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| PPT-CCTST-Element1.tifPPT-CCTST-Element1 | **Center for Clinical and Translational Science and Training**University of Cincinnati Academic Health Center3333 Burnet AvenueLoc. S, 10th Floor, Suite 300, ML 11028Cincinnati, OH 45229Voice: 513.803.1044Fax: 513.803.1039Web: cctst.uc.edu |
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***Center for Clinical and Translational Science and Training***

**“T1” Pilot, T1 Junior Investigator, and T1 Core Grant Application and Instructions**

**For grant year July 1, 2015 - June 30, 2016**

## DEADLINES

**Submission of Letter of Intent (LOI): October 17, 2014 before Midnight**

**Notification of Invitation to Submit Full application: by November 21, 2014**

 **Submission of Invited Application: December 19, 2014 before Midnight**

**Determination/Notification of Awards: February, 2015**

**Funds available: July 1, 2015**

For questions regarding these instructions, please visit the CCTST website ([**http://cctst.uc.edu/funding/t1**](http://cctst.uc.edu/funding/t1)) or contact Beth Hezlep (**beth.hezlep@cchmc.org** or 513-803-7039). **NEW THIS ROUND: Please note that LOI and full application submission must be completed through the CCTST Competition and Awards Program Site (CCAPS):** [**https://ccaps.research.cchmc.org/welcome**](https://ccaps.research.cchmc.org/welcome)**. Log in using your UC (“6+2”) or CCHMC username and password.**

**1. Deadlines:** All deadlines are final. Invited applications must be received through CCAPS prior to midnight, December 19, 2014.

**2. Funding Pools:** $800,000 from Cincinnati Children’s Hospital Medical Center (CCHMC) and $400,000 from the University of Cincinnati (UC). Either the Principal Investigator or a Co-Investigator must hold a faculty appointment at CCHMC with 80% FTE or greater to be eligible for the CCHMC funds. Partnership between UC and CCHMC faculty as co-investigators provides access to the entire pool of funds.

**3. Background:** The Center for Clinical and Translational Science and Training (CCTST) is supported by an NIH Clinical and Translational Science Award (CTSA) and UC, CCHMC, UC Health and the Cincinnati VA Medical Center (VAMC). Integral to the mission of the CCTST is stimulating the development of pre-clinical and human clinical trials that seek to improve medical care. For its major pilot award program, the CCTST “T1” mechanism has adopted, expanded and replaced the pilot award program previously administered at CCHMC as part of the Translational Research Initiative (TRI).

**4. Definitions:** “T1” research seeks to apply clinical or basic research knowledge in an identifiable pathway towards the development of trials and studies in humans. “T2” research is validation of T1 research in phase 2 and 3 trials, while “T3” research is aimed at enhancing the adoption of best practices in the community. This RFA is to support T1 research, and is especially designed to support novel findings developed at the Academic Health Center (AHC) encompassing CCHMC; the UC Colleges of Medicine, Pharmacy, Allied Health and Nursing; UC Medical Center (formerly UC Health University Hospital); the UC Health West Chester Hospital; and VAMC. Inter-institutional and interdisciplinary projects, especially with faculty on the UC West Campus, are encouraged.

T1 translational research seeks to develop the translation of observations made in the AHC research laboratories and clinics into clinical studies involving humans, or the use of clinical observations to define basic research hypotheses or studies. Innovative use of clinical material in basic laboratories is considered translational research. A research study is responsive to the RFA as T1 translational if it:

A. Uses new approaches or discoveries to address clinical problems;

B. Develops new experimental or diagnostic reagents and procedures for diagnosis or treatment; and/or

C. Develops new models of human diseases (including tissue culture and animal models) and verifies the relevance of these to the clinical issues in human subjects.

