RULE #1: ALWAYS READ THE FOA!

Award Amount: 600,001 – $2,000,000[1]
Application Deadline: 5/31/17

SECTION 1: GENERAL PROGRAM INFORMATION

OVERVIEW

The objective of the High End Instrumentation Grant (HEI) Program is to make available to institutions expensive research instruments that can only be justified on a shared-use basis and that are needed for NIH-supported projects in basic, translational or clinical areas of biomedical and bio-behavioral research.

The program encourages applications from groups of NIH-supported investigators to purchase or upgrade a single item of expensive, state-of-the-art, specialized, commercially available instruments or integrated instrumentation systems that cost at least $601,001. There is no maximum price requirement; however, the maximum award is $2,000,000. Types of instruments supported include, but are not limited to: X-ray diffractometers, mass and nuclear magnetic resonance (NMR) spectrometers, DNA and protein sequencers, biosensors, electron and light microscopes, cell sorters, and biomedical imagers.

ORIP intends to fund an estimate of 20 awards, corresponding to a total of $30M for fiscal year 2018. Instruments must be for research purposes only. Foreign-made instruments are allowed.

Awards are made for one year only.

There is no restriction on the number of applications an institution can submit to the SIG and/or High-End Instrumentation (HEI) Programs each year, provided the applications request different types of equipment.

In general, concurrent SIG, HEI and/or Shared Instrumentation for Animal Research (SIFAR) applications for the same instrument (or the same type of instrument with added special accessories to meet the HEI budget requirement) are not allowed.

If two or more S10 (either SIG, HEI, or SIFAR) applications are submitted for similar equipment from the same institution, documentation from a high level institutional official must be provided stating that this is not an unintended duplication, but part of a campus-wide instrumentation plan.

A single application requesting more than one type of instruments (for example, a mass spectrometer and a confocal microscope) is not appropriate for this FOA.

The HEI Program will ***not*** support requests for:

- An instrument with a base cost of less than $600,001;
- Multiple instruments bundled together;
- Purely instructional equipment;
- Instruments used for clinical (billable) care;
- Institutional administrative management systems, clinical management systems;
- Software, unless it is integral to the operation of the requested equipment;
- General purpose equipment or an assortment of instruments to furnish a research facility and equipment for routine sustaining infrastructure (such as standard machine shop equipment, standard computer networks, autoclaves, hoods, and equipment to upgrade animal facilities).

[1] **Equipment/systems requested may be more expensive than $2,000,000, but program award maximum is $2,000,000.**

Special Use Instruments (SUI)
In rare special circumstances when an Institution cannot justify sole use of the high-end instrument for NIH-supported and other biomedical research, the Institution may contribute a portion of the cost of the requested instrument commensurate with the proposed use of the instrument for other than biomedical research. This rare request will be designated as a Special Use Instrument (SUI). In such situations, the instrument's Biomedical Research Time (BRT) must be at least 50% of the Accessible User Time (AUT) or the portion of the NIH funds of the cost of the instrument, whichever is larger. Definitions of how to calculate BRT and AUT appear in the "Justification of Need" Section of the Instrumentation Plan. If an Institution makes a request for SUI, the non-NIH funds must not be less than 25% of the total instrument price. All other requirements outlined in the FOA still apply.

The non-biomedical research activities supported by the instrument may include research in other fields, curricular instructions, and billable clinical care. The Institution must provide specific long term plans to secure and protect access to the instrument for biomedical researchers, as detailed in Instrumentation Plan under "Special Use Instrument (SUI)".

If an Institution is considering a SUI request, the applicant is strongly advised to consult with Scientific/Research Contact(s) and Financial/Grants Management Contact(s) (Section 6: Agency Contacts, provided below) before submitting an application as it is likely that special administrative procedures will have to be followed.

PD/PI ELIGIBILITY:
Multiple PDs/PIs are not allowed under the S10 mechanism.

PD/PI:
- must have an eRA Commons account that is affiliated with the applicant organization;
- does not need to have an NIH research grant or any other research support, but is expected to be an expert on the requested instrument;
- must document (in the biographical sketch) their technical expertise directly related to the type of chosen instrument;
- may be a Core director, tenured, or non-tenured faculty member of the applicant organization.

