

Funding Opportunity Announcement/Solicitation: **Oklahoma Health Research HR19**

Key Dates:

Application Submission Period Open

January 1, 2019

Application Due On/Before

Applicants are encouraged to submit applications in advance of the deadline because of the anticipated high volume of applications submitted in the last few hours of the submission period window.

March 1, 2019

(5:00 PM Central Time)

Applicants Notified of Award On/After

June 18, 2019

Submission of Required Documentation Due

June 25, 2019

Earliest Project Start

July 1, 2019

About this Funding Opportunity Announcement (FOA)

Purpose

This Funding Opportunity Announcement (FOA), also referred to as the Solicitation, is intended for informational purposes and reflects current planning; it does not obligate OCAST to make any specific number of awards. Awards are contingent upon the availability of state funds. If there is any inconsistency between the information contained in this FOA and the terms of any resulting contract, the terms of the contract are controlling.

This FOA may be amended by OCAST. Amendments can be found on OCAST's website under the section Funding Opportunities. It is the responsibility of the applicant to review any such amendments and make necessary changes in the application to meet the amended FOA requirements.

Users of this FOA

Principal Investigators (PIs), Contract Officials and/or Administrative Staff affiliated with Oklahoma-based colleges, universities, and companies

This FOA is available at https://www.ok.gov/ocast/FUNDING_OPPORTUNITIES/index.html

Application Submission

Applications must be submitted through the state's online grant management system, OKGrants, at <https://grants.ok.gov>. Neither additional materials nor changes will be accepted after an application is submitted. Individuals wishing to change an application that has already been submitted may have their submitted application cancelled and submit a new application prior to the application deadline.



Failure to include all required documentation with the application at the time of submission will result in rejection of the application without review.

FOA Document Revision History

Pre-Release:

Typo corrected from previous year FOA: Minimum font size corrected to 11 point font.

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1. Award Summary

| | |
|---------------------------------------|---|
| Description | The Oklahoma Health Research program provides funding to investigators to pursue their ideas for increased scientific understanding of important problems in human health, and lays the foundation for driving economically significant future innovations. This program funds qualified basic research projects conducted by Oklahoma-based investigators for the multiple purposes of (1) enhancing the competitiveness of Oklahoma health researchers in their pursuit of additional research funds, (2) recruiting and retaining outstanding health research scientists for the state, (3) improving health care for Oklahoma citizens and (4) strengthening the state's health care industry. Research funded under this program investigates the causes, diagnosis, treatment and prevention of human diseases and disabilities and facilitates the development of health care products and services. |
| Award Funding | Minimum of \$10,000 and maximum of \$45,000 of OCAST funds per year (for a maximum of \$135,000 for three years). |
| Award Project Period | One to three years |
| Anticipated Project Start Date | July 1, 2019 |

2. Eligibility

| | |
|-------------------------------|---|
| Eligible Projects | This Health Research Award program provides OCAST funding for a project that is “a specific examination, experimentation or investigation or initiative to provide research resources oriented principally toward basic, applied and developmental scientific inquiry related to the causes, diagnosis, prevention and treatment of human diseases and disabilities and mental health and emotional disorders and the rehabilitation of persons afflicted with such diseases, disabilities and disorders; new knowledge, better understanding and innovative methods to improve the processes by which health care services are made available and how they may be provided more efficiently, more effectively and at a lower cost, for all the citizens of this state; and the development of new products and services which shall form the basis of new high-technology health research and care industry for this state” (74 O.S., Section 5060.4). |
| Eligible Organizations | Eligible applicant organizations shall include Oklahoma-based companies, public or private colleges or universities, or non-profit research institutions. |
| Eligible Individuals | <p>Principal Investigator</p> <p>The Principal Investigator (PI) for this program is the person responsible for the execution of the Health Research Award (co-PIs are not allowed).</p> <p>The principal investigator (PI) preparing an application (1) shall be employed by or affiliated with an eligible applicant organization and (2) must be an Oklahoma resident. Investigator is statutorily defined as a person who proposes research projects and is primarily responsible for the execution of the proposed projects and is employed by or affiliated with an institution of</p> |

Eligible
Individuals,
continued

higher education, a nonprofit research institution in this state or a private enterprise. Investigators must be residents of Oklahoma before the ninetieth (90) day after a professional services contract to which they will be functioning as an investigator, has been awarded by OCAST. Peer reviewers carefully consider the experience and expertise of applicants as documented in the application.

If the PI of a proposed project becomes unable to perform the research between submission of the application and the initial contract start date, OCAST will not allow a change in PI. Consequently, if the original PI ceases to head the project between application submission and review, the project will not be eligible for review; if the original PI is lost to the project prior to award, the project will not be considered for award. The PI cannot change organizations between the time of application submission and the project start date. When a PI on a proposed project becomes unable to perform, the applicant organization(s) must inform OCAST within 10 days. If funds have been awarded, monies will revert to the Oklahoma Health Research fund.

The PI may hold only one Oklahoma Health Research contract at a time; however, a currently funded PI may compete with a new project and, if successful, terminate the current contract to accept the new award. A currently funded PI may also apply if the current project funding ends prior to the beginning of funding of the new Health Research award.

Previous Recipients of Health Research Awards

OCAST requires PIs receiving previous Oklahoma Health Research awards to have submitted at least one application to a national funding organization prior to applying for new funding from OCAST. Previous recipients must address this in the Required Attachment document, Section #3: Biosketch, under Research Support.