Non-clinical Translational Research: Non-clinical translational research is laboratory research that leads to a plan or design for new or improved elements of health care, whether intended for internal use or use by others outside of the AHC. It includes the conceptual formulation, design, pre-clinical, and post-clinical testing of a range of diagnostic and therapeutic products and procedures. In some cases the term “non-clinical” is preferred to “pre-clinical,” because non-clinical also encompasses laboratory testing done after the introduction and testing of an agent, device, or procedure in humans.

Clinical Translational Research: Clinical translational research is the confirmation in human clinical testing or observation that the products, procedures and health services processes created to improve health deliver the expected benefits without unacceptable side effects. While this category includes Phase I through IV clinical trials, with assessments of safety and clinical effectiveness, T1 research is typically limited to Phase I or II studies. In addition, clinical translational research encompasses the use of clinical observations or reagents to drive basic laboratory studies. For this RFA, clinical trials should have some aspect of translational research; of particular interest will be those projects utilizing local research laboratory expertise. Projects that are purely clinical research will not be considered responsive to this RFA. Similarly, the CTSA T1 grant program is not a viable mechanism for supporting large-scale phase III/IV trials.

**5. Project priorities:** There is a wide spectrum of projects that can be considered translational. *Priority will be given to those projects that are farthest along in preclinical or early clinical development.* For example, while development of a mouse model of a disease for the purpose of therapeutic drug testing falls within the realm of the T1 program, such a project, in general, will be given a lower priority than a mouse toxicology study needed to file an IND with the FDA in order to launch a phase 1 clinical trial. Similarly, collection of tissue samples to discover a tractable genotype or SNP for a disease or for drug metabolism will be given less priority than development of a diagnostic chip for a genotype or SNP whose association with a disease or a metabolic phenotype has already been discovered. Priority in this program is given to projects that include collaborations between CCHMC and UC investigators and will lead to extramural funding by Public Health Service (PHS) agencies, VA, Department of Defense, and Foundations and those leading to patent or licensing opportunities.

**6. Collaborations:** The CCTST encourages interactions between scientists at UC and CCHMC. Projects in which UC and CCHMC faculty are collaborating will be given higher priority in the review process. Studies which include the participation of both clinicians and basic scientists are preferred. Among similarly-scored projects, those involving interdisciplinary collaborations will be given priority during the administrative review.

**7. Available Grant Types:**

A. T1 Pilot Research Grant (New Submissions): These grants are for one year of support. Funds will be available July 1, 2015 and must be spent by June 30, 2016. The maximum allowable budget (direct costs) is $100,000. The number of awardees will be determined by the quality of the proposals, the total amounts of the requested budgets of sufficiently meritorious proposals, and available funds.

B. T1 Pilot Research Grant (Competing Renewal): For those projects previously supported by the CCTST, a second year of support may be sought. Those applying for a second year are not required to submit a Letter of Intent (LOI), only an email to **beth.hezlep@cchmc.org** by October 17, 2014 stating they plan to submit a 5 page renewal by the final application deadline. Renewal applications will be reviewed in the same manner as new applications. Renewals must include a one page “Progress to Date” section, and must convincingly justify the need for more support.

C. T1 Innovative Core Grant: To help build adequate local infrastructure to support clinical and translational research, funds are available for the establishment of new cores. Core proposals up to $50,000 per year for up to two years of funding will be considered.

D. T1 Junior Investigator Grant: This funding mechanism is for new research proposals only, for one year of support. Funds will be available July 1, 2015 and must be spent by June 30, 2016. **The maximum allowable budget (direct costs) for the junior investigator grants is $25,000.** NOTE: This is a one year grant program, designed to lead to other funding such as the full T1 Pilot Awards or extramural awards. Thus, no renewals for a 2nd year of support will be considered.

We will accept only one application per investigator of the 4 types of grants listed above. If a junior faculty member feels their project is competitive for the T1 program he/she may submit a LOI for the T1 program.