PD/PI RESPONSIBILITIES:
Program Director/Principal Investigator (PD/PI) must be able to assume administrative and scientific oversight responsibility for the requested instrumentation.

The PD/PI also will be responsible for:
- Requesting no-cost extensions of the project period, if needed;
- At the end of the project period, preparing (and working with UF to submit) a Final Progress Report (FPR) that:
  - describes the purchased instrument;
  - lists all users and publications resulting from use of the instrument; and
  - outlines the value of the instrument to the investigators and to the institution as a whole.
- Submitting Annual Usage Reports (AURs) of the instrument to the NIH for a period of four years after the expiration of the award.

An **Advisory Committee** must be named to assist the PD/PI in administering the grant and overseeing the usage of the instrument. For details on the composition of the Advisory Committee, see A.6. "Administration" under "Other Attachments". The PD/PI and the Advisory Committee are responsible for the development of guidelines for:
- Maximum utilization of the instrument, including time allocation;
- A detailed plan for the day-to-day management and safe operation of the instrument;

- A plan to ensure that access to the instrument is limited to users whose projects have received approval from institutional human subjects, animal welfare or biosafety committees, as applicable;
- A financial plan for the long-term operation and maintenance of the instrument during the post-award period;
- The relocation of the instrument within or outside the institution or changes of ownership, if such changes are necessary;
- Recommending a new PD/PI, if such a need arises.

The PD/PI and the Advisory Committee should convene meetings and issue annual reports on the instrument status, including their recommendations for the instrument operations.

Major User Group

- Three Major Users who have substantial need for the instrument must be identified.
- Each Major User must be a PD/PI on a distinct active NIH research award in an area of basic, translational, or clinical research. (The requirement is one award per investigator, with more awards per investigator allowed. An award given to multiple PDs/PIs is counted only once towards the fulfillment of this requirement.)
- PDs/PIs on NIH training or fellowship grants (i.e., T and F mechanisms) and other non-research grants are not eligible to be Major Users.
- Once this eligibility requirement of three Major Users with NIH-funded research projects has been met, additional users with active research awards from NIH or other sources may be added as Major or Minor Users.
- Investigators with funding from sources such as other Federal agencies (e.g., NSF, DoE, DoD), private foundations or academic institutions can be added as Major Users, provided they are engaged in basic, translational or clinical research and can demonstrate a substantial need for the instrument.
- Major Users can be researchers from the same department or from several departments, divisions or schools at the applicant institution, or from nearby or regional institutions.
- In certain circumstances, as technology dictates, Major Users may come from distant institutions, but they must demonstrate the need for the instruments and describe plans for regular access to the instrument.
- To demonstrate the clear need for the requested instrument, the projects supported by NIH research grants should together require at least 75 percent of the Accessible User Time (AUT) or 75 percent of Biomedical Research Time (BRT) if a Special Use Instrument (SUI) is requested.
- Major Users supported by NIH grants should together require at least 35 percent of the AUT (or 35 percent of BRT – if a SUI is requested).
- The Major User group must meet the eligibility requirement at the time of submission. In addition, if/when the application is considered for funding, the HEI Program Staff will check that the Major User group eligibility requirement is also met at the time of award.

SECTION 2: APPLICATION INSTRUCTIONS

Follow the Research (R) Instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise in the FOA () or in a Notice from the NIH Guide for Grants and Contracts.

Follow the Research (R) Instructions in the SF424 (R&R) Application Guide, including Supplemental Grant Application Instructions except where instructed in this funding opportunity announcement (FOA) to do otherwise. Program-specific instructions are usually found in Section IV of an NIH FOA.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Application and Submission Information

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits must be followed, with the following exceptions or additional requirements:

For this FOA, there is no overall page limit for the entire Instrumentation Plan. However, there are specified page limits for each section of the Instrumentation Plan as described below. All tables, graphs, figures, diagrams, and charts must be included within the page limits for these sections. The applicants should make every effort to be succinct. It is expected that the length of the Plan's narrative will depend on the type of the requested instrument and the number of users. To be successful, an application does not have to reach the page limits described here.

