

Manual of Policy and Procedures

AOA Council on Research



AMERICAN OSTEOPATHIC ASSOCIATION

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MANUAL of POLICY AND PROCEDURES

AOA COUNCIL ON RESEARCH

Statement of Purpose

The Board of Trustees (Board) established the Council on Research (Council) in 2003, combining the prior Bureau of Research and the Council on Research Grants into one Council entity under the parent Bureau of Osteopathic Clinical Education and Research (Bureau).

The Council is the representative body of the American Osteopathic Association (AOA) charged with the administration of the biomedical and clinical research programs of the association, and their evaluation and funding. The Council also acts as an advocate for osteopathic clinical and biomedical research, and makes recommendations on research policy in osteopathic medical education and for the profession. The Council may assess current policies and procedures relevant to building and maintaining excellence in osteopathic research, and will make recommendations for the AOA Board of Trustees or component committees to these ends.

Statement of Responsibilities

The Council is responsible for the administration and oversight of the various AOA research programs, including but not limited to Research Grants and Fellowships and other programs funded from the Osteopathic Research and Development Fund (ORDF). The Council will administer such programs for maximum effectiveness of the ORDF for the profession. The Council also manages the annual Research Conference. Program guidelines are published in the *AOA Research Handbook (Handbook)*.

The Council makes recommendations on research policy and funding, and works with osteopathic institutions and organizations on policy and strategic planning for biomedical and clinical research, and for research education and training. The Council will serve as an advocate for research within the association, other osteopathic institutions, and with research funding agencies and organizations. The Council will work with other osteopathic entities to facilitate the communication of research outcomes on efficacy and mechanisms in relation to coding, reimbursement and other needs of the osteopathic profession. The Council shall conduct itself according to the processes stated in this Manual of Policies and Procedures (*Manual*) and shall review the Manual every two years.

Council Structure

The Council has thirteen (13) voting members, including the Chair and Vice chair, appointed by the President of the AOA. The Council may have two (2) advisors and up to two (2) consultants as needed for the conduct of its duties; consultants and advisors will be non-voting members.

The Council operates under Robert's Rules of Order, and a simple majority (7 of 13 voting members) will constitute a quorum. Members should be able to commit to two meetings of the Council per year; all meetings will have conference call capacity. A member who is not able to attend the Annual or Fall Meeting of the Council, including by teleconference, shall contact the

Chair, Vice Chair, or Council Secretary in advance of the meeting.

Chair and Vice Chair: The AOA president appoints the Chair and Vice Chair for renewable one year terms from the membership of the Council. The Chair shall be a member of the AOA Board of Trustees. The Chair and Vice Chair shall be osteopathic physicians who have demonstrated experience in and/or knowledge of the conduct of biomedical/clinical research.

Duties of the Chair: The Chair issues the Calls to Meeting, sets the agenda for and presides over all meetings of the Council, and shall direct the membership of the Council in the fulfillment of the its responsibilities. The Chair shall appoint the membership of subcommittees as described in this manual and *ad-hoc* committee as required for the fulfillment of stated Council responsibilities.

Duties of the Vice Chair: The Vice Chair shall assume the duties of the Chair in the event the Chair is absent for cause, or if the Chair so designates.

Council Membership: The Council on Research shall consist of thirteen (13) members. Eleven (11) members are appointed for three (3) year terms. A student member and an intern/resident member are appointed for 1-year terms.

- 1 – Chair (member of Board of Trustees)
- 1 – Qualified research physician
- 1 – PhD representative from osteopathic colleges
- 1 – AACOM representative
- 1 – Primary care specialist
- 1 – OMM (Osteopathic Manipulative Medicine) specialist
- 1 – Representative from the Osteopathic Research Center (ORC)
- 1 – Intern/Resident (1 year term)
- 1 – Student (1 year term)
- 4 – Members-at-Large

Each representative from a practice and a non-practice organization shall be appointed from a list of no less than three (3) nominees submitted by each group to the AOA President. Members will submit updated curriculum vitae to the Secretary of the Council and that file will be maintained for the member's tenure.

