



AOA Research Handbook

**The Research Handbook
of the
American Osteopathic Association**

**American Osteopathic Association
142 East Ontario Street
Chicago, Illinois 60611**

BOT 2005

2005 AOA RESEARCH HANDBOOK
The Research Handbook of the
American Osteopathic Association

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I. GENERAL INFORMATION AND PROCEDURES

I. 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 research at the direction of the Board. The Council reports to the Bureau of Osteopathic Clinical Education and Research (Bureau) and receives support from the Division of Research Development in the AOA Department of 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 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) 202-8006 or (800) 621-1773, Ext. 8006; Fax (312) 202-8306

A. 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 Principles and Practice (OPP) and Osteopathic Manipulative Medicine (OMM);
 - b) Develop the research capacity of the osteopathic profession by supporting the training and research of career track investigators.

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 lead 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 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.

B. 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, fellowships and awards shall follow procedures described in the *Handbook*. The Council is responsible for maintaining the *Handbook*.

C. FUNDING RESOURCES

Grants, fellowships and awards 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. 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 of 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 constructive criticism. Researchers and student researchers are also invited to submit abstracts, which are published in the Research Conference Program and in the *JAOA - Journal of the American Osteopathic Association*. Abstracts are presented at the Conference in a Poster Presentation. Students of osteopathic medicine are especially encouraged to participate in the Poster Presentation, and the Council sponsors a Student Prize Competition, a judged event.

A. ABSTRACTS AND POSTER PRESENTATION

1. The Poster Presentation session is an integral part of the Research Conference. A Call for Abstracts is issued early in the year; the submission deadline is on or near **March 15** of each year. The Council reviews the abstract submissions, and those that are approved are published in the August and September issues of the *JAOA* prior to the conference. Abstracts are submitted under four headings:

- (P) OMM/OPP
- (C) Clinical Studies
- (B) Basic Sciences
- (M) Medical Education

The formal Poster Presentation takes place during the second day of the conference and presenters should be available with their posters during that time. Students may elect to enter their posters in the Student Prize Competition at the time of abstract submission (see page 7). Posters should be exhibited on each day that the exhibit halls are open.

2. Abstract requirements

The information presented in the abstract must be original, not a duplicate and not previously published.

- All abstracts must have clearly stated Hypothesis, Materials and Methods, Results, and Conclusions.

- The abstract must be submitted through a medical organization or other recognized AOA organization, and should be authored by at least one osteopathic physician or full-time faculty member from one of the colleges of osteopathic medicine.
- If the abstract is entered in the Student Prize Competition, the first author must be a student at a college of osteopathic medicine at the time the research is performed.
- Research that has been funded by the Council on Research, conducted at a college of osteopathic medicine, or which defines osteopathic principles and practices will be given priority consideration.

B. LOUISA BURNS MEMORIAL LUNCHEON

Each year, a luncheon is held in honor of Louisa Burns, DO (1870-1958), an early pioneer in osteopathic research. Annual Awards are presented at the luncheon, one of which is the Louisa Burns Memorial Lecture. The Luncheon is a way for the Council to show their appreciation for those who have contributed to the Research Conference each year and to those who contribute to osteopathic research throughout their careers. This is not a ticketed event.

C. ANNUAL 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. Awards are presented annually at the Research Conference at the Louisa Burns Memorial Luncheon. Awardees receive a cash gift of unrestricted funds and reimbursement of conference attendance expenses.

Each year the Council will issue a Call for Nominations for annual awards. The Council will determine the award each year, but in no year will the cash award exceed \$5,000 per individual. Awards will be given only in years when qualified nominees are submitted, and will be conferred at the Council's discretion. The Council may hold nominations of worthy individuals for re-consideration for awards for the following year, but individuals nominated five (5) or more years previously must be re-nominated.

1. NOMINATION and AWARD PROCEDURES

Nominations may come from anyone in the osteopathic profession and from colleagues of osteopathic physicians. Nominations should include the following: (A) Ten copies of a sponsor's letter, which presents a detailed account of the contributions the person has made to research and education; (B) Ten copies of the current curriculum vita of the nominee; and (C) One copy of the applicant's five most important research publications.

Nominations shall be submitted in writing to the Council in the care of the AOA Department of Research. Nominations shall be postmarked before 11:59 P.M. on March 15. If March 15 is a Saturday or Sunday, the deadline shall be extended to 11:59 P.M. on the next Monday, immediately following March 15. All nominations will be acknowledged, and all members of the Council will receive a copy of each nomination file. Awards will be announced in a timely manner, and all nominees will receive notice of the outcome of the awards process.

2. GUTENSOHN - DENSLOW AWARD

The award is given in honor of J. S. Denslow, DO, a noted researcher in viscerosomatic reflexes and biomechanics, and in honor of Max T. Gutensohn, D.O., a noted educator and past Chairman of the Council, then Bureau, on Research. Both men served the osteopathic profession in many capacities over the years and made

many valuable contributions. The purpose of the award is to recognize outstanding contributions to the osteopathic profession in the areas of research, scholarly activity and education.

ELIGIBILITY

- A nominee must be either an osteopathic physician or hold a doctoral level degree and be on the faculty or staff of an osteopathic institution.
- A nominee must be, or have been, actively involved in clinical or basic science research with publications in refereed journals to their credit.
- A nominee should be, or have been, active in osteopathic education and/or training and serve as a model researcher by passing his/her knowledge and expertise on to others in the profession, via lectures, the classroom, and/or postdoctoral training programs.

3. IRVIN M. KORR AWARD

The Irvin M. Korr award recognizes exemplary commitment to basic science research in an osteopathic institution. The award was created to honor Irvin M. Korr, PhD, a noted researcher, professor and advocate of osteopathic research. The award is given to a basic scientist who has embraced the challenges of a professional career in a college of osteopathic medicine. This person will have maintained a full and rewarding career in research. The individual will be an active participant in the academic and research community at the osteopathic institution, and in the appropriate professional society related to his or her area of research endeavor. Candidates who have focused their research on the clinical or basic science aspects of osteopathic medicine and manipulative treatment are especially sought.

