

**FINANCIAL ASSISTANCE
FUNDING OPPORTUNITY ANNOUNCEMENT**



U.S. Department of Energy

**Office of Science
Office of Biological and Environmental Research**

***Integrated Nuclear Medicine Research and Training Projects
of Excellence***

Funding Opportunity Number: DE-FOA-0000646

Announcement Type: Initial

CFDA Number: 81.049

ISSUE DATE: January 20, 2012

Pre-Application Due Date: February 23, 2012
(Pre-Applications are required)

Application Due Date: March 28, 2012

NOTE: REQUIREMENTS FOR GRANTS.GOV

Where to Submit: Applications must be submitted through Grants.gov to be considered for award. You cannot submit an application through Grants.gov unless you are registered. Please read the registration requirements carefully and start the process immediately. Remember you have to update your Central Contract Registry (CCR) registration annually. If you have any questions about your registration, you should contact the Grants.gov Helpdesk at 1-800-518-4726 to verify that you are still registered in Grants.gov.

Registration Requirements: There are several one-time actions you must complete in order to submit an application through Grants.gov (i.e., obtain a Dun and Bradstreet Data Universal Numbering System (DUNS) number, register with the CCR, register with the credential provider, and register with Grants.gov). To register with Grants.gov go to “Get Registered” at http://grants.gov/applicants/get_registered.jsp. Use the Grants.gov Organization Registration Checklist at <http://www.grants.gov/assets/OrganizationRegCheck.pdf> to guide you through the process. Designating an E-Business Point of Contact (EBiz POC) and obtaining a special password called an MPIN are important steps in the CCR registration process. Applicants, who are not registered with CCR and Grants.gov, should allow at least 21 days to complete these requirements. It is suggested that the process be started as soon as possible.

IMPORTANT NOTICE TO POTENTIAL APPLICANTS: When you have completed the process, you should call the Grants.gov Helpdesk at 1-800-518-4726 to verify that you have completed the final step (i.e. Grants.gov registration).

Questions: Questions relating to the registration process, system requirements, how an application form works, or the submittal process must be directed to Grants.gov at 1-800-518-4726 or support@grants.gov. Part VII of this Funding Opportunity Announcement (FOA) explains how to submit other questions to the Department of Energy (DOE).

Application Receipt Notices

After an application is submitted, the Authorized Organization Representative (AOR) will receive a series of four e-mails. It is extremely important that the AOR watch for and save each of the emails. It may take up to two (2) business days from application submission to receipt of email Number 2. The titles of the four e-mails are:

Number 1 - Grants.gov Submission Receipt Number

Number 2 - Grants.gov Submission Validation Receipt for Application Number

Number 3 - Grants.gov Grantor Agency Retrieval Receipt for Application Number

Number 4 - Grants.gov Agency Tracking Number Assignment for Application Number

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PART I – FUNDING OPPORTUNITY DESCRIPTION

GENERAL INQUIRIES ABOUT THIS FOA SHOULD BE DIRECTED TO:

Technical/Scientific Program Contact:

Program Manager: Dr. Prem Srivastava
Office of Biological and Environmental Research
Phone: 301-903-4071
E-Mail: prem.srivastava@science.doe.gov

STATUTORY AUTHORITY

Public Law 95-91, US Department of Energy Organization Act
Public Law 109-58, Energy Policy Act of 2005

APPLICABLE REGULATIONS

U.S. Department of Energy Financial Assistance Rules, codified at 10 CFR Part 600
U.S. Department of Energy, Office of Science Financial Assistance Program Rule, codified at 10 CFR Part 605

SUMMARY:

The U.S. Department of Energy's Office of Science, Office of Biological and Environmental Research (BER) hereby announces its interest in receiving applications for potential funding of **Integrated Nuclear Medicine Research and Training Projects of Excellence** to serve three important goals:

1. Research and development of new and highly innovative radiotracer methods and radiotracers as potential imaging agents for nuclear medicine research and application to advance the understanding of normal human physiology and gene expression, diagnosis and management of disease, in drug research and development, and in translational science;
2. Integrated involvement of postdoctoral fellows (Ph.D. radiochemists) and M.D., or M.D.-Ph.D fellows with specialties in Nuclear Medicine *with applications to human health* in developing and deploying new radiotracers for nuclear medicine imaging and potential clinical use in humans for disease-specific applications; and
3. Enhancement of training opportunities to ensure the future availability of human resources for highly specialized fields of radiotracer development chemistry and clinical nuclear medicine research and allied disciplines.

Applicants must have access to existing advanced facilities and an interdisciplinary collaborative team of radiochemists, synthetic chemists, biochemists and other expertise including physician scientists specialized in human disease- or disorder-specific nuclear medicine imaging, with the ability to support a robust research training environment. Institutional settings with easy access to nuclear medicine imaging specialties such as positron emission tomography (PET) and SPECT (single photon emission computed tomography) are required and should offer broad ranging research collaborations from research and development of radiotracers to translation for potential clinical use in humans. For further details, refer to the provided supplementary information.

