

Solicitation



Oklahoma Center for the Advancement of Science & Technology

Oklahoma Health Research Program FY 03 Funding Competition

Intent submission deadline:	December 11, 2002 5:30 PM
Application submission deadline:	January 22, 2003 5:30 PM
Institutional Review Approval deadline:	February 7, 2003 5:00 PM

This solicitation with forms is available at:

<http://www.ocast.state.ok.us>

This solicitation may be amended by OCAST. Amendments can be found on OCAST's web site under the section "Health Research Solicitation Amendments." It is the responsibility of the applicant to review any such amendments and make necessary changes in the application to meet the amended solicitation requirements.

**Oklahoma Center for the Advancement of Science & Technology (OCAST)
Research & Development Programs Division
4545 N. Lincoln Boulevard, Suite 116
Oklahoma City, Oklahoma 73105
Phone: (405) 524-1357
Fax: (405) 521-6501**

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**OKLAHOMA HEALTH RESEARCH PROGRAM
FY03 FUNDING COMPETITION
PROPOSAL SOLICITATION**

Oklahoma Center for the Advancement of Science and Technology (OCAST)

PROGRAM PURPOSE

The Oklahoma Health Research Program provides seed funding to superior research projects conducted by Oklahoma-based investigators for the multiple purposes of (1) enhancing the competitiveness of Oklahoma health researchers for national 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.

PROGRAM DESCRIPTION

Under this program OCAST awards competitive health research funds, through professional service contracts, to public and private colleges and universities in Oklahoma, nonprofit health research organizations in the State and private enterprises of special importance to the Oklahoma economy. 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.

Health Research Project Defined

is defined in Oklahoma Statute as:

. . . 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).

Regular Oklahoma Health Research Program

The Regular Oklahoma Health Research Program funds projects for one to three years at a maximum level of \$45,000 per year. Considerably smaller requests are approved for funding. Funding awards are made on a year-by-year basis. Neither approval of a multiple-year award nor funding of any year of a contract shall automatically lead to funding in subsequent years. For each year originally awarded, funding shall be dependent on a satisfactory, annual performance evaluation and the availability of funds.

Health Research Scientist Recruitment and Retention Projects

These awards support the research projects of health research scientists **who are new to Oklahoma**, for one to three years at a maximum of \$100,000 per year. The awards are specifically designed to increase the pool of health research talent in the State. An eligible applicant shall be a researcher who meets the following qualifications: (1) is employed by, or affiliated with, an eligible applicant organization; (2) holds at least the rank of assistant professor if at a college or university, or its equivalent in education and experience, as certified by the Chief Executive Officer of the applicant organization; and (3) submits an application within four years of accepting employment, or becoming affiliated with, the applicant organization. An eligible applicant shall be employed as a researcher [as defined in (1), (2), and (3)] in the State of Oklahoma for no more than four years. Eligibility for the New Scientist Recruitment and Retention Program requires that a researcher must have been a new hire in the State of Oklahoma as a researcher after January 22, 1999.

All applicants to the Health Research Scientist Recruitment program will also be considered for funding under the Regular Health Research Program (note: The Regular Oklahoma Health Research Program funds projects for one to three years at a maximum level of \$45,000 per year). **In such cases, do not submit two separate applications. For a researcher making application under the Health Research Scientist Program, the investigator must include a research plan and budget forms for the Regular Health Research project as a separate appendix in their Health Research Scientist Recruitment application. Such applicants must meet all requirements for the Regular Research Program.**

PROGRAM ADMINISTRATION

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 Research and Development (R&D) 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 (OHRC) 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 OHRC is available at the OCAST website.

The OHRC 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 OHRC also advises and assists in the annual performance evaluation of funded Oklahoma Health Research Program projects.

APPLICANT ELIGIBILITY

OCAST has purposely kept strict applicant eligibility requirements to a minimum. While this encourages broad participation in Oklahoma's Health Research Program, it also means that the Program receives more applications than it can fund. Peer reviewers, who reside outside Oklahoma, review and rank all applications. These reviewers carefully consider the experience and expertise of applicants as documented in the application. An average of 26% of those applying received awards. Before undertaking the long process of preparing an application, eligible applicants should keep in mind the competitive character of the award process.

Eligible Organizations. By statute, an *eligible applicant organization* is (1) an Oklahoma public or private college or university, (2) a non-profit research organization or (3) an enterprise of special importance to the Oklahoma economy.

Enterprise is defined as a firm with its principal place of business in Oklahoma.

