CTPR PILOT PROJECT APPLICATION GUIDELINES

Application Information

This instruction booklet should serve as a guide when completing the Pilot Project Application Packet. All forms contained within the packet are derived from NIH SF424 Application Packages. For additional information on the SF424, see https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf. The CTPR Pilot Project Application Packet closely matches the NIH R21 funding application, though some form pages have been removed to streamline the review process. All associated format and guidelines should be observed when completing the application, **including page limits**. An example application is available (www.archildrens.org/archildrens-COBRE).

Required Forms

Detailed Budget
Budget Justification
Biosketches (for PI and all senior/key personnel)
Facilities and Resources
Equipment
Research Plan
Specific Aims (1 page limit)

Research Strategy (6 page limit)

References
Letters of Support
Institutional approvals, if applicable (IRB or IACUC)

The application packet should be completed in its entirety and uploaded as a single pdf to https://is.gd/ctpr_app. Contact Sonet Weed (SMWeed@uams.edu) if you need assistance completing or uploading the document. Incomplete or incorrect applications may disqualify your submission.

Interested individuals must contact Dr. Alan Tackett (<u>AJTAckett@uams.edu</u>) prior to submitting an application to ensure the proposed research matches the themes and goals of the CTPR.

Applicant Requirements

Applicants for Pilot Projects must be tenure track Assistant Professors (PhD, MD, or equivalent) that currently have faculty appointments with protected research time. Applicants that have yet to receive R01-level funding will be given higher priority for funding. A letter of support from the applicant's Department Chair is required and should outline the applicant's protected time for the proposed pilot project research, protected time for research in general, start-up funding, and dedicated research space.

Award Information

A Pilot Project Award will provide up to \$75,000 for one year in direct costs. Prior awardees may apply for a second year of funding; however, applicants seeking a second year of funding will be reviewed with all other applications submitted in that year. These applications will need to show a high level of progress and a demonstrable need for additional funding to be competitive.

Pilot Project Policies

Research should be performed through ACRI/ACH (please contact Dr. Tackett to discuss). Funds may not be used for PI salary support, capital equipment purchases, patient-care related expenses, or trainee fees/tuition. Support for lab personnel or technicians may be appropriate depending on the needs of the project. No consortium agreements, sub-contracts, or sub-awards are allowed. Applicants are required to utilize and budget appropriately for at least one CTPR Core Facility. Letters of support from CTPR Core Facility Directors are required, and should outline the ability of the core to perform the work with a quoted price for the services requested.

SENIOR KEY PERSONNEL, OTHER SIGNIFICANT CONTRIBUTORS, & HUMAN EMBRYONIC STEM CELLS

Senior/Key Personnel

Senior/key personnel are defined as all individuals who contribute in a meaningful way to the design, development, or execution of a project, whether or not salary is covered. These individuals may include: Pls, Co-ls, biostatisticians, etc. Traditionally, technicians and students are not considered senior/key personnel.

List all senior/key personnel along with the role they will occupy on the project. Please include PI information in this section.

All individuals listed as senior/key should have an accompanying biosketch included with this application.

Other Significant Contributors

Other significant contributors are individuals who are committed to the design and development of the project, but are not contributing any measurable effort. These individuals typically fulfill duties to the project on an "as needed" basis. Traditionally, technicians and students, regardless of salary coverage, are not considered other significant contributors.

List all significant contributors in this section, along with their role on the project.

Human Embryonic Stem Cells

If your project involves the use of human embryonic stem cells (hESC), provide the 4-digit registration number of the specific cell from the hESC Registry (https://grants.nih.gov/stem_cells/registry/current.htm). A cell-line registration number is required prior to award.

DETAILED BUDGET FORM

Limit detail on the budget form. Justification and line item calculations should be included in the budget justification form.

Personnel

Include all personnel receiving salary coverage. **PI salary coverage is not an allowable cost.**List senior/key personnel first, followed by other personnel. Effort allocations should be in the form of person months and not percent effort. For more information regarding person/calendar months reporting and conversion, see https://grants.nih.gov/grants/policy/person months fags.htm#1040.

Personnel listed as other significant contributors in the previous section should not be included in the detailed budget form.

Provide base salaries, amount of salary and fringe requested, and totals for each person receiving salary support. This information can be obtained by contacting the individual's department administrator.

Supplies

List the total amounts requested for materials and supplies, broken down by category. For example, total amounts for all reagents required for the project may be combined into one line item. Provide the total for all requested supplies.

Travel

Travel to one regional IDeA meeting is required of all individuals receiving Pilot Project Awards. A budgeted amount of \$2000 is required in the detailed budget form.

CTPR Core Facility Fees

All Pilot Projects are required to make use of at least one CTPR Core Facility. Fees for service should be included in this section. Applicants should contact CTPR Core Facility Directors for a quote on service fees.

Other Expenses

Any other expenses should be listed by category in this section. This may include publication fees, participant compensation (if human subjects are required, with the exception of patient-care related expenses), etc. List all other expenses categorically by line and provide total other expenses amount.

***No PI salary coverage, equipment purchases, and patient-care related expenses are allowed on the Pilot Project. No consortium, contractual, or sub-agreements are allowed.

BUDGET JUSTIFICATION

Key Personnel

List all senior/key personnel, including PI, including total calendar month effort contributed to the project. Describe the individual's role on the project, including duties and responsibilities.

Other Personnel

List all non-key personnel listed on the project who are receiving salary coverage. Include their total calendar month effort, role on the project, and any duties or responsibilities.

Supplies

Justify the categorical items requested in the budget. Include cost calculations where needed.

Travel (required)

\$2000 is requested for travel to regional IDeA Meetings with other members of the CTPR.