**Regulatory
Requirements**

If the project involves any of the following, documentation of regulatory review and approval must be provided to OCAST prior to contract initiation:

- **Human Subjects, Human Derived Materials, Human Data**
- **Recombinant DNA, Vertebrate Animals**
- **Narcotics, Dangerous Drugs, Radioisotopes**
- **Biological Hazards**

Note: regulatory approval documents do not need to be submitted with the application; they can be submitted prior to contract initiation of the funded project.

**Contract
Requirements**

Oklahoma statute requires that the funding mechanism for an Award in the Oklahoma Health Research program must be a professional services contract between OCAST, the applicant organization, and any additional applicant organizations. The contract shall include commitments on the part of the contractor to perform the activities described in the application and funded by OCAST. The approved application becomes a component of the contract for performance of the research project.

The Contractor is the applicant organization that: (1) employs or is affiliated with the PI, (2) provides research services and/or facilities for the funded project, and (3) executes the contract. All applicant organizations and additional applicant organizations, which shall be providing research services or facilities for the funded project, shall be signatories to the contract. The Fiscal Agent is employed by the applicant organization and shall receive and account for all contract payments from OCAST and is designated as such in the application. The contract shall include commitments on the part of the contractor(s) to perform the activities described in the

Contract
Requirements,
continued

application and funded by OCAST. However, the obligations of each party to a contract shall be limited to that portion of the contract they have committed to perform.

Any applicant organization or principal investigator who, in OCAST's judgment, has failed to correct a material breach of contract previously awarded under any of OCAST programs will not be eligible to be awarded a new funding contract.

Any PI who has a delinquent progress report or has not responded to other OCAST requests for information, impact survey data or special reports on a previously funded OCAST project will not be eligible to submit an application for new project funding. Any PI who has a delinquent progress report at the time of review will not be eligible for review. Any PI with a delinquent progress report at the time of award will not receive a contract until the progress report has been submitted. In the latter case, if the delinquent report has not been submitted within 60 days of the award date, OCAST will nullify the award and return the monies to the Oklahoma Health Research fund.

3. Application Submission

About OKGrants

Applications for the Health Research Awards must be submitted through the state's online grant management system, OKGrants, at <https://grants.ok.gov>. The OKGrants system can be used for monitoring the status of application submissions, and if awarded, managing project related activities such as Requests for Payment (RFP) requests, progress report submissions, contract modification requests, reviewer evaluations, and budget revisions. Additional information about using the OKGrants system can be found here:

https://www.ok.gov/ocast/documents/Prog_CO_Guide_OKGrants.pdf

Number of Applications

A PI may submit only one application per funding cycle.

Resubmissions

Applications that have previously been submitted but have not been approved for funding or did not rank above the funding line may be resubmitted during a subsequent funding cycle for the same or different program. There is no limit to the number of times an application may be resubmitted, as long it is only one application per Health Research program funding cycle. A PI resubmitting a proposed project that was not funded in a previous funding review must proceed as follows:

1. Indicate that the current proposal is a resubmission on the Project Information page in OKGrants and include the previous project number(s)
2. Prepare a Resubmission Index (see Required Attachment Outline section of this FOA)

Note: be sure to address all reviewer comments from the previous submission when making a resubmission

Applicant User Roles on OKGrants

The OKGrants system utilizes four user roles, each with different permissions for the Health Research Award application.

| Role on Health Research Award | Corresponding Role on OKGrants |
|---|--------------------------------|
| PI | Authorized Official |
| Contract Official/Contract Administrator for Applicant Organization | Agency Administrator |
| Fiscal Agent / Accountant | Financial Officer |
| Contributor/Other | Writer |

Only the Agency Administrator has the authority to allow/deny access of the other roles to a specific application. Additional information about these roles, along with other useful application tips can be found in the OKGrants Quick Reference Guide at

https://www.ok.gov/ocast/documents/Prog_CO_Handout_OKGrantsWorkshop.PMf

Initiating the Application on OKGrants

Applications **must** be submitted through the state’s online grant management system, OKGrants, at <https://grants.ok.gov>.

If you are the PI:

1. If you do not already have an account on OKGrants, you must first contact the Contract Official, Grant/Contract Administrator or similar individual of your organization and request to be setup in OKGrants. **Please do not contact OCAST as they will be unable to do this for you.** If you already have an account in OKGrants, please skip this step.

After you are set up in OKGrants as the Authorized Official role by your Contract Official (Agency Administrator role), a username and temporary password will be emailed to you. When you log in for the first time, the system will immediately require you to change your password in order to access the system.

2. Once logged in, click the VIEW OPPORTUNITIES button under the View Available Opportunities heading to see all funding programs that are open and accepting applications. Scroll down to find the desired funding program and click the APPLY NOW button. Once you click “I accept” on the agreement page, a project number will be automatically assigned to your application and a notification email sent to the Contract Official (Agency Administrator) of your organization.

Note: Only the PI (Authorized Official role) may initiate the application process on OKGrants.

If you are the Contract Official for the Applicant Organization:

1. If your organization is NOT already registered on OKGrants, you will need to register by going to <https://grants.ok.gov/> and clicking on the “New User Link” to begin the registration process. Otherwise, skip this step.
2. Once you have received notification that your account has been approved by OCAST, set up a new account in OKGrants for the PI as the Authorized Official role, if an account does not already exist.
3. As the Agency Administrator, you will not be able to initiate the application. Only the PI (Authorized Official role) can initiate the application.
4. You will be the last person to make any changes to an application and must approve the application prior to submission to OCAST.