ELIGIBILITY

- The nominee shall be a Ph.D. Basic Scientist who is a full time faculty member at a college of osteopathic medicine.
- A nominee shall have a demonstrated excellence in research in an osteopathic college.
- The nominee demonstrates career achievement in the communication of research and scientific knowledge through a) publication, b) teaching, and c) postdoctoral training.

4. LOUISA BURNS MEMORIAL LECTURE

The award consists of an invited lecture at the Louisa Burns Memorial Luncheon held during the Research Conference, as well as a cash award as described above. It is given to a DO or PhD scientist at an accredited osteopathic institution whose pioneer spirit and innovative vision are evident in their commitment to the advancing osteopathic medicine and osteopathic principles and practice. By tradition, the Council will alternate a DO and a PhD lecturer when considering this award.

ELIGIBILITY

- The nominee should be, or have been, involved in research of high merit and in particular to the development of osteopathic theory and practice.
- The nominee shall have contributed to the development of institutional research capabilities.
- Nominees have been engaged in the development of programs to train researchers for the osteopathic profession, or developing research programs for osteopathic physicians in the clinical setting.

5. DARRYL A. BEEHLER, DO RESEARCH MENTOR OF THE YEAR

The Council established this award in 2004 to acknowledge the importance of research mentoring in the development of future researchers in the osteopathic profession. Darryl A. Beehler, DO, has served the AOA as a member of the Board of Trustees since 1992. He designated his AOA Presidency as the “Year of the Mentor” in recognition of the significant role of mentors and the contributions they make to the studies and careers of osteopathic physicians.

ELIGIBILITY

- The nominee shall be a DO or PhD who is now, or has been, active in the education process.
- The nominee shall be, or have been, involved in service, teaching, research and publication in osteopathic education.

D. STUDENT AWARDS

1. BURNETT OSTEOPATHIC STUDENT RESEARCH AWARD

This award is granted by application rather than direct nomination. The award recognizes a student of osteopathic medicine who submits the most outstanding concept paper pertaining to an osteopathic oriented research proposal. The award is formally given at the annual Research Conference; it consists of a \$100 cash prize and an all-expense paid trip for the full three days of the conference. The award is named in honor of the contributions made to the osteopathic profession by John H. Burnett, D.O. and Mary M. Burnett, D.O.

The concept paper should describe the rationale for developing a research protocol that concerns osteopathic philosophy or practice and may include studies of osteopathic manipulative treatment. The paper should include a description of the problem to be studied, a brief review of previous work on the problem, a general overview of the research plan, and a description of the significance of the research with respect to osteopathic principles and practice or osteopathic manipulative treatment. Emphasis should be on the conceptual analysis of the problem with attention to the identification of relevant variables and their relationships.

Submission deadlines will always be on the same date as nominations for the Annual Awards and will be announced with the Call for Nominations. Applicants will be notified in writing of the results of the competition

ELIGIBILITY

- Eligibility is limited to students enrolled in AOA-accredited colleges of osteopathic medicine.

APPLICATION

- Applications are included in this *Handbook* (See Appendix A) and are available at DO On-line.
- The application form must be signed by the Dean of the College (or a designate).
- Applicants are encouraged to consult with faculty advisors in the development of the paper.
- The paper must be typed double-spaced and must be no longer than 15 pages. References, tables and figures may be included and will not be counted toward the 15 pages.
- One (1) original and ten (10) copies of the paper and application form must be submitted to the AOA Division of Research. The submission deadline will be the same as for nominated awards above.

- The Council will judge papers on content and form. The paper shall be of sufficient quality to be submitted to the **JAOA** for possible publication.

2. STUDENT POSTER PRIZE

Two prizes of \$250 are awarded following the formal poster session at the Research Conference. To be eligible, a participant must be a predoctoral student at an AOA-accredited college of osteopathic medicine *at the time the research is conducted*. Students who want to participate must so indicate when submitting their abstracts.

A team of judges will review each competing poster during the Poster Session. Students should be prepared to present their findings and answer questions within a limited time. Students are judged on Science, Poster layout and graphics, Knowledge, Presentation style, and Originality. Winners of awards are announced at the end of the poster session.

III. RESEARCH GRANTS

A. PRIORITIES AND PROCEDURES

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

- The grant Principal Investigator will be qualified and dedicated.
- The Institution which supports the Principal Investigator will demonstrate a commitment to osteopathic research.
- 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.
- 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. While there is no maximum time for funding, investigators should not expect to be funded for more than two years.

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 principles, practices (OPP), and osteopathic manipulative treatment (OMT):

- 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.
2. 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

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.

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, 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. 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.

PHS Forms and Format in 2006

Following the December 1, 2005 application cycle, the application forms and format for AOA Research Grants and Fellowships will change.

The AOA will require the use of PHS 398 Forms and Format as currently used by the National Institutes of Health. <http://grants2.nih.gov/grants/funding/phs398/phs398.html>

Researchers who plan to submit funding applications during the 2006 award cycle are advised to familiarize themselves with that grant application system. Updates will be posted to DO Online, "Research and Grants."

D. DEADLINE & SUBMISSION INFORMATION

Application forms are available from the Division of Research Development of the AOA Department of Research and are available at DO Online, "Research and Grants". Applicants are invited to contact the Division staff if there is a question about the meaning of a specific provision in the application. By the time the application is received for evaluation, it must be complete.

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. Late applications will be returned unread. Applications must be complete to be considered.

The original plus ten (10) single-sided copies of each application and an NIH-style biographical sketch (see Form J) of the principal investigator and all co-investigators are required. Six (6) copies of appended materials are needed. The original must be signed by 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. The department chairman'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.