The **Principal Investigator** preparing an application shall be employed by, or affiliated with, an eligible applicant organization. *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 higher education, a nonprofit research institution in this state, or a private enterprise.

The *Principal Investigator* is commonly referred to as the *PI*.

Change of PI. If the PI of a proposed project becomes unable to perform the proposed research between submission of the application and the initial contract period, OCAST will not allow a change in PI. Consequently, if the original PI ceases to head the project between 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. When a PI on a proposed project becomes

unable to perform, the applicant organization(s) must inform OCAST within ten (10) days. If funds have been awarded, monies will revert to the Oklahoma Health Research fund.

Previous Recipient Eligibility. OCAST requires previous recipients of Oklahoma Health Research contracts to demonstrate evidence of submission to a national funding organization prior to submission of a new application for funding. OCAST informs reviewers regarding *satisfactory or unsatisfactory* performance on previous OCAST contracts.

An individual 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, decline the current award 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 a new FY 03 award.

Any PI, who has a **delinquent progress report** 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 sixty (60) days of the award date, OCAST will nullify the award and return the monies to the Oklahoma Health Research Fund.

Conflict of Interest. Neither members of the OSTRaD 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 [Center] has any direct or indirect interest in 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 the Center prior to the taking of final action by the Center 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 the Center and entered upon the minutes of the Center. 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 the Center (74 O.S., Section 5060.7).

SUBMISSION REQUIREMENTS AND DEADLINES

OCAST CANNOT LEGALLY MAKE EXCEPTIONS REGARDING INTENT AND APPLICATION SUBMISSION DEADLINES AND RECOMMENDS EACH PI SCHEDULE SUFFICIENT DELIVERY TIME

Statement of Intent Deadline: December 11, 2002, 5:30 PM. Each PI submitting an application must submit a Statement of Intent form by the required deadline. Only those applicants who comply with this requirement shall be eligible to submit an application. Intents may be faxed to meet the deadline and followed with an original hard copy by mail; however, the applicant assumes the risk that the OCAST fax machine may be over-loaded or otherwise inoperable close to the deadline.

Statement of Intents that have been logged into a commercial delivery service with a “delivery guaranteed” before 5:30 PM on December 11, 2002 will be accepted if the applicant can provide acceptable documentation that the Intent statement was provided to the delivery service with delivery to the address listed below guaranteed prior to the closing date and time.

Statement of Intent Submission Address:

Oklahoma Center for the Advancement of Science & Technology (OCAST)
Research & Development Programs Division
4545 N. Lincoln Blvd. Suite 116
Oklahoma City, Oklahoma 73105-3413

Application Submission Deadline: January 22, 2003 5:30 PM. Each PI applying may submit only one proposal per competition. With the exception of documentation of institutional review board (IRB) approval of experiments using human subjects, vertebrate animals or recombinant DNA, OCAST must receive all materials pertaining to the application by the required deadline. Applications that have been logged into a commercial delivery service with a “delivery guaranteed” before 5:30 PM on January 22, 2003 will be accepted if the applicant can provide acceptable documentation that the proposal was provided to the delivery service with delivery to the address listed below guaranteed prior to the closing date and time.

Application submission address:

Oklahoma Center for the Advancement of Science & Technology (OCAST)
Research & Development Programs Division
4545 N. Lincoln Blvd. Suite 116
Oklahoma City, Oklahoma 73105-3413

This solicitation with editable application forms is available online at www.ocast.state.ok.us. Using the online tools are optional and are not required to prepare an application. Applications will not be accepted via facsimile, electronic mail or in any electronic format.

All required IRBs, if not included at time of submission, must be received by OCAST by February 7, 2003 5:00 PM, in order to be provided to reviewers. Applications pending IRBs after the deadline may not be reviewed for funding. If reviewed, the lack of documentation may jeopardize an otherwise successful proposal.

No applications or supplemental materials other than institutional reviews shall be accepted after the submission deadline except at the request of OCAST. OCAST will verify receipt of your proposal if a self-addressed, stamped postcard is attached to the *original*.

Required Materials. Applications eligible for review should contain all items listed in the sample Table of Contents in application Item 21. OCAST may return applications, which are judged to be incomplete or inappropriately completed, without review. Applications, which do not include all of the required information described in the Research Plan Section (Application required attachment Item 33), or the required Letter of Commitment (Application required attachment Item 35) may be returned without review.

Each Oklahoma Health Research Program applicant shall submit the following materials organized as specified below:

Number of copies	Documents
3	Sets of application forms each of which includes the following: Application form pages 1 – 8.
1	Original application with appendices attached (stapled or fastened with a binder clip in the upper left corner and marked original in upper right corner).
8	Copies of application with appendices (individually stapled or fastened with a binder clip in the upper left corner).