CTPR Core Facility Fees

Include cost calculations for the Core Facility Fees. Applicants should contact CTPR Core Facility Directors for a quote on service fees.

Other Expenses

Include any other necessary expenses for the project that do not fall into one of the above categories. Include cost calculations, if applicable.

BIOGRAPHICAL SKETCH

Please refer to the instructions below in order to complete sections A, B, C and D of the Biographical Sketch. These instructions can also be found in the <u>General Application Guide for NIH and Other PHS Agencies, R&R Senior/Key Person Profile Form.</u>

Samples are available <u>here</u> for your reference.

Biographical Sketches may not exceed five pages.

Figures, tables (other than those included in the provided format pages), or graphics are not allowed in the biosketch. Do not embed or attach files (e.g. video, graphics, sound, data).

Name:

Fill in the name of the senior/key person or other significant contributor in the "Name" field of the Biosketch Format Page.

eRA Commons User Name:

All Key Personnel and the PI must be registered in <u>eRA Commons</u>. Fill in the eRA Commons User Name in the "eRA Commons User Name" field of the Biosketch Format Page.

Position Title:

Fill in the position title of the senior/key person or other significant contributor in the "Position Title" field of the Biosketch Format Page.

Education/Training

Complete the education block. Begin with the baccalaureate or other initial professional education. Include postdoctoral, residency, and clinical fellowship training, as applicable, listing each separately.

For each entry provide:

- the name and location of the institution
- the degree received
- the month and year of end date
- the field of study

A. Personal Statement

Briefly describe why you are well-suited for your role(s) in this project. Relevant factors may include: aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and/or your past performance in this or related fields.

You may cite up to four publications or research products that highlight your experience and qualifications for this project. Research products can include, but are not limited to, audio or video products; conference proceedings such as meeting abstracts, posters, or other presentations; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.

Note the following additional instructions for ALL applicants/candidates:

• If you wish to explain factors that affected your past productivity, such as family care responsibilities, illness, disability, or military service, you may address them in this "A. Personal Statement" section.

- Indicate whether you have published or created research products under another name.
- You may mention specific contributions to science that are not included in Section C. Do not present or expand on materials that should be described in other sections of this Biosketch or application.

B. Positions and Honors

List in chronological order the positions you've held that are relevant to this application, concluding with your present position. For individuals who are not currently located at the applicant organization, include the expected position at the applicant organization and the expected start date.

List any relevant academic and professional achievements and honors.

C. Contribution to Science

Format:

Briefly describe up to five of your most significant contributions to science. The description of each contribution should be no longer than one half page, including citations.

Content:

For each contribution, indicate the following:

- the historical background that frames the scientific problem;
- the central finding(s);
- the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology;
- your specific role in the described work.

For each contribution, you may cite up to four publications or research products that are relevant to the contribution. If you are not the author of the product, indicate what your role or contribution was. Note that while you may mention manuscripts that have not yet been accepted for publication as part of your contribution, you may cite only published papers to support each contribution. Research products can include audio or video products; conference proceedings such as meeting abstracts, posters, or other presentations; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.

You should provide a URL to a full list of your published work. This URL must be to a Federal Government website (a .gov suffix). NIH recommends using My Bibliography.

D. Research Support

List ongoing and completed research projects from the past three years. Briefly indicate the overall goals of the projects and your responsibilities. Do not include the number of person months or direct costs.

Do not confuse "Research Support" with "Other Support." Other Support information is not collected at the time of application submission.

FACILITIES AND OTHER RESOURCES

Describe the scientific environment in which the research will take place and how this will contribute to the likelihood of success for the project.

Describe any special facilities or collaborative arrangements that will facilitate the proposed research project.

EQUIPMENT

List major items of equipment available for the project and how they will be utilized (briefly).	

RESEARCH PLAN INSTRUCTIONS

Specific Aims:

1-page limit. The Specific Aims do NOT count toward your Research Strategy, which has a 6-page limit.

- Concisely state the goals of the proposed research.
- Summarize the expected outcomes, including impact on pediatric research
- Succinctly list objectives of proposed research (e.g., to test a hypothesis, create a novel design, solve a specific problem, etc.).

Research Strategy:

6-page limit

- A. Alignment of Research with Mission of CTPR
 - Describe how the proposed project fits within the scientific mission of the CTPR
- B. Use of CTPR Core Facilities
 - Detail proposed use of CTPR Core Facilities.

C. Significance:

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

D. Innovation:

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.

E. Approach:

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims
 of the project. Include how the data will be collected, analyzed, and interpreted as well as any
 resource sharing plans as appropriate.
- Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.

- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
- If your study involves human subjects or animal populations, discuss why the proposed project requires use of either humans or animals. Justify proposed sample proportions (e.g.- numbers of male and female participants) to be used.
- Provide a timeline with quantitative milestones showing that the proposed work can be completed within the 1 year timeframe of the award

REFERENCES

No page limit.

List all references included in the Research Plan, including PMIDs or PMCIDs. E-pub or in-progress publications may also be included if cited above.

LETTER OF SUPPORT

A letter of support from the applicant's Department Chair is required and should outline the applicant's protected time for the proposed pilot project research, protected time for research in general, start-up funding, and dedicated research space.

Letters of support from CTPR Core Facility Directors are required, and should outline the ability of the core to perform the work with a quoted price for the services requested.

Scanned copies of signed original letters should be attached to the pdf application, which should be submitted as a single document with all required attachments included.

INSTITUTIONAL APPROVALS

If the proposed project involves the use of animals or human subjects, IRB or IACUC approval letters are required at the time of submission. If the proposed research involves human subjects, but is exempt from regulatory oversight, an IRB Exemption Letter is required in place of an Approval Letter. Please contact Sonet (SMWeed@uams.edu) if you need assistance obtaining the appropriate approvals.