E. FORMAT FOR GRANT APPLICATIONS

Applications should be in the following format:

1. Grant forms listed below, in alphabetical order.
2. Table of Contents of the research proposal.
3. Text of the research proposal: typed single-spaced on one side of the paper. Page numbers should be at the bottom center of each page. The text must be divided in sections, and must adhere to the page length stipulations specified in the requirements listed below.
4. A biographical sketch on Form J of the Principal Investigator and all Co-Investigators (10 copies)
5. Six (6) copies of **relevant** articles or other appended materials by the investigator(s) and, if applicable, a progress report.

F. INSTRUCTIONS FOR GRANT APPLICATION FORMS

A grant application requires the following forms:

ABSTRACT for AOA Grant Application: Do not exceed 7 1/4" by 4 1/8".

Form A: This is the application cover sheet. A single principal investigator is required. (See "Programs" section.)

Form B: Funding Data Sheet. If the principal investigator has previously received funding from the AOA, 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, and include one (1) copy of each publication with the current application.

Form C: Administrative Data Sheet. Note that each applicant has the option of recommending three (3) potential reviewers for their application. 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. To exercise this option, the applicant's name and application title

along with the potential reviewers' names, complete addresses, and office telephone numbers should be included on a separate sheet of paper WITH the original and one (1) copy stapled to the back of the original copy of Form C. Although the potential reviewers that you provide may or may not be asked to review the application, it is in the best interest of both the applicant and the Council to insure that competent, impartial external reviewers can be identified and solicited for review of each application.

Form D: Certificate of Compliance, Protection of Research Subjects. (See sub-sections on Protection of Human Research Subjects and Protection of Vertebrate Animals in Sections IV and V for details.) 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 D. 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".

Form E: Summary of Budget & Financial Statement. The applicant must provide a specific budget for proposed expenditures which would be made under this grant. The budget should show the items and the amounts requested from the AOA as well as funds available from other agencies or institutions.

Each budget item greater than \$500 must be justified, including cost of that item, using attached explanatory sheets as necessary. Explanatory sheets must be placed immediately after Form E. 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 Form E. The following expenses are allowable as direct costs:

1. Technician's Salary (fundable at the discretion of the Council): The Council does pay fringe benefits for salaried technicians. The Council can fund personnel 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.
2. Research Fellowship Stipend for Students: 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 Form E. The finance department of the institution is responsible for payment of the stipend to the student.
3. 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 for 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.

4. 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).
5. Capital Equipment: Individually list items with an expected duration of usable life greater than (3) three years. Requests for expensive or unusual equipment must be fully explained and justified. Funds for major equipment are generally not provided.

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.

6. Miscellaneous: Publication costs may be requested. However such costs must be specifically identified.
7. Travel funds are permitted for consultation on research design and for presentation at other professional meetings. (See "Travel Allowance for AOA Research Conference" for an explanation of the travel allowance.).

The following expenses are not allowable:

- Physical plant renovations or improvements.
- Professional development activities, including: dues for professional society memberships, tuition for continuing education activities, and tuition for continuing medical education activities.
- 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.

Form F: Project Summary: This form must be completed in the space provided. 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 Council at its presentation to the Council. The summary will also be used for releases to AOA publications to explain your project.

Form G: Keyword Descriptor Form: Keywords will be used administratively to describe the substantive area of your project.

Form J: Biographical Sketch: Please use this form to list professional and research experience.

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. The Checklist (Form C) 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

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. **One (1) page is recommended for this section.**

B. BACKGROUND AND SIGNIFICANCE

Provide a clear, detailed background for the present proposal. Critically evaluate 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 in the present proposal will relate to the long-term objectives stated in section a of the proposal. **Two (2) to three (3) pages are recommended for this section.**

C. PRELIMINARY STUDIES

Discuss the current status or final results of any studies, done by the applicant, pertinent to the proposal. **Include one copy 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. **This section should not exceed six (6) pages,** exclusive of appended materials.

D. EXPERIMENTAL DESIGN & METHODS

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.

Point out any procedures, situations, or material that may be hazardous to personnel and the precautions to be exercised. **This section should not exceed ten (10) pages.**

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 made 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, 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 which documents, relative to the proposed research, the following criteria:

- Licensure or registration of the principal investigator as a health care provider;
- Training and experience of the principal investigator in the procedures proposed; and
- 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. Estimate the percentage of each individual's effort which will be devoted to the project and his/her source of support. The following information must be addressed:

1. For professional personnel, include a curriculum vitae using Form J of the principal investigator and of co-investigators. For continuing grant applications the publications list must be updated each year. Each curriculum vitae should not be long; but it should include the applicant's position, major degrees, journals in which he/she has published, a list of approximately six most important publications, and a list of publications that resulted from work supported, in full or in part, by an AOA grant. The vitae should also include a list of previous grant support from the AOA and other funding agencies. The Council may request additional information, if necessary. **Each curriculum vita should be attached to the research proposal.** (See Form J)
2. For non-professional personnel, **a description of the work to be done should be attached to the proposal immediately after Form E.** (See "Instructions for Grant Applications Forms", Section III, F)
3. For student 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. **The description should be attached to the proposal immediately after Form E.** (See "Instructions for Grant Applications Forms", Section III, F).

The principal investigator must submit a written evaluation of the fellow's progress when he/she submits his/her 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.

The written evaluation of the student's progress will be due upon completion of the fellowship. Student fellows working on non-AOA funded grants would report in the same manner and on the same schedule as student fellows working on AOA-supported grants. 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.

The Council reserves the right to alter the schedule for evaluation reports and progress reports as needed to fit a particular situation.

4. 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

All literature citations occurring in the text should be identified by number only. 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, "Human Subjects", 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 OF GRANT APPLICATIONS

The AOA Division of Research Development acknowledges all grant applications and prepares a "Grant Application Review Face Sheet" for each, noting any format deficiencies. The Council is responsible for initial review of all grant proposals. The Council may also direct the Division of Research Development to send a proposal to one to three scientists knowledgeable in the field(s) involved in the application for their auxiliary review and evaluation. Each reviewer receives a copy of the *Handbook*, including the "Outline for Review of Research Projects"; reviewers submit written reviews by mid-February.