DO NOT USE binders or notebooks, rubber bands or regular paper clips. OCAST recommends that individual major sections (e.g. abstract, the budget section, and Required attachment sections) be set off by the inclusion of different colored sheets. No text should be typed on the colored sheets. Reviewers find such proposals more accessible. The applicant should also be aware that applications in which the materials are not organized as described often cause difficulty for the reviewers.

Institutional Reviews; Hazardous Substances. Work with human subjects, vertebrate animals, recombinant DNA, narcotics and dangerous drugs, radioactive substances and biological hazards require special approval or license and, in some cases, specialized training in order to engage in certain research. In addition, many chemicals require special handling or equipment. The applicant organization is responsible for ascertaining that State, as well as applicable Federal requirements, are met. The PI and applicant organization shall supply evidence of compliance, qualification, or license(s) as specified (see Attachment Requirements Item 36).

Resubmissions. Resubmissions have fared well in OCAST competitions; however, it is important that the applicant include ALL required materials listed below. A PI resubmitting a proposed project which was not funded in a previous Oklahoma Health Research Program funding competition, must proceed as follows:

- (1) indicate it is a *resubmission* on Application Form Item 4,
- (2) prepare a **separate appendix** which includes the following:
 - a. a letter, which responds to the reviewers' comments from the previous review and notes all changes in the new research plan,
 - b. a copy of the previously submitted application and
 - c. all reviews of that application.

REVIEW PROCESS

Oklahoma Statute obligates 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 investigators, and the facilities in which the proposed health research projects shall be performed.”

Scientists, who reside outside the State of Oklahoma and are nominated and approved by the Oklahoma Health Research Committee, review all applications. Reviewers rank applications for funding on the basis of the scientific merit of the proposed research. The reviewers establish the budget amount for each application recommended for funding. The amount is not modified by OCAST after the date of award.

The staff provides reviewer recommendations to the OSTRaD Board which grants approval for funding.

Evaluation Criteria. Peer reviewers evaluate applications for scientific merit according to the following specific criteria:

1. **Quality of the Proposed Research.** In general, this criterion evaluates the strengths and weaknesses in the approach and content of the proposal, the originality and creativity of the proposed research and the design and methodology of the research.
2. **Qualifications of the PI.** In general, this criterion evaluates the recent research record or other evidence of research potential of the PI, the likelihood of the PI making an important and original contribution and his or her capability of performing the proposed research.
3. **Appropriateness of Institutional Facilities.** In general, this criterion evaluates the research environment and the equipment and other resources that are available to accomplish the proposed research.
4. **Appropriateness of the Budget.** In general, this criterion evaluates the reasonableness of the budget.

Economic Impact Potential. Part of the legislative mandate for the Oklahoma Health Research Program is to stimulate economic growth by facilitating technological development. Although a developing program may require many years to have a meaningful impact, the Oklahoma Health Research Committee and the OSTRaD Board and staff are making a serious effort to develop this aspect of the program. Accordingly, OCAST asks reviewers to recognize and reward excellent applied research as well as that which has fundamental importance. Reviewers may complete a Commercial Potential Form for each proposal in which they can identify any product, concept or service which, in their opinion, has potential. OCAST forwards any such information to the PI in hopes that he or she and the applicant organization can find a successful means to develop it. Commercialization potential is not a review criteria.

RELEASE OF INFORMATION

The meetings of the OSTRaD Board and the Oklahoma Health Research Committee are subject to the Open Meeting Act and the Open Records Act. However, Oklahoma Statute exempts the following:

Any information submitted to or compiled by the Oklahoma Center for the Advancement of Science and Technology with respect to marketing plans, financial statements, trade secrets, research concepts, methods or products, or any other proprietary information of persons, firms, associations, partnerships, agencies, corporations, institutions of higher education, nonprofit research institutions or other entities shall be confidential, except to the extent that the person or entity which provided such information or which is the subject of such information consents to the disclosure. Executive sessions may be held to discuss such materials if deemed necessary by the board of directors (74 O.S., Section 5060.7).

Unless specifically requested, OCAST will use the contents from Statement of Intent Forms, application abstracts and the executive summary of the annual progress reports for the required OCAST Annual Report or other publications without obtaining permission from the PI or applicant organization. **OCAST does not guarantee that the contents of any application will remain confidential.**

AWARD PROVISIONS

Award of contract shall be contingent upon the following:

1. Receipt by OCAST of certification of institutional review and approval of the research project if it involves human subjects, vertebrate animals or recombinant DNA;

2. 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 which has been approved for funding;
3. If the awardee is a former recipient of an Oklahoma Health Research Contract, 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.

