GENERAL GUIDELINES

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Each grantee must conduct his/her investigation in accordance with plans outlined in the proposed project plan 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. DEADLINE & SUBMISSION INFORMATION

1. The proposed project plan must be submitted to the Department of Research and Development via the AOA online grant submission software program by the due date listed on the Request for Application (RFA).

2. Applicants are encouraged to review all materials and instructions, and are invited to contact Department of Research & Development staff if there is a question about the meaning of a specific provision in the plan prior to submission. The proposed project plan must be complete when submitted to be considered. Incomplete plans will be returned.

3. Appended materials may be attached. Materials should be clearly relevant to the proposal, should not be excessive, and should not include curriculum vitae.

4. Applicants who chose to resubmit an project must provide a page report that explains how the previous reviewers’ critiques have been addressed in your application.

B. NOTIFICATION OF GRANT

The AOA Department of Research and Development will notify the applicant for approval or not approval of the proposed project plan by email letter, usually within six (6) weeks after approval by the AOA Board of Trustees and disbursements will begin according to the schedule specified in the approval letter.

C. ORGANIZATIONAL RESPONSIBILITIES

1. GENERAL ASSURANCES

Organizations serving as an applicant’s organization must present evidence that there is either a contract or a reasonable understanding with the principal investigator (PI) whose services will be necessary to conduct the project.

The applicant’s organization must also give assurance to the AOA that those responsible for conducting the project will be allowed sufficient freedom from other responsibilities, so as to have time to make significant progress in the project.

The applicant’s organization also must assure the AOA 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.

Organizations receiving funds for 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 the applicant’s organization, where the applicant may be completing a portion of his/her training program under the supervision of a consultant.

2. PROTECTION OF HUMAN RESEARCH SUBJECTS

All organizations in which AOA 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 organization must have an Institutional Review Board (IRB), or seek the approval of an affiliated 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).

An organization receiving funding from the AOA for studies involving human research subjects must provide the AOA with a statement describing the IRB organization, personnel, and functioning. Annual updates are required.

The applicant’s organization bears responsibility for safeguarding the rights and welfare of human subjects in research supported by the AOA. "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.

3. PROTECTION OF VERTEBRATE ANIMALS

All organizations receiving funds for an AOA research grant 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.

An organization receiving funding from the AOA for studies involving vertebrate research subjects must provide the AOA with a statement describing the IACUC organization, personnel, and functioning. Annual updates are required.

D. RELEASE OF INFORMATION

Information concerning the proposed project plan will be provided only to the principal investigator and the authorized official that signs for the applicant’s organization. Any other individuals seeking information concerning a specific plan will be denied that information.

E. DISBURSEMENT and USE OF FUNDS

Grant monies will be disbursed to the Finance Officer of the applicant’s organization on the schedule below when the Department of Research and Development receive and approve the progress, financial, and final reports submitted via the AOA online grant submission software program.

<table>
<thead>
<tr>
<th>FUNDS DISBURSEMENT SCHEDULE</th>
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<tbody>
<tr>
<td>Start of Grant Cycle</td>
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<tr>
<td>18-month Awards</td>
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<tr>
<td>24-month Awards</td>
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</tbody>
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See “F. REQUIRED REPORT” for detailed information regarding what and when to submit reports.

The applicant’s organization is responsible for disbursing the funds to the PI.

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

Any funds unexpended at the end of the grant period must be returned to the AOA. PI’s 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 will be released to an organization until all previous progress reports, final reports, and financial records are received and approved by the AOA.
F. REQUIRED REPORTS

A report schedule will be included in the notice of award. All reports must be submitted to the Department of Research and Development via the AOA online grant submission software program. PI’s and their organization should be pro-active in filing required reports, and shall not depend on notice from the AOA. Submission of the required reports will allow release of appropriate funds.

1. Progress and financial reports must be filed semi-annually (every six (6) months) after the first disbursement of funds is sent to the PI’s organization. The PI and their organization must submit their reports to the Department of Research and Development via the AOA online grant submission software program. If the grantee is awarded a no-cost extension, progress and financial reports should continue to be filed at semi-annual intervals to the Department of Research and Development via the AOA online grant submission software program.

2. The final project and financial reports are due at the end of the grant cycle. A 90 day grace period is given to all grantees. Grantees failing to submit their final report within the allotted time are deemed non-compliant. See Section J: Non-Compliance

3. Publications and presentations resulting from the grant made after the final report is submitted must be submitted to the Department of Research and Development via the AOA online grant submission software program as they are completed.