Required Attachment

In addition to completing the application forms on OKGrants, a document containing information outlined below must be uploaded to the Required Attachments page in OKGrants. When preparing this document, include each section heading as organized and indicated in **boldface** below and provide the requested information. Make sure to follow formatting instructions in the next section of this FOA. For your convenience, a checklist of the required sections can be found on page 18.



**File Upload:
Required
Attachment**

1. Research Plan (*required; 7 pages maximum, including figures, graphs, and charts*)

This section must contain a detailed description of the proposed work to be undertaken in the format shown below. Applications lacking a complete research plan may be returned without review. The research plan must include one page of specific aims and may include up to six pages of additional narrative. As applicants prepare their research plan, they should ensure that they answer the following questions: (1) What do you intend to do? (2) Why is the work important? (3) What has already been done? (4) How are you going to do the work? The research plan should be prepared in the following format:

- A. Specific Aims** (*one page maximum*): List the broad, long-term objectives and the goal of the specific research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop a new technology.
- B. Background and Significance**: Briefly sketch the background of the proposed project, critically evaluate existing knowledge and specifically identify the gaps that the project is intended to fill. State concisely the importance of the research described in this application by relating the specific aims to longer-term objectives. If the aims of the application are achieved, state how scientific knowledge or clinical practice will be advanced. What is the innovation? Describe the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive this field.
- C. Preliminary Studies**: Provide an account of the PI's progress that led to formulating the proposed project as well as any other information that will assist the reviewers in assessing the competence of the PI for performing the project.
- D. Research Design and Methods**: Discuss in detail the research design and the clinical framework, procedures and analyses to be used to accomplish the specific aims of the project. Describe the protocols to be used. Provide a tentative sequence or timetable for the investigation. Include the means by which the data will be analyzed and interpreted. Discuss any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and the alternative approaches to achieve the aims. Point out any procedures, situations or materials that may be hazardous to personnel and the precautions that will be exercised.

2. Budget Justification (*required; 2 pages maximum for all budget years*)

For each budget year, prepare an explanation and justification for the budget. All amounts rounded to the nearest dollar. Incomplete explanations may result in a requested item not being approved or the entire project not recommended for funding. This is a very important part of the proposal. Reviewers carefully evaluate all budgets, so request only what is necessary and reasonable to conduct the work. Items that are unallowable, excessive in cost,

Required
Attachment,
continued

or not appropriately justified may be removed from the budget at the discretion of OCAST and/or the reviewers.

Applicants should carefully review the list of unallowable costs here:

https://www.ok.gov/ocast/documents/Prog_CO_Reference_IndirectCostList.pdf.

Indirect costs are not allowable as a budget item. If an organization requires direct cost reimbursement for project-specific utility or compliance costs, these should appear as line items in the budget along with both the method of calculation and an explanation for their inclusion.

- A. Personnel:** List the names and positions of all personnel involved in the project, both professional and nonprofessional, whether or not salaries are requested. Estimate the hours per week on the project for all personnel. List the dollar amounts separately for each individual for salary and fringe benefits.

Money from the Oklahoma Health Research fund may not be used to replace or augment any part of the salary of (1) any full-time faculty member at an Oklahoma college or university or (2) any person of equivalent status in an organization other than a university or college if he or she is the PI or collaborator on an Oklahoma Health Research contract. Salaries or stipends for technicians, postdoctoral associates, students or other staff important to the success of the project are appropriate personnel costs that may become part of a professional service contract.

- B. Professional Travel:** Describe the purpose of any travel, giving the number of trips and the professional activities involved, the destination(s) and the number of individuals for whom funds are requested. The amount requested for travel must be fully explained in the budget justification. Professional travel may not exceed \$1,000 per year and the amount of travel approved by the reviewers cannot be increased after award.
- C. Supplies:** Itemize supplies such as glassware, chemicals and animals in separate categories. If animals are involved, state how many are to be used, their unit purchase cost and their unit care cost.
- D. Equipment:** List separately each item of equipment with a unit acquisition cost of \$500 or more. If funds are requested to purchase items of equipment that appear to duplicate or to be equivalent to items listed under Facilities, Instrumentation and Resources (see Item 4 below) or items used in preliminary studies, justify the reasons for duplication.
- E. Contractual Services:** Itemize and justify any work on the project that is going to be contracted.
- F. Patient Care Costs:** Include inpatient and outpatient charges only if they are an integral part of the research. Provide the names of the hospitals to be used and the amounts requested for each. Indicate in detail the basis for estimating costs in this category, including the number of patient days, estimated cost per day and cost per test or treatment. Patient care costs do not include patient travel and per diem costs; request these costs in the *Other Expenses* category.
- G. Alterations and Renovations:** Costs of building construction, per se, are not permissible charges. If the costs of essential alterations of facilities are requested (i.e., repairs, removal or installation of partitions, shielding or air conditioning), itemize such costs by category and justify each fully. When applicable, indicate the square footage involved and provide the basis for the costs, such as an architect's or contractor's detailed estimate. When possible, submit a line drawing of the alterations being proposed.

Required
Attachment,
continued

H. Other Direct Costs: Itemize other expenses, such as publication costs, page charges and books by category and unit cost. Itemize and justify such items as patient travel and per diem costs, donor fees, rentals, leases and computer costs. Reimbursement is allowable for personal expenses incurred by human subjects participating in the project, including travel with an escort if required. This reimbursement is applicable for all classes of research subjects, including inpatients, outpatients, donors and normal volunteers regardless of employment status. Travel associated with data gathering must be listed in this category, fully explained and detailed (miles, number of trips, duration, number of participants, travel locations, etc.) in the budget justification.

