Osteopathic Association the copyright and all other rights in the material comprising the abstract if the abstract is accepted. Co-authors reserve the following: a) all proprietary rights other than copyright, such as patent rights; and b) the right to use all or part of the abstract in future works of their own. The American Osteopathic Association, as holder of the copyright on the accepted abstract, reserves all rights of reproduction, distribution, performance, display, and the right to create derivative works in both print and digital formats.
- b.) A paper copy of the "assignment of copyright" is required – no abstract can be published without this document. All authors are required to sign the copyright form. JAOA—the Journal of the American Osteopathic Association will not publish an abstract without signatures from all the authors.
- c.) After submitting an abstract, secure all signatures using the "assignment of copyright" form and fax or mail the original to the:

Division of Research Development
American Osteopathic Association
142 East Ontario Street
Chicago, IL 60611-2864
research@osteopathic.org
(312) 202-8102 or Toll Free (800) 621-1773, ext. 8102; Fax
(312) 202-8402

- d.) It is strongly recommended that you procure signatures and submit the assignment of copyright form as early in the process as possible, and while all authors, especially students and residents, are available.

18. Abstract decision letters will be sent via email to the first author.
19. Research funded by the AOA Council on Research, funded by an osteopathic foundation, conducted at a college of osteopathic medicine, or which defines osteopathic principles and practices will be given priority consideration.
20. All decisions of the abstract review committee are final. The abstract review committee will not consider requests for appeals. Those abstracts rejected will receive anonymous feedback from the reviewer.

C. STUDENT POSTER COMPETITION

1. Students may elect to enter the poster competition. To be eligible, a participant must be:
 - a.) A pre-doctoral student at an AOA-accredited college of osteopathic medicine at the time that the research is conducted, and at the time that the abstract is submitted.
2. The poster should clearly state the following:
 - a.) Hypothesis:
 - State the primary objectives and scope of the study or the reasons why the document was written. Also, state the rationale for your research. Why did you do the research? Is the topic that you are researching ignored or a newly discovered one?
 - b.) Materials and Methods:
 - Design: Clearly state the study design, identifying it as observational or experimental. For observational studies, specify the temporal profile of the study as prospective, retrospective, or cross-sectional. Other description terms such as cohort, case control, or survey should be used as appropriate. Blinding should be described where relevant.
 - c.) Setting: For clinical investigations, describe the study site and/or,
 - Participants/subjects: Indicate the study population, study dates, inclusion/exclusion criteria, and method of sampling. If matching was employed, specify the criteria by which subjects were matched. If controls were utilized, identify them as concurrent or historical and/or,
 - d.) Interventions/observations: For experimental studies, clearly describe interventions. The data analysis section should include the type(s) of descriptive or inferential statistical methods used. The observations should be a list of major data elements or outcome measures relevant to the study objective. Negative studies should be accompanied by a statement of power, beta error, or confidence intervals and/or,
 - For most clinical research abstracts, the following areas are specifically mentioned: research design; research setting; number of patients enrolled in the study and how they were

selected; a description of the intervention (if appropriate); and a listing of the outcome variables and how they were measured. Finally, the statistical methods used to analyze the data are described and/or,

- For basic sciences abstracts, include enough detail for comprehension about study or program design and methods, sample size, type, selection method, instruments, protocols, procedures, interventions, treatments, highlight new techniques, validity, reliability issues, data sources, analysis, manipulation, techniques and/or approached used in your study.

e.) Results:

- Specify associations or differences between or among groups under comparison. Note total number of subjects or participants, number meeting inclusion criteria who were excluded, and number enrolled who were lost to follow-up. For those excluded, provide the reason for the exclusion. Next, list the frequencies of the most important outcome variable. If possible, present comparisons of the outcome variables between various subgroups with the study (treated vs. Untreated, young vs. old, male vs. females, and so forth). Numerical results should include standard deviations or 95% confidence limits and the level of statistical significance. If the results are not statistically significant, present the power of the study (beta-error rate) to detect a difference.
- For basic sciences, give a summary of the major and important findings, the data collected, the effects observed as informatively and concisely as possible. Statistics and significance levels where applicable. These results may be experimental or theoretical, just remember to make note of that in you abstract. Give special priority in your abstract to new and verified findings that contradict previous theories. Mention any limits to the accuracy or reliability of your findings.

f.) Conclusion:

- State concisely what can be concluded and its implications. The conclusion must be supported by the data presented in the abstract; never present unsubstantiated personal opinion. If there is room, address the generalizability of the results to population other than that studied and the weaknesses of the study.
- Basic sciences: your conclusions should in essence describe the implications of the results: why are the results of your study important to your field and how do they relate to the purpose of your investigation? Often conclusions are associated with recommendations, suggestions, implications for practice/research, and both rejected and accepted hypotheses. Highlight new relationships.

3. A team of judges will review each abstract and each competing poster during the poster presentation at the research conference. Students should be prepared to present their findings and answer questions within a limited time. Students will be judged on the following criteria:
 - a.) Science
 - a. Clear, Supported Hypothesis
 - b. Background
 - c. Methods
 - d. Results
 - e. Data Analysis
 - f. Conclusions
 - b.) Poster
 - a. Layout
 - b. Graphics
 - c. Presentation of Materials
 - c.) Student Presentation
 - a. Clear and Concise
 - b. Demonstrates Knowledge of Project
 - c. Able to Understand and Answer Questions
 - d. Statement of Osteopathic Concept Of Significance
 - d.) Originality
 - a. Reflects Student's Original Work
 - b. Reflects Mentor's Work
4. Winners of awards are announced at the end of the poster session. Three first prizes of \$500 and six second prizes of \$250 are awarded by the Council.

D. ANNUAL RESEARCH AWARDS

The Council recognizes the essential contribution of osteopathic research to the profession, and the long-term commitment and contributions of individuals in the profession to uniquely osteopathic research. Special awards have been established to publicly recognize those individuals whose work has furthered the principles and practice of osteopathic medicine through research.

The American Osteopathic Foundation (AOF) assumed support and management of the research awards in 2006. Current information on criteria, nominations, and deadlines can be found at their website at <http://www.aof-foundation.org>. Historical information about these awards is also available at our website at <http://history.osteopathic.org>

1. **Council on Research Awards (CORA)** - The purpose of the CORA is to serve as the review body for the AOF for the annual research awards. The CORA is a subcommittee of the Council, with membership, duties, and procedures described in the *Manual of Policy and Procedures for the Council on Research*. The Council Chair, who also chairs the subcommittee, appoints subcommittee members.

2. **Louisa Burns Research Award and Lecture.** - The Louisa Burns Research Award is given by the AOF. The winner of this award also presents an invited lecture at the annual Research Conference. The purpose of the award is to recognize an individual who serves as a pioneer for the profession through his or her contributions to osteopathic medicine through research, education, publication and public advocacy. It is named in honor of Louisa Burns, DO, who was the first osteopathic physician to commit her full career to research.
3. **Gutensohn/Denslow Award** - This award was established in honor of J. Stedman Denslow, DO, a noted researcher in visceromatic reflexes and biomechanics, and Max T. Gutensohn, DO, a gifted educator, for their devoted service and contributions to research and education within the osteopathic profession. The purpose of the award is to honor an osteopathic researcher of noteworthy accomplishment in his or her professional life in the areas of research, education, and service.
4. **Irvin M. Korr Award** - This award was established in honor of Irvin M. Korr, PhD, for his devoted service and contributions to research and education within the osteopathic profession. The award recognizes exemplary commitment to basic science research and is given to a basic scientist who has embraced the challenges of a professional career in a college of osteopathic medicine.
5. **Beehler Research Mentor of the Year** - This award was established to honor Darryl A. Beehler, DO, who designated his AOA presidency as the “Year of the Mentor”. Mentoring is an essential component of the learning experience for students, interns, residents and young practitioners, and provides an important support and guidance structure for those dedicated to the goals of the osteopathic medical profession.

The award honors an individual who has demonstrated outstanding excellence in research mentorship and recognizes the importance of the development of future researchers, while maintaining the spirit of osteopathic philosophy, principles, and practice. The goal of this award is to create a culture of research for future generations of DOs.

6. **Burnett Osteopathic Student Research Award** - This award was established in honor of the contributions made to the osteopathic profession by John H. Burnett, DO, and Mary M. Burnett, DO. The Burnett Osteopathic Student Research Award recognizes an osteopathic medical student for the most outstanding concept paper pertaining to an osteopathic-oriented research proposal.

III. RESEARCH GRANTS

A. RESEARCH PRIORITIES

Prospective applicants for AOA research funding are referred to Section I, B for a review of current research priorities and definitions. In addition, the Council will consider the following expectations in reviewing grant applications:

1. The grant Principal Investigator will be qualified and dedicated.

2. The Institution, which supports the Principal Investigator, will demonstrate a commitment to osteopathic research.
3. A major objective of AOA funded research is to develop osteopathic research projects and researchers. Applicants should therefore be able to demonstrate why they are not applying for other funding for this particular project. Applicants should also develop a plan to advance the current project, or researcher, to external funding for expanded investigation.
4. All submitted proposals should demonstrate scientific soundness, including osteopathic relevance; issues of high impact or prevalence; supporting evidence in the scientific literature; clearly stated research question, hypotheses and rationale; evidence of subject availability; appropriate research methodology, power analysis and statistical plan; and project feasibility.

B. GRANTS PROGRAM

The award program of the Council is able to support studies and recommend approval of funding on a yearly basis. All awards are subject to final approval by the AOA Board of Trustees. Requests for funding are usually made for one year with exceptions noted below.

1. For those applications which focus upon clinical research topics addressing questions of high priority for the osteopathic profession, and also propose studies that address osteopathic manipulative medicine (OMM) and osteopathic principles, practices (OPP), and:
 - a) The Council will review grant applications for studies with budgets not to exceed \$50,000 per year.
 - b) The Council will provide funds for a maximum of two years, for pilot studies.
 - c) The Council will consider research proposals for amounts greater than \$50,000 per year, or project duration greater than two years, only after submission and approval of a two-page letter of intent, which briefly summarizes the study. The letter of intent must be received by October 1.
 - d) The Council will only recommend funding of such applications that are of the highest merit, and strictly meet the guidelines stated in this *Handbook*.
 - e) The Council is under no obligation to review incomplete applications or applications that do not follow the format described herein.
 - f) Funding of approved projects of two years in length will require satisfactory progress review at the end of the first year and approval of funding on a yearly basis by the Board.

- g) The Council, with support from the Division of Research Development, also administers all funded programs, providing oversight, appropriate review, and direction. The Council will establish specific research priorities and recommend processes for grant applications, review criteria, grant review for funding and monitoring projects for progress and support. Individuals involved in these processes must have expertise in research methods and be supportive and knowledgeable of osteopathic philosophy.

C. ELIGIBILITY REQUIREMENTS FOR GRANT APPLICANTS

1. Funds for AOA research grants are awarded only to institutions meeting the requirements for general assurances, use of budgeted equipment, and protection of research subjects as described in "Institutional Responsibilities", Section V of this document.
2. The principal investigator of an application for funding from the AOA research grants program shall be:
 - a) An osteopathic physician, who holds a faculty or staff appointment at an AOA accredited, affiliated, or approved osteopathic institution; or
 - b) A biomedical researcher who demonstrates evidence of professional training and experience as appropriate for his/her individual discipline and who holds a faculty or staff appointment at an AOA accredited, affiliated or approved osteopathic institution; or
 - c) An osteopathic physician OR RESEARCHER, who holds a faculty or staff appointment at an academic or health care institution having accreditation, affiliation, or approval as appropriate for that institution's activities.
 - d) Undergraduate osteopathic medical students and postdoctoral osteopathic medical students (interns, residents, and fellows) are not eligible to apply for funding from the AOA research grants program.