CONTRACT PROVISIONS

Contract Initiation. Oklahoma statute requires that the mechanism for funding approved applications to the Oklahoma Health Research Program be a professional services contract between OCAST and the applicant organization(s). The Contractor is the applicant organization which

1. employs or is affiliated with the PI,
2. provides research services and/or facilities for the funded project and
3. executes the contract.

A principal investigator may hold only one Oklahoma Health Research Contract at a time. 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 a contract for performance of the research project. The professional services contract carries more strict performance requirements than most research grants; however, it is anticipated that the PI will revise his/her plans according to the difficulties and opportunities which may arise.

Concurrent Funding. Acceptance of funding from another source either prior to the beginning of, or during the period of, an OCAST contract, which duplicates support for the research described in the application submitted to OCAST, is considered *concurrent funding*. **A principal investigator shall not receive concurrent funding which duplicates support for any portion of the research described in the application.**

Contract Administration. The Contractor's responsibilities shall include the following:

1. Assuring and documenting 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 a project funded by OCAST, the Contractor must also assure such compliance.

2. Maintaining 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.
3. Complying 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 shall provide OCAST timely copies of reports on any audits that include funds received from OCAST.

The Contractor shall notify OCAST within ten (10) days of the occurrence of any of the following:

1. The official notification of resignation by the PI as an employee of the Contractor,
2. the official decision to terminate the PI as an employee of the Contractor,
3. the inability of the PI to perform the research described,
4. any occurrence which the Contractor determines will affect the successful completion of the research project and
5. receipt of notification of award of concurrent funding by the PI to support any portion(s) of the research described in the contract.

Any of the conditions stated in items 1-5 above may result in the termination of the contract at the discretion of OCAST. Receipt of *concurrent funding* by the PI to support ANY portion(s) of the research described in the contract (see item 5 above) shall result in termination of the contract at midnight of the day prior to the beginning date of the concurrent funding.

As discussed above, if the principal investigator is no longer employed by or affiliated with the Contractor, the contract may be terminated. However, if the PI is subsequently employed by or affiliated with another eligible applicant organization in the State of Oklahoma, and, if the second organization agrees to support the research project, OCAST may consider issuing a new contract negotiated between OCAST and the new organization to fund the research project initiated under the original contractor. If the *principal investigator* cannot perform on a contract for health or other reasons, the Contractor may request that OCAST consider continuing the contract with another eligible scientist designated as *Principal Investigator*.

Required Data Collection. Efforts to evaluate the Oklahoma Health Research Program and assess individual projects require periodic collection of information from the PI and/or Contractor. **Recipients are required to respond annually to an *Impact Survey for R&D Funded Projects*.** By applying for a professional service contract, the principal investigator and the Contractor become obligated to provide OCAST with the requested information. PI's may be required to respond several years after funding, if the project continues to produce impacts.

Required 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.

PERFORMANCE EVALUATION

Acceptance of a professional service contract, which is issued under the Oklahoma Health Research Program, obligates the PI to submit an annual progress report sixty (60) days prior to the ending date of each contract period except the final contract period. A final report must be submitted thirty (30) days after the end of the final contract period.

Annual project performance is evaluated by external reviewers. A satisfactory performance evaluation shall verify that the PI is complying with the terms of the contract and achieving project objectives in a timely manner. Progress report instructions are available on the OCAST website at www.ocast.state.ok. Continued funding is contingent upon satisfactory, annual performance evaluations and availability of funds. Failure to submit an annual progress report on or before the deadline, as specified, may result in the termination of funding.

Application Preparation Workshops

OCAST staff present workshops to assist applicants as well as institutional proposal writers prepare applications. Attendees should read the solicitation prior to attending. These workshops are provided at no cost. Registration for the workshops needs to be made on-line at www.ocast.state.ok.us. Workshops for the FY2003 competition are scheduled as follows:

Date	Location
November 5, 2002	Stillwater, Oklahoma
November 7, 2002	Oklahoma City, Oklahoma
November 14, 2002	Tulsa, Oklahoma
November 19, 2002	Norman, Oklahoma

Name of principal investigator:

Statement of Intent

Oklahoma Center for the Advancement of Science and Technology
OCAST Oklahoma Health Research Program
FY 03 Funding

EACH PRINCIPAL INVESTIGATOR MUST SUBMIT A STATEMENT OF INTENT BY THE STATEMENT OF INTENT DEADLINE: 5:30 PM, DECEMBER 11, 2002. ONLY APPLICANTS WHO COMPLY WITH THIS REQUIREMENT SHALL BE ELIGIBLE TO SUBMIT AND APPLICATION.