**8. Eligibility by Grant Type**:

A. T1 Pilot Research Grant: Eligible applicants include any individual affiliated with CCHMC or UC with a faculty appointment of 80% FTE or greater. Eligible applicants can be from the academic health center (UC, CCHMC, VAMC) or the UC main campus, including basic scientists, physicians, nurses, and other health care faculty with advanced degrees (RN, MD, PhD, MD-PhD, or equivalent). **Collaborative teams of investigators spanning disciplines, programs, and institutions made up of basic and clinical faculty are strongly encouraged to apply.** Investigators who have been awarded a T1 Pilot Research Grant in the previous fiscal year (July 1 – June 30) as a PI or Co-PI will not be eligible to obtain funding in the current round of applications. (This does not apply to recipients of T1 Junior Pilot Awards.)

B. T1 Junior Investigator Eligibility: This program is a variation on the CCTST T1, targeted at more junior investigators

1. Currently hold a faculty appointment at UC or CCHMC or expect to hold one at the time of the award at the level of Instructor, Assistant Professor, or Research Assistant Professor (note: if not yet faculty, the letter from your program director must verify expected hire by award start date);

2. Less than 8 years from first faculty appointment at the start of the award period;

3. Has never been PI or co-PI on an R-series NIH award or a Project Leader on a P01 (prior co-investigator on R-series is allowed, as is prior or current PI on K-series awards and Core Director on a P01)

4. Has not previously been a PI or co-PI on a T1 Pilot Award (prior co-investigator is allowed);

**9. Overview of Review Process**: The review of applications is performed in 3 phases: (1) Letters of Intent (LOI), (2) Scientific and Statistical Review, and (3) Administrative Review. During the first phase, the 1 page Letters of Intent will be scored and ranked, and the top ~30 applicants will be invited to submit formal 5 page applications. No critiques will be provided to applicants at the LOI phase. During the second phase, the 5 (FIVE) page applications will be reviewed by 2-3 scientific reviewers, a biostatistician, and a member of the intellectual property office. The committee will meet and discuss applications similar to an NIH study section, and members present for the discussion will rank applications. During the third and final phase, the applicant rankings will be reviewed by the CCTST leadership, and the cut-off for awards will be determined. Some budget cuts may be made during this phase if necessary to accommodate top-ranked applications. Interdisciplinary applications, particularly those from divergent arenas of the AHC, may be given priority during this administrative review. The success rate of invited applications is expected to be ~40%. Critiques from the second phase of the review will be provided to the applicants after awards are announced.

**10. Letter of intent (LOI)**: The LOI consists of the application face page and 1 page describing the hypothesis and specific aims. All new T1 Research Grant proposals should submit a LOI, while competing renewal T1 Research Grant proposals should not.

**No supplemental material will be accepted for the LOI**. The LOI is very important, since the content determines whether a proposal will be considered for submission as a full application. The aims should include a brief description of the research design and methods. State explicitly how the proposal is translational in nature and how data accrued from this award will lead to future extramural funding from either federal, foundation or industry sources (including submission target date). **A representative example of an excellent LOI is attached at the end of the instructions.** For core proposals, the LOI consists of the application face page and a one page description of the proposal. **All LOIs must be submitted with the PI and Co-PI (if applicable) NIH biosketch(es) as one collective PDF file through CCAPS (**[**https://ccaps.research.cchmc.org/welcome**](https://ccaps.research.cchmc.org/welcome)**).** An email confirmation of receipt will be returned to the applicant.

**The LOI must be received before Midnight on Friday, October 17, 2014. LOIs received after the deadline will be considered late and will not be reviewed.**

**11. Signatures:** For the invited applications, the signatures of all investigators and their respective division director or departmental chairperson(s) are required. No signatures are required for the LOI.

**12. Letter of Support**: Applications must include a letter of support from the primary applicant’s divisional director or departmental chairperson. Included in the letter of support must be a statement regarding the priority of the research proposal for the division or department, particularly as it relates to patient resources.