D. DEADLINE & SUBMISSION INFORMATION

Application forms are available at DO Online, under "Research and Grants" in both a fillable form and PDF format. Applicants are encouraged to review all materials and instructions, and are invited to contact Division staff if there is a question about the meaning of a specific provision in the application prior to submission. **Applications must be complete on submission to be considered. Late applications and incomplete applications will be returned and will not be reviewed.**

All applications, including continuation requests for a previously approved project must be postmarked before 11:59 P.M. on December 1. If December 1 is a Saturday or Sunday, the deadline shall be extended to 11:59 P.M. on the next Monday, immediately following December 1.

1. Application materials should not be stapled or bound; rubber bands and clips are acceptable. Materials must be clear and legible. Formatting instructions are in the next section.
2. Appended materials may be attached, with an original and six (6) copies. Materials should be clearly relevant to the proposal, should not be excessive, and should not include curriculum vitae. Appended materials may be two-sided and may be stapled in the upper left hand corner.

E. FORMS AND SPECIFICATIONS

1. Format Specifications
 - a) Font - for application materials, use Helvetica or Arial and a font size of 10 point or larger. A smaller font is acceptable for figures, graphs, charts, footnotes, etc., but must be clearly legible. Forms are pre-set.
 - b) The application materials should be single-spaced and margins must be at least one-half inch on standard size paper (8 ½ “by 11”).
 - c) Pages should be numbered consecutively throughout the application in the bottom right hand corner.
2. Grant Application Forms - Applications should be assembled in the following order using the format and forms included in this Handbook. Submit the first two forms separate from the application:
 - a) Form A, Administrative Data Sheet (1 original and 2 copies)
 - b) Form B, Keyword Descriptors (1 original and 2 copies)
 - c) Submit these materials in the following order, collated, with one (1) original and six (6) copies:
 1. Form C, Application Face Page
 2. Form D, Table of Contents
 3. Form E, Funding Data Sheet
 4. Form F, Resources
 5. Form G, Personnel
 6. Biographical Sketch(es)
 7. Budget Worksheet(s)
 8. Budget Justification Page(s) (Narrative)
 9. Abstract
 10. Form H, Project Summary
 11. Form I, IRB Approval
 12. Research Proposal – (INCLUDE SUBHEADINGS)
 13. Literature Cited
 14. Letters of Support
 15. **Optional:** Appended Materials with separate Table of Contents

F. INSTRUCTIONS FOR GRANT APPLICATION FORMS

1. **Form A:** Administrative Data Sheet

Note that each applicant has the option of recommending three (3) potential reviewers for their application. The Council will select one recommended reviewer. The potential reviewers shall not be employed at the applicant's current institution; have trained with the applicant; or currently be conducting research with the applicant. Although requested reviewers may or may not be asked to review the application, the Council will make every effort to insure that competent, impartial reviewers can be identified and solicited for review of each application.

2. **Form B:** Keyword Descriptor Form

Keywords will be used administratively to describe the substantive area of your project.

3. **Form C:** Application Face Page

- a) Section I – Principal Investigator A single principal investigator is required and must sign
- b) Section II – The Department Chair OR IMMEDIATE SUPERVISOR must sign.
- c) Section III – Official signing for Applicant Organization. This is the official who can guarantee that resources and personnel described in the proposal are available; and that funds will be used as described, i.e. Grants Official or Dean for Research. The official must sign.
- d) The individual who would be legally responsible for the research project and monetary obligations involved, i.e., the Principal Investigator and the appropriate officer of the sponsoring institution, must sign the form. The department chairperson OR IMMEDIATE SUPERVISOR'S signature assures that those responsible for the conduct of the project will be allowed sufficient freedom from other responsibilities to make significant progress in the project. **Secure signatures on this page before duplicating; all copies should have all signatures.**

4. **Form D:** Table of Contents

5. **Form E:** Funding Data Sheet

If the principal investigator has previously received funding from the AOA as Principal Investigator, named Co-investigator, or Research Fellow, list all grants or fellowships by number and title. List all published abstracts, manuscripts, book chapters, reviews, and books that resulted from the AOA funded research. It is understood that publications resulting from AOA funded research will be filed with the AOA, Division of Research Development, in a timely manner, and that the publications file will be up to date at the time of applications for new funds. (*See Required Reports, Section VII, C, 6*)

The Principal Investigator may also list other AOA grants and fellowships on which he/she acted in another capacity, including sponsorship of research fellows. Please do not include copies of publications on these grants.

As funds awarded through this program are “seed” funding for new researchers and pilot grants, the Council strongly encourages applicants to show evidence of familiarity with funding programs outside the AOA and to show evidence of future application of the research data or experience.

6. **Form F: Resources**

Describe facilities and resources to be used to conduct the research as directed on Form F. (See Section IV, H)

7. **Form G: Personnel**

a) **Section I**

(1) List information requested on Form G for personnel whose effort is central to the project, both salaried and unsalaried, and attach a Biosketch for each. Salaried personnel should be included on the budget worksheet.

b) **Section II**

(1) List information requested for research fellows or student trainees and attached a Biosketch. Trainees are not required on AOA grants. Salaried trainees should be included on the budget worksheet.

c) **Section III**

(1) Other contributors, unsalaried, may have roles that are more indirect in the project and are not required on AOA grants. Do not include Biosketch.

8. **Biosketch** (4-page maximum)

Use the NIH-style Biosketch included with the following forms or an NIH Biosketch. Do not exceed four pages, and do not submit Curriculum Vitae. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and representative earlier publications pertinent to this application. The Council encourages researchers and developing researchers to create and maintain a Biosketch in their files.

9. **Budget Worksheet**

Provide a specific budget for proposed expenditures. The budget should show the items and the amounts requested from the AOA. Funds available from other sources should be identified on Form E. **Only direct costs can be funded.**

Each budget item greater than \$500 should be itemized and justified. If permanent equipment having a cost greater than \$500 is requested, a copy of a bid quotation or catalog price must be included and placed immediately after the Budget Worksheet. The following expenses are allowable as direct costs:

a) **Salary support – Investigators**

The Council may provide partial salary support equal to one-half of the total percent of effort by the principal investigator up to a maximum of 10% salary and benefits. The Council will consider requests for salary support with the same limits for a co-investigator provided that the request is adequately justified in the application. Salary funding by the sponsoring institution is understood to indicate strong support for proposed research projects.

b) **Salary support – Technicians**

The Council may pay salary and fringe benefits for technicians but only for time spent directly related to work on the approved project. For all salaries, indicate rate (hourly, weekly, or annually). Estimate the percentage of the technician's effort, which will be, devoted to the research program and his/her source of support. Include a description of the work to be done by this individual during the conduct of the research program.

c) **Research Fellowship Stipend**

For a student fellow, a description of the fellowship is needed (see Section IV, G, "Personnel and Consultants"). The fellowship stipend is a maximum of \$2,400 per year and the amount requested should be listed on the Budget Worksheet. The finance department of the institution is responsible for payment of the stipend to the student.

d) **Equipment**

Costs specific to the project should be listed and justified. Capital Equipment refers to items with an expected duration of usable life greater than (3) three years.

Funds for major equipment are generally not provided. Requests for expensive or unusual equipment must be fully explained and justified. The AOA will consider funding capital equipment costing in excess of \$10,000 only if there is equal cost sharing from the institution or other funding sources.

e) **Expendable Supplies**

List by category such as animals, chemicals and drugs, radioisotopes, and other expendables (i.e. items with a use/lifetime of less than one year).

f) **Travel funds** are permitted for consultation on research design and for presentation at other professional meetings. Do not include costs for travel to present at the AOA Research Conference (See Section VII, D.)

g) **Human Research Subjects**

Funds may be requested for payments to human research subjects taking part in clinical projects. Indicate in detail the basis for estimating costs of both inpatient and outpatient care, including numbers and estimated unit costs of: inpatient days; patient treatments; and diagnostic procedures. Tests done for research purposes are usually done free. Appropriate cautions should be taken to assure that payment or reimbursement of travel expenses is not the primary motivation of the subject for participation in the study. Any expenses for such tests, including payment for expert interpretation of the tests, must be listed in detail, fully explained, and justified.

h) **Provider Payments for Treatment**

Where OMT effectiveness or other measures are a major factor in the proposal, payment may be made to treatment providers for \$80 for an initial visit and \$50 for subsequent visits. Treatment providers should be identified in the proposal (i.e. clinic staff, students, etc.)

i) **Disallowed Expenses** - The following are NOT allowed:

- (1) Physical plant renovations or improvements.
- (2) Professional development activities, including dues for professional society memberships, tuition for continuing education activities, and tuition for continuing medical education activities.
- (3) Indirect costs to the sponsoring institution, or any other participating institutions.
- (4) Development and/or engineering of equipment.

If an applicant or a sponsor is uncertain whether a particular expense is allowable, he/she should contact the Division of Research Development prior to preparing the final budget for submission.

10. Budget Continuation and Justification

Provide detailed justifications on all expenditures listed on the budget worksheet. Also, provide a bid quote or catalog price for each equipment purchase greater than \$500.

11. Abstract for AOA Grant Application

Do not exceed 7 1/4" by 4 1/8" or 2500 characters including spaces.

12. Form H: Project Summary

The summary should provide a concise overview of the project. Information on details or explanations will be obtained from the grant application. The summary will be included with the recommendation of the Review Committee in its presentation to the Council. The summary may also be used for releases to AOA publications to explain your project.

13. Form I: IRB (Internal Review Board) Certificate of Compliance, Protection of Research Subjects

(See Sections IV and V for details on Protection of Human Research Subjects and Protection of Vertebrate Animals.) If the proposed research will involve human research subjects, a copy of the informed consent form, as approved by the IRB, must be included immediately following Form I. If the IRB has received an assurance of compliance number from the OPRR of the National Institutes of Health, list that number; if such approval has not been received, write "none". If the IACUC has received an animal welfare assurance number from the DHHS National Institutes of Health, list that number; if such approval has not been received, write "none".

If the institution will not conduct a full review until the grant award is made, please note that no funds will be released until certification of approval is filed with the AOA.

14. Research Proposal (See Section IV)

G. CONTINUATION APPLICATIONS

Grantees may reapply for support on a year-by-year basis beyond the initial year of support. The aims of the project cannot change significantly and the title should remain the same. The continuing application procedure is the same as that used for the original application and must contain a report of progress that has been made in the previous year. Form A should clearly indicate that this is a Continuing Application.

IV. THE RESEARCH PROPOSAL

A grant application also requires a research proposal containing the following information presented in the order stated:

A. SPECIFIC AIMS

One (1) page is recommended for this section. The broad, long-term objectives of the applicant's research program should be stated. These objectives would 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 proposed is intended to accomplish. Clearly identify the extent to which the research has

significance for osteopathic philosophy or practice; such significance should be described in detail.

B. BACKGROUND AND SIGNIFICANCE

Two (2) to three (3) pages are recommended for this section. Provide a clear, detailed background for the present proposal. Critically evaluate existing knowledge. Specifically identify those gaps of knowledge that will be filled by the results of the present proposal. Describe how the importance of the research in the present proposal will relate to the long-term objectives stated in Section A of the proposal.

C. PRELIMINARY STUDIES

This section should not exceed six (6) pages, exclusive of appended materials. Discuss the status or results of any studies, done by the applicant, pertinent to the proposal. Include copies (as appended materials) of any manuscripts or abstracts accepted for publication, in press, or previously published which resulted from those studies. Include any other information that could help to establish the experience and competence of the applicant to pursue the proposed project.