Each member of the Council receives a copy of all grant proposals. While each member is expected to be familiar with all proposals submitted each year, each proposal is assigned to one Council member who is responsible for a written review and critique of the proposal.

A. RANKING SYSTEM

All proposals are considered for scientific acceptability, osteopathic significance and involvement of junior investigators and ranked as follows (a proposal may possess all or some of the attributes listed for each rank). Each grant application is given a priority score of 1.0 (highest) to 4.0 (lowest). Scientific merit is the principal criterion used in awarding grants. In addition, priority will be given to projects with osteopathic significance.

- 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.

A grant is deemed scientifically meritorious if there is conceptional correctness and a strong chance of success for completion. For a grant proposal with a rank of "4" in any one area, and which shows special promise, the Council may at their discretion request re-development of the proposal.

1. PRIORITY RANKING:

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

- a) Clinical Studies
- b) Principal investigators with an earned DO degree
- c) New investigators trying to become established through researcher development pilot grant funding.
- d) Investigators having a productive reporting history (both in terms of publications and participation in the AOA Research Conference)
- e) Funding for pilot data grants.
- f) Grant proposals with plan for leading to extramural funding.
- g) Osteopathic significance of the research plan.

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 must be given a "4" ranking and will not be considered for funding.

B. REVIEWER GUIDELINES

This two-page outline is intended to be used by invited reviewers as a suggested 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. If there are any aspects of the proposal not covered by the guidelines, which you feel should be considered please feel free to comment.

1. 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.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.
7. 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?
8. 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 (1.25, 1.50, 1.75, 2.25, 2.50, 2.75, 3.25, 3.50, 3.75) may be given.

A grant is deemed to be scientifically meritorious if there is conceptional correctness and a strong chance of success for completion.

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 proposal with clear application to osteopathic principles, practices, philosophy, or manipulative treatment.
- BO: Basic science proposal with clear application to osteopathic principles, practices, philosophy, or manipulative treatment.
- CN: Clinical proposal with application to medical science in general, but with NO discernible application to osteopathic principles, practices, philosophy, or manipulative treatment.
- BN: Basic science proposal with application to medical science in general, but with NO discernible application to osteopathic principles, practices, philosophy, or manipulative treatment.

The Council considers the initial recommendations of the Council together with the funds available and makes its recommendations on funding of applications to the Board of Trustees for their approval.

C. COUNCIL EVALUATION

Osteopathic Significance. As noted in the discussion above, 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. In studying each proposed project, the Council also considers the following:

1. Comments from reviewers and the responses from the principal investigator.
2. Adequacy of the proposed plan, including hypothesis, techniques, data analysis plans, and the ability of the applicant to describe the project.
3. 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.
4. Adequacy of the facilities available to the investigator.
5. Availability of sufficient time for the investigator and other personnel to conduct the study.
6. 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.
7. 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.
8. Ethical considerations, including completion of Form D, the Certificate of Compliance.

From time-to-time, when a need is apparent, osteopathic institutions may be supported in order to provide seed money to promote research within that institution.

Conflict of Interest. During the consideration of grant requests, any member of the Council who is a staff member of the institution from which a request emanates, shall excuse himself/herself from discussion of, and voting on, that request.

D. AWARD and NOTIFICATION

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 three weeks after it meets. Following formal approval by the AOA Board of Trustees, applicants with approved projects are notified by certified letter. 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 finance officer 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 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.

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.

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 pro-active in filing required reports, and shall not depend on notice from the AOA.

1. **Progress Reports.** Grants approved and funded by the AOA support projects which may require several years for completion.

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.

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. (Form E 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.

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.

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.

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.

4. **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.
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 - Journal of the American Osteopathic Association* for first refusal. Failure to present results for publication within this 2-year period 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.

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. 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").
Conference presentation or an abstract does not constitute a final report.
2. Make a written request 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.

A check 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. 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:

- a) Major reduction in that portion of the principal investigator's time available for research;
- b) Inability to obtain research subjects;
- c) Inability to obtain technical support personnel authorized in the grant application; or
- d) Inability to obtain new equipment authorized in the grant application.

The principal investigator is responsible for documenting the presence of any of the above conditions to the satisfaction of the Council.

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

INTRODUCTION

The AOA Research Fellowship is sponsored by the Council. 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.

A. ELIGIBILITY REQUIREMENTS

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.

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 at an AOA-accredited institution. Preference will be given to applicants in category (a). Individuals who have demonstrated research competency by virtue of competing successfully for major independent research grant support are not eligible for an AOA Fellowship.

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.

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.

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.

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.

PHS Forms and Format in 2006

See announcement on page 8 concerning Change of Application Forms and Format

B. 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 March 15. If March 15 is a Saturday or Sunday, the deadline shall be extended to 11:59 P.M. on the next Monday, immediately following March 15. Applications should be typed, single spaced and one-sided. Submit an original and ten (10) copies of the complete application.

C. FORMAT FOR FELLOWSHIP APPLICATIONS

Applications should be in the following format:

1. Grant forms listed below, in the order as listed.
2. Table of Contents of the research proposal.
3. Text of the research proposal: Typed single-spaced on one side of the paper. Page numbers should be at the bottom center of each page. It is suggested that the text be divided in sections according to the requirements listed below.
4. Applicant's curriculum vitae.
5. A letter or other document giving evidence of approval of the project by the prospective fellow's sponsor.
6. If appropriate, a letter or other document giving evidence of approval of the project by the prospective fellow's consultant.

D. INSTRUCTIONS FOR FELLOWSHIP APPLICATION FORMS

(See instructions pertaining to Forms under Section III, F, "Instructions for Grant Application Forms".)

Form H1: Application for fellowship grant. Complete both pages of this Form.

Form H2:

Form I: Personal Data Sheet. (self explanatory)

Form D: Certificate of Compliance, protection of research subjects.