SUPPLEMENTARY INFORMATION:

This FOA is to solicit applications for funding Integrated Nuclear Medicine Research Projects of Excellence (Projects) to fulfill the following important nuclear medicine research needs:

A. Radiochemistry and radiotracer development research - The applicant must offer to address the challenges and opportunities in the following areas of radiochemistry research needs:

- Development of new chemical reactions that meet the demands and synthetic constraints of working with radioisotopes at high specific activity. All aspects of radiotracer imaging will benefit from an increased number and improved set of chemical reactions that can be used to label molecules of interest with a radioisotope. Radiotracer chemistry methods are needed which are versatile and easy to translate from molecule to molecule, and which will catalyze the use of radiotracer technology for nuclear medicine research and disease-specific imaging applications.
- Utilization of physical chemistry to develop models that can predict and explain reactivity at the tracer mass scale. Such models are needed for increasing our understanding of critical parameters of chemical reactions at tracer scale, and optimizing reaction methodologies for accelerated use of labeling protocols.
- Construction of nanoparticle platforms that can incorporate one or more imaging agents and targeting moieties, including theranostics - Such particles may be important for dual-modality applications. There is a significant opportunity and need for the development of methods for highly efficient radiolabeling and purification techniques able to separate labeled and unlabeled macromolecules, proteins, and nanoparticles, thus increasing their specific activity.
- Creation/improvement of automation technology for radiotracer synthesis that is adaptable in a variety of reaction scenarios through modular or "kit-like" construction - Reliable kit-like labeling and purification protocols and versatile automated systems, which can potentially bridge the gap that exists in translating radiotracer technologies into new research areas, are needed.

B. Specific areas of radiotracer imaging applications. Research areas requiring development of fundamental radiotracer methodologies for potential use in nuclear medicine diagnosis of human health and disorders include:

- **Radiolabeled probes for imaging gene expression in real time in living biological systems:** These are to include new generation of radioligand molecules that will interact with the macromolecular nucleic acid structures *in vivo*, and technologies which will significantly improve the signal to background ratio and will make *in vivo* visualization of *in situ* chemical reactions and the effects of their perturbations feasible.
- **New radiotracer methodologies for *in vivo* targeting of proteins critical to epigenetic modifications (i.e., histone acetylases, histone deacetylases) as well as other proteins involved with carcinogenesis and tumor cell growth:** These include new radiolabeled molecular probes for targeting protein sites and mutations critical in mediating cellular signaling and abnormal cell function and growth as well as for *in vivo* measurement and understanding of developmental pathways to wayward genes.
- **New generation of radiotracers enabling quantitative *in vivo* imaging of neurotransmitter chemistry and brain function:** New generation of highly innovative radiotracer molecules for targeting cellular and subcellular elements of low abundance with high specificity and selectivity.

Addressing these specific areas of research opportunities will allow development of new techniques for radiolabeling of molecular probes of biological importance, with radionuclides currently available, with specific activities that approach the theoretical maximum for these specific probes. These new radiolabeling techniques should allow incorporation of preventive measures to protect the probe from auto-radiolysis *in vivo*. These new labeling techniques can be applicable to molecular probes for either PET or SPECT, or for multimodality imaging (e.g. two different radionuclides or one fluorescent- and one radio-label at two different sites of the same molecular probe) for simultaneous quantitative assessment of two different biochemical reactions that may reflect two different functional characteristics or a combination of structural and functional information.

C. Training: The applicant must offer postdoctoral fellow (Ph.D.) and M.D./or M.D.-Ph.D. fellow level training that is integrated with the research and development of new and highly innovative radiotracers as potential imaging agents, and developing and deploying new radiotracers for nuclear medicine imaging and potential clinical use in humans for disease-specific applications.

Ideally a Project will support both radiochemistry postdoctoral (Ph.D.)- and physician scientist (M.D./M.D.-Ph.D.)-fellow trainees. The training of these fellows is to be integrated through active participation in the nuclear medicine research areas outlined in Supplementary Information, Section B.

- D. Projects must have easy access to existing advanced facilities and an interdisciplinary collaborative team of radiochemists, synthetic (organic and inorganic) chemists, biochemists, and physician scientists to produce and quantify and characterize the behavior of radiolabeled molecular probes in biological systems of interest.**
- E. Institutional settings are to offer broad ranging intra- or inter-institutional research collaborations including facilities and imaging equipment necessary for the conduct of this project.**
- F. Projects must be in an academic environment, existing independently or in a partnership with a National Laboratory. They are required to have easy access to multispecialty capabilities such as radio- and radiolabeling-chemistry, radiation detector physics, biology and medical imaging.**

Required resources include cyclotron, reactor, or generator-based facilities for the production, isolation, and purification of radionuclides and radiolabeled chemical probes and radionuclide imaging capabilities such as positron emission tomography (PET) and single photon emission computed tomography (SPECT).

The research environment should be robust and multi-disciplinary, able to offer training opportunities that interlink the radiochemistry applied to radiolabeled probe development with applications research for use of radiolabeled probes in advancing biological and nuclear medicine imaging. The academic institution(s) should possess strong programs in chemistry, physics, and medical imaging with well-supported basic research in technology applications and/or translational research programs. The projects should be embedded in a multidisciplinary institutional setting with the opportunity to attract other federally funded grants in radiotracer development and nuclear medicine research.