D. EXPERIMENTAL DESIGN & METHODS

This section should not exceed ten (10) pages. Outline the experimental design and the procedures to be used to test the hypotheses of the project, including the expectations for all proposed experiments. For each experiment, describe the control groups, methods to be employed, data to be collected, and statistical design for analysis of the data. 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.

E. HUMAN SUBJECTS

For studies involving the use of human subjects, the following nine (9) concerns must be addressed:

1. Provide a detailed description of the proposed involvement of human subjects in the work previously outlined in "Experimental Design and Methods" in this section. Describe the characteristics of the subject population, including their anticipated number, age, ranges, sex, ethnic background, and health status. Identify the criteria for inclusion or exclusion. 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.
2. 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.

3. Describe 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.

The consent Form, which must have IRB approval prior to the release of funds, must be included with the application (see "Instructions for Grant Applications Forms', Section III, F).

4. 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.
5. 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.
6. 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.
7. If the applicant has checked the following statement on Form D, "The project includes activities involving human products or unidentifiable patient data, and is exempt from review under DHHS regulations." then provide sufficient information to allow a determination that the designated exemptions are appropriate. (See "Protection of Human Research Subjects", Section V, and B for exempt activities)
8. 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.
9. In those studies where human research subjects will receive health care services including examination, or diagnosis, or treatment, the principal investigator should be an osteopathic physician. At the discretion of the Council, exemptions may be granted depending on the nature of the research proposed and the criteria enumerated below. Applicants seeking an exemption must consult with the AOA prior to submission of their application. To request an exemption, the application should include a cover letter that documents, relative to the proposed research, the following criteria:

- a) Licensure or registration of the principal investigator as a health care provider;
- b) Training and experience of the principal investigator in the procedures proposed;
and
- c) Inclusion of Co-Investigators who are physicians.

F. VERTEBRATE ANIMALS

For studies involving the use of vertebrate animals, the following five (5) concerns must be addressed:

- 1. 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.
- 2. 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.
- 3. Provide information on the veterinary care of the animals involved.
- 4. 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.
- 5. 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.

G. PERSONNEL AND CONSULTANTS

List the personnel who will be involved from Form G and describe the key tasks each will perform.

- 1. For research fellowships, the description of the fellowship must be submitted with the grant application for which a student fellow is being sought. This includes the time involved, the type of work, the expected achievement, and the method of evaluation. Fellowships are intended to provide opportunities for training and experience that are integrated into the research effort. The purpose of a student fellowship is to teach the student basic research methodology and principles. While the time spent on the project should be significant, it should not in any way interfere with the student's academic responsibilities.
- 2. The principal investigator will submit a written evaluation of the fellow's progress with regular project reports. The student fellow must submit a written report on his/her part of the project within 60 days of the end of the grant period except for continuing grants where a report will be due for each year the fellow works on the

project. An abstract for a poster or oral presentation on the project for the annual research conference would be accepted in lieu of a report.

3. The Council reserves the right to alter the schedule for evaluation reports and progress reports as needed to fit a particular situation. If consultant arrangements have been made, **each** consultant should provide a letter indicating the expertise and support that he/she will provide to the proposed research.

H. RESOURCES AND FUNDING SUPPORT

1. List the facilities available for carrying out this project, including laboratories, clinical resources, animal care facilities, computer facilities, office space, major pieces of equipment, secretarial support, machine shop facilities, and electronics shop facilities.
2. List all research funding available for the principal investigators. For each individual, classify the funding according to the following three groups:
 - a) All current support;
 - b) All applications and proposals pending review or funding; and
 - c) Applications and proposals planned or being prepared for submission.
3. For each grant that is currently funded, include:
 - a) The source of support, identifying number and title;
 - b) Percentage of appointment on the project;
 - c) Dates of entire performance period;
 - d) Annual direct costs;
 - e) A brief description of the project;
 - f) Whether the grant overlaps, duplicates, or is being replaced or supplemented by the present application; delineate and justify the nature and extent of any scientific and/or budgetary overlaps or boundaries; and
 - g) Any modifications that will be made should the present application be funded.

I. LITERATURE CITED

Number only should identify all literature citations occurring in the text. Each citation should be listed in this section and include names of all authors; name of the book or journal; volume number; page numbers and year of publication.

V. INSTITUTIONAL RESPONSIBILITIES

A. GENERAL ASSURANCES

Institutions and AOA affiliated organizations sponsoring applications of investigators or institutions and AOA affiliated organizations submitting applications for grants-in-aid to specific projects must present evidence that there is either a contract or a reasonable understanding with those whose services will be necessary for the conduct of the project over a sufficient period for reasonable progress to be made.

The grantee organizations must also give assurance to the Council that those responsible for the conduct of the projects will be allowed sufficient freedom from other responsibilities, so as to have time to make significant progress in the projects.

The grantee organizations also must assure the Council that adequate space and other customary facilities will be provided. Expenditures for physical plant renovations or improvements will not be approved for payment in research grants.

Grantee organizations receiving an AOA research grant are responsible for observing any applicable local, state, and federal regulations pertaining to the conduct of research. This includes, but is not limited to, regulations involving use of biotechnology products, vertebrate animals, human research subjects, and autopsy materials. This responsibility extends also to those sites, other than at the sponsoring institution, where the applicant may be completing a portion of his/her training program under the supervision of a consultant.

B. PROTECTION OF HUMAN RESEARCH SUBJECTS

All grantee organizations in which Council supported research is conducted must conform to the standards established by the U.S. Department of Health and Human Services (DHHS) for use of human research subjects. Each institution must have an Institutional Review Board (IRB), which is required to review and approve all research activities involving human subjects. Basic requirements are given in DHHS regulation 45 CFR 46 *PROTECTION OF HUMAN SUBJECTS* (or as revised). These regulations are available from the Office for Protection from Research Risks, National Institutes of Health, Bethesda, MD 20205, (301-496-7041).

At the first time that an institution qualifies for receipt of funding from the Council for studies involving human research subjects, the Council must receive a statement describing IRB organization, personnel and functioning; annual updates will be required.

The applicant organization bears responsibility for safeguarding the rights and welfare of human subjects in research supported by the Council. "Human subject" is defined as a "living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information." The regulations apply to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable state and local law and is not directly regulated by 45 CFR 46.

Investigators who conduct research involving fetuses, pregnant women, children, human *in vitro* fertilization, or prisoners must follow the provisions of the regulations in subparts B, C, and D of 45 CFR 46, which describe the additional protections required for these subjects.

Research, which is exempt from coverage by the regulations, are activities in which the only involvement of human subjects will be in one or more of the following six (6) categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2)(B) of this section, if: (a) The human subjects are elected or appointed public officials or candidates for public office; or (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject.
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, be the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

If following review of proposed research activities that are exempt as described in the six paragraphs above, the Council and Bureau determine that the proposed research program presents a danger to the physical, mental, or emotional well-being of a participant or subject of the research or demonstration project, then the Council will not authorize expenditure of funds for such a research program without the written informed consent of each participant or subject.

See also Section IV, E, "Human Subjects", for information on incorporating guidelines governing Human Subjects into the Research Proposal.

C. PROTECTION OF VERTEBRATE ANIMALS

All institutions in which Council supported research is conducted must conform to the standards established for use of vertebrate animals by the U.S. Department of Health and Human Services (DHHS). Federal regulations for use of animals require the research facility to have an Institutional Animal Care and Use Committee (IACUC).

Federal requirements for procurement and care of animals are enforced by the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA). DHHS requirements related to animal use are found in: *PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions; U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*; and *Guide for the Care and Use of Laboratory Animals* (or as revised). These regulations are available from the Office for Protection from Research Risks, National Institutes of Health, Bethesda, MD 20205.

At the first time that an institution qualifies for receipt of funding from the Council for studies involving vertebrate research subjects, the Council must receive a statement describing IACUC organization, personnel and functioning; annual updates will be required.

See also Section IV, F, "Vertebrate Animals", for information on incorporating guidelines governing Vertebrate Animals into the Research Proposal

D. ACCESS TO MAJOR PIECES OF EQUIPMENT

If major equipment is a budgetary item, it is the institution's responsibility to assure the Council that the principal investigator or competent investigators will be available for productive research involving this equipment for the duration of the AOA-sponsored research.

VI. PROCESSING and EVALUATION of GRANT APPLICATIONS

The AOA Division of Research Development administers all applications for funding. The Review Committee of the Council on Research is responsible for initial review of all grant proposals. Review of grant and other funding applications is described in detail in the *Manual of Policy and Procedure for the Council on Research*.

A. RANKING SYSTEM

Proposals are evaluated for scientific acceptability, osteopathic significance and other criteria as listed on the Grant Review Worksheet (see Appendix). Each application is given a priority score of 1.0 (excellent) to 4.0 (fatally flawed).

- 1.0* Highest rank; clear osteopathic significance, heavy involvement of junior investigators (e.g. student fellows, residents); no revisions in protocol needed; excellent experimental design; important research problem; original approach; highly qualified investigator(s); suitable facilities; appropriate budget for proposed work; outstanding performance on previous AOA-funded projects, where applicable; clear plan to develop NIH or other external funding for expanded investigation.
- 2.0* Moderate rank; moderate osteopathic significance, some involvement of junior investigators; minor revisions in protocol needed; average experimental design; good research problem; good approach; qualified investigator(s); suitable facilities; appropriate budget for proposed work; above average performance on previous AOA-funded projects, where applicable; adequate plan to develop NIH or other external funding.
- 3.0* Low rank; little osteopathic significance, little involvement of junior investigators; major revisions in protocol needed; poor experimental design; old research problem; poor approach; problems with investigator(s) qualifications; problems with facilities; budget problems; barely acceptable scientifically, could be salvaged for later cycle if the research problem is good; average, acceptable performance on previous AOA-funded projects, where applicable; plan to develop other funding is not adequate.
- 4.0* Lowest rank; not scientifically acceptable; project could be salvaged only by totally rethinking and rewriting the protocol; expert consultation needed.; acceptable; project could be salvaged only by totally rethinking and rewriting the protocol; expert consultation needed; poor, unacceptable performance on previous AOA-funded projects, where applicable; no plan to develop external funding for future investigation.

1. Priority Ranking:

In establishing a rank, the Council also considers the following factors and gives preference to:

- a) Clinical Studies and in particular those addressing OMT mechanisms and efficacy;
- b) Principal investigators with an earned DO degree or PhD faculty investigating topics relevant to OMM and OPP;
- c) New investigators trying to become established through researcher development pilot grant funding;
- d) Pilot data grants that show promise for osteopathic research;

- e) Grant proposals with plan for leading to extramural funding; and
- f) Osteopathic significance of the research plan.

Investigators with a productive history on AOA grants are always encouraged to develop projects in promising areas of research. However, the intent of the grants program is to develop pilot grants and researchers. Successful investigators are also strongly encouraged to develop projects for external funding.

In cases where a revision in the proposal is requested, budgetary allocation is made before the revision is requested, but the Council must approve the revised application before releasing any grant funds. Proposals that are not deemed acceptable scientifically will not be considered for funding. The Council may request re-development of a proposal that has a low rank but shows special promise.

B. REVIEWER GUIDELINES

This outline is intended to be used by invited reviewers as a guide to prepare written comments on research grant applications. Use of these guidelines should assure coverage of all aspects essential for careful substantiation of the recommendations made by the Council. Reviewers may submit additional comments on issues not specifically mentioned in the guidelines.