Form F: Project Summary:

Form G: Keyword Descriptor Form:

Form J: Biographical Sketch:

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:

1. Specific Aims: 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.

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. **Sections A and B should not exceed two (2) pages.**

- 2 Background & Significance: 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. **Sections A and B should not exceed two (2) pages.**

3. Preliminary Studies: 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: 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. **This section should not exceed five (5) pages.**

5. Human Subjects: Using the instructions at "The Research Proposal ", Section IV, E, address concerns 1-8.

6. Vertebrate Animals: Using the instructions at "The Research Proposal ", Section IV, F, address concerns 1-5

7. Personnel and Consultants: The following information must be included:

- a) 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.
- b) If consultant arrangements have been made, the **application should include, for each consultant, a letter indicating:**
 - Consultant's support for the application;
 - Agreement to provide supervision of the applicant; and
 - 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 available for the sponsor and consultant(s). For each individual, classify the funding according to the following three groups:
 - i. All current support;
 - ii. All applications and proposals pending review or funding; and
 - iii. For each grant that is currently funded, include:
 - The source of support, identifying number and title;
 - Percentage of appointment on the project;
 - Dates of entire performance period;
 - Annual direct costs;
 - A brief description of the project;
9. Literature Cited -- All literature citations occurring in the text should be identified by number only. 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.

Incomplete applications, that is, those lacking essential information, sponsor approval, or evidence of compliance with regulations for protection of research subjects (where indicated by type of proposal) cannot be accepted. Those received after the deadline date will be returned unread.

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.

1. 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, consisting of a \$4,250 stipend and a \$750 travel allowance to attend the annual AOA Research Conference during the year of the fellowship. Funds 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 Council.
- b) \$750 in travel funds for the Research Conference, to be paid upon receipt of an abstract for the Conference and no later than May 1. When the Council supports travel costs for Fellows to attend the Research Conference, it expects Fellow attendance at the poster session, the Louisa Burns Luncheon 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.

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 the section "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. REQUIRED REPORTS

All reports should be sent to the Division of Research Development. 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 in written letter format which:

- Discusses 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 curriculum vitae of the consultant; and
- Includes the signatures of the fellow, sponsor, and any consultants to the fellowship.

- a) Research Abstract: Fellows must submit an abstract for a paper (oral) presentation, on the form provided by the AOA Division of Research Development by the abstract deadline, for inclusion in a special section of the AOA Research Conference program. 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.
- b) 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.
- c) The final report is due October 1, 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 unless the fellow specifies otherwise.

The AOA Division of Research Development will furnish copies of the reports 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.

IX. SPECIAL RESEARCH PROGRAMS

A. EFFICACY OF AN OSTEOPATHIC APPROACH TO REPRESENTATIVE CLINICAL ENTITIES

1. INTRODUCTION

Various managed health care delivery plans and third-party purchasers of health care services in the private and public sector are striving to reduce the costs of their services. As an example, reimbursement for osteopathic diagnosis and manipulative management performed by osteopathic physicians and other forms of manual treatment performed by other practitioners are being closely scrutinized in relation to costs.

The osteopathic profession has need for more research into the medical efficacy and cost effectiveness of treatment of patients using osteopathic manipulative management. To address this need, the House of Delegates of the American Osteopathic Association (AOA) has directed the Council to "... Implement a research protocol to determine the effectiveness of osteopathic manipulative management, when appropriately practiced, in restoring the health of patients in a cost-effective manner..." (AOA House of Delegates resolution 271, *OMT Research Data*, Approved July, 1990).

The Council has been working since 1987 to support the development of a protocol to address one aspect of osteopathic efficacy -- evaluation of osteopathic manipulative treatment in management of patients with low back pain. In 1991 the Council expanded that effort to include demonstrations in other clinical entities and issued a request for applications entitled "Efficacy of an Osteopathic Approach to Representative Clinical Entities". In September 1992 the Council identified that research area for incorporation as a special program of its annual grant program.

2. PURPOSE AND RESEARCH OBJECTIVES

The purpose of the "Special Research Program: Efficacy of an Osteopathic Approach to Representative Clinical Entities" (Osteopathic Efficacy) is to encourage assessment of the efficacy, including cost-effectiveness and safety of the integration of osteopathic manipulative interventions into a total osteopathic approach using controlled

experimentation which evaluates objective, quantifiable outcomes. The desired research will investigate specific osteopathic manipulative interventions used both in the care of ambulatory and hospitalized patients. Examples of potential interventions include, but are not limited to the following representative clinical entities:

- a) Acute Neuromusculoskeletal
- b) Chronic Neuromusculoskeletal
- c) Acute Viscerosomatic/somaticovisceral
- d) Chronic viscerosomatic/somaticovisceral

The targeted outcomes, as appropriate to each specific intervention, should include one or more of the following: perception of pain, use of analgesics, range of motion, time lost from work, return to work, recurrence rates, functional criteria of disability, and use of pharmacological agents.

3. ELIGIBILITY REQUIREMENTS FOR THE OSTEOPATHIC EFFICACY PROGRAM

All eligibility requirements as stated under the "Eligibility Requirements for Grant Applicants" section of this document apply to this program. Applicant institutions must meet the requirements for general assurances, use of budgeted equipment, and protection of research subjects as described in the "Institutional Responsibilities" section of this document.

Applications may be submitted by public or private nonprofit organizations such as universities, colleges, research institutions and organizations, and hospitals. Osteopathic colleges, hospitals, and other AOA recognized institutions are especially encouraged to apply.

4. APPLICATION INSTRUCTIONS FOR THE OSTEOPATHIC EFFICACY PROGRAM

Applications for special grants require prior approval by the Council. Applications should be made according to the procedures described in the "Instructions for Grant Applications" section of this document. In addition, when completing Form C "Administrative Data Sheet", applicants should make two entries under the section entitled, "Type of Project":

- a) Select new, continuation, or resubmission as appropriate; and
- b) Select "Osteopathic Efficacy".