Collaboration

Multi-disciplinary team-collaborations are encouraged to enhance and strengthen research capabilities as needed for overall conduct and performance of the project. All collaborative applications should include letters of agreement from each collaborator who would receive funding. These letters should specify the contributions the collaborators intend to make if the application is accepted and funded. Applications for multi-investigator projects should present a management structure for integrating collaborating investigators. **For collaborative projects with combined budgets, only one application from the Lead Institution/Lead PI is needed. However, if the collaborating institution is a DOE Lab, then the DOE Lab portion of the budget (included in the total budget) will be separately identified with a separate budget page and justifications. If the grant is approved, the DOE Lab portion of funding will be provided directly to the DOE Lab. The Lead Institution to which the grant is funded will not be allowed to charge any indirect expenses for the DOE Lab portion.**

PART II – AWARD INFORMATION

A. TYPE OF AWARD INSTRUMENT.

DOE anticipates awarding Grants under this FOA.

B. ESTIMATED FUNDING.

It is anticipated that up to \$10 million total will be available for multiple awards to be made in FY 2012 for Radiotracers for Nuclear Medicine Imaging Science Research. The number of awards will be contingent on satisfactory peer review, the availability of appropriated funds, and the size of the awards. Awards are expected to be in the range of \$2,000,000. Applicants may request project support for up to four years. When submitting the application, include only one budget page for the entire project period (up to 48 months). Under this FOA, there are no provisions for continuation funding on an annual basis.

DOE is under no obligation to pay for any costs associated with the preparation or submission of an application. DOE reserves the right to fund, in whole or in part, any, all, or none of the applications submitted in response to this FOA.

C. MAXIMUM AND MINIMUM AWARD SIZE.

See B. Estimated Funding section above.

D. EXPECTED NUMBER OF AWARDS.

See B. Estimated Funding section above.

E. ANTICIPATED AWARD SIZE.

See B. Estimated Funding section above.

F. PERIOD OF PERFORMANCE.

See B. Estimated Funding section above.

G. TYPE OF APPLICATION.

DOE will accept new applications under this FOA.

PART III - ELIGIBILITY INFORMATION

A. ELIGIBLE APPLICANTS.

All types of entities are eligible to apply, except other Federal agencies, Federally Funded Research and Development Center (FFRDC) Contractors, and nonprofit organizations described in section 501(c)(4) of the Internal Revenue Code of 1986 that engaged in lobbying activities after December 31, 1995. Synergistic collaborations with researchers in Federal Laboratories and Federally Funded Research and Development Centers (FFRDCs), including the DOE National Laboratories are permitted. Collaborations should be limited to filling critical voids in expertise and can represent no more than 50 percent of the total budget.

B. COST SHARING.

Cost sharing is not required.

C. OTHER ELIGIBILITY REQUIREMENTS.

N/A

PART IV – APPLICATION AND SUBMISSION INFORMATION

A. ADDRESS TO REQUEST APPLICATION PACKAGE.

Application forms and instructions are available at Grants.gov. To access these materials, go to <http://www.grants.gov>, select "**Apply for Grants**", and then select "**Download a Grant Application Package**". Enter the CFDA and/or the funding opportunity number located on the cover of this FOA and then follow the prompts to download the application package.

B. LETTER OF INTENT AND PRE-APPLICATION.

1. Letter of Intent.

N/A

2. Pre-Application.

Potential applicants **are required to submit** a brief pre-application, referencing Funding Opportunity Announcement (FOA) DE-FOA-0000646 for receipt by DOE by 4:30 p.m., Eastern Time, **February 23, 2012**. Pre-applications should be sent as a text file without attachments or a single PDF file attachment via e-mail to: radiochem@science.doe.gov with "**Pre-application DE-DE-FOA-0000646 - [Integrated Nuclear Medicine Research and Training Projects of Excellence]**" as the subject. No FAX or mail submission of pre-applications will be accepted. Pre-applications will be reviewed for conformance with the guidelines presented in this FOA and suitability in the technical areas of nuclear medicine involving radiotracer development research and training, and availability of project supporting infrastructure including inter/or intra-institutional collaborations, personnel, equipment and facilities specified in this FOA. A response to the pre-applications encouraging or discouraging formal applications will be communicated to the applicants by **February 28, 2012**. Applicants who have not received a response regarding the status of their pre-application by this date are responsible for contacting the program to confirm this status.

Pre-applications are limited to **two pages total**, including the cover page. The cover page should include the title of the project, the institution or organization, principal investigator name, telephone number, fax number, and e-mail address. Pre-applications should consist of no more than **one** page of narrative stating the project objectives, describing the technical approach(es) and nuclear medicine involving both radiochemistry and clinical imaging training-supporting infrastructure, personnel and facilities, and identifying the proposed team members and their expertise. No budget information or biographical data need be included, nor is an institutional endorsement necessary. The intent in requesting a pre-application is to save the time and effort of applicants in preparing and submitting a formal Project application that may not meet the program goals.

Only those pre-applicants who receive notification from DOE encouraging a formal application may submit full applications. No other formal applications will be considered.