- a) Proposal: Discuss the strengths and weaknesses of various aspects of the proposal. Is an adequate understanding of the pertinent literature demonstrated? Are the aims logical? Is the purpose timely, relative to the current status of research in this field? Is the design adequate to support or refute the hypothesis? Are the procedures feasible? What problems do you anticipate? Will the research add useful data to the body of knowledge? Is the purpose realistic? If this is a continuing project request, comment on the progress to date.
- b) Data collection and analysis: Are the observations, measurements, and records, which are proposed, adequate to insure a productive project? When appropriate and your expertise includes this knowledge, please comment on the statistical design of this project.
- c) Osteopathic relevance: When appropriate include your expertise this knowledge, please comment on the significance of this project in relation to osteopathic or structural concepts or concerns.
- d) Investigator(s): Is the applicant capable and prepared to develop the project and publish results? Discuss any special attributes of the personnel who would be associated with the project. Has enough time been allotted for the personnel to devote to this project to insure its timely progress? Discuss qualifications and previous accomplishments of the personnel.
- e) Resources and environment: Discuss any special aspects of the facilities or equipment. Comment on the availability of such resources as special animal species, tissue preparations, and clinical case material, when appropriate. Also, when

appropriate, discuss the extent of departmental, interdepartmental, and institutional cooperation.

- f) Budget: Is the budget realistic in terms of the aims and methodology? Are all the items justified based on the procedures and data analysis proposed? Itemize and provide specific reasons for any reductions you suggest in time or amount. If this is a continuing project, it may be appropriate to comment on the relation of this budget to previous budgets.
- g) Other considerations: Are there ethical issues, which should be addressed? Is the welfare of subjects adequately protected? Are any potentially hazardous materials or procedures proposed? Has the investigator considered these problems and proposed adequate protection?
- h) Reviewer's recommendation: Summarize your recommendation in terms of action that the Council should consider. When appropriate, discuss the revisions you feel should be made before this project receives support. Assign a rank (1.0 - 4.0) to the proposal which reflects its technical merit. A proposal may possess all or some of the attributes listed for each rank. Intermediate ranks (i.e. 1.25, 1.50, and 1.75) may be given.

C. COUNCIL EVALUATION

1. Osteopathic Significance - The relevance of the project to OMM/OPP is of utmost importance. The investigator should establish this relevance very clearly in the development of the hypothesis.
2. Ranking Considerations - In studying each proposed project, the Council also considers the following:
 - a) Comments from reviewers and the responses from the principal investigator.
 - b) Adequacy of the proposed plan, including hypothesis, techniques, data analysis plans, and the ability of the applicant to describe the project.
 - c) The qualifications of the principal investigator, including publications and publication plans for the current project. The performance of the principal investigator on projects previously supported by the AOA will also be taken into consideration. If publications are not adequate for this project so far, or for previous projects, no further grants to that investigator or group will be made.
 - d) Adequacy of the facilities available to the investigator.
 - e) Availability of sufficient time for the investigator and other personnel to conduct the study.
 - f) The budget. The Council will delete from the budget, funds for items that are not allowed. The Council may also recommend budget reductions for items that are not appropriately justified. Based upon the availability of funds for research, the Council may elect to reduce the budget by a percentage and ask the investigator to revise the budget within the new limit. A revised budget must be submitted to

the Division of Research Development and approved before grant funds will be released.

- g) Alternative sources of funding. All other things being equal, the Council will assign lower priority if the researcher has not sought other sources of funding in cases where there is an obvious possibility for such support. Furthermore, the Council will give lower priority to projects which have had more than two years of funding and have remained similar or unchanged in scope, or for which the principal investigator has demonstrated insufficient effort to obtain other sources of funding.
- h) Ethical considerations, including completion of Form I, the IRB Certificate of Compliance.

3. Classification Considerations:

After all proposals have been ranked, the Council reconsiders all proposals, assigning them to one of four classes, and makes funding recommendations to the Council. Those recommendations include a classification of the nature of the research within the proposal. The four classes are as follows:

CO – *Clinical with osteopathic significance* - Clinical proposal with clear application to osteopathic principles, practices, philosophy, or manipulative treatment.

BO – *Basic Science with osteopathic significance* - Basic science proposal with clear application to osteopathic principles, practices, philosophy, or manipulative treatment.

CN – *Clinical with no osteopathic significance* - Clinical proposal with application to medical science in general, but with little or no discernible application to osteopathic principles, practices, philosophy, or manipulative treatment.

BN – *Basic Science with no osteopathic significance* - Basic science proposal with application to medical science in general, but with no discernible application to osteopathic principles, practices, philosophy, or manipulative treatment.

D. AWARD AND NOTIFICATION

The Council considers the initial recommendations of the Review Committee together with the funds available and makes its recommendations. All initial funding recommendations of the Council are submitted to the Bureau for review and approval of final recommendations, which are then made to the AOA Board of Trustees for final approval at its Annual Meeting in July. The A.T. Still Osteopathic Foundation and Research Institute approves relevant funding requests at its annual meeting.

The Council, through the AOA Division of Research Development, notifies the applicants of its actions by letter, usually within six weeks after it meets and following approval of those actions by the Bureau. Following formal approval by the AOA Board

of Trustees, applicants with approved projects are notified by letter and disbursements begin. Information provided to applicants is limited to the disposition of the application and does not include details pertaining to the basis for the decisions made by the Council and/or the Bureau.

The performance period is one calendar year beginning on September 1 and ending on August 31 of the next calendar year. Funds are released over six months beginning on September 1.

E. RELEASE OF INFORMATION

Information concerning grant applications will be provided only to the principal investigator and the authorized official that signs for the applicant's institution. Any other individuals seeking information concerning a specific grant will be denied that information.

VII. GRANT REQUIREMENTS

Each grantee must conduct his/her investigation in accordance with plans outlined in the application for which the grant was made and must also keep a careful record of his/her project and all matters pertinent to it, including an accounting of funds, materials, and equipment.

A. DISBURSEMENT and USE OF FUNDS

Grant monies will be distributed to the grant fund administrator of the grantee's institution on the following schedule: one-half of all awarded funds on September 1, one-fourth on December 1, and one-fourth on March 1. The finance officer is provided with a list of the funds awarded to each grantee. The institution is responsible for distributing the funds to the grantees.

If the institution will not conduct a full review until the grant award is made, please note that no funds will be released until certification of approval is filed with the AOA.

1. If the principal investigator can show that the regular disbursement schedule would be detrimental to the progress of the project, the chief fiscal officer of the institution may request a change in the schedule. Such a request should be sent to the AOA Division of Research Development and must be postmarked before August 15 with a written justification for the change in the disbursement schedule.
2. Any funds unexpended at the end of the grant period must be returned to the research fund. Grantees may consider encumbered funds a regular part of expenditures for purposes of filing financial reports; however, a supplemental financial report must be filed when the expenditure is actual.
3. No new grant funds can be released to any institution until approved progress reports, final reports and financial records due to that point are received for all previous grants to that institution (*see C, this section, "Required Reports"*).

B. EQUIPMENT

Only under special circumstances are funds provided for major equipment, and applicants are discouraged from budgeting for major equipment. Grantees (institution) are accountable for all major and/or movable items of equipment purchased with funds derived from grants-in-aid. The grantee is responsible for reasonable care, maintenance, and insurance against liability resulting from use of such equipment and is responsible for providing written evidence of such insurance to the Council.

It is presumed that the equipment will remain in the possession of the grantee so long as it serves a useful research purpose, but its transfer to other investigators who may have need for it may be requested when it is no longer in use. It is understood that in some instances, the equipment will become part of a permanent installation and transfer would not be feasible under any conditions. Transfers of equipment between institutions are allowed only after prior written approval of the Council (see below).

Inventories of equipment purchased by each grantee from funds provided by the AOA are to be included in reports submitted by grantees.

C. REQUIRED REPORTS

A report schedule will be included in the notice of award. All reports should be filed in a timely manner with the Division of Research Development. Grantees should be proactive in filing required reports, and shall not depend on notice from the AOA.

1. Progress Reports

Progress reports should be filed with Division of Research Development six (6) months after the first disbursement of funds is sent to the grantee institution. If the grantee is awarded any extension of, the grant period – either a no-cost extension or additional funds extension – progress reports should continue to be filed at intervals no less than every 6 months.

Reports for one-year grants are required as part of any continuing application process, at the time the continuing application is submitted (i.e., December 1). This is in addition to other items required on application Form A. Progress reports must include progress made in relation to the program as outlined in the application, problems that occurred regarding techniques and other matters, consultations, prognosis as to anticipated progress during continued studies, and conclusions, if any, on work done.

Publications or manuscripts may be accepted in lieu of progress reports. However, the published abstract of a presentation given at the AOA research conference, or any other scientific or clinical conference, will not be accepted in lieu of a progress report. The Bureau or Council may publish results of investigations without review.

2. Financial Reports

Detailed financial reports are due on October 31 following the close of the grant period (i.e., 60 days after the expiration of the performance period). For projects

that have been funded more than one year, i.e. through continuation grants from the AOA, a financial report is due on October 31 following each grant period. An itemized listing of expenditures is required.

The Budget Worksheet may be used to report expenditures. (See also "Use of Funds", section.)

3. Final Report

When a project is completed, a final report on the conduct of the study shall be submitted within eight weeks following the close of the grant period. This report should include statements of techniques used, the results of the study, the problems encountered, conclusions concerning the value of the investigation, suggestions concerning further study, an inventory of equipment purchased with grant funds, and a final financial report. An abstract or conference presentation or an abstract does not constitute a final report

4. Reports for Extended Grants

If a grant is extended beyond the original funding period, either at not cost or with additional funds, progress reports shall be filed as in (1) in the section. The final report is due within eight (8) weeks of the completion of the project. If the grant has been funded as a multi-year project, progress reports shall be filed as in (1) in this section and the final report is due within eight (8) weeks of the end date for the grant.

5. Research Conference Presentation

All recipients of grant awards are strongly urged to present the results of their study at a subsequent Research Conference, within two years after awarding of the grant. Travel support is available (see this Section, D). Failure to present results within this 2-year period will strongly influence any decisions regarding future grant awards. Should the grant be returned intact, the investigator is released from this requirement.

6. Publications

When the results of AOA-sponsored research are published, a reprint or a copy of the paper shall be submitted to the Division of Research Development. It is the expectation of the Council that, wherever appropriate, papers will be submitted to the *JAOA—The Journal of the American Osteopathic Association* for first refusal.

Each grantee, when publishing results of his/her investigations, shall acknowledge support of the project by the "American Osteopathic Association." Copies of manuscripts or reports shall be furnished to the Chairman of the Council and the Division of Research Development.

Failure to present results for publication within the 2-year period after awarding of the grant will strongly influence any decisions regarding future grant awards. When difficulty in publication is encountered, the Council is readily available to confer

with the grantee and to facilitate the publication. AOA grant support will be appropriately acknowledged.

7. Non-Compliance

No new or continuing grants will be considered until reports that are due are submitted and approved. Should reports of a study not be received in a reasonable time (six months after the close of the grant period), the Council may recommend withdrawal of support of the study and further recommend the return of any portion, or all, of the funds originally awarded to the principal investigator for that study. The final recommendations of the Council would be referred to the Board (or its Executive Committee) for final approval.