All applications will be processed according to the procedures described in the "Processing of Grant Applications" section of this document. Applicants receiving research funding are responsible for adhering to the procedures described in the "Information for Grantees" section of this document.

B. OSTEOPATHIC OUTCOMES RESEARCH

1. DEFINITION

The definition of outcomes research is the evaluation of the effectiveness of an intervention on the promotion of health and on the prevention and/or the treatment of disease or dysfunction. In the case of osteopathic medicine, it is the evaluation of the osteopathic principles and practice and osteopathic manipulative treatment. The end points of outcomes research may include, but are not limited to patient health, quality of life, patient satisfaction and/or cost effectiveness. The principal methodology utilized in outcomes research is clinical trial utilizing modern methods of research design and data analysis.

2. OBJECTIVES

The objectives of the clinical outcomes research initiative of the Council are to assess one or more of the following:

- Effectiveness of OPP/OMT;
- Contribution of DOs applying OPP/OMT in primary care;
- Contribution of DOs applying OPP/OMT in specified populations;
- Contribution of DOs applying OPP/OMT in preventive medicine; and/or
- Cost effectiveness of health care delivered by DOs applying OPP/OMT.

3. ELIGIBILITY REQUIREMENTS FOR THE OSTEOPATHIC OUTCOMES RESEARCH PROGRAM

All eligibility requirements as stated under the "Eligibility Requirements for Grant Applicants", Section III, C of this document, apply to this program. Applicant institutions must meet the requirements for general assurances, use of budgeted equipment, and protection of research subjects as described in "Institutional Responsibilities", Section V of this document.

Applications may be submitted by public or private nonprofit organizations such as universities, colleges, research institutions and organizations, and hospitals. Osteopathic colleges, hospitals, and other AOA recognized institutions are especially encouraged to apply.

4. APPLICATION INSTRUCTIONS FOR THE OSTEOPATHIC OUTCOMES RESEARCH PROGRAM

Applications for special grants require prior approval by the Council. Applications should be made according to the procedures described in "Instructions for Grant Applications", Section III, F of this document. In addition, when completing Form C "Administrative Data Sheet", applicants should make two entries under the section entitled, "Type of Project":

- (a) select new, continuation, or resubmission as appropriate; and
- (b) select Osteopathic Outcomes Research

In addition, each application must address the following:

- c) Specify choice of (and rationale for) specific outcomes parameters to include: (a) patient satisfaction with care; (b) health status; (c) health status change; and (d) structure/function (and/or somatic dysfunction) change.
- d) Specify populations of physicians studied and quantify mechanisms for assessing application of OPP/OMT by this/these population(s).
- e) Specify overall relevance of the topic studies to: (a) primary care; or (b) preventive medicine; or (c) underserved populations; or (d) cost-effectiveness of health care.
- f) Provide background literature and/or discussion of previously studied parameters related to this grant proposal. Apply this information in providing a rationale for the grant proposal's choice of parameters or study design.
- g) Discuss the method of recording osteopathic structural findings and for reporting change in these findings.

- h) Provide a thorough discussion of the statistical methodology and expectations for the statistical interpretation. A letter of support and explanation from a statistician is strongly recommended.

C. TERMS OF AWARD

Eligible institutions may apply for these competitive research grants. The following allowances shall also apply:

- 1. Training session(s) to enhance inter-examiner reliability in the case of multi-site studies is allowed where specific learning objectives and measures of success are outlined for these training sessions;
- 2. The cost of direct transmission of data via mail, e-mail, or fax is permitted;
- 3. Costs are **not** allowed for computers, computer access charges, computer communication software, dedicated communication lines or subscriptions to electronic communication systems.

D. REVIEW PROCEDURES FOR SPECIAL GRANT APPLICATIONS

The following procedures will apply to the review of grant applications received by the Council outside of the following programs: AOA Research Grants as described in the *Handbook*; and the Clinical Investigator Development Award. These procedures are designed to ensure that the long-range goals of the Council are met. Special grant applications funded by the Council meet the same high standards for quality as required for the standing research programs of the Council.

1. Initial Processing by AOA Staff

- a) Staff will provide the applicant with a copy of this document and the current *Handbook*.
- b) Staff will determine if programmatic interest exists.
- c) Staff will discuss scope of program with applicant, advise as necessary.
- d) Staff will assist applicant with budget development, advise as necessary.
- e) Staff will provide applicant with AOA grant application (from current *Handbook*), request completed application, including names of potential external reviewers.

2. Review by Council

- a) Special grant applications will be presented to the Chair for determination of whether external review is required.
- b) If external review is required, special grant applications will be sent to at least two (2) reviewers. Review shall be based upon criteria in current *Handbook*. Sixty (60) days or more shall be allowed for this review.
- c) While external review is ongoing, special grant applications will be presented to members of COR for review based upon criteria in current *Handbook*. Forty-five (45) days or more shall be allowed for this review.
- d) All reviews shall be assembled for presentation to the Council.

The Council will review a special grant application only after those procedures described in parts I. and II. have been completed. Thirty (30) days or more shall be allowed for review. A special grant application will be presented to the Council for review based upon:

- a) Adherence to the programmatic goals of the Council;
- b) Scientific quality as assessed by the reviews provided by members of the COR;
- c) Scientific quality as assessed by the reviews provided by external reviewers.

Upon review of a special grant application, the actions of the Council actions shall include any of the following:

- a) Request for further information from the applicant;
- b) Request for appearance of the applicant before the Council, in person or by teleconference;
- c) Request that the applicant modify the grant application;
- d) Decision on the application.

Decisions recommending funding shall be transmitted to the AOA Board of Trustees (AOA Board) for final action. The applicant will receive notification of this action, and of final action by the AOA Board. Decisions recommending denial of funding are final. The grant applicant shall be notified of decisions to deny funding.