- Introduction to Resubmission: 3 pages (if applicable)
- Justification of Need: 9 pages in total
- Technical Expertise: 3 pages in total
- Research Projects section must not exceed 30 pages in total. This section can be divided into subsections for Major Users *(limit of 4 pages, or less, per each Major User's project; 3 pages or less are strongly recommended)* or by Specific Research Topic. Regardless of which of these subsections you choose, conclude the Research Projects section with a subsection for "Other Users' Projects" *(limit of 4 pages total for this subsection)*, if appropriate.
- Summary Table(s): 6 pages in total
- Administration (Organizational / Management Plan): 6 pages in total
- Institutional Commitment: 3 pages in total
- Overall Benefit: 3 pages in total

Note: Letters of Support and Biosketches of Major/Minor Users and Tech personnel are not included in the page limitations.

Instructions for Application Submission – full instructions are in FOA

Please refer to the full FOA for complete details on any forms or fields not covered in this generic overview. The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover:

Descriptive Title: Enter the generic name of the instrument requested in the title (for example, 600MHz NMR Spectrometer or High Throughput DNA Sequencer).

Proposed Project: Enter start date of 02/01/2018 and end date of 01/31/2019.

Estimated Project Funding:

- *Total Federal Funds Requested:* Enter the total Federal funds for the requested instrument. This entry cannot exceed $2,000,000 which is the maximum award under the HEI Program. If the cost of the instrument is more than $2,000,000 enter $2,000,000 (or any lower amount of the requested Federal Funds).
- *Total Non-Federal Funds:* If Total Federal Funds Requested (described immediately above) and Total Federal & Non-Federal Funds (described immediately below) are not the same, enter the difference in this line. Explain how the difference will be paid in the Equipment section on the SF424 (R&R) Other Project Information form (described below).
- *Total Federal & Non-Federal Funds:* Enter the total cost of the instrument from the quote.
- *Program Income:* Enter zero it as does not apply to the HEI Program.

NOTE: A warning will be generated during submission for any S10 with a budget in excess of $500,000. This warning can be ignored.

SF424(R&R) Other Project Information

Project Summary/Abstract: The Project Summary/Abstract is meant to serve as a succinct and accurate description of the requested instrument and the need of the research projects for the instrument. State the application's broad, long-term objectives, concisely describing how access to the instrument will enhance the health-related goals of the research projects. This section should be informative to other persons working in the same or related fields and understandable to a scientifically or technically literate reader.
***NOTE:* The Project Summary/Abstract must be no longer than 30 lines of text.**

Project Narrative: Using no more than two or three sentences, describe the relevance of this research to public health. In this section, be succinct and use plain language that can be understood by a general, lay audience.

Bibliography & References Cited: List only publications that demonstrate the researchers' expertise in operation and usage of the requested instrument or are relevant to research projects, which will be supported by the instrument. References of the Research Projects Section may appear in this section or may be listed at the end of individual research subsections.

Facilities & Other Resources: Not Applicable. Do not include an attachment here.

Equipment: Describe the requested instrument by stating its manufacturer, model number, specific features, and accessories. Provide a detailed budget breakdown of the main instrument and requested accessories, including tax and import duties, if applicable. An itemized quote, with any appropriate discount, from a vendor is required. The quote must be scanned and combined in a single attachment with the equipment description as part of this upload. As described above in SF424 Cover form, include an explanation of Total Non-Federal Funds in this section (if applicable).

If human, animal, or infectious materials, which could create a potential biohazard, are to be analyzed, funds for accessory containment equipment for the instrument may be requested in the budget.

Do not describe the need for the instrument or accessories in this section; such narrative should be a part of the Justification of Need section of the Instrumentation Plan.