**13. Required format**: **Applications (including the letter of support) must be submitted electronically** **as one collective PDF file of assembled elements in the required order through CCAPS (**[**https://ccaps.research.cchmc.org/welcome**](https://ccaps.research.cchmc.org/welcome)**)**. Application forms (modified from PHS 398) are attached or may be downloaded from the CCTST website.

Proposals must be submitted in single spaced text, with one-half inch margins, and no smaller than an 11-point font. Arial or Helvetica typefaces are preferred. The primary applicant’s name must appear in the upper right hand corner of each page, and each page must be numbered in the order of the required elements. **Invited proposals are limited to 5 (five) pages (including figures but excluding animal and human subject protections and references)**. Standard PHS 398 forms for budget, biosketch, other support, and resources should be used.

**14. CCTST Membership**: All applicants for T1 Pilot grant consideration must be CCTST Members. Membership is free and open to all. For more information about CCTST membership, and our online membership registration form, go to [**http://cctst.uc.edu/user/register**](http://cctst.uc.edu/user/register).

**15. Biostatistical review:** Please note that each application will undergo a statistical review of the study design and data analysis plan. To help guide your application, you may consider consultation provided by the CCTST through the BERD (Biostatistics, Epidemiology and Research Design) core: the first 10 hours will be free of charge. For clinical studies, the following types of questions will be addressed by the statistical reviewers:

A. Specify if the study is essentially about: (1) Estimating (2) Hypothesis testing (3) Both (4) Other

B. Do the Hypotheses, Specific Aims or the Study Summary clearly specify outcomes (primary and secondary endpoints) and intervention/exposure variables, if any?

C. Do the Hypotheses, Specific Aims or the Study Summary clearly specify comparison/control group, if any?

C. Are the types (nature) and the units of measurement of the outcomes clearly specified?
 [Type: nomial/ordinal/continuous/count/percent/discrete/scores/time-to-event]

E. Are the types and units of measurement of the covariates (including intervention/exposure, if any) specified?

F. Is the unit of analysis specified?

G. Is the study design specified? i.e., (1) Cross sectional (2) Prospective (3) Retrospective (4) Case-control (3) Cohort/longitudinal (4) Interventional (5) others (case series, hybrid, factorial design, repeated measures, etc.)

G. Are considerations given to justify the sample size/power?

H. Is the statistical analysis plan appropriate with measures of anticipated effects clearly specified for each Specific Aim/Hypothesis? [measures of anticipated effects: mean difference (absolute/relative)/relative risk/risk ratio/odds ratio/hazard ratio/others (correlation, measures of association, regression coefficients etc)].

I. Does the analysis plan describe methods for assessment and treatment of outliers, missing values, distributional assumptions and transformations?

**16. Budget detail:** Please provide a detailed budget including reasonable direct costs necessary for the performance of the research award, including any biostatistical support required. All projects including consortium/contractual expense items need to submit a separate detailed budget on Form Page 4 and a budget justification.  Each item listed on Form Page 4 must be clearly justified on Form Page 5.

**Allowed Costs:** Salary support for technicians or graduate students is allowed. Only direct costs are allowed. Facilities and administration (F&A) costs are not allowed and should not be included. Salary support for faculty is not allowed: such costs are considered to be a cost share with the applicant’s Division or Department. Awards will be drawn from a UC or CCHMC funding source and will not be eligible for revision during the project year without prior written approval.

Budget Guidelines by Award Types:

T1 Pilot Research Grant (New and Competing Renewal) – Direct Cost Funding Maximum $100,000

T1 Innovative Core Grant – Direct Cost Funding Maximum $50,000 per Year for Two Years

T1 Junior Investigator Grant – Direct Cost Funding Maximum $25,000

**17. Supplemental items:** Supplemental items are not allowed and will not be provided to reviewers to consider in their scientific review.