9. Funding Procedures

- a) Funding of special grant applications approved through this mechanism shall commence on September 1 following final approval by the AOA Board.
- b) Release of funds, reporting requirements, and all other administrative procedures shall follow those established for AOA grants as described in the current *Handbook*.

APPENDIX A

BURNETT OSTEOPATHIC STUDENT RESEARCH AWARD

APPLICATION FORM

Your Full Name:

Title of Paper:

College:

Current Mailing Address:

Telephone Number:

(Signed) Applicant

(Signed) Dean of College

AOA GRANTS AND FELLOWSHIPS

APPLICANT'S CHECKLIST: This is an application guide. Do NOT submit this form with the application.

FOR GRANT AND FELLOWSHIP APPLICATIONS:

Form D ____

Form F ____

Form G ____

Form J ____

Research Proposal ____

Optional - List of 3 potential reviewers (see Form C) ____

FOR AOA GRANT APPLICATIONS ONLY:

Form A ____

Form B ____

Form C ____

Form E ____

Description of student fellowship ____

FOR AOA FELLOWSHIP APPLICATIONS ONLY:

Form H ____ (2 pages)

Form I ____

Photo of applicant ____

Sponsor's letter of support for the application ____

APPENDIX B: REQUIRED FORMS

(Application forms can be downloaded in Word format from the AOA Website. Please go to “Research and Grants” on the opening page, then select “Grants and Fellowship Application Forms” for the download dialogue box.)

ABSTRACT for AOA Grant Application Do not exceed 7 1/4” by 4 1/8”.

Form A:	Application for a Research Grant
Form B:	Funding Data Sheet
Form C:	Administrative Data Sheet
Form D:	Protection of Research Subjects
Form E:	Budget & Finance Statement
Form F:	Project Summary
Form G:	Keyword Descriptor Form
Form H:	Application for AOA Research Fellowship (2 pages)
Form I:	Personal Data Sheet
Form J:	Biographical Sketch

ABSTRACT for AOA Grant Application

Postmark Deadline: December 1, 2005.

Principal Investigator/Program Director (Last, first, middle):

DESCRIPTION. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Describe concisely the research design and methods for achieving these goals. Avoid summaries of past accomplishments and the use of the first person. 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. **DO NOT EXCEED THE SPACE PROVIDED at 7 1/4" x 4 1/8".**

FORM A

2005

RESEARCH PROJECT

Eleven copies required

Please Print or Type

Do not write in this space

Date received

Control No.

Amount requested

Rating

Amount granted

**APPLICATION FOR RESEARCH GRANT FROM THE COUNCIL ON RESEARCH
AMERICAN OSTEOPATHIC ASSOCIATION**

Application is hereby made for a grant in the amount of \$_for the period September 1, 2005_through
August 31, 2006 for the purpose of conducting a research project on the following subject:

Title of Project:

Name of Principal Investigator (One Only):

Title of Principal Investigator:

Institution:

Department:

Address:

Co-investigators:

AGREEMENT IN REGARD TO GRANTS-IN-AID AS A RESULT OF THIS APPLICATION

The undersigned agree:

- (1) to expend funds granted by the American Osteopathic Association solely for research purposes specified herein.
- (2) to keep careful records of the conduct of this project and all matters pertinent to it, including a detailed accounting of funds, materials, and equipment. Reasonable care, maintenance, and insurance of all major equipment shall be provided, and written evidence of such insurance shall be furnished to the AOA.
- (3) to return any unexpended funds at the end of the grant period.
- (4) to submit a progress report based on the grant to date to be included with or as a part of any application for further support of the project. If further support is not requested, no progress report is required. A final report will be submitted eight weeks after the conclusion of the grant period.
- (5) that when publishing results of investigations, AOA support shall be acknowledged.

Name & Title of Official

(Signed) Official authorized to sign for institution

Name of Principal Investigator

(Signed) Principal Investigator

Name of Department Chair

(Signed) Department Chair

FORM B

2005

Eleven copies required

Please Print or Type

**AMERICAN OSTEOPATHIC ASSOCIATION
FUNDING DATA SHEET**

Name of Principal Investigator:

Title of Project:

OTHER FUNDING:

Please list other agencies which support this type of research. Also list other agencies to which this study has been submitted and any action taken by the agency or the date action is anticipated. (Use continuation pages as necessary).

List all other support you currently have for this study and the date funding ceases. (Use continuation pages as necessary).

RECIPIENTS OF CURRENT OR PREVIOUS FUNDING FROM THE AOA:

Please list the numbers and titles of all previous grants or fellowships funded by the AOA. Include a list of all publications which resulted from those studies and include one (1) copy of each publication. (Use continuation pages as necessary).

FORM C

2005

Eleven copies required

Please Print or Type

**AMERICAN OSTEOPATHIC ASSOCIATION
ADMINISTRATIVE DATA SHEET**

Name of Principal Investigator:

Title of Project:

TYPE OF PROJECT:

_____ **NEW:** never before submitted to the AOA; the title must be different from any previous application submitted by the same investigator.

_____ **CONTINUATION:** request for support for a study currently, or in the past, supported by the AOA or A. T. Still Foundation. 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 prior grant number _____

_____ **RESUBMISSION:** an application that has been considered by the AOA in an earlier cycle, but was 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.

_____ **OSTEOPATHIC OUTCOMES RESEARCH:** Requires letter of approval from the Council on Research to submit an application. Request for support for a study to assess one or more of the following: (1) the effectiveness of OPP/OMT; (2) the contribution of D.O.'s applying OPP/OMT in primary care; (3) the contribution of D.O.'s applying OPP/OMT in specified populations; (4) the contribution of D.O.'s applying OPP/OMT in preventive medicine; and/or (5) the cost effectiveness of health care delivered by D.O.'s applying OPP/OMT.

_____ **OSTEOPATHIC EFFICACY:** Requires letter of approval from the Council on Research to submit an application. Request for support for a study to assess the efficacy, including cost effectiveness and safety, of the integration of osteopathic manipulative interventions in a total osteopathic approach, investigating specific osteopathic manipulative interventions.

