



OSTEOPATHIC MEDICAL STUDENTS RESEARCH PROGRAM GENERAL GUIDELINES

Outline

A.	DEADLINE & SUBMISSION INFORMATION.....	2
B.	NOTIFICATION OF GRANT AWARD	2
C.	ORGANIZATIONAL RESPONSIBILITIES.....	2
1.	GENERAL ASSURANCES.....	2
2.	PROTECTION OF HUMAN RESEARCH SUBJECTS.....	3
3.	PROTECTION OF VERTEBRATE ANIMALS	3
D.	RELEASE OF INFORMATION.....	4
E.	DISBURSEMENT and USE OF FUNDS	4
F.	REQUIRED REPORTS.....	5
G.	OMED PODIUM PRESENTATION	5
H.	PUBLICATIONS.....	6
I.	MAJOR PIECES OF EQUIPMENT.....	6
J.	NON-COMPLIANCE	7
K.	GRANT EXTENSIONS	7
L.	REALLOCATION OF FUNDS.....	7
M.	TRANSFERS	7



Each applicant must conduct his/her investigation in accordance with the submitted grant proposal , and must 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. All applications 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. Incomplete applications will be returned.
3. All supplemental materials must be attached to the submitted application. Materials should be clearly relevant to the proposal, should not be excessive, and should not include curriculum vitae.

B. NOTIFICATION OF GRANT AWARD

The AOA Department of Research and Development will notify the applicant of all final award decisions by email letter, usually within six (6) weeks after the AOA Board of Trustees approves final recommendations. 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 fellowships.



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 fellowship 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 grant proposal 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 proposal 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.

Activity – 6 Month Studies	Month	Amount
Start of Grant Cycle	0	50%
Progress Report	3	20%
Poster Presentation at OMED	6	20%
Final Report	6	10%

Activity – 12 Month Studies	Month	Amount
Start of Grant Cycle	0	50%
Progress Report	6	20%
Poster Presentation at OMED	12	20%
Final Report	12	10%



See “**F. REQUIRED REPORT**” for detailed information regarding what and when to submit reports.

The applicant’s organization is responsible for disbursing the funds for the project. The AOA is responsible for disbursing the stipend 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 (30) days of the effective date of the grant award, AOA will rescind the award.

Any funds unexpended at the end of the fellowship 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 fellowship 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.
2. The final project and financial reports are due at the end of the grant period. 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, but 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 PODIUM PRESENTATION

Grantees are required to present their research findings at the upcoming Osteopathic Medical Conference & Exposition (OMED) Poster session. Grantees are released from this requirement if all the disbursed funds are turned to the AOA.



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, 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 funding 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 fellowships-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 grantee.



J. NON-COMPLIANCE

Grantees will not be considered for any new grant awards until all reports are submitted and approved. Should reports of a study not be received in a reasonable time (90 days 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 grantee 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

Program extensions are prohibited. If grantees do not complete their project in the allotted time, all funds disbursed to the institution must be returned to the AOA.

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. TRANSFERS

A transfer of grant monies or equipment to another organization is prohibited.