Other Attachments:

A. **Instrumentation Plan** (in lieu of Research Plan section).
The entire Instrumentation Plan (with the sections described below) must be saved as a single PDF file – named "Instrumentation Plan" – and attached via Other Attachments. Organize the Instrumentation Plan in the specified order (described below), starting each section with the appropriate section heading (i.e., Justification of Need, Technical Expertise, Research Projects, etc.). Do not include links to websites for further information. Do not include animations/videos.

1. *Introduction (3 pages, if applicable):* Only in the case of a resubmission, include an Introduction describing the changes that have been made in response to comments in the previous review.
2. *Justification of Need (9 pages):* Name the requested instrument. Compare performance of the requested model with other similar instruments available on the market. Justify the need for specific features and special accessories of the requested instrument. Each such accessory must be utilized by at least three Major Users. Explain why the chosen model and its manufacturer are the most suitable for your user group. Preliminary data are not required, though if feasible, you may include preliminary data to justify your choice. Provide an inventory of similar instruments existing at your institution, neighboring research institutions, or otherwise accessible; describe why each similar instrument is unavailable or inappropriate for the proposed research. If similar instruments are listed as "unavailable," add a letter to the Letters of Support section from the instrument manager explaining why the instrument is not available to your user group.

- Include specific documentation on the current usage and downtime of each of these existing instruments in annual hours and a realistic estimate of the projected usage for the requested instrument. You may use tables to clarify the presentation. Tables included within this section will count towards the specified page limit.

- For the requested instrument, define and justify the Accessible User Time (AUT) which is the number of annual hours the instrument can be used for any research purpose. If a SUI is requested, AUT represents annual hours the instrument is used for research and other activities, such as billable clinical care or teaching. AUT hours may be limited by the times an instrument operator is available (if an operator is required), site or building access schedules, estimated or scheduled maintenance, start-up and standardization, and any other factors that take time away from the use of the instrument. Justify the AUT for the proposed instrument based on the individual situation at the applicant institution. AUT for the same instrument may differ among different institutions.

- If a SUI is requested, provide the Biomedical Research Time (BRT) for the instrument. BRT is the number of annual hours that the instrument is available to conduct biomedical research. If the total cost of the instrument is requested from the NIH or the instrument will be exclusively used for biomedical research, the BRT is equal to AUT. BRT cannot be less than 50% of AUT. If a SUI is requested, its choice cannot be justified by the needs of non-biomedical researchers (researchers other than Major and Minor Users). However, if such other users require special accessories, clearly explain what they are as they are exempted from the justification by the Major Users' need. Use of the Table of Accessories may help clarify a description of SUI (see Summary Tables below).

3. *Technical Expertise (3 pages):* Describe the technical expertise of individuals who will set up and run the instrument. Specify who will ensure that the instrument is safely operated and appropriately maintained. State who will train new users. If the instrument requires complex sample preparation or consultation for experimental designs, describe the expert individuals who will serve in that capacity. Address technical support for data collection, management, and analysis.

4. *Research Projects (not to exceed 30 pages in total):* In this section, describe the benefit of the requested instrument to enhance research projects.
This section can be divided into subsections for Major Users or by Specific Research Topic. Regardless of which of these subsections you choose, conclude the Research Projects section with a subsection for "Other Users' Projects", if appropriate.

- If you choose to divide the Research Projects into "Research Projects of Major Users" subsections, list the PD/PI's name and grant information (number, title, project start and end dates) in the beginning of each subsection. All Major Users must have substantial need for the requested instrument. *There is a limit of 4 pages, <u>or less</u>, per Major User's project*.

- If you choose to group the Research Projects into "Specific Research Topics" subsections, in the beginning of each subsection list Major Users, their funded grants that you describe therein, and their cumulative usage as measured by the percentage of the AUT (or BRT – if a SUI is requested). This format may be especially useful to avoid redundancies in the presentation of research projects if several Major Users pursue research topics which follow similar protocols and where scientific benefits of the new instrument for their projects are comparable.