3. Biosketch (*required; 5 pages maximum for each individual*)

Instructions and a template for the Biographical Sketch can be found here:

http://www.ok.gov/ocast/documents/OCASTBiosketch_HR_TemplateGuide.docx

A sample Biographical Sketch can be found here:

www.ok.gov/ocast/documents/OCASTBiosketch_HR_Sample.docx

4. Facilities, Instrumentation and Resources (*required; 1 page maximum*)

Describe any specialized facilities, instrumentation and/or resources necessary and available for this project.

5. Literature Cited (*required; no page limit*)

Compile list of citations in a format appropriate for the research project's discipline.

6. Letter(s) of Commitment (*required; up to 3 letters at 1 page maximum each*)

All applicants must submit a signed letter of commitment on official letterhead from an official authorized to commit the resources of the applicant organization (i.e., department, division or unit head) detailing organizational plans and commitments on the applicant's behalf. These comments should include plans and commitments beyond the tenure of the proposed research. The letter should also include commitments for such items as equipment, computer services, facilities and release time for key personnel and/or technical and clerical support that the organization will provide for the project.

7. Letter(s) of Recommendation (*optional; up to 3 letters at 1 page maximum each*)

Applicants in the early stages of their research careers are encouraged to submit up to three letters of recommendation from individuals able to evaluate the applicant's scientific potential.

8. Letter(s) of Support (*optional; up to 3 letters at 1 page maximum each*)

Applicants may include up to three letters of support from supporters of their project.

9. Appendix I - Institutional Approvals and Certifications (*required, if applicable; no page limit*)

Institutional approvals and certifications are not required at the time of submission of the application or prior to the OCAST peer review process, unless the applicant organization requires such approval prior to submission. If approvals have been received, include documentation of institutional approval and certifications in Appendix I.

No OCAST Health Research award will go to contract without institutional approvals and/or certifications when the research involves:

- human participants, human derived materials, human data
- vertebrate laboratory animals
- recombinant DNA
- narcotics/dangerous drugs
- radioisotopes

Required
Attachment,
continued

- biological hazards

For each required institutional approval and certification related to the relevant areas listed below, provide the following information and also include in Appendix I:

Human Subjects

First, identify the sources of the potential human subjects, human derived materials or human data. Describe the characteristics of the subject population, state the anticipated number, age, gender, ethnic background and state of health. Identify the criteria for inclusion or exclusion. Explain the rationale for the use of special classes of subjects, such as fetuses, pregnant women, children, institutionalized mentally disabled, prisoners or others, especially those whose ability to give voluntary informed consent may be in question.

Second, describe the recruitment and consent procedures to be followed, including the circumstances under which consent will be solicited and obtained, who will seek it, the nature of information to be provided to prospective subjects and the methods of documenting consent. (A copy of the consent form must be provided if requested by OCAST.)

Third, describe any potential risks – physical, psychological, social, legal or other – and assess their likelihood and seriousness. Describe alternative methods, if any, that were considered and why they need not be used.

Fourth, describe the procedures for protecting against or minimizing any potential risks and include an assessment of their likely effectiveness. Include a discussion of confidentiality safeguards, where relevant, and arrangements for providing medical treatment if needed.

Fifth, describe and assess the potential benefits to be gained by the subjects, as well as the benefits that may accrue to society in general, as a result of the planned work.

Finally, discuss the risks in relation to the anticipated benefits to the subjects and to society.

If human subjects, human derived materials or human data are to be used in this project, indicate it on the Performance Sites and Compliance page in OKGrants and, if IRB approval has been received, submit documentation of institutional approval (IRB) in Appendix I.

Research on human subjects, derived materials or data utilizing resources awarded under the Oklahoma Health Research program must follow federal guidelines as promulgated in 45 CFR. In addition, **these funds may not be used to “undertake any research which has abortion, as defined by Section 1-730 of Title 63 of the Oklahoma statutes, as its purpose” (74 O.S., Section 5054).**

The federal regulation is available from Office of Human Research Protection, www.hhs.gov/ohrp. The regulation provides a systematic means, which is based on generally accepted ethical principles, for protecting the rights and welfare of individuals who may be exposed to the possibility of physical, psychological or social injury while they are participating as subjects in research, development or related activities. The regulation extends to the human fetus (either in utero or ex utero), the dead, organs, tissues and body fluids as well as graphic, written or recorded information derived from human sources. It covers activities which present no physical risk to the subject but which may create legal risks or expose subjects to public embarrassment or humiliation through breach of confidentiality or invasion of privacy.

The major focus of a project (for example, on a medical procedure) may not be the sole determinant of the types of risks involved or the need for additional protection. The safeguarding and confidentiality of medical records and other forms of data collected on

Required
Attachment,
continued

individuals and groups, the use of such data by the investigator conducting the original research, the concurrent uses of the data by other investigators and the use of the data for research purposes at a later time are considered within the scope of this policy.

The regulation requires institutional assurances, including the implementation of procedures for review and the assignment of responsibilities for adequately protecting the rights and welfare of human subjects. Safeguarding the rights and welfare of human subjects is the responsibility of the applicant organization. In particular, the applicant organization is responsible for ensuring that the activity described in the application and any additional information relating to human subjects, derived materials or data are reviewed and approved by an institutional review board (IRB) defined in statute as:

a committee composed of (at least) investigators, lay representatives and legal counsel for the express purpose of determining the appropriateness of any research involving human subjects (74 O.S., Section 5060.4).