Council Actions

The Council will act to approve applications for research grants and research fellowships. The Council will appoint the Chair(s) for the annual research conference, and will make every effort to appoint Chair(s) for two years in advance. A Request for Proposals (RFP) for the research conference may or may not be issued, in accordance with the *Handbook*. The Council will approve and update a strategic plan for the above and other business.

The Council acknowledges that maintaining predictable and adequate funding for biomedical clinical research is fundamental to the health of the AOA research programs. The Council shall receive and review reports on funds available for research programs, as provided by the AOA Department of Finance, at quarterly intervals or more frequently if requested. The Council shall develop a

budgetary plan and funding needs assessment for research expenditures, and will make recommendations on the funding of biomedical clinical research programs to the Bureau, the Board and the AOA Bureau of Finance. The Council shall review policy changes pertaining to the investment of research funds as requested by the AOA Bureau of Finance or its designee.

Subcommittees of the Council

The Chair of each subcommittee will submit a report of meetings and recommendations for action to the Chair of the Council. The Council will review the reports and take action as required at their next regularly scheduled meeting. Chairs of subcommittees will be appointed by the Chair of the Council

Review Committee:

The Chair of the Council will appoint a subcommittee to be known as the “Review Committee of the Council on Research” for the purpose of providing quality and in depth review of research grant and fellowship applications and making recommendations to the larger Council at the Annual Meeting. The Review Committee will maintain updated evaluation forms, reports and processes and these will be compatible with NIH processes where possible.

The Review Committee will have six (6) members; the Council chair will serve as an *ex officio* member. Members of the Council may serve on the Review Committee and members may also be appointed from a list of nominations submitted by the Research Directors of the colleges of osteopathic medicine.

The Review Committee shall hold one regularly scheduled meeting per year, to occur in sequence with the Annual Meeting of the Council on Research, and may hold meetings by conference call as required for the discharge of its responsibilities.

The Review Committee will review applications for research grants and research fellowships as described below, and will present reports and recommendations for funding to the Council at their Annual Meeting. The Review Committee will maintain a list of ad hoc reviewers, who may be nominated by the Research Directors of the colleges of osteopathic medicine, and ad hoc reviewers will be active as necessary to conduct thorough readings of all applications for research programs.

Meetings of the Review Committee involving consideration and recommendation on applications for funding for research grants and fellowships and other funding disbursements may be held in executive session, and members will observe confidentiality. Members of the committee will not make disclosure of funding recommendations except to the Council. However, where clarification is necessary for such recommendation, including budget review, members of the Committee or staff may make inquiries without commitment of funds at the direction of the Chair.

Council on Research Awards (CORA)

The Chair of the Council will appoint the CORA from the membership of the Council and will serve as the Chair of this subcommittee. The purpose of the CORA is to serve as the review body

for the American Osteopathic Foundation (AOF) for the Annual Research Awards. The CORA will review nominations for Research Awards and make recommendations based on submitted materials and a scoresheet developed by AOF. A teleconference meeting will be held to make the final recommendation to the AOF Board of Trustees no later than July 1 or as otherwise designated by the AOF.

Any member of the Council may be nominated for an Annual Research Award by a colleague who is not a member of the Council. Any member nominated for an award will recuse themselves from any and all discussion or selection of nominees for that award.

Meetings of the CORA involving consideration and recommendation on nominations for the awards will be held in executive session and members will observe confidentiality. Disclosure of recommendations will be made only to the AOF.

Operating Procedures

The Council on Research shall hold two regularly scheduled meetings per year in the spring and fall in accordance with AOA Cluster Meeting policy. The Council will hold their Annual Meeting sequential to the Review Committee meeting (within 1 day) and make formal recommendations for grant funding approval to the Board of Trustees through the parent Bureau.

Meetings of the Council will be open meetings. The Council will only assume expenses for meeting attendance of Council members and others as invited specifically and for whom the Chair has enumerated reimbursement of expenses. The Council will not assume attendance expenses for persons appearing at the request, or in the interest of, other agencies and individuals. The presence of observers and guests will be acknowledged by the Chair and recorded in the minutes. Observers are advised to notify the Council or the Secretary of intent to attend.