- Since the projects have been previously peer reviewed, describe their details only as necessary to explain how the requested instrument will advance the projects' research objectives. <u>(Do not simply copy the Specific Aims section from a funded application.)</u> Present sufficient technical details about types of samples or specific experimental protocols to be employed to allow evaluation of whether the instrument is appropriate, would be effectively utilized, and would provide advantages over other methods and other similar existing or new instruments. In particular, explain the need for special features and accessories of the requested instrument by describing the specific studies that will utilize these options as at least three Major Users must

need any of these special options. Preliminary data are not required, but if available, they may be used to illustrate the benefit of the requested instrument to the research projects. Describe how generated data will be handled and analyzed so that benefits of the entire experimental set-up can be judged. Summarize benefits that the requested instrument will provide towards answering specific scientific questions. Be succinct and clear.

- Conclude the Research Projects sections with a subsection "Other Users' Projects" to describe the need of the requested instrument to advance projects from Minor Users and the user community at UF (i.e. unfunded users who have significant need for the instrument to develop their research programs or users whose expected needs are at the level of 1% or less of AUT). *This Minor Users/Other Users subsection is limited to 4 pages, or less, in total*.

- In cases of certain technologies (such as computer systems or X-ray detectors), a large number of users, exceeding what is necessary to make a strong case for the need of the instrument, may be expected. In such cases, you may select a representative smaller group of Major Users and describe their research projects' needs in detail in subsections "Research Projects of Major Users". Then, devote a separate subsection "Other Users' Projects" to describe research and instrumentation needs of your large user community, including Minor Users'. Keep in mind that the sole number of users is not a compelling factor to justify scientific needs for the requested instrument.

- This Research Projects section must focus on detailed explanation of how the requested instrument will advance research projects. Research projects may be drawn from a broad array of topics in basic science, translational investigation or clinical trials; in particular, research projects on advancements of technologies for the benefit of biomedical research may be included. Demonstrate that NIH-funded investigators will use the instrument at the level of at least 75% of AUT (or 75% of BRT – if a SUI is requested).

5. *Summary Table(s) (6 pages):* As a reminder, state AUT (and BRT – if a SUI is requested) in annual hours, as introduced in the "Justification of Need" Section. Then, show a table summarizing Research Projects of Users. The table should have the following columns: User's name, grant number (for NIH awards list the grant numbers as R01IC123456), brief title of the project, grant start and end dates, and estimated percentage of AUT (or BRT – if a SUI is requested) hours. If there are multiple Users funded by the same grant, list a total of their estimated percentage of AUT (or BRT – if a SUI is requested) hours of use of the instrument for projects supported by that grant. In addition, make a separate table to indicate the users' needs for any requested accessories. In particular, if a SUI is requested, this table should clarify accessories which are not needed for the Major or Minor Users. Do not list users whose annual usage is at the level of 1% or less of AUT.

6. *Administration (Organizational/Management Plan) (6 pages)*: Describe the organizational plan to administer the grant. Describe how the instrument will be utilized, how requests to use the instrument will be made, how time will be allocated among Major Users, how other projects and new users will be enlisted. Describe how users will be trained in experimental design, instrument operation and data analysis. Describe typical day-by-day management of the instrument.

- List the names and titles of the members of the local Advisory Committee. The membership of this Committee should be broad to balance interests of different users and should include members without conflicts of interest (non-users of the requested instrument) who can resolve disputes, if they arise. The membership of this Committee should include at least one senior institutional official who will represent the financial commitment of the institution. Major and other active Users of the instrument may be members, but none may Chair the Advisory Committee. The PD/PI cannot be a voting member of the Advisory Committee.

- The Advisory Committee should meet on a regular basis and should prepare an annual report, which will become part of the Final Progress Report and the Annual Usage Reports.