D. TRAVEL ALLOWANCE FOR AOA RESEARCH CONFERENCE

A travel allowance up to \$800 is reimbursable to the institution of the principal investigator of AOA supported research (or co-investigator if designated by the principal investigator) to attend the Research Conference and present findings. One allowance is available per grant and should be used within two (2) years of the close of the grant period (see Section C, 5 above). The allowance will be provided to investigators who meet each of the following conditions:

1. Submit the Final Report prior to October 31 (See this section, C, "Required Reports");
2. Make a written request to the Division for the travel allowance;
3. Submit a conference abstract with appropriate forms prior to abstract deadline (see www.do-online.org or contact AOA Division of Research Development for details);
4. Attend the Conference and present findings that are a direct result of the AOA supported research.

Reimbursement will be sent to the institutions meeting the above requirements after the Conference presentation is made. Do not include the Travel Allowance in the grant budget.

E. GRANT EXTENSIONS

An extension of the grant period beyond one year with a holdover of funds may be made only by written authorization from the Council. The principal investigator is responsible for documenting the presence of any of the above conditions to the satisfaction of the Council.

Extensions will only be granted in extenuating circumstances that have prohibited completion of the research proposed in the original application and which could not have been anticipated in the original research plan:

1. Major reduction in that portion of the principal investigator's time available for research;
2. Inability to obtain research subjects;
3. Inability to obtain technical support personnel authorized in the grant application; or

4. Inability to obtain new equipment authorized in the grant application.

A written request to extend the performance period of a grant must be filed within ten (10) days of the end of the grant period (i.e. on or before September 10). The request must include the approval of appropriate research administrators and/or other administrative officers at the principal investigator's institution. Progress reports and financial reports to date must accompany requests. However, a request for an extension of time precludes release of new funds for continuation of the same project. Based upon the evidence presented, the council may grant extension of the performance period for up to six (6) months.

F. REALLOCATION OF FUNDS

Grant funds must be used for the purpose requested in the budget presented with the application. The only exception to this would be if the principal investigator and an authorized officer of the institution request permission, in the course of the investigation, to reallocate funds and the Council approves. The investigator prior to the reallocation of funds must receive formal written approval.

For a reallocation within the guidelines involving less than ten percent (10%) of the total grant, formal authorization from the Council is not required. Any such alteration should be explained in the final financial report. The total of all reallocations may not exceed 10% of the total grant without Council authorization.

1. Transfers

Transfers of grant monies or equipment will only be permitted between AOA-accredited, affiliated or approved institutions. Any such transfers must receive formal approval by the Council. Before the transfer of grant monies or equipment purchased with grant monies will be considered, letters of agreement must be received from both the relinquishing and receiving institutions.

VIII. RESEARCH FELLOWSHIPS

A. INTRODUCTION

The Council sponsors the AOA Research Fellowship. It is designed as a mechanism for supporting the research training of the applicant and will enable the applicant to conduct a basic science or clinical research project that will make a significant contribution to osteopathic medicine. The fellowship is, in effect, seed funding to encourage an osteopathic physician or physician in training to contribute to research throughout his/her career in osteopathic medicine.

The fellowship involves the completion of a project under the direction of the sponsor. Both the sponsor and the applicant accept responsibility for the conduct of the project and the reporting of the scientific results attained. A portion of the research-training program may be conducted at an institution other than the sponsoring institution. However, the sponsor must have obtained the services of a consultant who will offer on-site supervision of that portion of the fellow's program, which is not completed at the sponsoring institution.

Procedures that are specific to the AOA Fellowship are described in the pages that follow. However, references will also be made to those policies and procedures that are common to the AOA research grants program described earlier in this document.

B. ELIGIBILITY REQUIREMENTS

Each fellowship supports one individual. Applications requesting support for more than one individual will not be accepted. An AOA Research Fellow may reapply for a second year of support. Not more than two consecutive or nonconsecutive fellowships may be awarded to an individual.

Funds for AOA Fellowships are awarded only to institutions meeting the requirements for general assurances, use of budgeted equipment, and protection of research subjects as described in "Institutional Responsibilities", Section V of this document.

1. The applicant for a fellowship shall, during the performance period of the fellowship, be:
 - a) A postdoctoral osteopathic medical student, possessing an earned D.O. degree awarded by an AOA-accredited institution, and be enrolled in an internship, residency, or Research Fellowship; or,
 - b) An undergraduate osteopathic medical student enrolled in an AOA-accredited institution.
 - c) Preference will be given to applicants in category (a).
 - d) Individuals who have demonstrated research competency by virtue of competing successfully for major independent research grant support are not eligible.
2. The sponsor of an applicant for a fellowship shall be:
 - a) An osteopathic physician, who holds a faculty or staff appointment at an AOA accredited, affiliated, or approved osteopathic institution; or
 - b) A biomedical researcher who demonstrates evidence of professional training and experience as appropriate for his/her individual discipline and who holds a faculty or staff appointment at an AOA accredited, affiliated or approved osteopathic institution; or
 - c) An osteopathic physician, who holds a faculty or staff appointment at an academic or health care institution having accreditation, affiliation, or approval as appropriate for that institution's activities.
 - d) Experienced in directing research projects as evidenced by track record regarding productivity, funding and previous sponsorship.

3. Applicants who propose research programs where human research subjects will receive health care services including examination, or diagnosis, or treatment must be under sponsorship of an osteopathic physician.
4. The consultant to an applicant shall meet at least one of the criteria specified above for sponsorship of an applicant, or shall be a biomedical researcher who demonstrates evidence of professional training and experience as appropriate for his/her individual discipline and who holds a faculty or staff appointment at an academic or health care institution having accreditation, affiliation, or approval as appropriate for that institution's activities.

C. DEADLINE AND SUBMISSION INFORMATION

Applications must be submitted to the AOA Division of Research Development, Department of Research, American Osteopathic Association, 142 East Ontario Street, Chicago, IL 60611-2864 and be postmarked before 11:59 P.M. on January 30. If January 30 is a Saturday or Sunday, the deadline shall be extended to 11:59 P.M. on the next Monday, immediately following.

Applicants are encouraged to review all materials and instructions, and are invited to contact division staff if there is a question about the meaning of a specific provision in the application prior to submission. **Applications must be complete on submission to be considered. Late applications and incomplete applications will be returned and will not be reviewed.**

Submit the original plus six (6) single-sided copies of each application. Application materials should not be stapled or bound; rubber bands and clips are acceptable. Materials must be clear and legible.

D. FORMS AND SPECIFICATIONS

1. Format Specifications
 - A) Font - for application materials, use Helvetica or Arial and a font size of 10 point or larger. A smaller font is acceptable for figures, graphs, charts, footnotes, etc., but must be clearly legible.
 - B) The application materials should be single-spaced and margins must be at least one-half inch on standard size paper (8 ½ "by 11").
 - C) Pages should be numbered **consecutively** throughout the application in the bottom right hand corner.
2. Fellowship Application Forms
 - a) Applications should be assembled in the following order and collated using the format and forms included in this *Handbook*. Please consult Section III, F, "Instructions for Grant Application Forms" for detailed directions.

- b) Submit Form B Keyword Descriptor of research project (1 original and 2 copies) separate from the application; do not attach.
- c) Form C, Fellowship Application Face Page (attach photo to original)
 - (1) Section I – The Research Fellow must sign
 - (2) Section II – The Sponsor must sign.
 - (3) Section III – Official signing for Applicant Organization (This is the official who can guarantee that resources and personnel described in the proposal are available for use as described, i.e. the Department Chair or Research Director.)
- d) Form D, Table of Contents
- e) Biosketch (NIH Biosketch accepted)
- f) Biosketch for Sponsor (NIH Biosketch accepted)
- g) Abstract
- h) Form H, Project Summary
- i) Form I, IRB Approval
- j) Research Proposal Narrative (See “E” for detailed instructions)
- k) Sponsor Letter which outlines the sponsor’s experience to direct the proposed research project as evidenced by productivity, funding and previous sponsorship.
- l) Letters of Support – Optional
- m) Budget Worksheet
 - (1) Submit the Budget Worksheet according to the following instructions. Direct expenses are allowed up to \$5000.
 - (a) Provide a specific budget for proposed expenditures. The budget should show the items and the amounts requested from the AOA. Funds available from other sources should be identified on Form E. **Only direct costs can be funded.**
 - (b) Each budget item should be itemized and justified. If permanent equipment having a cost greater than \$500 is requested, a copy of a bid quotation or catalog price must be included and placed immediately after the Budget Worksheet. The following expenses are allowable as direct costs:

- (c) Equipment
 - (i) Costs specific to the project should be listed and justified. Capital Equipment refers to items with an expected duration of usable life greater than (3) three years.
 - (ii) Funds for major equipment are generally not provided. Requests for expensive or unusual equipment must be fully explained and justified.
- (d) Expendable Supplies
 - (i) List by category such as animals, chemicals and drugs, radioisotopes, and other expendables (i.e. items with a use/lifetime of less than one year).
- (e) Human Research Subjects
 - (i) Funds may be requested for payments to human research subjects taking part in clinical projects. Indicate in detail the basis for estimating costs of both inpatient and outpatient care, including numbers and estimated unit costs of: inpatient days; patient treatments; and diagnostic procedures. Tests for research purposes are often conducted at no cost to the subject. Appropriate cautions should be taken to assure that payment or reimbursement of travel expenses is not the primary motivation of the subject for participation in the study. Any expenses for such tests, including payment for expert interpretation of the tests, must be listed in detail, fully explained, and justified.
- (f) Provider Payments for Treatment
 - (i) Where OMT effectiveness or other measures are a major factor in the proposal, payment may be made to treatment providers for \$80 for an initial visit and \$50 for subsequent visits. Treatment providers should be identified in the proposal (i.e. clinic staff, students, etc.)
- (g) Disallowed Expenses - The following are NOT allowed:
 - (i) Physical plant renovations or improvements.
 - (ii) Professional development activities, including dues for professional society memberships, tuition for continuing education activities, and

- tuition for continuing medical education activities.
- (iii) Indirect costs to the sponsoring institution, or any other participating institutions.

If an applicant or a sponsor is uncertain whether a particular expense is allowable, he/she should contact the Division of Research Development prior to preparing the final budget for submission.

n) **Budget Continuation and Justification**

Provide detailed justifications on all expenditures listed on the budget worksheet. Also, provide a bid quote or catalog price for each equipment purchase greater than \$500.

E. THE RESEARCH PROPOSAL OF FELLOWSHIP APPLICATIONS

An AOA Fellowship application also requires a research proposal containing the following information presented in the order stated. (See also Section V, “The Research Proposal”.)

1. **Specific Aims**

- a) One (1) page is recommended for this section. The broad, long-term objectives of the applicant's research training program should be stated. These objectives would include the research proposed in the current application.
- b) Describe in a concise and realistic manner what the research proposed is intended to accomplish. Clearly identify the extent to which the training and research have significance for osteopathic philosophy or practice; such significance should be described in detail.

2. **Background & Significance**

- a) Two (2) pages are recommended for this section. Provide a brief overview of the background for the present proposal, including the most relevant existing knowledge. Specifically identify those gaps of knowledge, which will be filled by the results of the present proposal. Describe how the importance of the research proposed in the present proposal will relate to the long-term objectives stated in section A of the proposal.

3. **Preliminary Studies**

- a) Discuss the current status or final results of any studies, done by the applicant, pertinent to the proposal. Include one (1) copy of any manuscripts or abstracts accepted for publication, in press, or previously published which resulted from those studies. This section should not exceed one (1) page, exclusive of appended materials.

4. **Experimental Design & Methods**

- a) Five (5) pages are recommended for this section. Outline the experimental design and the procedures to be used to test the hypotheses of the project, including the expectations for all proposed experiments. For each experiment describe: the control groups, methods to be employed, data to be collected, and statistical design for analysis of the data. Point out any procedures, situations, or material that may be hazardous to personnel and the precautions to be exercised.