**18. Required format and composition for T1 Pilot Research Grant proposals (new and competing renewal) and T1 Junior Investigator Grant proposals:\***

A. Face page (check all appropriate IBC, IACUC, IRB, or Radiation Safety approvals or indicate pending if submitted)

B. Abstracts (scientific and lay)

C. Detailed Budget (1 year; use PHS 398 form provided)

D. Budget justification

E. Biosketch(es) (include PI and co-investigators; use PHS 398 form)

F. Other support (PHS 398 form)

G. Hypothesis and Specific Aims (1 page)

H. Background and Significance

I. Preliminary Results or, if 2nd year renewal, Progress Report

J. Research Design and Methods

K. Data management and analysis plan

L. Statement of how proposal is translational

M. Statement about how data generated will lead to extramural funding and the potential source (federal, foundation, industry).

N. Outcomes (grants, publications, patents, licensing rights) derived from any previous T1 grants (if applicable)

O. Statement of Commercialization Potential (include any issues of intellectual property)

P. Statements regarding human subjects and/or animals

Q. Literature cited

R. Consortium/Contractual Arrangements

S. Letter of support from division director or department chairperson

T. Letters of support from collaborators or consultants

**\*Notes:**

A. New and competing renewal T1 Pilot and T1 Junior Investigator Grant applications must include the elements listed in the order shown here.

B. **Sections G-M must not exceed 5 (FIVE) pages**.

C. The merit for each proposal will be based upon the criteria used for all NIH grants.

D. The likelihood that the proposal will lead to extramural funding from a federal, foundation or industry source or will lead to a patent with potential licensing of a product will be strongly considered.

**19. Required format and composition of T1 Innovative Core Grant proposals:\***

A. Face page (check all appropriate IBC, IACUC, IRB, or Radiation Safety approvals or indicate pending if submitted))

B. Abstracts (scientific and lay)

C. Budget (1-2 years; use PHS 398 form provided)

D. Budget justification

E. Biosketch(es) (include PI and co-investigators; use PHS 398 form)

F. Other support for core (PHS 398 form)

G. Resources of PI (PHS 398 form)

H. Methods and Services provided by core

J. Background and Significance

K. Anticipated Users (include table if possible)

L. Benefits of Core to Users

M. Plans for Allocation of Core Resources13. Methods for Protecting Human Subjects

N. Plans for Oversight

O. Facilities and Resources for core

P. Plans for Future Core Support

Q. Statement of how core supports the CCTST mission

R. Letter of support from division director or department chairperson

\*Notes:

A. T1 Innovative Core Grant applications must include the elements listed in the order shown here.

**B. Sections H-Q must not exceed 5 (FIVE) pages**.

**C**. The merit of each core proposal will be judged on the following criteria:

1. Quality of the science supported by the core

2. Quality of the product and cost-efficiency of the service

3. Potential breadth of users (cores anticipated to be utilized by multiple investigators in multiple divisions will be given priority)

4. Justification of the budget request

5. Potential effectiveness for strengthening the infrastructure in the basic, clinical and/or population sciences as they relate to promoting translational research

6. Potential effectiveness for taking advantage of scientific opportunities afforded by other investigators’ proposed studies

7. Plans for continued funding of the core following exhaustion of CCTST funds

The CCTST is primarily interested in supporting new, innovative cores that promote the mission of building a local or networked infrastructure for conducting non-clinical or translational/clinical research. Established cores seeking bridge or supplemental funding, or cores that primarily support basic (discovery) research, are not likely to be successful through this mechanism. Cores supported by this program may include laboratory and clinical facilities, equipment, and services that will be shared by multiple investigators.

The core service plan should include a description of the services to be provided and the background and significance for the core. The applicant should present a clear description of methods and services to be provided and (if appropriate) discussion of human subject protections and inclusions, as well as a data safety monitoring plan/board. Cores may contain a non-hypothesis driven research activity, provided that the research is designed to improve core services. The applicant should clearly present the facilities, resources, and professional skills that the core will provide to investigators. A plan for funding of the core beyond the 2 year period supported by the CCTST is essential.