- Describe a plan for managing access to the instrument if users' projects involve human subjects, vertebrate animals or biohazards such as infectious materials.
- Submit a specific financial plan for long-term operation and maintenance of the instrument. Explain how various operational costs will be met; specifically, costs associated with routine operation and maintenance of the instrument, and costs for support personnel. The financial plan *must* include a table for year one of operation with approximate dollars for anticipated expenditures and anticipated income, showing how these estimates were derived. For year one specific dollar amount are required; for years 2 - 5 approximate amounts are recommended.
- Typically, during year one, the maintenance costs are fully covered by one year manufacturer's warranty. In subsequent years, costs of maintenance must be considered in the financial plan. Include a description of projected changes of the financial plan over the subsequent four years.
  - *Operation:* Include salary support of expert personnel that will operate the instrument and oversee routine care and procedures for standardization.
  - *Maintenance:* May include a service contract, or funds for parts and local technical personnel who will maintain the instrument (if such personnel are qualified to do so).
  - *Supplies:* Include necessary supplies for operating the instrument such as chemicals, cryogenics, and other expendable items.
  - *Anticipated Income:* Enumerate the sources of income such as charge back fee structure, grants, or institutional support.
- *Special Use Instrument (SUI):* In a special case of a SUI, the applicant must include a section entitled ***"Plan to Protect Access of Major and Minor Users to the Instrument"***. According to the eligibility requirement, the Major and Minor User group must have access to the instrument at least 50% of the BRT, but also no less than the portion of the NIH contributions towards the purchase of the instrument. General description of the times and days that are assigned to the user group's biomedical research must be detailed. Provide a description of the other uses of the instrument and demonstrate the effect (positive or negative), if any, on the Major and Minor Users. If a change of instrument configuration is required to serve the other uses, you must show how such changes will be implemented and describe plans to decrease their burden on Major and Minor Users. The process of implementing potential adjustments in scheduling and of other aspects of the instrument administration must be described, for the expected lifetime of the instrument. If a SUI is requested, it is the responsibility of the Advisory Committee to safeguard the research interests of the Major and Minor Users group. It is expected that the Advisory Committee will monitor the instrument use and issue an annual report that documents how the appropriate access of biomedical researchers to the instrument is maintained.
- If a SUI is requested, the PD/PI must describe and document source(s) of funds from UF, other Federal or State agencies, or private foundations which will be used to purchase this instrument. The PD/PI must describe special requirements, if any, associated with expenditure of how the non-NIH funds will be allocated. In particular, if the PD/PI applies for other grants where the costs will be allocated for this instrument at the same time frame as this application is being submitted these efforts must be detailed.

7. *Institutional Commitment (3 pages):* Describe the institutional infrastructure available to support the instrumentation, including space to house the instrument and site for sample preparation, if applicable.

- Confirm the institutional support toward the maintenance and operation of the instrument. In particular, confirm that UF will commit to provide backup of the financial plan for five years from installation of the instrument or for its effective/usable lifetime. The expected usable lifetime depends on the type of requested instrument. Describe institutional support for personnel.

8. *Overall Benefit (3 pages):* Explain how the instrument will impact NIH-funded research and contribute to UF's long-range biomedical research goals.

B. **Letters of Support** *(not included in page limitations)*: All letters of support should be combined in a single PDF file named Letters of Support and uploaded as a separate attachment via Other Attachments. This combined file should include, as applicable:

Letters from institutional officials:

1. Institutional back-up for the proposed financial plan*(PI to initiate discussion with their College Dean, who may further discuss with Office of Research to confirm level(s) of College and institutional support)*;

2. Letters about inventory of instruments at the institution which are unavailable to the PD/PI (as noted in the Justification of Need Section).

3. The institution must also provide a table that includes information about performance of all previous S10-awarded instruments within the past five years; that is, FY 2011 - 2016. The table should have the following columns *(Letter from VP for Research – contact Office of Research, Dr. Jeevan Jyot, to initiate)*:

a) *S10 Grant Number;*

b) *Year of Award;*

c) *Installation Date of the Instrument (PDs/PIs of S10 Awards to provide to Office of Research);*

d) *PD/PI's name; Generic Name of Instrument;*

e) *Instrument Status: Active* (instrument in use), *Pending* (order placed, but instrument not delivered, instrument received but not installed or not calibrated for general use), *Upgraded* (or replaced), *Not Available* (sold, decommissioned, transferred); *(PDs/PIs of S10 Awards to provide to Office of Research)*

f) *Actual Usage Time:* actual total time in hours per year the instrument was used for research; if the instrument has been installed less than a year ago, the hours can be extrapolated for an estimate of hours per full year; *(PDs/PIs of S10 Awards to provide to Office of Research)*

g) *Maintenance Agreement: Active* (Warranty in place), *In-House* (or Self-Insured), *None* (Fee for Service, Pending), *Not Available* (no longer supported by manufacturer); *(PDs/PIs of S10 Awards to provide to Office of Research)* and

h) *Number of Publications Citing the S10 Award. (PDs/PIs of S10 Awards to provide to Office of Research)*