Meetings of the Council involving consideration and recommendation on applications for funding for research grants and fellowships and other funding disbursements may be held in executive session, and members will observe confidentiality. Disclosure of recommendations will be made, by letter, by the Chair of the Council and the Chair of the Bureau.

Formal Resolutions to the Bureau

Resolutions intended for deliberation by the Bureau or by the AOA Board of Trustees will be forwarded to the Bureau prior to their next regularly scheduled meeting. The Council requests that resolutions that are not approved by the Bureau be returned with an explanation of objections, or other action. If the Bureau does not approve a resolution submitted by the Council, the Council requests the opportunity to revise the resolution to meet the objections of the Bureau.

Annual Meeting:

The spring meeting shall be the Annual Meeting and will be a face-to-face meeting. At the Annual Meeting the Council will:

- 1) Receive the recommendations of the Review Committee and conduct reviews of applications for

AOA research grants and AOA research fellowships and make recommendations for funding approval;
2) Conduct other business not covered at the Fall meeting and as required for the discharge of Council responsibilities.

Recommendations and Resolutions will be forwarded to the parent Bureau for recommendation to the Board of Trustees at the AOA Annual Meeting.

Fall Meeting:

The Fall meeting may be held by teleconference except under extraordinary circumstances. At the Fall Meeting the Council will consider issues of policy, conduct document revisions, review and make recommendations on proposals for the annual Research Conference, and conduct other business as required for the discharge of Council responsibilities.

Recommendations and Resolutions will be forwarded to the parent Bureau for recommendation to the Board of Trustees at the AOA Midyear Meeting.

Conflict of Interest Policy

This policy statement governs treatment of actual, apparent and alleged conflicts of interest and appearances of impropriety that may arise during the deliberations, recommendations and other actions of the Council on Research.

A conflict of interest arises where an individual on the Council, due to a financial, professional, personal or other relationship with a person or institution applying for AOA research programs, may be unable to act based solely on an objective analysis of the information presented. A conflict of interest may include, but is not limited to, a business, financial, direct familial, employment or consultant relationship with an individual under consideration.

It is incumbent on Council members to disclose such a relationship and to abstain from casting a vote on an application or nomination where such a relationship exists. Council members who are on faculty or staff at a college of osteopathic medicine will abstain from votes to recommend funding on grant and fellowship applications submitted by colleagues or fellows at that college and will abstain from votes to recommend a nominee for an annual award from that college which carries a financial award.

Questions regarding conflicts or potential conflicts of interest by a Council member should be directed to the Chair before a vote is taken. Resolution of a conflict of interest may be addressed by the following:

1. Recusal of the member from voting, but allow participation in the deliberation and, if appropriate, to offer testimony about the matter. The member will remain in the room but will not deliberate and will not vote.
2. Recusal of the member from both deliberating and voting. The member will remain in the room

for the deliberation and vote, but will not participate.

3. Recusal of the member from participation, deliberation and voting; the member will be asked to leave the room while the item is discussed and acted upon.

Council meetings are open meetings and discretion should be applied when asking a member to leave the room for deliberations that are held in an open meeting. The member should only be asked to leave the room if their presence is determined to be detrimental to those participating in the deliberation and voting, or to those offering testimony about the issue to be acted upon. Members will be invited back into the meeting when the issue is resolved, and without penalty. No other information to which the absent member is entitled will be entered into deliberation in the member's absence.

Review Process and Procedure: Funded Research Programs

The primary requirement of the grant review process is to identify those proposals that are above average in scientific significance and design and that best meet the research priorities of the osteopathic profession. Secondly, the review process can serve to engage applicants in the research process, to encourage participation in research activities, and can be instructional for new and developing researchers.

As in all business of the Council or its subcommittees, any conflicts of interest, as defined in this *Manual*, will apply to all members and reviewers in these review procedures. The basic documents governing the review of grant proposals will be the *AOA Research Handbook (Handbook)* and the *Manual of Policy and Procedure of the Council on Research (Manual)*.