Intents may be faxed to meet the deadline and followed with a hard copy by mail; however, the applicant assumes the risk that the OCAST fax machine may be over-loaded or otherwise inoperable close to the deadline. Intents should be delivered to the following address:

OCAST
Research & Development Programs Division
4545 N. Lincoln Blvd. Ste. 116
Oklahoma City, Oklahoma 73105
Fax: (405) 521-6501

1. Name of principal investigator:

2. Position or title of principal investigator:

3. Organization of principal investigator:

4. Address of principal investigator:

5. Phone number and fax number of principal investigator

6. E-mail of principal investigator

7. Title of project (this may differ from final proposal). Do not exceed 56 spaces.

8. Estimated request for OCAST funds. May differ from final proposal.

Year 1 \$	Year 2 \$	Year 3 \$	Total \$
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Name of principal investigator:

Statement of Intent

9. Describe the proposed project. Do not exceed 100 words.

10. Five scientific key words

11. Will any of these be used in the project?

Human subjects	Yes	No
Biological hazards	Yes	No
Vertebrate animals	Yes	No
Narcotics/dangerous drugs	Yes	No
Recombinant DNA	Yes	No
Radioisotopes	Yes	No

12. Signature of principal investigator

<input type="text"/>	Date:
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13. Research area of proposal. Check one category.

Cell/Molecular Biology	<input type="checkbox"/>
Chemistry & Biochemistry	<input type="checkbox"/>
Genomics and Gene Expression	<input type="checkbox"/>
Immunology	<input type="checkbox"/>
Infectious Disease	<input type="checkbox"/>
Instrumentation/Data Sciences/Clinical Evaluation	<input type="checkbox"/>
Neurobiology	<input type="checkbox"/>
Nutrition/Psychology/Public Health	<input type="checkbox"/>
Physiology/Pharmacology	<input type="checkbox"/>

Name of principal investigator:

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Statement of Intent

Note for Items 14 and 15. Suggested Reviewers . Optional. Provide the names and addresses of potential reviewers who are experts in the field of the proposed research. Do not include former research mentors, collaborators, or colleagues at your current or former institutions. Please include the names of experts residing in the States other than Oklahoma, as our reviewers cannot reside in state.

14. Potential reviewer.

Name, title, address, phone number and email

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15. Potential reviewer

Name, title, address, phone number and email

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Principal investigator:

	Project number: HR03-
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Application Forms for FY 03 Funding Oklahoma Health Research Program

1. **Title of proposal.** Limited to 56 characters.

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2. **Amount of funding requested.**

Year 1 \$	Year 2 \$	Year 3 \$	Total \$
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3. **Type of project. Check one.**

<input type="checkbox"/>	Regular Health Research Program	<input type="checkbox"/>	New Scientist
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4. **Is this a resubmission?**

<input type="checkbox"/>	Yes	If yes, what year:	<input type="checkbox"/>	No
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5. **Name of principal investigator:**

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6. **Position or title of principal investigator.**

7. **Terminal degree**

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8. **Mailing address, phone number, e-mail, web site and fax number of principal investigator:**

	Phone number:
	E mail:
	Web site:
	Fax:

9. **Human subjects?**

Yes: <input type="checkbox"/>	No: <input type="checkbox"/>		
Is institutional approval pending?	Yes: <input type="checkbox"/>	No: <input type="checkbox"/>	
Is institutional approval in Appendix I?	Yes: <input type="checkbox"/>	No: <input type="checkbox"/>	

10. **Vertebrate Animals?**

Yes: <input type="checkbox"/>	No: <input type="checkbox"/>		
Is institutional approval pending?	Yes: <input type="checkbox"/>	No: <input type="checkbox"/>	
Is institutional approval in Appendix I?	Yes: <input type="checkbox"/>	No: <input type="checkbox"/>	

11. **Recombinant DNA?**

Yes: <input type="checkbox"/>	No: <input type="checkbox"/>		
Is institutional approval pending?	Yes: <input type="checkbox"/>	No: <input type="checkbox"/>	
Is institutional approval in Appendix I?	Yes: <input type="checkbox"/>	No: <input type="checkbox"/>	

Principal investigator:

	Project number: HR03-
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12. Narcotics/Dangerous Drugs?