4. If the instrument is currently non-functional, the institution must provide a supplementary explanatory text. *(Letter(s) from VP for Research, Deans, Directors, as appropriate)*.

5. If human, animal, or infectious materials, which could create a potential biohazard, are to be analyzed, a signed letter from the institutional biosafety officer stating the proposed containment plan was reviewed and adheres to documented biosafety regulations. If relevant, this letter is required in the application *(Letter from IRB/IACUC Office or Compliance Office, as appropriate)*.

C. **Biosketches:** **NOTE: CHANGE FROM PREVIOUS FOA:** Include biosketches (in the standard NIH format) of Major Users, Minor Users, and technical personnel, as applicable. Combine into a single PDF and upload via Other Attachments. Biosketches don't count towards the page limitation.

SF424(R&R) Senior/Key Person Profile:

All instructions in the SF424 (R&R) Application Guide must be followed.
NOTE: CHANGE FROM PREVIOUS FOA: Include the profile of the PD/PI only.

Current and Pending Support: Current and pending support for the PD/PI is **required** at the time of application submission.

R&R Budget, PHS 398 Cover Page Supplement, and PHS Assignment Request Form:

Follow all instructions in the SF424 (R&R) Application Guide for these forms.

Intergovernmental Review (E.O. 12372):

This initiative is not subject to intergovernmental review.

Funding Restrictions:

- Under the S10 mechanism, funding requests are limited to the purchase cost of the instrument only. Support for technical personnel, service contracts, extended warranties, and supplies are not allowable.
- Cost sharing towards purchase of the instrument is not required and any institutional funds contributed to the costs of the purchase of the instrument are voluntary. If the amount of funds requested does not cover the total cost of the instrument, describe the proposed source(s) of funding for the balance of the cost of the instrument and document the availability in a letter signed by an appropriate institutional official.
- The program does not provide facilities and administrative (F&A) costs or support for construction or alterations or renovations.
- Matching funds are not required. However, commitment of an appropriate level of institutional support, to ensure the associated sustaining infrastructure, is expected and should be described.
- Appropriate Grants will be awarded for a period of one year and are not renewable.
- Applicants proposing purchase of an instrument that the institution is planning to lease prior to award are urged to consult with their institutional sponsored projects office and the NIH Grant Management Office regarding applicable NIH policy prior to executing the leasing agreement. If the leasing agreement was executed more than one year prior to submission of the HEI application, the applicant must provide a strong justification for the requested Federal funds. This justification must demonstrate that the leased instrument is considered state-of-the-art at the time of submission – appropriate award adjustments may be necessary.
- Execution of a purchase order or agreement, making a down payment or other formal commitment to purchase the equipment prior to award will automatically eliminate an applicant from eligibility for an award.

Post Submission Materials: Applicants are required to follow the instructions for post-submission materials, as described in the policy. Do not submit animations/videos.

SECTION 3: APPLICATION REVIEW INFORMATION

1. CRITERIA

Only the review criteria described below will be considered in the review process. As part of the NIH mission, all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact/Benefit

Reviewers will provide an overall benefit score to reflect their assessment of the likelihood that the requested instrument will exert a sustained, powerful influence on the conduct of research projects and their scientific outcomes, in consideration of the following review criteria.

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact/benefit.