C. CONTENT AND FORM OF APPLICATION – SF 424 (R&R).

You must complete the mandatory forms and any applicable optional forms (e.g., SF-LLL-Disclosure of Lobbying Activities) in accordance with the instructions on the forms and the additional instructions below. **Files that are attached to the forms must be in Adobe Portable Document Format (PDF) unless otherwise specified in this FOA.**

1. SF 424 (R&R).

Complete this form first to populate data in other forms. Complete all the required fields in accordance with the pop-up instructions on the form. The list of certifications and assurances referenced in Field 17 can be found on the DOE Financial Assistance Forms Page at <http://energy.gov/management/office-management/operational-management/financial-assistance/financial-assistance-forms>, under Certifications and Assurances.

2. RESEARCH AND RELATED Other Project Information.

Complete questions 1 through 6 and attach files. The files must comply with the following instructions:

Project Summary/Abstract (Field 7 on the Form).

The project summary/abstract must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained document that identifies the name of the applicant, the project director/principal investigator(s), the project title, the objectives of the project, a description of the project, including methods to be employed, the potential impact of the project (i.e., benefits, outcomes), and major participants (for collaborative projects). This document must not include any proprietary or sensitive business information as the Department may make it available to the public. The project summary must not exceed one page when printed using standard 8.5” by 11” paper with 1” margins (top, bottom, left and right) with font not smaller than 11 point. To attach a Project Summary/Abstract, click “Add Attachment.”

Project Narrative (Field 8 on the Form).

The Project Narrative comprises the research plan for the project and is limited, including text, figures and tables, to **20 pages maximum** (8.5” by 11” paper of single-spaced, standard 11 point type with 1” margins). It should contain enough background material in the Introduction, including review of the relevant literature, to demonstrate sufficient knowledge of the state of the science. The project narrative must also include a **Project Objectives** section, which should provide a clear, concise statement of the specific objectives/aims of the proposed project. The major part of the narrative should be devoted to a description and justification of the proposed project, including details of the methods to be used. It should also include a timeline for the major activities of the proposed project, and should indicate which project personnel will be responsible for which activities.

The Project Narrative should begin with a **cover page** that includes the project title **and** the lead Principal Investigator's name and complete contact information. The cover page WILL NOT count in the project narrative page limitation.

The **cover page** of your narrative must include the following information:

Project Title:

Applicant/Institution:

Street Address/City/State/Zip:

Principal Investigator (PI):

PI Postal Address:

PI Telephone Number:

PI Email:

Funding Opportunity Announcement Number: DE-FOA-0000646

DOE/Office of Science Program Office: Office of Biological & Environmental Research

DOE/Office of Science Program Manager Contact: Dr. Prem Srivastava

Is this a Collaboration? If yes, each applicant including collaborators or subcontractors need to submit only one consolidated formal application. Independent applications from subcontractors or collaborators are not required – also refer to Collaboration under SUPPLEMENTARY INFORMATION.

The project narrative must include:

Project Objectives:

This section should provide a clear, concise statement of the specific objectives/aims of the proposed project.

Appendix 1: Biographical Sketch.

Provide a biographical sketch for the project director/principal investigator (PD/PI) and each senior/key person listed in Section A on the R&R Budget form. **Provide the Biographical Sketch information as an Appendix to your Project Narrative. Do not attach a separate file. The Biographical Sketch Appendix will not count in the Project Narrative page limitation.**

The biographical information (curriculum vitae) for each person must not exceed two pages when printed on 8.5" by 11" paper with 1" margins (top, bottom, left, and right) with font not smaller than 11 point and must include:

Education and Training. Undergraduate, graduate and postdoctoral training, provide institution, major/area, degree and year.

Research and Professional Experience: Beginning with the current position list, in chronological order, professional/academic positions with a brief description.

Publications. Provide a list of up to 10 publications most closely related to the proposed project. For each publication, identify the names of all authors (in the same sequence in which they appear in the publication), the article title, book or journal title, volume number, page numbers, year of publication, and website address if available electronically. Patents, copyrights and software systems developed may be provided in addition to or substituted for publications.

Synergistic Activities. List no more than 5 professional and scholarly activities related to the effort proposed.

Identification of Potential Conflicts of Interest or Bias in Selection of Reviewers. Provide the following information in this section:

Collaborators and Co-editors: List in alphabetical order all persons, including their current organizational affiliation, who are, or who have been, collaborators or co-authors with you on a research project, book or book article, report, abstract, or paper during the 48 months preceding the submission of this application. For publications or collaborations with more than 10 authors or participants, only list those individuals in the core group with whom the Principal Investigator interacted on a regular basis while the research was being done. Also, list any individuals who are currently, or have been, co-editors with you on a special issue of a journal, compendium, or conference proceedings during the 24 months preceding the submission of this application. If there are no collaborators or co-editors to report, state "None."

Graduate and Postdoctoral Advisors and Advisees: List the names and current organizational affiliations of your graduate advisor(s) and principal postdoctoral sponsor(s) during the last 5 years. Also, list the names and current organizational affiliations of your graduate students and postdoctoral associates during the past 5 years.

Appendix 2: Current and Pending Support.

Provide a list of all current and pending support (both Federal and non-Federal) for the Project Director/Principal Investigator(s) (PD/PI) and senior/key persons, including subawardees, for ongoing projects and pending applications. For each organization providing support, show the total award amount for the entire award period (including indirect costs) and the number of person-months per year to be devoted to the project by the senior/key person. **Provide the Current and Pending Support as an Appendix to your Project Narrative. Do not attach a separate file. The Current and Pending Support Appendix will not count in the Project Narrative page limitation.** Concurrent submission of an application to other organizations for simultaneous consideration will not prejudice its review.