G. OMED POSTER PRESENTATION SESSION

The PI or its designee is required to present their research findings at the Osteopathic Medical Conference & Exposition (OMED) Poster session immediately following the end of their grant period. Failure to present results within two (2) years after the close of the grant period will strongly influence any decisions regarding future grant awards. Returning all funds to the AOA releases the investigator from this requirement.

H. PUBLICATIONS

a. When the results of AOA-sponsored research are published, a reprint or a copy of the paper shall be submitted to the Department of Research and Development via the AOA online grant submission software program. It is the expectation of the AOA that research project results are submitted for publication in a peer review journal and that, whenever appropriate, the grantees are strongly encouraged to consider the Journal of the American Osteopathic Association (JAOA).

b. Each research team member, when publishing results of his/her study, shall acknowledge support of the project by the “American Osteopathic Association” and include the AOA grant number. Copies of manuscripts or reports shall be furnished to the Department of Research and Development via the AOA online grant submission software program.
c. Failure to present results for publication within the two (2) year period after awarding of the grant will strongly influence any decisions regarding future grant awards. When difficulty in publication is encountered, the AOA is readily available to confer with the research team and provide guidance on publication.

I. MAJOR PIECES OF EQUIPMENT

Only under special circumstances are funds provided for major equipment, and applicants are discouraged from budgeting for major equipment. Organizations receiving funds from the AOA are accountable for all major and/or movable items of equipment purchased with funds derived from grants-in-aid. The PI’s organization 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 Department of Research and Development.

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

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.

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

J. NON-COMPLIANCE

No new grants will be considered until all reports are submitted and approved. Should reports of a study not be received in a reasonable time (six (6) months after the close of the grant period), the AOA 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 the study. The final recommendations of the AOA will be referred to the AOA Board of Trustee (or its Executive Committee) for final approval.

K. GRANT EXTENSIONS

1. An extension of the grant period beyond the initial grant period with holdover of funds already disbursed may be made only by written authorization to the Department of Research and Development via the AOA online grant submission software program. Extensions will only be granted in extenuating circumstances that have prohibited completion of the research proposed in the original project plan and which could not have been anticipated in the original research plan:
1. Inability to obtain research subjects; and/or
2. Inability to obtain or retain technical support personnel authorized in the proposed project plan; and/or
3. Inability to obtain new equipment authorized in the proposed project plan.

The principal investigator is responsible for documenting the presence of any of the above to the satisfaction of the Department of Research and Development.

A written request to extend the performance period of a grant must be filed three (3) months prior to the end of the grant period. The request must include the approval of appropriate research administrators and/or other administrative officers at the principal investigator's organization. Updated progress reports and financial reports must accompany requests. Based upon the evidence presented, the AOA may grant an extension of the performance period for up to six (6) months. Only two (2) six (6) month extensions will be approved.

L. REALLOCATION OF FUNDS

For a reallocation within the budget guidelines involving more than ten percent (10%) of the total grant, formal authorization from the AOA is required. The PI and their organization must submit a letter to the AOA explaining their need to reallocate funds. The PI and their organization must also submit an updated Form E and F with the new allocations and justifications. The AOA will send an email letter to the organization representatives of their decision within four (4) weeks of receipt of the above mentioned information.

For a reallocation within the budget guidelines involving less than ten percent (10%) of the total grant, formal authorization from the AOA is not required. Any such alteration should be explained in the financial report.

M. DISCLOSURES

If a grantee receives funding from an outside source in addition to AOA funding on the same project, the grantee must disclose this additional funding to the AOA and specify the expenses being supported by each entity. AOA will review the information and retain the right determine whether it will continue to provide funding for the project.

N. TRANSFERS

A transfer of grant monies or equipment to another organization is permitted. The following guidelines must be met before grant monies and/or equipment is approved for transfer:

1. All project progress reports must be submitted and approved.
2. The current PI and the organization’s official must submit a formal letter to the AOA requesting the grant monies and/or equipment are transferred to another organization. This letter must include a detail explanation of why the PI and their organization are requesting a
3. The current organization’s official must return all unused grant funds and a final financial report to the AOA.

4. The new organization’s official must submit a letter to the AOA requesting that the funds are transferred to their instruction. This letter must include a detailed explanation of why they should receive approval of the transfer.

5. The new organization official(s) must complete and sign, where applicable, Forms A through H.

6. The new organization must submit an IRB approval letter to the AOA.

The AOA will send an email letter to both organizations’ officials of their decision within six (6) weeks of receipt of all the above mentioned information from both organizations. If approved, the new organization and PI must comply with all the AOA guidelines to continue receiving fund disbursements.

**Note:** The AOA highly recommends that the organizations work together to submit their requests to the AOA at the same time to expedite the approval process.