Yes:	No:
If the registrant is not the PI, state name and address of the individual whose registration number from the Oklahoma State Bureau of Narcotics and Dangerous Drugs and the U. S. Drug Enforcement Administration will be used.	
Name:	
Address:	
Use number:	

13. Radioisotopes?

Yes:	No:
State name, address and radioactive use number of the individual under whom radioisotopes will be purchased, stored and used.	
Name:	
Address:	
Use number:	

14. Biological hazards? Yes: No:

15. Research performance site physical location (name of organization and address):

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16. Applicant organization. Name and address of which employs, or is affiliated with the principal investigator and will be the Contractor in event of award.

Name:	
Address:	
Federal ID Number:	

Principal investigator:

	Project number: HR03-
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17. Official signing for applicant organization:

Name:	
Title:	
Address:	
Phone:	
E-mail	
Fax:	

18. Signature of official signing for application organization.

<p>Certification and acceptances. I certify that the statements and budget figures herein are true and complete. If an Oklahoma Health Research Contract is awarded, I accept the obligation to comply with the laws of the State of Oklahoma and the requirements of OCAST as they pertain to the performance of this project. I further affirm that none of the funds provided for this project will be used to undertake any research which has abortion as its propose as defined in Oklahoma Statute (O.S. 63, Sections 1-730). I understand that, if this proposed project is funded, both the PI and a representative of the contracting organization are required to attend the statutorily required Oklahoma Heath Research Conference.</p>	
<input checked="" type="checkbox"/>	Date:
Signature of official signing for applicant organization	

19. Signature of principal investigator:

<p>I hereby accept responsibility for the scientific conduct of the project, for providing the materials required for annual contract performance evaluation and for providing the information requested in the annual Project Impact Survey. I give consent for the materials in this application to be viewed, as required, by members of the OCAST staff, Board, OHRC and review panels. I affirm that none of the funds provided for this project will be used to undertake any research which has abortion as its purpose as defined in Oklahoma Statute (O.S. 63, Sections 1-730). I understand that, if I am funded, I am required to attend the statutorily required annual Oklahoma Health Research Conference to retain eligibility for funds under this program.</p>	
<input checked="" type="checkbox"/>	Date:
Signature of principal investigator	

Principal investigator:

Project number: HR03-

20. Statement of purpose. Describe in 150 words or less how the proposed project fulfills one or more of the following purposes: 1) 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; 2) 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; 3) the development of new products and services which shall form the basis of new high-technology health research and care industry for this state.

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21. Complete the Table of Contents page numbers.

Application form pages (Items 1- 20)	Application form pages 1-3
Table of Contents (Item 21)	Application form page 4
Abstract (Item 24)	Application form page 5
Budgets (Items 26-27)	Application form pages 6-8
Budget justification	
Biographical Information	
Facilities, Instrumentation and Resources	
Research Plan	
Literature Cited	
Appendix I: Required Documentation	
Other Appendices	

Principal investigator:

	Project number: HR03-
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22. Title of proposal. Limited to 56 characters.

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23. Research area. Check one category.

Cell/Molecular Biology	
Chemistry & Biochemistry	
Genomics and Gene Expression	
Immunology	
Infectious Disease	
Instrumentation/Data Sciences/Clinical Evaluation	
Neurobiology	
Nutrition/Psychology/Public Health	
Physiology/Pharmacology	

24. Abstract. Within the space provided, concisely describe the proposal including specific aims and methodology, with special reference to its long-term benefit.

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25. Five scientific key words.

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Principal investigator:

	Project number: HR03-
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26. Budget Request. Direct Costs Only

Year 1

Personal			Amount Requested (dollars only)		
Name	Title/position	Hours week	Salary	Fringe benefits	Totals
	PI		-0-	-0-	-0-
Subtotals					
Professional travel (maximum is \$1,000)					
Supplies (itemize by category)					
Equipment (list items over \$500)					
Contractual services (itemize)					
Patient care costs			Outpatient	Inpatient	
Alternations and renovations					
Other direct costs (itemize, include travel associated with data gathering).					
Total direct costs					

OCAST approval:	Date:
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Principal investigator:

	Project number: HR03-
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27. Budget Request. Direct Costs Only

Year 2

Personal			Amount Requested (dollars only)		
Name	Title/position	Hours week	Salary	Fringe benefits	Totals
	PI		-0-	-0-	-0-
Subtotals					
Professional travel (maximum is \$1,000)					
Supplies (itemize by category)					
Equipment (list items over \$500)					
Contractual services (itemize)					
Patient care costs			Outpatient	Inpatient	
Alternations and renovations					
Other direct costs (itemize, include travel associated with data gathering).					
Total direct costs					