Appendix 3: Bibliography and References Cited.

Provide a bibliography of any references cited in the Project Narrative. Each reference must include the names of all authors (in the same sequence in which they appear in the

publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Applicants should be especially careful to follow scholarly practices in providing citations for source materials relied upon when preparing any section of the application. **Provide the Bibliography and References Cited information as an Appendix to your Project Narrative. Do not attach a separate file. This Appendix will not count in the Project Narrative page limitation.**

Appendix 4: Facilities and Other Resources.

This information is used to assess the capability of the organizational resources, including subawardee resources, available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Describe other resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project. **Provide the Facilities and Other Resources information as an Appendix to your Project Narrative. Do not attach a separate file. The Facilities and Other Resources Appendix will not count in the Project Narrative page limitation.**

Appendix 5: Equipment.

List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities. **Provide the Equipment information as an Appendix to your Project Narrative. Do not attach a separate file. The Equipment Appendix will not count in the Project Narrative page limitation.**

Appendix 6: Other Attachment.

If you need to elaborate on your responses to questions 1-6 on the “Other Project Information” document, **please provide the Other Attachment information as an Appendix to your Project Narrative. Do not attach a separate file. The Other Attachment Appendix will not count in the Project Narrative page limitation.**

Do not attach any of the requested Appendices described above as files for fields 9, 10, 11, and 12. Instead follow the above instructions to include the information as Appendices to the Project Narrative file (these Appendices will not count in the Project Narrative page limitation).

3. RESEARCH AND RELATED BUDGET.

Complete the Research and Related Budget form in accordance with the instructions on the form and the following instructions. You must complete a separate budget for each year of support requested. The form will generate a cumulative budget for the total project period. You must complete all the mandatory information on the form before the NEXT PERIOD button is activated. You may request funds under any of the categories listed as long as the item and amount are necessary to perform the proposed work, meet all the criteria for allowability under the applicable Federal cost principles, and are not prohibited by the funding restrictions in this FOA (See PART IV, G).

Budget Justification (Field K on the form).

Provide the required supporting information for the following costs: equipment; domestic and foreign travel; participant/trainees; material and supplies; publication; consultant services; ADP/computer services; subaward/consortium/contractual; equipment or facility rental/user fees; alterations and renovations; and indirect cost type. Provide any other information you wish to submit to justify your budget request. **Attach a single budget justification file for the entire project period in Field K.** The file automatically carries over to each budget year.

4. R&R SUBAWARD BUDGET ATTACHMENT(S) FORM.

Budgets for Subawardees, other than DOE FFRDC Contractors. You must provide a separate cumulative R&R budget for each subawardee that is expected to perform work estimated to be more than \$100,000 or 50 percent of the total work effort (whichever is less). If you are selected for award, you must submit a multi-year budget for each of these subawardees. Download the R&R Budget Attachment from the R&R SUBAWARD BUDGET ATTACHMENT(S) FORM and e-mail it to each subawardee that is required to submit a separate budget. After the Subawardee has e-mailed its completed budget back to you, attach it to one of the blocks provided on the form. Use up to 10 letters of the subawardee's name (plus .xfd) as the file name (e.g., ucla.xfd or energyres.xfd).

5. PROJECT/PERFORMANCE SITE LOCATION(s).

Indicate the primary site where the work will be performed. If a portion of the project will be performed at any other site(s), identify the site location(s) in the blocks provided.

Note that the Project/Performance Site Congressional District is entered in the format of the 2 digit state code followed by a dash and a 3 digit Congressional district code, for example VA-001. Hover over this field for additional instructions.

Use the Next Site button to expand the form to add additional Project/Performance Site Locations.

6. SF-LLL Disclosure of Lobbying Activities.

If applicable, complete SF- LLL. Applicability: If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the grant, you must complete and submit Standard Form - LLL, "Disclosure Form to Report Lobbying."

Summary of Required Forms/Files

Your application must include the following documents:

Name of Document	Format	Attach to
SF 424 (R&R)	Form	N/A
RESEARCH AND RELATED Other Project Information	Form	N/A
Project Summary/Abstract	PDF	Field 7
Project Narrative, including required appendices	PDF	Field 8
RESEARCH & RELATED BUDGET	Form	N/A
Budget Justification	PDF	Field K
PROJECT/PERFORMANCE SITE LOCATION(S)	Form	N/A
SF-LLL Disclosure of Lobbying Activities , if applicable	Form	N/A

D. SUBMISSIONS FROM SUCCESSFUL APPLICANTS.

If selected for award, DOE reserves the right to request additional or clarifying information for any reason deemed necessary, including, but not limited to:

- Indirect cost information
- Other budget information
- Name and phone number of the Designated Responsible Employee for complying with national policies prohibiting discrimination (See 10 CFR Part 1040.5)
- Representation of Limited Rights Data and Restricted Software, if applicable
- Commitment Letter from Third Parties Contributing to Cost Sharing, if applicable