The above stated federal requirements have been adopted by the Oklahoma Health Research Committee and OCAST.

Vertebrate Animals

If vertebrate laboratory animals are to be used in this research project, indicate such on the Performance Sites and Compliance page in OKGrants. Include this information in Appendix I, if available, submit documentation of institutional approval. In Appendix I state the species, strains, ages and numbers of the animals involved. If the animals are in short supply, costly or to be used in large numbers, provide the rationale for their use and their numbers. Describe the procedures for adequate care of any animals involved. Describe the procedures to avoid unnecessary discomfort, pain or injury to the animals, such as surgical anesthesia, post-trauma analgesia, tranquilizing drugs and comfortable restraining devices.

In recent years, there have been extensive changes in federal requirements for the use of vertebrate animals in research. Investigators, their projects and their institutions must adhere to these requirements beginning with the date of submission of a proposal.

As part of its compliance with these regulations, an applicant institution must duly constitute a review committee to assist in assuring humane treatment and care of animals.

Recombinant DNA

If recombinant DNA technology will be used in the project, indicate such on the Performance Sites and Compliance page in OKGrants and submit, if available, documentation of institutional approval in Appendix I. On a separate sheet state the level of containment to be used and explain why this level is appropriate for the proposed project; include this information in Appendix I.

Applicant institutions are required to comply with federal guidelines regarding the application of recombinant DNA technology as of the date of application submission. The applicant institution must establish an institutional biosafety committee which must judge appropriate proposals and approve only those that conform to the guidelines.

Narcotics and Dangerous Drugs Letter

The use of narcotics and dangerous drugs is regulated by the Oklahoma State Bureau of Narcotics and Dangerous Drugs and by the Drug Enforcement Administration of the U.S. Department of Justice. The PI must identify the individual or organization under whose auspices narcotics or dangerous drugs will be used.

If these substances will be used in the project, the PI must do as follows: (1) Indicate such on the Performance Sites and Compliance page in OKGrants and (2) include a letter in Appendix I

Required
Attachment,
continued

which states the registration number with the Oklahoma State Bureau of Narcotics and Dangerous Drugs and the U.S. Drug Enforcement Administration to be used in this project. If the registrant is not the PI, the PI must (1) provide the registrant's name, title, address and phone number on the Performance Sites and Compliance page and (2) submit a letter from the responsible individual which (a) states the registration number with the Oklahoma Bureau of Narcotics and Dangerous Drugs and the U.S. Drug Enforcement Administration and (b) grants permission for its use in this project. The Narcotics and Dangerous Drugs section of the Performance Sites and Compliance page must be satisfactorily completed and the required letter submitted, as appropriate, if a proposed health research project is to receive funding.

Radioisotopes Letter

Use of radioactivity is regulated by the U.S. Nuclear Regulatory Commission. Appropriate licenses must have been obtained by the applicant organization as well as the PI, his or her sponsor or a responsible colleague. If radioisotopes are to be used in the performance of the proposed project, the PI must proceed as follows: (1) Indicate such on the Performance Sites and Compliance page in OKGrants and, (2) if the responsible individual is someone other than the PI, include in Appendix I a letter granting permission for the use of radioisotopes in this project under this license. The Radioisotopes section of the Performance Sites and Compliance page must be satisfactorily completed and the required letter submitted, as appropriate, if a proposed health research project is to receive funding.

Biological Hazards

If any contact with infectious agents or substances containing them is anticipated, indicate such on the Performance Sites and Compliance page in OKGrants and, on a separate sheet, identify any potential biological hazards, explain procedures to protect individuals from infection or injury, state the level of containment to be used and explain why it is appropriate; include this information in Appendix I.

Various barrier techniques are advised when work is performed with potentially infectious agents or with substances that may contain infectious agents. A guide to the level of containment for infectious agents based upon the recommendations of the Center for Disease Control may be obtained from the U.S. Government Printing Office Washington, D.C. 20402, HHS publication NO. (CDC) 88-8395, entitled Biosafety in Microbiological and Biomedical Laboratories.

It is the sole responsibility of the contractor – the applicant institution, who is the employer of or affiliated with the PI – to maintain a safe working environment and to make any changes required by subsequent regulations or law. The biological hazards must be satisfactorily addressed if a proposed health research project is to receive funding.

10. Appendix II – Resubmission Index *(required if application is a resubmission; no page limit)*

Projects that have been previously submitted but not awarded a contract may be resubmitted at any time. A resubmission is a new proposal and not prepared by simply commenting on the previous reviewers' comments; a full, new application must be submitted to OCAST. A resubmission must include the following:

- A. A letter responding in detail to the reviewers' comments from the previous review
- B. All reviews of the most recently submitted unfunded application

**Required
Attachment –
Formatting**

Document Requirements:

File Size and Uploading to OKGrants

The document must be uploaded into the appropriate field in OKGrants. **The document file size must not be greater than 20MB.** Any submitted application that is missing a required attachment will be returned without review.

Paper Size and Margins

Use paper size no larger than standard letter paper size (8 ½" x 11"). Provide at least one-half inch margins (top, bottom, left, and right) for all pages.