5. **Human Subjects**

- a) Using the instructions at "The Research Proposal ", Section IV, E, address, page 21, and address concerns 1-8.

6. **Vertebrate Animals**

- a) Using the instructions at "The Research Proposal ", Section IV, F, page 23, and address concerns 1-5.

7. **Personnel and Consultants**

- a) The following information must be included if these services are used in the project:
 - (1) If any technical personnel will be involved in the proposed studies, provide a brief description of their role and their percent effort devoted to the project.
 - (2) If consultant arrangements have been made, the **application should include a letter for each consultant indicating:**
 - (a) Consultant's support for the application;
 - (b) Agreement to provide supervision of the applicant; and
 - (c) Expertise and support that will be provided to the applicant.

8. **Resources and Funding Support:**

- a) List the facilities available for carrying out this project, including laboratories, clinical resources, animal care facilities, computer facilities, office space, major pieces of equipment, secretarial support, machine shop facilities, and electronics shop facilities.
- b) List all research funding provided for the sponsor and consultant(s) through other funding. For each individual, classify the funding according to the following three groups:
 - (1) All current support;
 - (2) All applications and proposals pending review or funding; and

- (3) For each grant that is currently funded, include:
- (4) The source of support, identifying number and title;
- (5) Percentage of appointment on the project;
- (6) Dates of entire performance period;
- (7) Annual direct costs;
- (8) A brief description of the project;

9. **Literature Cited:** number only should identify all literature citations occurring in the text. Each citation should be listed in this section and include names of all authors; name of the book or journal; volume number; page numbers; and year of publication.

F. COUNCIL EVALUATION

All initial funding recommendations of the Council are submitted to the Bureau for review and approval of final recommendations, which are then made to the AOA Board of Trustees for final approval at its annual meeting in July. The fellowship will begin August 1 of that year and end on July 31 of the subsequent year. All correspondence concerning the program and/or awarded fellowships should be directed to the Division of Research Development.

i. Ranking System for Fellowship Applications

All proposals are considered for scientific acceptability and osteopathic significance as follows (a proposal may possess all or some of the attributes listed for each rank):

- 1.0 Highest rank; clear osteopathic significance, no revisions in protocol needed; excellent experimental design; important research problem; original approach; highly qualified applicant; highly qualified sponsor(s); suitable facilities; outstanding performance on previous funded fellowship, where applicable.
- 2.0 Moderate rank; moderate osteopathic significance, minor revisions in protocol needed; average experimental design; good research problem; good approach; qualified applicant; qualified sponsor(s); suitable facilities; above average performance on previous funded fellowship, where applicable.
- 3.0 Low rank; little osteopathic significance, major revisions in protocol needed; poor experimental design; old research problem; poor approach; problems with applicant's or sponsor's qualifications; problems with facilities; barely acceptable scientifically, average, acceptable performance on previous funded fellowships, where applicable.
- 4.0 Lowest rank; no osteopathic significance, not scientifically acceptable; project could be salvaged only by totally rethinking and rewriting the protocol; expert consultation needed; poor, unacceptable performance on previous funded fellowship, where applicable.

2. Award Notification and Disbursement

The award is for \$5,000, made payable to the Fellow, consisting of a \$4,250 stipend and a \$750 travel allowance to attend the annual AOA Research Conference during the year of the fellowship. Up to an additional \$5000, made payable to the institution, is available to allow for itemized budgeted costs. See Section D.2 for an explanation of allowable costs.

Funds, payable to the Fellow, are made available as follows:

- a. \$2,250 when the official notification of the award is made, by certified letter as soon as possible after the Annual Meeting of the AOA Board.
- b. \$750 in travel funds for the Research Conference, to be paid upon receipt of an abstract for the Conference and no later than April 30. When the Council supports travel costs for Fellows to attend the Research Conference, it expects Fellow attendance at the poster session and scientific sessions.
- c. \$1,000 upon receipt, and approval, of a midyear progress report, due January 31.
- d. \$1,000 upon receipt, and approval, of the final progress report, due October 1.

Funds, payable to the institution, for allowable costs, are made available as follows:

- a. 75% when the official notification of the award is made
- b. 25% upon receipt, and approval, of a midyear progress report, due January 31

It is expected that the research will be conducted during a period beginning August 1 of the calendar year in which the application is made and ending July 31 of the calendar year after that in which the application is made. It is the responsibility of the fellow to complete the work within this period and to submit the required reports as prescribed in Section G, "Required Reports" which follows below.

In exceptional circumstances, an extension of nine (9) months may be granted to allow completion of research and reporting. Application for an extension should be made to the Council in writing and should include reasons for the request and a timetable for completion for the project. However, in no case will a fellowship be permitted to extend beyond two (2) years. Fellows who fail to complete the requirements for the receipt of the funds of this award within two years will forfeit the remainder of all funds outstanding.

Those fellowship awardees who fail to meet the requirements in the above circumstances will not be considered eligible for any future awards within this program and will be required to pay back all fellowship funds disbursed.

G. TRANSFERS

If, during the conduct of the fellowship, the sponsor and applicant wish to conduct any portion of the fellowship at a site other than that described in the application, the fellow and sponsor may request that the Council authorize the additional performance site. Requests must be submitted to the Council in writing and should include the following:

- Discuss the reasons for selection of an additional site;
- Identifies the additional performance site;
- Identifies the consultant who will supervise the fellow at the new site;
- Include a current Biographical Sketch of the consultant; and includes the signatures of the fellow, sponsor, and any consultants to the fellowship.

H. REQUIRED REPORTS

All reports should be sent to the Division of Research Development; staff will distribute to the Council. All publications and reports that result from this fellowship award must note the author as an AOA Research Fellow. Completion of all reports will allow release of appropriate funds.

a. Research Abstract:

Fellows must submit an abstract for the next successive Research Conference (*see Section II, A*). Fellows and their sponsors are invited to attend the entire conference program, but a special session will be provided for presentation of the fellow's projects, and for constructive review and discussion.

- The midyear report is due February 1, six months after the start of the fellowship year. Both the fellow and the sponsor must sign the report.
- The final report is due October 1, sixty (60) days after the completion of the fellowship year. Both the fellow and the sponsor must sign the report. It must include an outline of a paper suitable for publication (or the manuscript itself) or of a presentation to be made at the next Research Conference. Approved final reports will be submitted for consideration of publication to JAOA—The Journal of the American Osteopathic Association unless the fellow specifies otherwise.
- The final financial report outlining budgeted expenditures of allowable costs made payable to the institution is due on October 1, sixty (60) days after the completion of the fellowship year. An itemized listing of expenditures is required. The Budget Worksheet may be used to report expenditures.

APPENDIX

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ADMINISTRATIVE DATA SHEET

Name of Principal Investigator:

Title of Project:

GRANT CATEGORY:

NEW APPLICATION
Proposal not previously submitted to the AOA
(The title must be different from any previous application submitted by the same investigator.)

CONTINUATION APPLICATION
Request for support for a study currently, or in the past, supported by the AOA. *(The title should be the same as that of the prior application. If the aims of the project have changed significantly, submit the project as a NEW application.)*

*Note grants number:

RESUBMISSION
Previous application considered by the AOA but not funded. *(The title should be the same as that of the prior application. If the aims of the project have changed significantly, submit the project as a NEW application.)*

*Note grants number:

Optional – Requested External Reviewers

The Principal Investigator may submit names of up to three potential reviewers (*see instructions for Form A*). Include the full name, address, work phone number, and e-mail address on this form.

KEYWORD DESCRIPTOR FORM

Use the following list to select no more than three (3) code numbers and respective keywords that describe the substantive area of your research project.

Keyword List Osteopathic Terminology:

- 1)
- 2)
- 3)

9999000	Osteopathic Medicine	9999009	Osteopathic Manipulative Treatment
9999001	Articular Strain	9999010	Palpation
9999002	Axoplasmic Flow	9999011	Palpatory Diagnosis
9999003	Chapman's Reflex	9999012	Physiologic Motion of the Spine
9999004	Cranial Concept Manipulation	9999013	Somatic Dysfunction
9999005	Massage	9999014	Tissue Texture Abnormality
9999006	Motion, Inherent	9999015	Trigger Point
9999007	Myofascial Trigger Point	9999016	Viscero-Somatic Reflex
9999008		9999018	Acquired Immune Deficiency Syndrome - AIDS

Keyword Your Own Terminology: The available keyword terms may not adequately describe your research project. You may use your own terminology to provide two additional keywords. The council on research strongly encourages you to use terminology from the "Glossary of Osteopathic Terminology (revised April 2009)". This handbook can be downloaded from www.aacom.org.

- 1)
- 2)

AOA RESEARCH GRANTS APPLICATION		INTERNAL USE ONLY	
PROJECT TITLE (<i>Do not exceed space provided</i>):		ID NUMBER:	IRB:
I. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR		NEW INVESTIGATOR TO AOA <input type="checkbox"/> YES <input type="checkbox"/> NO	
NAME (<i>last, first, middle</i>)		DEGREE(S)	
POSITION TITLE		MAILING ADDRESS (<i>Street, city, state, zip code</i>)	
DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT			
MAJOR SUBDIVISION			
E-mail (required):			
PHONE:	FAX:	HUMAN SUBJECTS RESEARCH <input type="checkbox"/> YES <input type="checkbox"/> NO	
VERTEBRATE ANIMALS RESEARCH <input type="checkbox"/> YES <input type="checkbox"/> NO		IRB APPROVAL ATTACHED <input type="checkbox"/> YES <input type="checkbox"/> PENDING	
APPLICANT ORGANIZATION Name and Address:		NO FUNDS WILL BE RELEASED WITHOUT IRB APPROVAL	
Terms of grant <input type="checkbox"/> 1 YEAR Term of grant is September 1, 2008 through August 31, 2009 Total Budget Request: <input type="checkbox"/> 2 years Term of Grant is September 1, 2008 through August 31, 2010 Total Budget Request:		II. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Name, Title and Address (if different from Applicant Organization))	
		E-mail (required):	
		III. GRANT FUND ADMINISTRATION OFFICIAL (Name, Title and Address)	
		PHONE	FA X
AGREEMENT IN REGARD TO AOA GRANT-IN-AID AS A RESULT OF THIS APPLICATION			
Signatories below agree to:			
1) Expend funds granted by the American Osteopathic Association solely for research purposes specified within this application;			
2) Keep careful records of the conduct of this project and all matters pertinent to it, including a detailed accounting of funds, materials, and equipment, and to keep reasonable care, maintenance, and insurance of all major equipment, and that written evidence of such insurance shall be furnished to the AOA upon request; Return any unexpended funds at the end of the grant period;			
3) Submit progress reports, final reports and financial reports as required by the <i>AOA Research Handbook</i> ;			
4) Acknowledge AOA grant support when publishing results of these investigations.			
PRINCIPAL INVESTIGATOR /PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete, and accurate to the best of my knowledge.		SIGNATURE of PI/PD (<i>In ink; "per" signature not accepted</i>)	
DEPARTMENT CHAIR: I certify that the statements herein are true, complete, and accurate to the best of my knowledge.		SIGNATURE OF DEPARTMENT CHAIR (<i>In ink; "per" signature not accepted</i>)	
OFFICIAL SIGNING FOR APPLICANT ORGANIZATION: I certify that the statements herein are true, complete, and accurate to the best of my knowledge.		SIGNATURE of OFFICIAL SIGNING FOR APPLICANT ORGANIZATION: (<i>In ink; "per" signature not accepted</i>)	

AOA RESEARCH GRANT PROPOSAL

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IRB Approval (Form I).....	
Research Proposal Narrative.....	
Specific Aims (limit 1 page).....	
Background and Significance (limit 3 pages)	
Preliminary Studies (limit 6 pages)	
Experimental Design & Methods (limit 10 pages)	
Human Subjects (limit 2 pages)	
Vertebrate Animals (limit 2 pages)	
Personnel and Consultants	
Resources and Funding Support	
Literature Cited	
Letters of Support	

FUNDING DATA SHEET AND PILOT PROJECT RATIONALE

CONTINUE FOR ONE (1) ADDITIONAL PAGE AS NEEDED.