E. SUBMISSION DATES AND TIMES.

1. Letter of Intent.

N/A

2. Pre-Application.

Potential applicants **are required to submit** a brief pre-application, referencing Funding Opportunity Announcement (FOA) DE-FOA-0000646 for receipt by DOE by 4:30 p.m., Eastern Time, **February 23, 2012**. Pre-applications should be sent as a text file without attachments or a single PDF file attachment via e-mail to: radiochem@science.doe.gov with "**Pre-application DE-DE-FOA-0000646 - [Integrated Nuclear Medicine Research and Training Projects of Excellence]**" as the subject. No FAX or mail submission of pre-applications will be accepted. Pre-applications will be reviewed for conformance with the guidelines presented in this FOA and suitability in the technical areas of nuclear medicine involving radiotracer development research and training, and availability of project supporting infrastructure including inter/or intra-institutional

collaborations, personnel, equipment and facilities specified in this FOA. A response to the pre-applications encouraging or discouraging formal applications will be communicated to the applicants by **February 28, 2012**. Applicants who have not received a response regarding the status of their pre-application by this date are responsible for contacting the program to confirm this status.

Pre-applications are limited to **two pages total**, including the cover page. The cover page should include the title of the project, the institution or organization, principal investigator name, telephone number, fax number, and e-mail address. Pre-applications should consist of no more than **one** page of narrative stating the project objectives, describing the technical approach(es) and nuclear medicine involving both radiochemistry and clinical imaging training-supporting infrastructure, personnel and facilities, and identifying the proposed team members and their expertise. No budget information or biographical data need be included, nor is an institutional endorsement necessary. The intent in requesting a pre-application is to save the time and effort of applicants in preparing and submitting a formal Project application that may not meet the program goals.

Only those preapplicants who receive notification from DOE encouraging a formal application may submit full applications. No other formal applications will be considered.

3. Formal Applications.

APPLICATION DUE DATE: March 28, 2012, 11:59 PM Eastern Time

Formal applications submitted in response to this FOA must be received by March 28, 2012, 11:59 PM Eastern Time, to permit timely consideration of awards in Fiscal Year 2012. **You are encouraged to submit your application well before the deadline. APPLICATIONS RECEIVED AFTER THE DEADLINE WILL NOT BE REVIEWED OR CONSIDERED FOR AWARD.**

F. INTERGOVERNMENTAL REVIEW.

This program is not subject to Executive Order 12372 Intergovernmental Review of Federal Programs.

G. FUNDING RESTRICTIONS.

Cost Principles. Costs must be allowable in accordance with the applicable Federal cost principles referenced in 10 CFR Part 600. The cost principles for commercial organization are in FAR Part 31.

Pre-award Costs. Recipients may charge to an award resulting from this FOA pre-award costs that were incurred within the ninety (90) calendar-day period immediately preceding the effective date of the award, if the costs are allowable in accordance with the applicable Federal

cost principles referenced in 10 CFR Part 600. Recipients must obtain the prior approval of the contracting officer for any pre-award costs that are for periods greater than this 90-day calendar period.

Pre-award costs are incurred at the applicant's risk. DOE is under no obligation to reimburse such costs if for any reason the applicant does not receive an award or if the award is made for a lesser amount than the applicant expected.

H. OTHER SUBMISSION AND REGISTRATION REQUIREMENTS.

1. Where to Submit.

APPLICATIONS MUST BE SUBMITTED THROUGH GRANTS.GOV TO BE CONSIDERED FOR AWARD.

Submit electronic applications through the "Apply for Grants" function at www.Grants.gov. If you have problems completing the registration process or submitting your application, call Grants.gov at 1-800-518-4726 or send an email to support@grants.gov.

2. Registration Process.

You must COMPLETE the one-time registration process (all steps) before you can submit your first application through Grants.gov. We recommend that you start this process at least three weeks before the application due date. It may take 21 days or more to complete the entire process. To register with Grants.gov go to "Get Registered" at http://grants.gov/applicants/get_registered.jsp. Use the Grants.gov Organization Registration Checklist at <http://www.grants.gov/assets/OrganizationRegCheck.pdf> to guide you through the process. IMPORTANT: During the CCR registration process, you will be asked to designate an E-Business Point of Contact (EBIZ POC). The EBIZ POC must obtain a special password called "Marketing Partner Identification Number" (MPIN). When you have completed the process, you should call the Grants.gov Helpdesk at 1-800-518-4726 to verify that you have completed the final step (i.e., Grants.gov registration).

You cannot submit an application through Grants.gov unless you are registered. Please read the registration requirements carefully and start the process immediately. Remember you have to update your CCR registration annually.

3. Application Receipt Notices.

After an application is submitted, the Authorized Organization Representative (AOR) will receive a series of four e-mails. It is extremely important that the AOR watch for and save each of the emails. It may take up to two (2) business days from application submission to receipt of email Number 2. The titles of the four e-mails are:

Number 1 - Grants.gov Submission Receipt Number

Number 2 - Grants.gov Submission Validation Receipt for Application Number

Number 3 - Grants.gov Grantor Agency Retrieval Receipt for Application Number

Number 4 - Grants.gov Agency Tracking Number Assignment for Application Number

PART V - APPLICATION REVIEW INFORMATION

A. CRITERIA.

1. Initial Review Criteria.

Prior to a comprehensive merit evaluation, DOE will perform an initial review in accordance with 10 CFR Part 605.10(b) to determine that (1) the applicant is eligible for the award; (2) the information required by the FOA has been submitted; (3) all mandatory requirements are satisfied; and (4) the proposed project is responsive to the objectives of the funding opportunity announcement. Applications that fail to pass the initial review will not be forwarded for merit review and will be eliminated from further consideration.