- **Justification of Need:** Is the need for the instrument clearly and adequately justified? Is the equipment essential and appropriate? Are all specific features and special accessories of the requested instrument well justified; in particular, by their need of Major Users? Is Accessible User Time (AUT) well defined and explained? Is AUT reasonable? If a SUI is requested, is BRT well defined and reasonable? Justification of selection of the proposed instrument may include, but is not limited to, comparison with other commercially available instruments of similar function.
- **Technical Expertise:** Does the institution have the technical expertise to make effective use of the requested equipment? How well-qualified are the participating investigators or other assigned personnel to operate and maintain the instrument, conduct the projects, and evaluate the research results, including analysis and interpretation of data? How will new users be trained? How will biosafety procedures be implemented?
- **Research Projects:** Will research with the requested instrument advance the knowledge and understanding of the proposed projects? How will the research projects of individual Users be enhanced? Do Users adequately justify the requested instrument for the needs of their specific projects? If accessories are requested for the instrument, do at least three Major Users require each of the accessories for their research projects?
- **Administration:** Is the plan for the management and maintenance of the requested instrument appropriate? Is the membership of the Advisory Committee broadly based to oversee the use of the instrument for the appropriate range of biomedical investigators, to balance interests of different users, and to resolve disputes, if they arise? How will research time be allocated among the projects? Are the sharing arrangements equitable? If needed, are the policies to manage projects which have human subjects, animals or biohazards adequate? Is the financial plan for the instrument for five years or the expected lifetime of the instrument reasonable and secured, balancing anticipated expenditures and anticipated income? Is the expected usable lifetime of the instrument reasonable?

  If a SUI is requested, is the Plan to Protect Access of Major and Minor Users to the Instrument well designed? Will a SUI put an unreasonable burden on the Major and Minor User groups? Does the commitment letter of institution sufficiently protect the research time and efforts of the Major and Minor user groups?

- **Institutional Commitment:** Did the Institution provide the required letter of commitment to back-up the submitted financial plan in the event of a shortfall of income? Is the institutional commitment to back-up the financial plan provided for a time period consistent with the expected effective lifetime of the requested instrument? Has the institution provided the required "Letter of Support" table listing previous S10 instruments awarded and installed within the past five years? Is the management of awarded S10 instruments adequate? Does the Institution provide adequate infrastructure support for the requested instrument including space to house the instrument and site for sample preparation, if needed?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

- **Protections for Human Subjects:** Generally Not Applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.
- **Inclusion of Women, Minorities, and Children:** Generally Not Applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.
- **Vertebrate Animals:** Generally Not Applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

- **Biohazards:** Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.
- **Resubmissions:** For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.
- **Renewals:** Not Applicable
- **Revisions:** Not Applicable

Additional Review Considerations
As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

- **Applications from Foreign Organizations:** Not Applicable
- **Select Agent Research:** Not Applicable
- **Resource Sharing Plans:** Not Applicable
- **Authentication of Key Biological and/or Chemical Resources:** Not Applicable
- **Budget and Period of Support:** Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. Reviewers will comment whether applicants employed the best economical approaches, including securing academic discounts, to formulate the cost-effective budget while meeting users' scientific needs.

2. REVIEW AND SELECTION PROCESS

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the Center for Scientific Review, in accordance with NIH peer review policy and procedures, using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Program balance among various types of instruments supported and geographical distribution of awards.

Review Dates:
Scientific Merit Review: August – November, 2017
Advisory Council Review: January 2018
Earliest State Date: February 1, 2018

SECTION 5: AWARD ADMINISTRATION INFORMATION

1. AWARD NOTICES

Applicants should ignore eRA/Commons system-generated just-in-time (JIT) requests which are typically sent soon after peer review. If an application is considered for funding, ORIP HEI Program staff will send PD/PI special instructions on how to submit a JIT update, from the e-mail address s10reports@od.nih.gov

Once an application is selected for funding, the Grants management Office may request additional information.

For full information on Award Administration and Reporting requirements, refer to the full FOA.

SECTION 6: AGENCY CONTACTS

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Scientific/Research Contact(s)

Abraham Levy, PhD *(provide name and address to institutional representatives for Letters)*
Office of Research Infrastructure Programs (ORIP)
Telephone: 301-435-0772
Email: HEI@mail.nih.gov

Financial/Grants Management Contact(s)

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