I. OTHER FUNDING:

List other agencies to which this study has been submitted and any action taken by the agency or the date action is anticipated. If other application has not been made, please explain rationale for submission to AOA.

List all other support you currently have for this study and the date funding ceases.

II. PREVIOUS FUNDING FROM AOA:

List the numbers and titles of all previous grants or fellowships awarded by AOA to you as Principal Investigator or Co-Investigator. Include a list of all publications resulting from those studies and include one (1) copy of each publication in a separate appendix.

Grant/Fellowship #

Title

III. SEED GRANT JUSTIFICATION:

AOA supports seed grants to researchers creating pilot data or to beginning researchers. Briefly explain how the pilot data obtained in a successful research grant will lead to external funding. List other agencies that support this type of research. For new investigators, briefly explain how you will develop seed funding on this grant to become eligible for external funding.

RESOURCES

Continue for one (1) additional page as necessary.

Facilities: Specify the facilities to be used for the conduct of the proposed research. Indicate the performance sites and describe capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Under “Other” identify support services such as machine shop, electronics shop and specify the extent to which they will be available to the project.

Laboratory:

Clinical:

Animal:

Computer:

Office:

Other:

Major Equipment: List the most important equipment items currently available for this project, noting the location and capabilities of each pertinent to the proposed project:

PERSONNEL

Continue for one (1) additional page as needed.

- I. List **Key Personnel**, salaried and unsalaried, at the applicant organization or elsewhere who will participate in the project during the proposed budget period. Include all degrees, role on project and annual percent of effort. Include Biosketch for Key Personnel.

Name	% Effort	Organization	Role on Project
------	----------	--------------	-----------------

- II. List **Trainees** (i.e. Research Fellows as defined in the *Handbook* or students) who will be involved in the project during the proposed budget period. Include Biosketch.

Name	Organization	Role on Project
------	--------------	-----------------

- III. List **Other Contributors**, unsalaried, who will participate in the development or execution of the project during the proposed budget period but are not committed to a specified measurable effort. Include all degrees and role on project .

Name	Organization	Role on Project
------	--------------	-----------------

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications.

PI Name:

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and trainees in the order listed Parts I and II, Form G
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as*

INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY

NOTE: The Biographical Sketch may not exceed four pages. Follow the formats and instructions on the attached sample.

- A. Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

- B. Selected peer-reviewed publications (in chronological order).** Do not include publications submitted or in preparation.

- C. Research Support.** List selected ongoing or completed (during the last three years) research projects (federal and non-federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and your role (e.g. PI, Co-Investigator, and Consultant) in the research project. Do not list award amounts or percent effort in projects.

BUDGET WORKSHEET
AOA Research Grants Application

Submit original plus 6 copies

PI NAME:

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY				FROM September 1, 20__	THROUGH August 31, 20__	
<i>PERSONNEL From I and II, Form G</i>		%	Inst. Base Salary	Dollar Amount Requested (<i>omit cents</i>)		
NAME	Role On Project	Effort On Project		Salary Requested	Fringe Benefits	Total
	Principal Investigator					
	Research Fellow					
SUBTOTALS				→		
Equipment (<i>Itemize</i>)						
Expendable Supplies (<i>Itemize by category</i>)						
Travel (Do not Include AOA Research Conference)						
Compensation to Research Subjects (Include rate)						
Treatment Costs (Provider Payments)	Inpatient					
	Outpatient					
Other Expenses (<i>Itemize by category</i>)						
TOTAL DIRECT COSTS						

Budget Continuation and Justification Page

Continue for one (1) additional page as needed.

ABSTRACT for AOA GRANT APPLICATION

APPLICANT NAME:

GRANT TITLE:

DESCRIPTION. State the application's broad, long-term objectives and specific aims, referring to the osteopathic relatedness of the project. Describe concisely the research design and methods. Describe the rationale and techniques you will use to pursue these goals.

This description is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the application is funded, this description, as is, will become public information. Therefore, do not include proprietary/confidential information. Avoid summaries of past accomplishments and the use of the first person.

DO NOT EXCEED THE SPACE PROVIDED at 7 1/4" x 4 1/8", or a Character Limit of 2500 including spaces.

PROJECT SUMMARY

Continue for one (1) additional page as needed.

Hypothesis : (Note how the hypothesis expresses a significant relationship to osteopathic philosophy or practice.)

Major Methods: (Procedures, controls, subjects, variables, special techniques.)

Data Collection: (What observations, measurements, and/or records will be made? Examples: medical record, specific laboratory measurement.)

Analysis of Results: (Overview of planned analysis and summary of data.)

Background for Development of Project: (Your experience directly relating to this project, number of publications in your curriculum vitae related to this project, major literature resource you will use as a reference.)

**CERTIFICATE OF COMPLIANCE
PROTECTION OF RESEARCH SUBJECTS**

To be filed with each research proposal, and with each fellowship application where applicable. Please attach copies of all consent permissions as applicable.

Title of project:

PI Name:

Institution:

HUMAN SUBJECTS

I, as chairman of the Institutional Review Board (IRB), certify that the IRB meets the regulations in all federal, state, and local laws concerning the use of human subjects.

Typed or Printed Name

Signature

Date

OPRR Assurance of Compliance Number:

Committee on use of human subjects

Our committee has reviewed this project and the following is noted:

- The project does not include activities involving human subjects.
- The project includes activities involving human products or unidentifiable patient data, and is exempt from review under DHHS regulations.
- The project does include activities involving human subjects. The committee reviewed and approved it on (date) _____
- Review and Approval Pending Award

Signed _____

Name _____

Title _____

Date _____

VERTEBRATE ANIMALS

I, as chairman of the Institutional Animal Care and Use Committee (IACUC), certify that the IACUC meets the regulations in all federal, state, and local laws concerning the use of vertebrate animals.

Typed or Printed Name

Signature

Date

OPRR Animal Welfare Assurance Number:

Committee on animal welfare

Our committee has reviewed this project and the following is noted:

- The project does not include activities involving animal subjects.
- The project includes activities involving animal products, and is exempt from review under DHHS regulations.
- The project does include activities involving animal subjects. The committee reviewed and approved it on (date) _____
- Review and Approval Pending Award

Signed _____

Name _____

Title _____

Date _____

RESEARCH FELLOWSHIP APPLICATION FORMS

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KEYWORD DESCRIPTOR FORM

Use the following list to select no more than three (3) code numbers and respective keywords, which describe the substantive area of your research project.

Keyword List Osteopathic Terminology:

1)

2)

3)

9999000	Osteopathic Medicine	9999010	Palpation
9999001	Articular Strain	9999011	Palpatory Diagnosis
9999002	Axoplasmic Flow	9999012	Physiologic Motion of the Spine
9999003	Chapman's Reflex	9999013	Somatic Dysfunction
9999004	Cranial Concept	9999014	Tissue Texture Abnormality
9999005	Manipulation	9999015	Trigger Point
9999006	Massage	9999016	Viscero-Somatic Reflex
9999007	Motion, Inherent	9999018	Acquired Immune Deficiency Syndrome - AIDS
9999008	Myofascial Trigger Point		
9999009	Osteopathic Manipulative Treatment		

Keyword Your Own Terminology: The available keyword terms may not adequately describe your research project. You may use your own terminology to provide two additional keywords. The council on research strongly encourages you to use terminology from the "Glossary of Osteopathic Terminology (revised April 2009)". This handbook can be downloaded from www.aacom.org.

1)

2)

AOA Research Fellowship Application				Internal Use Only			
Name (<i>last, first, middle</i>)				ID Number:		IRB Approval:	
Project Title (<i>Do not exceed space provided</i>):				New Investigator to AOA		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Human Subjects Research		<input type="checkbox"/> Yes <input type="checkbox"/> No		IRB Approval Attached		<input type="checkbox"/> Yes <input type="checkbox"/> Pending	
Vertebrate Animals Research		<input type="checkbox"/> Yes <input type="checkbox"/> No		No funds will be released without IRB approval			
College		College Address:					
Department, service, laboratory, or equivalent							
Status (i.e. OMS year, intern)							
Applicant Preferred Contact: <input type="checkbox"/> Home <input type="checkbox"/> College <input type="checkbox"/> Work (if other)				II. Sponsor Name and Title:			
Applicant address:				Sponsor address			
E-mail (required):				E-mail (required):			
Phone		Fax		Phone		Fax	
<p>Agreement Regarding Funds Received as A Result of this Application</p> <p>The undersigned agree:</p> <ol style="list-style-type: none"> 1) To complete the project as outlined herein, and to submit reports as outlined in the <i>AOA Research Handbook</i>; 2) To observe institutional responsibilities concerning protection of research subjects as applicable and as outlined in the <i>Handbook</i>; 3) To make available the results of the studies through appropriate scientific publication channels with credit to AOA support for this project; 4) That applicant has permission to conduct the described research at this institution; 5) That applicant has arranged for pursuing his/her medical degree (or internship, or residency) program during the period of this application. 							
<p>Research Fellow: I certify that the statements herein are true, complete, and accurate to the best of my knowledge.</p>				<p>Signature of fellow (<i>In ink; "per" signature not accepted</i>)</p>			
<p>Sponsor: I certify that the statements herein are true, complete, and accurate to the best of my knowledge.</p>				<p>Signature of sponsor (<i>In ink; "per" signature not accepted</i>)</p>			
<p>Official signing for applicant organization: I certify that the statements herein are true, complete, and accurate to the best of my knowledge.</p>				<p>Signature of Official signing for applicant organization: (<i>In ink; "per" signature not accepted</i>)</p>			

AOA RESEARCH FELLOWSHIP PROPOSAL

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Specific Aims (limit 1 page)	
Background and Significance (limit 3 pages).....	
Preliminary Studies (limit 6 pages)	
Experimental Design & Methods (limit 10 pages).....	
Human Subjects (limit 2 pages).....	
Vertebrate Animals (limit 2 pages).....	
Personnel and Consultants	
Resources and Funding Support	
Literature Cited	
Sponsor Letter	
Letters of Support	
Budget Worksheet.....	
Budget Continuation and Justification (continue for 1 additional page).....	

BIOSKETCH (NIH Biosketch Accepted)

Submit original plus 6 copies

AOA Research Fellowship Application

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present situation, list, in chronological order previous education, employment, experience, and honors. Include present membership on any student or civic committees. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications.

Applicant Name:

Article I. BIOGRAPHICAL SKETCH

DO NOT EXCEED FOUR PAGES.

NAME	POSITION TITLE

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY

NOTE: The Biographical Sketch may not exceed four pages. Follow the formats and instructions on the attached sample.

- A. Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any student or civic committee.

- B. Military service record:** Branch of service, length of service, etc.

- C. Selected peer-reviewed publications (in chronological order).** Do not include publications submitted or in preparation.

- D. Research Support.** List selected ongoing or completed (during the last three years) research projects and financial support. Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and your role (e.g. PI, Co-Investigator, and Technician) in the research project.