OCAST approval:	Date:
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Principal investigator:

	Project number: HR03-
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28. Budget Request. Direct Costs Only

Year 3

Personal			Amount Requested (dollars only)		
Name	Title/position	Hours week	Salary	Fringe benefits	Totals
	PI		-0-	-0-	-0-
Subtotals					
Professional travel (maximum is \$1,000)					
Supplies (itemize by category)					
Equipment (list items over \$500)					
Contractual services (itemize)					
Patient care costs			Outpatient	Inpatient	
Alternations and renovations					
Other direct costs (itemize, include travel associated with data gathering).					
Total direct costs					

OCAST approval:	Date:
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Application Required Attachments

IMPORTANT NOTE: STRICTLY ADHERE TO THE FORMAT PRESCRIBED. Items 29 through 37 are prepared on 8 ½ x 11-inch white paper with a font size from 10 through 13, black typeface. Use the presentation order and headings below. If a section is not applicable, it must be acknowledged and indicated as not applicable. All applicants must adhere to the following guidelines: Photographs, oversized documents and materials that do not reproduce well, should be submitted as appendices. Applications should not include three-dimensional materials. The name of the PI should appear on **every page** of the application attachments in the upper right corner.

29. Budget justification. Required attachment. (4 pages maximum). Carefully prepare a detailed accompanying explanation of the budget. The budget justification section plays an important role in the review process. Award amounts are established by the reviewers and cannot be modified after the date of award. Excessive or unexplained costs are cut by reviewers. Request only the amount necessary to conduct the research. Complete the required items for **each** year of requested funding. List the costs requested for performance of the proposed project. If obvious budget items are omitted, the PI should provide information in the *Budget Justification* regarding the alternative resources available.

Personnel. Monies 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 which may become part of a professional service contract.

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. Fringe benefits may be requested to the extent that they are treated consistently by the applicant organization as a direct cost to all sponsors.

Note: For each professional, state the hours per week the project will be worked on. In computing salary charges to an Oklahoma Health Research Contract, an individual's base salary must represent the total authorized annual compensation that an applicant organization would be prepared to pay for a specified work period, whether an individual's time is spent on government sponsored research, teaching or other activities. The base salary must exclude income that an individual may be permitted to earn outside of full-time duties to the applicant organization.

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 35 below)

or items used in preliminary studies, **justify the reasons for duplication**. In most cases, reviewers have denied requests for microcomputers unless they are dedicated to the project.

Contractual Services. Itemize and justify any work on the project that is going to be contracted.

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.

Patient care costs. Include inpatient and outpatient charges only if they are an integral part of the research supported by a professional service contract. 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.

Professional travel. Describe including the purpose of the travel, the number of trips, the destination and the number of individuals for whom funds are requested. Professional travel may not exceed \$1000 per year and the Reviewer approved amount may not be increased. Budgeted funds do not carry over to a subsequent contract year.

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.

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.

Indirect costs are disallowable. If an organization requires direct cost reimbursement for project specific utility or compliance costs, these should appear as specific line items in the budget along with both the method of calculation and an explanation for their inclusion.

- 30. Biographical Information and Other Support. Required attachment. (2 pages maximum for each for each individual).** Begin with the PI. Do not designate co-principal investigators for an Oklahoma Health Research Project. For each item give the source of *Other Support*, identifying number, project title, name of investigator, time or percent of effort on the project by the professional named, annual direct costs and entire period of support. (If part of a larger project, provide the titles of both the parent grant and the subproject and give the annual direct costs for each.) Briefly describe the contents of each item listed. If any of these overlap, duplicate or are being replaced or supplemented by the

present application, justify and delineate the nature and extent of the scientific and budgetary overlaps or boundaries. Please be certain to include abstracts of all pending and funded proposals. The PI is advised that failing to describe other funded or pending support may adversely affect the assessment of this proposal. or each of the professionals involved in the project. **List Other Support** (include all federal, non-federal, and institutional grant and contract support) in three categories:

- a. **active support**
- b. **applications pending review**
- c. **applications planned or being prepared for submission.**

If none, state *None*.

31. **Previous OCAST funding. Required attachment. (1 page maximum)** If a previous recipient of OCAST funding, list all awards and briefly describe the results of these efforts (e.g. publications and non-OCAST funding received).
32. **Facilities, instrumentation and resources. Required attachment. (1 page maximum)** Describe any specialized facilities, instrumentation and/or resources necessary and available for this project.
33. **Research plan. Required attachment. (15 pages maximum, not counting figures, graphs, and charts.)** This section should be carefully prepared. **It 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.