Font and Line Spacing

Font size must be 11 points or larger. Smaller text in figures, graphs, diagrams and charts is acceptable as long as it is legible when the page is viewed at 100%. Line spacing: must be no more than six lines per vertical inch. Text color must be in black color. Preferred fonts include Times New Roman, Arial, Georgia, Garamond, Helvetica, Verdana, or Palatino Linotype.

Page Limits

You must adhere to the page limits stated in the Required Attachment Outline section of this FOA. Section text length page limitations include text, inserted graphs, charts and figures as part of the total section page length.

Headers and Footers

The project number and PI's last name should appear on every page of the Required Attachment document in the upper right corner. Reviewers also appreciate page numbers in the lower right corner of every page.

Images

Digital images must only be included within the page limits of the Project Plan. Use image compression (e.g. JPEG or PNG) if possible before placement into document. Please be aware of the 20MB file size limit when working with images.

**Submitting the
Application on
OKGrants**



The application is due no later than March 1, 2019 at 5:00 PM Central Time; the OKGrants system is hard coded to shut down the application submission window at precisely 5:00 PM CT. Applicants are **STRONGLY** encouraged to submit applications in advance of the deadline given the anticipated high volume of applications submitted in the last few hours of the submission period window.

No corrections will be allowed or supplemental materials will be accepted after an application has been submitted, even if the request is made before the deadline. OCAST does not have authority to access and/or modify submitted application information and documents. Individuals who want to make changes to an application that has already been submitted may cancel their submitted application and submit a new application prior to the application deadline.

Failure to include all required information and documentation with the application at the time of submission will result in rejection of the application without review.

Please note that an application has not been submitted until confirmation is received. There are several ways to confirm successful submission of your application: by checking the status of the application in OKGrants (best), by receiving an e-mail from OKGrants indicating that your application was submitted, or by contacting OCAST to confirm that your submission was

successful. When in doubt, please contact Casey Harness at OCAST to confirm that your application was received.

4. Application Review and Award

Overview of the Review Process

Oklahoma statutes require OCAST to ensure that funding to support health research projects is awarded only on the basis of scientific merit. Statutorily, a review must evaluate the merits of proposed health research projects, the qualifications of PIs and the facilities in which the proposed health research project shall be performed. All applications submitted for funding consideration are judged solely on the basis of scientific merit.

Applications are reviewed by scientists who reside outside the state of Oklahoma and are approved by the Oklahoma Health Research Committee. Reviewers rank applications for funding on the basis of the scientific merit of the proposed research.

OCAST staff provides reviewer recommendations to the OSTRaD board, which considers those recommendations when determining which applications will receive funding.

Evaluation Criteria

Peer reviewers will evaluate properly completed applications on the basis of scientific merit. In general, in addition to evaluating the appropriateness of the budget, peer reviewers evaluate applications for scientific merit according to the following criteria:

- 1. Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services or preventive interventions that drive this field?
- 2. Approach:** Are the conceptual or clinical framework, design, methods and analyses adequately developed, well integrated, well-reasoned and appropriate to the aims of the application? Does the applicant acknowledge potential problem areas and consider alternative tactics?
- 3. Innovation:** Is the project original and innovative? For example: Does the application challenge existing paradigms or clinical practice, or address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools or technologies for this area?
- 4. Investigators:** Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project?
- 5. Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Does the proposed study benefit from unique features of the scientific environment or subject populations, or does it employ useful collaborative arrangements? Is there evidence of institutional support? :

Award Notification

Upon approval by the OSTRaD Board, all applicants will be notified of the award funding decision by e-mail from OKGrants. Please ensure that your email server is set up to receive emails from OKGrants. Once these decisions are made, evaluations will be available to view within OKGrants. Notice of Award Letters for funded applicants will be emailed to PIs and Contract Officials within seven business days of the award funding decision. The Notice of Award Letter will contain important information regarding any missing or incomplete documentation needed for award contract initiation.

Contract Initiation

Prior to contract initiation of the first year of the Health Research Award (and each subsequent award year), the applicant organization(s) shall:

- Submit to OCAST all required documentation and information requested in the Notice of Award Letter by the “Submission of Required Documentation Due” date on the front page of this FOA;
- Document and submit to OCAST as requested in the Notice of Award Letter compliance with state and federal requirements pertaining to human subjects, vertebrate animals, recombinant DNA, radioactive substances, and narcotics and dangerous drugs which require special approval or license. This responsibility shall also extend to any subcontract funded through this Contract;
- Have on file verification that the PI is not presently receiving funds from another source to support any portion(s) of the proposed research described in the Oklahoma Health Research program application that has been approved for funding;
- If the awardee is a former recipient of an Oklahoma Health Research contract, have on file evidence of submission to a national funding organization between the contract starting date of the previous award and the submission of a proposal for a subsequent Oklahoma Health Research award. Evidence of submission includes: (a) the face sheet of an application for funding, or (b) a notice of award or rejection within the above designated period.

Concurrent Funding

Acceptance of funding from another source—either prior to the beginning or during the period of an OCAST contract—that duplicates support for the research described in the application submitted to OCAST is considered concurrent funding. A PI shall not receive concurrent funding that duplicates support for any portion of the research described in the application.

5. Administration of Awarded Project

Administrative Requirements

During the performance of each OCAST contract for the duration of the project, the Contractor (Applicant Organization) shall:

- Assure and document, for the duration of the project, compliance with state and federal requirements pertaining to human subjects, vertebrate animals, recombinant DNA, radioactive substances, narcotics and dangerous drugs and/or biological hazards which require special approval or license before issuing a subcontract for any portion of the project funded by OCAST. This requirement shall also extend to any subcontract funded through this Contract.