2. Merit Review Criteria.

Applications will be subjected to scientific merit review (peer review) and will be evaluated against the following evaluation criteria which are listed in descending order of importance codified at 10 CFR Part 605.10(d):

1. Scientific and/or Technical Merit of the Project
2. Appropriateness of the Proposed Method or Approach
3. Competency of Applicant's Personnel and Adequacy of Proposed Resources; and
4. Reasonableness and Appropriateness of the Proposed Budget.

The evaluation process will include program policy factors such as the relevance of the proposed research to the terms of the FOA and the agency's programmatic needs. Note that external peer reviewers are selected with regard to both their scientific expertise and the absence of conflict-of-interest issues. Both Federal and non-Federal reviewers may be used, and submission of an application constitutes agreement that this is acceptable to the investigator(s) and the submitting institution.

C. ANTICIPATED NOTICE OF SELECTION AND AWARD DATES.

DOE is striving to make **awards within six months**. The time interval begins on the date applications are due or the date the application is received, if there is no specified due date/deadline. Awards will be made in Fiscal Year 2012.

PART VI - AWARD ADMINISTRATION INFORMATION

A. AWARD NOTICES.

1. Notice of Selection.

Selected Applicants Notification: DOE will notify applicants selected for award. This notice of selection is not an authorization to begin performance. (See Part IV.G with respect to the allowability of pre-award costs.)

Non-selected Notification: Organizations whose applications have not been selected will be advised as promptly as possible. This notice will explain why the application was not selected.

2. Notice of Award.

An Assistance Agreement issued by the contracting officer is the authorizing award document. It normally includes, either as an attachment or by reference: 1. Special Terms and Conditions; 2. Applicable program regulations, if any; 3. Application as approved by DOE; 4. DOE assistance regulations at 10 CFR Part 600; 5. National Policy Assurances to Be Incorporated As Award Terms; 6. Budget Summary; and 7. Federal Assistance Reporting Checklist, which identifies the reporting requirements.

For grants and cooperative agreements made to universities, non-profits and other entities subject to OMB Circular 2 CFR, the Award also includes the Research Terms and Conditions located at <http://www.nsf.gov/bfa/dias/policy/rtr/index.jsp>

B. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS.

1. Administrative Requirements.

The administrative requirements for DOE grants and cooperative agreements are contained in 10 CFR Part 600 and 10 CFR Part 605 (See: <http://ecfr.gpoaccess.gov>). Grants and cooperative agreements made to universities, non-profits and other entities subject to Title 2 CFR are subject to the Research Terms and Conditions located on the National Science Foundation web site at <http://www.nsf.gov/bfa/dias/policy/rtr/index.jsp>.

DUNS and CCR Requirements.

Additional administrative requirements for DOE grants and cooperative agreements are contained in 2 CFR, Part 25 (See: <http://ecfr.gpoaccess.gov>). Prime awardees must keep their data at CCR current. Subawardees at all tiers must obtain DUNS numbers and provide the DUNS to the prime awardee before the subaward can be issued.

Subaward and Executive Reporting.

Additional administrative requirements necessary for DOE grants and cooperative agreements to comply with the Federal Funding and Transparency Act of 2006 (FFATA) are contained in 2 CFR, Part 170. (See: <http://ecfr.gpoaccess.gov>). Prime awardees must register with the new FSRS database and report the required data on their first tier subawardees. Prime awardees must report the executive compensation for their own executives as part of their registration profile in the CCR.

2. Special Terms and Conditions and National Policy Requirements.

The DOE Special Terms and Conditions for Use in Most Grants and Cooperative Agreements are located at: <http://energy.gov/management/office-management/operational-management/financial-assistance/financial-assistance-forms>.

The National Policy Assurances to Be Incorporated As Award Terms are located at <http://www.nsf.gov/bfa/dias/policy/rtc/appc.pdf>.

Intellectual Property Provisions.

The standard DOE financial assistance intellectual property provisions applicable to the various types of recipients are located at <http://energy.gov/gc/standard-intellectual-property-ip-provisions-financial-assistance-awards>.

Statement of Substantial Involvement.

Either a grant or cooperative agreement may be awarded under this FOA. If the award is a cooperative agreement, the DOE Contract Specialist and DOE Project Officer will negotiate a Statement of Substantial Involvement prior to award.

C. REPORTING.

Reporting requirements are identified on the Federal Assistance Reporting Checklist, DOE F4600.2, attached to the award agreement. For a sample Checklist, see <http://energy.gov/management/office-management/operational-management/financial-assistance/financial-assistance-forms>.

PART VII - QUESTIONS/AGENCY CONTACTS

A. QUESTIONS.

Questions regarding the content of the FOA must be submitted through the FedConnect portal. You must register with FedConnect to respond as an interested party to submit questions, and to view responses to questions. It is recommended that you register as soon after release of the FOA as possible to have the benefit of all responses. More information is available at:

https://www.fedconnect.net/FedConnect/PublicPages/FedConnect_Ready_Set_Go.pdf.