Organize sections **A-D** of the Research Plan to answer these questions. (A) What do you intend to do? (B) Why is the work important? (C) What has already been done? (D) How are you going to do the work? The Research Plan should be prepared in the following format:

- A. Specific Aims:** State concisely and realistically what the research described in this application is intended to accomplish and/or what hypothesis is to be tested. A maximum of one (1) page is suggested.
- B. Significance:** Briefly sketch the background of the proposed project, critically evaluate existing knowledge and specifically identify the gaps which 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. A maximum of three (3) pages is suggested.
- C. Preliminary Studies:** Provide an account of the PI's progress, which led to formulating the proposed project, as well as any other information which will assist the reviewers in assessing the competence of the PI for performing the project. Figures, graphs and other material may be submitted in the appendices. A maximum of seven (7) pages is suggested.
- D. Research Design and Methods:** Discuss in detail the research design and the procedures to be used to accomplish the specific aims of the project. Describe the protocols to be used and the tentative sequence of 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 which will be exercised. A maximum of eight (8) pages is suggested.

34. Literature cited. Required attachment. The literature cited does not count toward the page limitations. **Do not scatter complete literature citations throughout the text.** Some reviewers have found the inclusion of titles to be very helpful. **Number the references in order of appearance, and provide the complete citations, which correspond to the numbers, in a list at the end of the Research Plan.** Each citation must include the names of all the authors, the name of the book or journal, volume number, page numbers and year of publication. Although no page limitation is specified for this part of the application, make every attempt to be judicious in compiling a relevant and current bibliography. It need not be exhaustive.

35. Letter of Commitment. Required attachment. OCAST requires all applicants to submit a *Letter of Commitment* 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 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 which the organization will provide for the project. This information is essential to document that applicants will have the facilities and time necessary to conduct the proposed research and the opportunity to follow-up promising results.

Letters of Recommendation. OCAST encourages applicants in the early stages of their research careers to also submit up to two (2) letters of recommendation from individuals able to evaluate the applicant's scientific potential.

36. Appendix I. Required attachment. Only the following required documentation should be included. **Human Subjects, Derived Materials or Data.** If human subjects, human derived materials or human data are to be used in this project, complete Item 9, **and submit documentation of institutional approval (IRB) in Appendix I.**

On a separate sheet(s) address the following issues and include in Appendix I:

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.

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, <http://ohrp.osophs.dhhs.gov/> . 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 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. **If OCAST has not received certification of institutional review and approval by February 7, 2003, a proposed health research project using human subjects may not be reviewed for funding.**

Vertebrate Animals. If vertebrate laboratory animals are to be used in this research project, complete Item 10, and submit documentation of **institutional approval (IRB) in Appendix I.** On a separate sheet 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; include this information in Appendix I.

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. **If OCAST has not received certification of institutional review and approval by February 7, 2003, a proposed health research project using vertebrate animals may not be reviewed for funding.**

Recombinant DNA. If recombinant DNA technology will be used in the project, complete Item 11, and submit documentation of **institutional approval (IRB) 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. **If OCAST has not received certification of institutional review and approval by February 7, 2003, a proposed health research project using recombinant DNA technology may not be reviewed for funding.**

Biological Hazards. If any contact with infectious agents or substances containing them is anticipated, complete Item 14, 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.**

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) Check *yes* on Item 12, and (2) include a letter in Appendix I 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 in Item 12 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. Item 12 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) complete Item 13, HR02-1a, 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. **Item 13 must be satisfactorily completed and the required letter submitted, as appropriate, if a proposed health research project is to receive funding.**

37. Additional Appendices. Required attachment if needed.

Health Research Scientist Recruitment Retention. All applicants to the Health Research Scientist Recruitment program will also be considered for funding under the Regular Health Research Program. In such cases do not submit two separate applications. For a researcher making application under the Health Research Scientist Program, the investigator must include a research plan and budget forms for the **Regular Health Research** project as a separate appendix in their Health Research Scientist Recruitment application. Such applicants must meet all requirements for the Regular Research Program.

Resubmissions: Persons resubmitting an application submitted to a previous OHR competition **must** prepare a separate appendix that includes the following:

- a. a letter that responds to the reviewers' comments from the previous review and notes all changes in the new research plan.
- b. a copy of the previously submitted application and
- c. all reviews of that application.

Other Appendices: Figures, graphs, photographs, oversized documents or materials, which do not reproduce well, should be submitted as additional appendices.