Administrative
Requirements,
continued

- Maintain records and accounts that properly document and account for the source and application of all project funds. All such records and accounts shall be made available on demand by OCAST for inspection and use in carrying out its responsibilities for administration of the funds.
- Understand and comply with all requirements of the award contract especially with regard to use of state funds in strict accordance with the budget section of the approved application.
- Be able to provide upon request specified documentation of matching expenditures to OCAST with each request for payment. At no time shall the amount invoiced from OCAST exceed the amount of documented matching funds expended. Failure to document the required matching amount could result in a decrease in the OCAST funding amount and/or a termination of all-subsequent OCAST funding.
- Comply with the audit policy of OCAST and, as OCAST deems necessary, permitting authorized representatives of OCAST and the state of Oklahoma full access and the right to fully examine all project records and accounts. The contractor or designated fiscal agent shall provide OCAST timely copies of reports on any audits that include funds received from OCAST. The contractor, at OCAST's request, shall provide OCAST with an independent audit report of all funds expended on each contract in which the amount of OCAST funds awarded. In the event an audit results in the determination that the contractor or designated fiscal agent has expended contract funds on unallowable costs, the contractor or designated fiscal agent shall reimburse OCAST in full for all such costs.

If the PI becomes unable to perform the proposed research, the applicant organization must inform OCAST within 10 days. More specifically, the contractor shall inform OCAST within 10 days of the occurrence of any of the following:

- Official notification of resignation by the PI as an employee of one of the parties to the contract
- Official decision to terminate the PI as an employee of one of the parties to the contract
- Inability of the PI to perform the research described in the application
- Any occurrence which the contractor or fiscal agent determines will affect the successful completion of the research project
- PI leaves Oklahoma
- Majority of the research will not be performed in Oklahoma
- Receipt of notification of an award from another funding agency by the PI that duplicates or overlaps with any portion of the OCAST award supported by OCAST funds. The areas of overlap can include scientific overlap, budget overlap, and/or commitment overlap.

Any of the conditions above may result in the termination of the contract at the discretion of OCAST. If the PI is subsequently employed by another eligible applicant organization in the state of Oklahoma that agrees to support the research project, OCAST may consider issuing a new contract negotiated between OCAST and the new organization including new intellectual property agreements, if applicable. If a PI cannot perform on a contract, the applicant organization may request that OCAST consider continuing the contract with a new PI with sufficient skills and background.

Required Attendance to Health Research Conference

Oklahoma statute requires OCAST to sponsor an annual conference of health research investigators, representatives of institutions of higher learning, non-profit research institutions and representatives of industry to facilitate and accelerate the commercial development of new products and services conceived or developed as a consequence of professional service contracts supporting health research projects. **Acceptance of an Oklahoma Health Research contract obligates both the PI and a representative of the contracting organization** to attend this conference.

Progress Reports

Acceptance of a Health Research Award contract obligates the PI to submit an annual progress report 60 days prior to the ending date of each contract period, except for the final year. For one-year projects or the final year of multiple-year projects, a final report must be submitted no later than 30 days after the end of the final contract period. Failure to meet these deadlines will result in the termination of an existing contract or in the case of the final report result in nonpayment of the final request for payment and ineligibility for future OCAST funding. In most instances, the original reviewers of the application evaluate the annual progress reports to gauge project performance. Continued funding is contingent upon satisfactory annual performance evaluations that verify the PI is complying with the terms of the contracts and achieving project objectives.

Information Requests

Efforts to evaluate the Health Research Program require periodic collection of information from investigators and contractors. The PI and contractor are required to provide OCAST with the requested information during and after the funding period. This information may include, but is not limited to, impact survey information, site visits, and reverse site visits during which the PI may be required to present his or her Health Research funded project related information to OCAST staff, the OCAST board of directors, members of the Oklahoma legislature and other interested parties.

Audits

OCAST may perform compliance reviews and audits of contracts executed by the agency for all OCAST programs including the Health Research program. The acceptance of a Health Research professional research contract obligates the contractor to permit authorized representatives of OCAST and the state of Oklahoma to have full access to, and the right to fully examine, all such records and documentation pertaining to the project.

Release of Information

OCAST is subject to the Open Meeting and Open Records Acts. OCAST may use the contents from application abstracts from OKGrants and summaries from annual progress reports for the required OCAST annual report or other publications without obtaining permission from the applicant or applicant organization(s). Public release of information in any proposal or application submitted will be subject to existing statutory and regulatory requirements.

6. Contact OCAST

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|---|------------------|--------------|--|
| Main Office | 405-319-8400 | | |
| Program Manager & OK Grants Help | Casey Harness | 405-319-8404 | Casey.Harness@ocast.ok.gov |
| Contract Manager | Laura Sohl-Smith | 405-319-8408 | Laura.Sohl-Smith@ocast.ok.gov |
| Director of Programs | Dan Luton | 405-319-8415 | Dan.Luton@ocast.ok.gov |

7. Other Information

Key Terms

Additional Applicant Organization: organization(s) providing research services and/or facilities for the funded project while collaborating with the applicant organization, and included as a party to the OCAST contract. All additional applicant organizations must be Oklahoma-based entities. Eligible additional applicant organizations include Oklahoma-based universities, colleges, and non-profit research foundations, as well as companies with their principal place of business in Oklahoma.