_____ **OTHER** (specify)
Requires a letter of approval from the Council on Research to submit an application

OPTIONAL - POTENTIAL REVIEWERS: You may elect to submit the names, addresses, and telephone numbers of up to three potential reviewers. (See instructions)

FORM D

**AMERICAN OSTEOPATHIC ASSOCIATION
Certificate of Compliance
PROTECTION OF RESEARCH SUBJECTS**

2005

Eleven copies required

Please Print or Type

To be filed with each research proposal, and with each fellowship application where applicable.

Title of project:

Name of principal investigator (or fellowship applicant):

Name of sponsor (for fellowship applications):

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:

Please attach copies of all consent permissions as applicable.

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).

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)

Signed _____

Name _____

Title _____

Date: _____

FORM E**AMERICAN OSTEOPATHIC ASSOCIATION SUMMARY OF BUDGET AND FINANCIAL STATEMENT****2005**

Eleven copies required

Please Print or Type

(Attach explanatory sheets as necessary. Each Item greater than \$500 must be accompanied by a statement of justification)

	Requested Budget From AOA	Funds From Other Sources	Total Budget
Investigators' Salaries:			
Physical Plant renovations (not funded):	XXXXXXXXXXXXX		XXXXXXXXXXXXX
Technician's Salary:			
Research Fellowship			
HUMAN RESEARCH SUBJECTS			
Subject Compensation _____ \$ _____			
Laboratory Analysis _____ \$ _____			
Diagnostic Procedures _____ \$ _____			
Expendable Supplies _____ \$ _____			
_____ \$ _____			
_____ \$ _____			
_____ \$ _____			
Permanent Equipment			
_____ \$ _____			
_____ \$ _____			
Miscellaneous			
_____ \$ _____			
_____ \$ _____			
_____ \$ _____			
TOTALS			

FORM F

**AMERICAN OSTEOPATHIC ASSOCIATION
PROJECT SUMMARY**

2005

Eleven copies required

Please Print or Type

Name of Principal Investigator: _____

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)

FORM G**AMERICAN OSEOPATHIC ASSOCIATION
KEYWORD DESCRIPTOR FORM****2005**

One copy required

Please Print or Type

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

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

Osteopathic Terminology: Please note that the keyword lists contain several osteopathic terms.**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.**KEYWORD DESCRIPTORS OF RESEARCH PROJECT**

USING THE ABOVE LIST, please provide no more than three (3) code numbers and respective keywords that describe the substantive area of your research project. (See Instructions)

Keyword List

1)

2)

3)

Your Terminology: If the keyword terms do not adequately describe your research project, USE YOUR OWN TERMINOLOGY to provide no more than two (2) additional keywords which describe your research project.

1)

2)

NAME OF PRINCIPAL INVESTIGATOR:

TITLE OF PROJECT:

FORM H-1

2005

Ten copies required

Please print or type

Do not write in this space

Date received

Control No. F

Disposition

**APPLICATION FOR FELLOWSHIP GRANT
AOA RESEARCH FELLOWSHIP**

Application is hereby made for an AOA Research Fellowship, for the year beginning September 1, 2005 and ending August 31, 2006 for the purpose of conducting a research project on the following subject:

Title of Project:

Name of Fellowship Applicant:

Status (intern, etc.):

Institution where work will be done:

Department in which work will be done:

Telephone:

Mailing address:

Name of Sponsor: (Preceptor, Advisor):

Title of Sponsor:

Institution:

Department:

AGREEMENT REGARDING FUNDS RECEIVED AS A RESULT OF THIS APPLICATION

The undersigned agree:

- (1) To complete the project as outlined herein, and to submit reports as outlined in the *Handbook* of the Council on Research;
- (2) To observe institutional responsibilities concerning protection of research subjects (where applicable), as outlined in the current *Handbook* of the Council on Research;
- (3) To make available the results of the studies through normal scientific publication channels, as appropriate, with credits designating the author as an AOA Research Fellow.

(Signed) Applicant

(Signed) Sponsor

(Date)_____

FORM H-2

2005

Ten Copies Required
Please Print or Type

APPLICATION FOR FELLOWSHIP

Approval of hospital officer or dean of college and department chairman.

This applicant, _____ has
permission to conduct at this institution the research project outlined in this application. During the period of
performance of this application, the applicant will be serving in capacity of:

(Title and year, if applicable)

at (Name of Institution):

located in (City, State, ZIP):

In giving our permission, we certify that the applicant has made appropriate arrangements for pursuing his/her
(medical degree / internship / residency) program during the period of this application.

We also have reviewed and approved Form D, "Certificate of Compliance, Protection of Research Subjects," which
is attached to this application if indicated by type of project.

(Signature) Department Chairman

(Signature) Hospital Officer or Dean

Name of Department Chairman

Name of Hospital Officer or Dean

Date

Title of Hospital Officer or Dean

Date

FORM I

**APPLICATION FOR FELLOWSHIP
PERSONAL DATA SHEET**

2005

Ten copies required
Please Print or Type

Name:
(last name, first, middle)

Address:

Telephone:

Social Security #:

Graduate of which osteopathic college?:
(Include year)

Postdoctoral education to date (program, institution, years):

Military service record:

Branch of service _____ Length of service_____

Academic degrees other than D.O.:

College or University	Years Attended	Degree
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Scientific papers (bibliographic information for published, dated for unpublished):

Have you had or are you applying for other research or educational grants?

Name	Date	Amount
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FORM J

**American Osteopathic Association
BIOGRAPHICAL SKETCH**

2005

NAME:

EDUCATION:

INSTITUTION AND LOCATION	DEGREE	DATE	FIELD OF STUDY
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RESEARCH AND PROFESSIONAL EXPERIENCE: List in chronological order, previous employment experience and honors. List the titles, all authors, and complete references to all publications during the past three years and to earlier publications pertinent to this application.