Objectives

In the review of grant proposals submitted to the AOA for funding consideration, the review process will:

1. Render fair, thorough and unbiased reviews of all proposals that assess the scientific and osteopathic strength of grant proposals
2. Provide a merit score based on published criteria, formal committee member reviews, committee and/or council discussion, and specialty content focused reviews of the proposal;
3. Provide synopses and written evaluations of the proposal by the reviewers for use by the evaluating committee and/or council, based on strengths and weaknesses of the proposal sufficient to support the merit score;
4. Provide written evaluations of the proposal for use by the applicant that will address areas critical to strengthen the proposal for resubmission, or new submissions to this or other funding organizations;
5. Assure that the approved policies and research priorities are appropriately represented in grant proposals recommended for funding;
6. Make recommendations, when appropriate, for budget modifications consistent with AOA basic documents and available funds.
7. Identify areas for procedural improvement for use by the committee and/or council.

Grant Review Reports:

Grant applications will be postmarked on or near December 1 (see *Handbook*) and will be distributed by AOA staff to the Review Committee as quickly as possible and no later than within 45 days. Reviewers will prepare reports for the Review Committee within 45 days, and no later than March 1. The Review Committee will review reports and grants shall submit funding recommendations to the Council at their Annual Meeting.

Grant reviews by the Primary and Secondary reviewers and ad hoc reviewers will be filed with the AOA no later than 30 days prior to the annual meeting of the committee and/or council. Only the Primary reviewer is responsible for providing a detailed synopsis of the study and its design. Wherever possible, the reviewers should supply supporting references. The report will address the evaluation criteria (see *Worksheet*), and the Committee will establish and maintain Report Guidelines for reviewers.

Scores will be kept separate from the written evaluation, and will be shared with the committee and/or council at the review meeting.

Grant Review Worksheet:

The grant review worksheet consists of a number of individually scored criteria reflecting the quality of the science (50% weight), osteopathic relevance of the proposal (30% weight), and other significant areas 20% weight). The Worksheet is appended to this document.

Scores will be recorded on a scale from 1 (meaning excellent) to 4 (meaning significantly flawed) on the grant review worksheet. All scores of three (3) or higher require a specific explanatory comment from the reviewer. Unless otherwise voted upon by the committee and/or council, science subset totals greater than 2.5 or which have a single unchallenged score greater than 3.5 (indicating a fatal flaw) will not be recommended for funding.

The Review Committee may establish a final rank for each proposal based on the submitted worksheets, reports and discussion. Proposals will be presented to the Council with funding recommendations in Rank order. Proposals given full review but not recommended for funding may be designated as “Not Ranked”. Proposals with high subset scores or fatal flaws may be designated as NFR (Not for Further Review) and will not be recommended for a full committee review.

Fellowship Reviews

Fellowship applications are due on or near January 15 (see *Handbook*), and staff shall send applications to reviewers within 30 days. Reviewer Worksheets and reports shall be submitted within 45 days, and no later than March 1. Recommendations for funding will be based on Reviewer Reports and Worksheets and will be competitive. The Review Committee will make recommendations for funding to the Council for their Annual Meeting.

Applications will be evaluated by staff for completeness and adherence to the format guidelines published in the Handbook. Incomplete applications and applications that do not otherwise adhere to the published instructions will not be reviewed further and notification of such action will be forwarded to the applicant and sponsor. Applications may be resubmitted prior to the January 15

deadline.

Applications will be reviewed by members of the Committee or Council and other reviewers as designated in consultation with the Chair. Applications will be evaluated for adherence to criteria set in the Fellowship Worksheet (appended to this document), and in thorough review and discussion.

The Committee and Council may set the number of Fellowship awards each year at no more than ten (10), and the number of fellowships may vary depending on the quality of applications for both fellowships and grants. The Council will make every effort to maintain a minimum number of fellowships each year that applications of merit are presented. Recommendations on funding for Fellowships will be made at the Annual Meeting of the Council.