The core proposal should also include a discussion of the decision-making processes for core activities including prioritization of service and allocation of resources, the establishment of any oversight committees, and the planned mechanisms for promoting communication and collaboration among users of the core.

To aid in the review, it is suggested that a table, to show the anticipated use of the core by each investigator, be included in the application. Justify the core by discussing ways in which the centralized services improve quality control, produce an economy of effort, and/or save overall costs for investigators (benefits of core).

**20. Additional Considerations:**

All proposals will be reviewed according to the following scientific criteria:

1. Scientific merit
2. Innovation
3. Likelihood of leading to extramural funding, patent or commercialization
4. Collaboration

Ten most common reasons that a T1 application is denied

1. Scientific priority low
2. No evidence that proposal will stimulate collaboration
3. No planned/future T1 dependent grant application or patent submission cited
4. Overlap with existing proposals
5. CCTST funding obtained in last 12 months
6. Scope of project outside T1 mechanism
7. Prior CCTST grant funded, but no extramural grant or patent submitted
8. Not clear that data generated would be necessary and sufficient to support future grant application
9. Grant funds not likely to be spent within grant period
10. Proposal is not truly translational

**SAMPLE LETTER OF INTENT (LOI)**

Gene therapy for hemophagocytic lymphohistiocytosis (HLH)

Principal Investigator: Michael Jordan MD; Co-investigators: Punam Malik MD and Kimberly Risma MD PhD

Hemophagocytic lymphohistiocytosis (HLH) is a fatal immune dysregulatory disorder primarily affecting infants and children which is characterized by symptoms of extreme inflammation and the development of cytopenias, hepatitis, and CNS damage. Defects of the perforin-dependent pathway of lymphocyte cytotoxicity underlie most cases of HLH. Indeed mutations in the perforin gene (prf1) itself are the prototypical and most common cause of HLH. Such defects hamper a critical immune regulatory mechanism and lead to extreme immune ac-tivation after sometimes trivial stimuli. Treatment of HLH consists of an initial phase of immune suppression followed by hematopoietic cell transplantation (HCT) to prevent (inevitable) future disease recurrences. Though HCT is the definitive cure for HLH, it carries unusual risks in this patient population. Mortality after HCT in pa-tients with HLH ranges from 20-50%. Notably, even partial donor chimerism (the coexistence of both host and donor hematopoiesis after transplantation) has been found to lead to long-term cure of patients with HLH.

We found that, like humans, perforin deficient (prf-/-) mice respond to viral challenge by mounting a highly ex-aggerated immune response and develop an HLH-like condition. We have utilized this model to study how HCT can rescue prf-/- mice from the development of HLH. We have found that as little as 10% wild type (prf+/+) donor chimerism is sufficient to restore normal immune regulation and prevent the development of HLH after subsequent viral infection. This finding is useful for not only for guiding clinical care after HCT, but also provides a clear and achievable ‘threshold’ for autologous genetic correction. Thus, we hypothesize that HLH due to prf1 defects could be cured by gene transfer of wild type perforin via lentiviral vectors into a frac-tion of hematopoietic cells. Instead of exposing patients to the substantial risks of HCT, patients could be cured of HLH by correcting gene expression in autologous hematopoietic cells via gene therapy.

In collaboration with Drs. Malik and Risma, we have developed lentiviral vectors which are suitable for further clinical development for gene therapy of HLH, and have begun to test them in our preclinical models. Prelimi-nary studies show that we can obtain high level chimerism (well in excessive of 10%) of transduced hemato-poietic cells in prf-/- mice. Simultaneously, we are developing the next generation of lentiviral vectors to opti-mize tissue-specific perforin gene expression (using miR-target sequences in the vectors to prevent ectopic perforin expression in hematopoietic stem/progenitor cells) and facilitate long-term gene correction. Finally, we have obtained perforin-deficient cells from patients and plan to assess the capacity for lentiviral transduction to correct the cytotoxic defects in these human cytotoxic lymphocytes.