DOE will try to respond to a question within 3 business days, unless a similar question and answer have already been posted on the website.

Applications submitted through FedConnect will not be accepted.

Questions relating to the registration process, system requirements, how an application form works, or the submittal process must be directed to Grants.gov at 1-800-518-4726 or support@grants.gov. DOE cannot answer these questions.

B. AGENCY CONTACTS.

Technical/Scientific Program Contact:

Program Manager: Dr. Prem Srivastava
Office of Biological and Environmental Research
Phone: 301-903-4071
E-Mail: prem.srivastava@science.doe.gov

PART VIII - OTHER INFORMATION

A. MODIFICATIONS.

Notices of any modifications to this FOA will be posted on Grants.gov and the FedConnect portal. You can receive an email when a modification or an FOA message is posted by registering with FedConnect as an interested party for this FOA. It is recommended that you register as soon after release of the FOA as possible to ensure you receive timely notice of any modifications or other FOAs. More information is available at <http://www.fedconnect.net>.

B. GOVERNMENT RIGHT TO REJECT OR NEGOTIATE.

DOE reserves the right, without qualification, to reject any or all applications received in response to this FOA and to select any application, in whole or in part, as a basis for negotiation and/or award.

C. COMMITMENT OF PUBLIC FUNDS.

The Contracting Officer is the only individual who can make awards or commit the Government to the expenditure of public funds. A commitment by other than the Contracting Officer, either explicit or implied, is invalid.

D. PROPRIETARY APPLICATION INFORMATION.

Patentable ideas, trade secrets, proprietary or confidential commercial or financial information, disclosure of which may harm the applicant, should be included in an application only when such information is necessary to convey an understanding of the proposed project. The use and disclosure of such data may be restricted, provided the applicant includes the following legend on the first page of the project narrative and specifies the pages of the application which are to be restricted:

“The data contained in pages _____ of this application have been submitted in confidence and contain trade secrets or proprietary information, and such data shall be used or disclosed only for evaluation purposes, provided that if this applicant receives an award as a result of or in connection with the submission of this application, DOE shall have the right to use or disclose the data herein to the extent provided in the award. This restriction does not limit the government’s right to use or disclose data obtained without restriction from any source, including the applicant.”

To protect such data, each line or paragraph on the pages containing such data must be specifically identified and marked with a legend similar to the following:

“The following contains proprietary information that (name of applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation.”

E. EVALUATION AND ADMINISTRATION BY NON-FEDERAL PERSONNEL.

In conducting the merit review evaluation, the Government may seek the advice of qualified non-Federal personnel as reviewers. The Government may also use non-Federal personnel to conduct routine, nondiscretionary administrative activities. The applicant, by submitting its application, consents to the use of non-Federal reviewers/administrators. Non-Federal reviewers must sign conflict of interest and non-disclosure agreements prior to reviewing an application. Non-Federal personnel conducting administrative activities must sign a non-disclosure agreement.

F. INTELLECTUAL PROPERTY DEVELOPED UNDER THIS PROGRAM.

Patent Rights. The government will have certain statutory rights in an invention that is conceived or first actually reduced to practice under a DOE award. 42 U.S.C. 5908 provides that title to such inventions vests in the United States, except where 35 U.S.C. 202 provides otherwise for nonprofit organizations or small business firms. However, the Secretary of Energy may waive all or any part of the rights of the United States subject to certain conditions. (See “Notice of Right to Request Patent Waiver” in paragraph G below.)

Rights in Technical Data. Normally, the government has unlimited rights in technical data created under a DOE agreement. Delivery or third party licensing of proprietary software or data developed solely at private expense will not normally be required except as specifically negotiated in a particular agreement to satisfy DOE’s own needs or to insure the commercialization of technology developed under a DOE agreement.

G. NOTICE OF RIGHT TO REQUEST PATENT WAIVER.

Applicants may request a waiver of all or any part of the rights of the United States in inventions conceived or first actually reduced to practice in performance of an agreement as a result of this FOA, in advance of or within 30 days after the effective date of the award. Even if such advance waiver is not requested or the request is denied, the recipient will have a continuing right under the award to request a waiver of the rights of the United States in identified inventions, i.e., individual inventions conceived or first actually reduced to practice in performance of the award. Any patent waiver that may be granted is subject to certain terms and conditions in 10 CFR 784.12, http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title10/10cfr784_main_02.tpl.

Domestic small businesses and domestic nonprofit organizations will receive the patent rights clause at 37 CFR 401.14, i.e., the implementation of the Bayh-Dole Act. This clause permits domestic small business and domestic nonprofit organizations to retain title to subject inventions. Therefore, small businesses and nonprofit organizations do not need to request a waiver.

H. NOTICE REGARDING ELIGIBLE/INELIGIBLE ACTIVITIES.

N/A

I. AVAILABILITY OF FUNDS.

Funds are not presently available for this award. The Government's obligation under this award is contingent upon the availability of appropriated funds from which payment for award purposes can be made. No legal liability on the part of the Government for any payment may arise until funds are made available to the Contracting Officer for this award and until the awardee receives notice of such availability, to be confirmed in writing by the Contracting Officer.