Initial Review Procedure

1. Submission Deadline - Grant proposals are postmarked to the AOA office no later than December 1 of each year .
2. Initial Administrative Review - Grant proposals will be reviewed by staff for completeness of application and for adherence to the format guidelines as published in the *Handbook*. Incomplete proposals and proposals that do not otherwise adhere to the published instructions will not be reviewed further and notification of such action will be forwarded to the principal investigator. Proposals may be resubmitted prior to the December 1 deadline.
3. Assignment of Reviewers - Staff will make every effort to identify a primary and a secondary reviewer from the Review Committee, and two external reviewers. Assignment of reviewers will be assessed with the chairperson or other representative/s of the Review Committee.
4. Requested Reviewers - Where the applicant makes requests for specific reviewers, staff will expedite that request to named reviewers so that the schedule can be maintained wherever possible. One requested reviewer will be selected from a list of up to three names.
5. Distribution of Proposals – Every effort will be made to distribute proposals to the committee and any other reviewers by the first week of January and no later than January 15.
6. Additional Reviewers - The Primary or Secondary reviewer may request inviting an additional reviewer in the appropriate area of expertise. Proposals requiring an additional reviewer should be identified as early in the process as possible, and no later than six (6) weeks prior to the first grant review meeting. The additional reviewer may be drawn from the Council or from a list of ad hoc reviewers maintained by staff at AOA. Such invited reviewers will provide a focused evaluation of the proposal that addresses the issue(s) of concern.

Formal Review Procedure

1. Streamlined Review

The Review Committee will, at the discretion of the Chair, hold an initial meeting by phone to determine NFR designations, and will hold said meeting as early as possible and at minimum two (2) weeks prior to the face-to-face meeting of the Committee. All written reports and completed worksheets will be distributed to the Review Committee as early as possible prior to this meeting. Proposals that have limited or no osteopathic significance, limited or no scientific merit (with a score of greater than 2.5), or that have major flaws (with a score of 3.5 or greater in any one science area) can be identified for No Further Review (NFR).

The Committee may, at their discretion, direct queries to the PI (Principal Investigator) of any grant proposal to clarify essential information or for budget adjustments. Such queries will be sent in writing and immediately, and the PI will respond to the Committee as directed. The response will be included in the review materials for full Committee review.

2. NFR (Not for Further Review) Designation

Proposals identified for NFR by the Primary and/or Secondary reviewer will be reviewed by the committee on an individual basis at the Streamlined Review. There should be a clear rationale for this designation. The Chair will put the question to a vote for each proposal thus identified. When both the Primary and Secondary reviewers agree to the NFR designation and there are no dissenting opinions from the committee, the proposals will be officially designated for NFR and will receive no further consideration.

If one or more members of the Committee or the Council, without conflict of interest, request a full review, the proposal will be entered onto the agenda for funding consideration by the full Committee. The titles of all proposals with an NFR designation will be present on the agenda for the full Council, and at the request of any council member, the grant proposal will receive a full review

3. Review Meeting for Funding Recommendation

The full Committee will review all proposals that have not been otherwise designated as for NFR. Complete review materials, including all written reports, abstracts and worksheet tabulations, will be sent to all members to arrive no less than two (2) weeks prior to the Committee meeting.

For each proposal under consideration, the Primary reviewer will present his/her report, and respond to issues raised by members. The Secondary reviewer will add supplemental comments. Reports of outside reviews will be presented and the proposals will then be open for discussion by members. If a Primary or Secondary reviewer cannot be present, the report will be read into the record.

Following the discussion the Primary and Secondary reviewers will be asked to revise their merit scores based on the committee discussion; the revised scores will be announced to the committee. Each member who is in attendance will score the application, and these written scores will be passed to the Chair (and staff) for compilation.