Applicant Organization: The organization leading the project, with which the PI and fiscal agent are affiliated, and with whom OCAST goes to contract as the primary organization for the project. All applicant organizations must be Oklahoma-based entities. Eligible applicant organizations include Oklahoma-based universities, colleges, and non-profit research foundations, as well as companies with their principal place of business in Oklahoma.

Application: The complete package of information as required in the application section of this solicitation. If any required information is not supplied at the time the application is submitted the application will be returned without review.

Contract Official: The person who has the legal authority to designate funds and resources on behalf of the applicant organization. This is the person to whom OCAST will send all award or contract correspondence. If there are multiple applicant organizations, the designated contract official will be responsible for sharing contractual information with all other parties.

Contractor: The applicant organization who has been awarded and has signed a Health Research contract.

Enterprise: A company or firm with its principal place of business in Oklahoma.

Key Terms,
continued

Fiscal Agent: The entity who receives and accounts for all contract payments from OCAST. If more than one applicant organization is involved in a project a fiscal agent must be designated on the application.

Principal Investigator (PI): The person responsible for executing the project according to the research plan. Typically this person works in academia.

Professional Services Contract: The mechanism by which OCAST awards projects. Different from grants, these contracts allow OCAST to issue payments to contractors on a reimbursement basis upon receipt of satisfactorily completed requests for payment that are submitted to the agency.

Funding Program
Background

The Economic Development Act of 1987 (H.B. 1444) authorized the creation of the Oklahoma Center for the Advancement of Science and Technology (OCAST) with the purpose of being Oklahoma's technology-based economic development agency and to oversee the programs necessary for the development, transfer, and commercialization of technology (74 O.S., Section 5060.2). OCAST's mission is to "foster innovation in existing and developing businesses by supporting basic and applied research, by facilitating technology transfer between research laboratories and firms and farms, and by providing seed-capital for new innovative firms and their products . . . [and] to foster enhanced competitiveness in the national and international markets by small and medium-sized manufacturing firms located in Oklahoma by stimulating productivity and modernization of such firms" (74 O.S., Section 5060.2).

OCAST administers the Oklahoma Health Research program under the governance of the statutorily created Oklahoma Science and Technology Research and Development (OSTRaD) Board of Directors. The Programs Division of OCAST is responsible for the development of program specifications, production and distribution of proposal solicitations, processing of applications, organization and implementation of peer reviews, award of contracts and monitoring of contract performance.

The governor-appointed Oklahoma Health Research Committee acts in an advisory capacity to the OSTRaD board and OCAST staff. This statutorily created committee is required to include eight health research scientists and one member who is from the clergy or who has an advanced degree in philosophy from an accredited institution of higher learning. All nine members must satisfy stringent statutory requirements. A membership list of the Health Committee is available on the OCAST web site.

The Committee recommends program policies and procedures and advises and assists in the organization and implementation of the peer review of Oklahoma Health Research program applications. The Committee also advises and assists in the annual performance evaluation of funded Oklahoma Health Research program projects.

Program
Restrictions

Neither members of the OCAST board nor the Oklahoma Health Research Committee shall be precluded from participating directly in an Oklahoma Health Research program project. However, any director, officer, agent or employee of OCAST, including any member of an advisory committee or review panel, shall comply with the conflict of interest provisions from the OCAST statute, which reads as follows:

If a member of the board of directors, officer, agent or employee of the Oklahoma Center for the Advancement of Science and Technology (OCAST) has any direct or indirect interest in

Program
Restrictions,
continued

any approval, contract or agreement upon which the member, officer, agent or employee may be called upon to act or vote, the board member, officer, agent or employee shall disclose the same to the secretary of OCAST prior to the taking of final action by OCAST concerning such contract or agreement and shall so disclose the nature and extent of such interest and his or her acquisition thereof, which disclosure shall be publicly acknowledged by OCAST and entered upon the minutes of OCAST. If a board member, officer, agent or employee holds such an interest, he or she shall refrain from any further official involvement in regard to such contract or agreement, from voting on any matter pertaining to such contract or agreement and from communicating with other board members, officers, agents or employees concerning said contract or agreement . . .

Indirect interest shall include pecuniary or competitive advantage which exists or could foreseeably accrue as a result of the act or forbearance of OCAST (74 O.S., Section 5060.7).

**Required
Attachment
Checklist**

| | Section | Required? | Length | Done? |
|-----------|---|--------------------|--|--------------------------|
| 1 | Research Plan | Yes | 7 pgs max | <input type="checkbox"/> |
| 2 | Budget Justification | Yes | 2 pgs max | <input type="checkbox"/> |
| 3 | Biosketch | Yes | 5 pgs max for each individual | <input type="checkbox"/> |
| 4 | Facilities & Resources | Yes | 1 pg max | <input type="checkbox"/> |
| 5 | Literature Cited | Yes | No page limit | <input type="checkbox"/> |
| 6 | Letter(s) of Commitment | Yes | Up to 3 letters at 1 page maximum each | <input type="checkbox"/> |
| 7 | Letter(s) of Recommendation | Optional | Up to 3 letters at 1 page maximum each | <input type="checkbox"/> |
| 8 | Letter(s) of Support | Optional | Up to 3 letters at 1 page maximum each | <input type="checkbox"/> |
| 9 | Appendix I - Institutional Approvals and Certifications | Yes, if applicable | No page limit | <input type="checkbox"/> |
| 10 | Appendix II – Resubmission Index | Yes, if applicable | No page limit | <input type="checkbox"/> |