ABSTRACT for AOA FELLOWSHIP APPLICATION

APPLICANT NAME:

GRANT TITLE:

DESCRIPTION: State the application's broad, long-term objectives and specific aims, making reference to the osteopathic relatedness of the project. Describe concisely the research design and methods. Describe the rationale and techniques you will use to pursue these goals.

This description is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the application is funded, this description, as is, will become public information. Therefore, do not include proprietary/confidential information. Avoid summaries of past accomplishments and the use of the first person.

DO NOT EXCEED THE SPACE PROVIDED at 7 1/4" x 4 1/8", or a Character Limit of 2500 including spaces.

PROJECT SUMMARY

Continue for one (1) additional page as needed.

Hypothesis: (Note how the hypothesis expresses a significant relationship to osteopathic philosophy or practice.)

Major Methods: (Procedures, controls, subjects, variables, special techniques.)

Data Collection: (What observations, measurements, and/or records will be made? Examples: medical record, specific laboratory measurement.)

Analysis of Results: (Overview of planned analysis and summary of data.)

Background for Development of Project: (Your experience directly relating to this project, number of publications in your curriculum vitae related to this project, major literature resource you will use as a reference.)

Certificate of Compliance
PROTECTION OF RESEARCH SUBJECTS

To be filed with each research proposal, and with each fellowship application where applicable. Please attach copies of all consent permissions as applicable.

Title of project:

Name of Fellow:

Institution:

HUMAN SUBJECTS

I, as chairman of the Institutional Review Board (IRB), certify that the IRB meets the regulations in all federal, state, and local laws concerning the use of human subjects.

Typed or Printed Name

Signature

Date

OPRR Assurance of Compliance Number:

Committee on use of human subjects

Our committee has reviewed this project and the following is noted:

- The project does not include activities involving human subjects.
- The project includes activities involving human products or unidentifiable patient data, and is exempt from review under DHHS regulations.
- The project does include activities involving human subjects. The committee reviewed and approved it on (date) _____
- Review and Approval Pending Award

Signed _____

Name _____

Title _____

Date _____

VERTEBRATE ANIMALS

I, as chairman of the Institutional Animal Care and Use Committee (IACUC), certify that the IACUC meets the regulations in all federal, state, and local laws concerning the use of vertebrate animals.

Typed or Printed Name

Signature

Date

OPRR Animal Welfare Assurance Number:

Committee on animal welfare

Our committee has reviewed this project and the following is noted:

- The project does not include activities involving animal subjects.
- The project includes activities involving animal products, and is exempt from review under DHHS regulations.
- The project does include activities involving animal subjects. The committee reviewed and approved it on (date) _____
- Review and Approval Pending Award

Signed _____

Name _____

Title _____

Date _____

Budget Continuation and Justification Page
Continue for one (1) additional page as needed.

Checklist

(must be completed, signed, and submitted with the application – 1 copy attached to Cover Letter)

Grants

- Form A
- Form B
- Form C (**Signed**)
- Form D
- Form E
- Form F
- Form G -Biosketch
- Key Personnel
- Trainees
- Budget Worksheet
(One worksheet for each year of request)
- Budget Justification and Continuation Page
- Abstract
- Form H - Project Summary

Form I – IRB (Internal Review Board Certificate of Compliance,
Protection of Research)

- Human Subjects (**Signed**)
- Animal Welfare (**Signed**)

Research Proposal Narrative:

- Specific Aims – 1 page
- Background and Significance – 2 to 3 pages
- Preliminary Studies – 6 pages maximum
- Experimental Design and Methods –
10 pages maximum
- Human Subjects
- Vertebrate Animals
- Personnel and Consultants
- Resources and Funding Support
- Literature Cited

Miscellaneous:

- All pages are numbered consecutively
- The table of contents is completed accurately
- I have submitted one original and 6 copies

Fellowship

- Form B – Keyword Descriptor
- Form C – Application Face Page (**Signed**)
- Form D – Table of Contents
- Biosketch – PI
- Biosketch – Sponsor
- Abstract
- Form H - Project Summary

Form I – IRB (Internal Review Board Certificate of Compliance,
Protection of Research)

- Human Subjects (**Signed**)
- Animal Welfare (**Signed**)

Research Proposal Narrative:

- Specific Aims
- Background & Significance
- Preliminary Studies
- Experimental Design & Methods
- Human Subjects
- Vertebrate Animals
- Personnel and Consultants
- Resources and Funding Support
- Literature Site
- Sponsor Letter
- Letters of Support
- Budget Worksheet
- Budget Continuation Page

Miscellaneous:

- All pages are numbered consecutively
- The table of contents is completed accurately
- I have submitted one original and 6 copies

Signing this form acknowledges that I have reviewed this document and all required information is completed and included.

Principle Investigator (Print)

Principle Investigator (Signature)

EVALUATION WORKSHEETS

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AOA GRANT REVIEWER WORKSHEET

REVIEWER:

Grant No. and Title:

Principal Investigator:

For each criterion select the one best descriptor that reflects your evaluation of the grant proposal being evaluated, where 1 is the best score and 4 indicates a fatal flaw. You may indicate an intermediate score in increments of .25 (i.e. 1.25, 1.5, 1.75)- enter these values clearly on the score sheet. For each section, add the values selected for a subtotal. Staff will complete the calculations. Comments regarding concerns or strengths should be stated on a separate sheet(s) of paper. For a score of 3 or higher, please comment on the reason for this score.

SCIENTIFIC SIGNIFICANCE (50%)

Significance and research topic:

- 1. Important
- 2. Good
- 3. Old/little significance
- 4. Irrelevant/no importance

Data analysis plan:

- 1. Excellent
- 2. Adequate
- 3. Some problems
- 4. Significant problems

Hypothesis:

- 1. Excellent
- 2. Adequate
- 3. Some problems
- 4. Significant problems

Overall protocol and technique:

- 1. Excellent; no revisions needed
- 2. Adequate; minor revisions needed
- 3. Some problems; major revisions needed
- 4. Significant problems; not Scientifically Acceptable

Scientific literature review:

- 1. Fully researched
- 2. Adequately researched
- 3. Cursory review
- 4. Inadequate literature review

Investigator:

- 1. Highly qualified
- 2. Qualified
- 3. Problems with qualifications
- 4. Not qualified or major problems

Rationale and expectations:

- 1. Excellent
- 2. Average
- 3. Poor
- 4. Requires re-write

Sub-Total: _____

Subtotal Scientific Significance: _____ / of 28
Subtotal Osteopathic Significance: _____ / of 24
Subtotal Other Significance: _____ / of 28
TOTAL: _____ / of 80

Grant No. and Title:

OSTEOPATHIC SIGNIFICANCE (30%)

Osteopathic significance:

1. Clear
2. Moderate
3. Little
4. None

Class:

1. Clinical – Osteopathic
2. Biomedical – Osteopathic
3. Clinical – Non-osteopathic
4. Biomedical – Non-osteopathic

Osteopathic Priority:

1. High priority/important
2. Moderate priority/interesting
3. Low priority/old research problem
4. Lowest priority/no relation

Likely to advance profession or lead to profitable line of osteopathic research:

1. Excellent
2. Probable
3. Possible
4. Not Likely

Osteopathic literature review:

1. All major osteopathic literature cited
2. Adequate major osteopathic literature cited
3. Cursory presentation of osteopathic literature
4. Osteopathic literature review lacking

DO Degree:

1. DO degree for PI
2. DO degree co-investigator
3. No DO but PI with prior osteopathic research
4. No DO, no PI with osteopathic background

Subtotal _____

OTHER SIGNIFICANCE (20%)

Facilities:

1. Suitable
2. Some problems
3. Significant problems
4. Not suitable

Quality of manuscript:

1. Excellent, very well written
2. Adequate, logic is clear
3. Some problems in following logic
4. Significant problems impair overall integrity of application

Budget:

1. Appropriate for proposed work
2. Some budget problems for proposed work
3. Excessive budget or major problems
4. Budget not appropriate

Institutional support:

1. Excellent
2. Good
3. Adequate
4. Poor or none

Likelihood to complete in time allotted:

1. Excellent
2. Probable
3. Possible
4. Not likely

Potential for external funding after AOA sponsorship:

1. Excellent
2. Good
3. Possible
4. Not likely

Junior investigators (Student, Fellow, Resident) on project:

1. Significant involvement
2. Some involvement
3. Little involvement
4. No involvement

Subtotal _____

AOA FELLOWSHIP REVIEWER WORKSHEET

REVIEWER:

Fellowship No. and Title:

Applicant:

For each criterion select, the one best descriptor that reflects your evaluation of the fellowship application where 1 is the best score and 4 indicates a fatal flaw. You may indicate an intermediate score in increments of .25 (i.e. 1.25, 1.5, 1.75) - enter these values clearly on the score sheet. For each section, add the values selected for a subtotal. **Staff will complete the calculations.** Comments regarding concerns or strengths should be stated on a separate sheet(s) of paper. For a score of 3 or higher, please comment on the reason for this score.

SCIENTIFIC SIGNIFICANCE (50%)

Significance of research topic:

- (1) Important
- (2) Good
- (3) Old/little significance
- (4) Irrelevant/no importance

Hypothesis:

- (1) Excellent
- (2) Adequate
- (3) Some problems
- (4) Significant problems

Scientific literature review:

- (1) Obviously researched fully
- (2) Adequately researched
- (3) cursory review
- (4) Inadequate literature review

Rationale and expectations:

- (1) Excellent
- (2) Average
- (3) Poor
- (4) Only salvaged by total rewrite/rethink

Data analysis plan:

- (1) Excellent
- (2) Adequate
- (3) Some problems
- (4) Significant problems

Overall protocol and technique:

- (1) Excellent; no revisions needed
- (2) Adequate; minor revisions needed
- (3) Some problems; major revisions needed
- (4) Significant problems; not scientifically acceptable

Investigator:

- (1) Highly qualified
- (2) Qualified
- (3) Problems with qualifications
- (4) Not qualified or major problems

Mentor:

- (1) Highly qualified
- (2) Qualified
- (3) Problems with qualifications
- (4) Not qualified or major problems

Sub-Total : _____

OSTEOPATHIC SIGNIFICANCE (30%)

Osteopathic significance:

- (1) Clear
- (2) Moderate
- (3) Little
- (4) None

Class:

- (1) Clinical – Osteopathic
- (2) Biomedical – Osteopathic
- (3) Clinical – Non-osteopathic
- (4) Biomedical – Non-osteopathic

Osteopathic Priority:

- (1) High priority/important
- (2) Moderate priority/interesting
- (3) Low priority/old research problem
- (4) Lowest priority/no relation

Likely to advance profession or lead to profitable line of osteopathic research:

- (1) Excellent
- (2) Probable
- (3) Possible
- (4) Not Likely

Osteopathic literature review:

- (1) All major osteopathic literature cited
- (2) Adequate major osteopathic literature cited
- (3) cursory presentation of osteopathic literature
- (4) Osteopathic literature review lacking

Sub-Total : _____

OTHER SIGNIFICANCE (20%)

Facilities:

- (1) Suitable
- (2) Some problems
- (3) Significant problems
- (4) Not suitable

Quality of manuscript:

- (1) Excellent, very well written
- (2) Adequate, logic is clear
- (3) Some problems in following logic
- (4) Significant problems that impair overall application

Institutional support:

- (1) Excellent
- (2) Good
- (3) Adequate
- (4) Poor or none

Likelihood to complete in time allotted:

- (1) Excellent
- (2) Probable
- (3) Possible
- (4) Not likely

Sub-Total : _____

Subtotal Scientific Significance _____ /of 32

Subtotal Osteopathic Significance _____ /of 20

Subtotal Other Significance: _____ / of 16

TOTAL _____ / of 68