4. Weighting Scores, Prioritization, and Recommendations to the Bureau

All reviewed grant applications with cumulative average science scores less than or equal to 2.5 that have no fatal flaws and contain acceptable osteopathic relevance shall be have a single score calculated with 50% of the total score coming from the science subset average, 30% of the total score from the subset score for osteopathic relevance, and 20% of the score for the other factors subset average. The Review Committee shall then be presented with a prioritized list of grant proposals ranked in order of best (lowest) total weighted average score to highest weighted average score. This rank will be used to prioritize proposals for funding recommendations. The Chair will ask for a vote of the entire Review Committee to accept or adjust the scores and ranking as calculated. The Chair will also ask for a vote to recommend the proposal, by formal resolution, to the full Council for recommendation for funding. Should time permit, the Review

Committee may review and make recommendations related to the budget proposed for prioritized grant proposals.

Review grant proposals with cumulative average science scores of 2.5 or greater, and/or which have fatal flaws, and/or which have low osteopathic significance and which will not be recommended to the Council for funding recommendation may be given the designation of “Not Ranked”.

5. Consideration of Correctable Critical Flaws

Under some circumstances an otherwise exceptional proposal may have an identified critical flaw that the committee deems correctable. When the committee unanimously agrees that the flaw is correctable and the grant has merit, they may recommend funding contingent upon correction of the proposal.

6. Recommendation to the Council on Research

The Committee will draw up a prioritized list of proposals to be presented to the Council on Research in rank order and with budget recommendations. The Council will hear a report from the Chair of the Review Committee, may hear a full review of any proposal recommended for funding, and may hear a full review of any proposal not recommended by the Committee if cause for such action can be shown. The Council may, with cause, re-rank and prioritize proposals. The full Council will vote to recommend a slate of proposals for funding to the Bureau for recommendation to the Board of Trustees at their annual meeting.

Administrative Responsibilities

Document Retention Policy on Funded Programs:

Documentation submitted to the Council on Research pertaining to applications for funding for research programs described in the *Handbook* shall be retained as follows:

Funded Grant Proposals: The permanent file will retain the original application and review reports, progress reports, final reports, all financial reports, manuscripts resulting from the completed research and substantive correspondence.

Grant Proposals not funded: The file will retain the above documents for five (5) years. At the end of five years, only a summary file will be maintained with the application face page (Form A), abstract, and notification letter and substantive correspondence.

Funded Fellowship Proposals: The permanent file will retain the original application, progress and final reports, abstract, and substantive correspondence. Manuscripts or data on other research awarded to the fellow will be kept in the file.

Fellowship Applications not funded: The file will retain the above documents for five (5) years. At the end of five years, the file will be discontinued.

Business of the Council and Subcommittees

Agendas and minutes for all meetings of the Council and its subcommittees shall be maintained in a continuous and chronological paper record. Complete agenda books will be maintained in an electronic file. Minutes of previous organizations of the Council or Committee (i.e. Bureau on Research, Council on Research Grants) will be kept in a permanent file.

Resolutions generated by the Council and its subcommittees will be kept in a continuous and chronological paper record as well as an electronic file, and will be followed to the final approving body.

Correspondence of the Council or subcommittees will be maintained as is appropriate for sound administrative practices.

Staff Support:

The Division of Research Development shall provide administrative and other support services for the Council and its subcommittees, and staff from the division shall serve as Secretary to the Council on Research. Staff shall maintain records according to the Document Retention Policy set by the Council, and shall maintain all records necessary to the efficient functioning of the Council in the discharge of its responsibilities.

Staff shall maintain records and reports on grants issued and administered by the Council and its subcommittees. Staff shall also maintain an electronic database on research grants and fellowships funded through the Council from 1985 to the present, including five-year grant outcomes, and shall maintain semiannual status reports on all active funded grants and fellowships. Staff shall maintain annual and mid-year reports and all other reports for the Council to the Bureau and to the Board of Trustees.

Staff will provide the primary support for and staffing of the annual research conference, including conference arrangements, publicity, printed materials and other administrative support as required for a successful conference. Staff will also manage the abstract submission and review process and will coordinate publication with the *JAOA*.

Staff will maintain the “Research and Grants” page on DO-Online and will make regular updates of listings to promote appropriate communications on research programs and other activities of the Council and the AOA, and will perform other duties as requested by the Council and with the approval of the department director.