Over the next year we intend to pursue the following aims:

1. Define the level of genetic correction necessary to protect prf-/- mice from the development of HLH after viral infection.

2. Assess the selective advantage of next generation lineage-restricted vectors that utilize miR targeting and determine the cell type specificity of gene expression from these vectors in prf-/- mice.

3. Optimize an in vitro system of NK cell generation from normal human CD34+ hematopoietic precursors and assess the ability of gene correction to reverse cytotoxic defects in (prf-/-) patient samples.

These studies are a key step towards taking gene therapy for HLH to a clinical trial. We are in an ideal position to develop and lead this study because CCHMC is a leading institution for diagnosing and treating patients with HLH. We perform more HCT’s for patients with HLH than any other institution in the world today. Dr Jordan is currently leading a multi-institution clinical trial testing a new initial immunosuppressive therapy for patients with HLH. Furthermore CCHMC is currently conducting a gene therapy trial for patients with another immune defi-ciency, X-linked severe combined immune deficiency and is gearing up to open a second gene therapy trial for sickle cell anemia, led by Dr Malik. We have assembled a team of three investigators with complementary ex-pertise in animal models, human cytotoxic function, immunologic assessment of HLH (Jordan and Risma), gene therapy vectors, gene transfer into hematopoietic stem cells, and translation of gene therapy to the clinic (Malik) to expedite this effort. These studies will position us well for a successful application to the NIH for fur-ther R01 level funding. Such additional funding would allow us to complete all of the studies needed for filing an IND and to initiate a clinical trial to test gene therapy in patients with HLH.

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| University of Cincinnati CCTST PCS Pilot Grant Program*Grant Application* |
| 1. TITLE OF PROJECT *(Do not exceed 56 characters, including spaces and punctuation.)*      |
| 1a. Type of application: [ ]  T1 Research proposal [ ]  TR Faculty Development Award [ ]  Innovative Core [ ]  Junior T1 |
| **2. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR**  | **New CCTST Investigator [ ]  No [ ]  Yes** |
| 2a. NAME *(Last, first, middle)*      | 2b. DEGREE(S) |  |
|       |       |       |  |
| 2c. POSITION TITLE      | 2d. MAILING ADDRESS *(Street, city, state, zip code)*      |
| 2e. DIVISION      |
| 2f. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT       |
| 2g. TELEPHONE AND FAX *(Area code, number and extension)* | E-MAIL ADDRESS: |
| TEL:       | FAX:       |       |
| **3. CO-INVESTIGATOR**  | **New CCTST Investigator [ ]  No [ ]  Yes** |
| 3a. NAME *(Last, first, middle)*      | 3b. DEGREE(S) |  |
|       |       |       |  |
| 3c. POSITION TITLE      | 3d. MAILING ADDRESS *(Street, city, state, zip code)*      |
| 3e. DIVISION      |
| 3f. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT       |
| 3g. TELEPHONE AND FAX *(Area code, number and extension)* | E-MAIL ADDRESS: |
| TEL:       | FAX:       |       |
| 4. Human Subjects Research [ ]  No [ ]  Yes | 4a. Research Exempt  [ ]  No [ ]  Yes If “Yes,” Exemption No.       | 4b. Human Subjects Assurance No. 4c. NIH-Defined Phase I Clinical Trial  [ ]  No [ ]  Yes | 5. Human Subjects Protection Certification: [ ]  No [ ]  Yes5a. Certification Date:       |
| 6. Vertebrate Animals [ ]  No [ ]  Yes6a. If “Yes,” IACUC Approval Date      6b. Animal Welfare Assurance No.       | 7. IBC Protocol [ ]  No [ ]  Yes7a. If “Yes,” Approval Date:      7b. Approval Number:       | 8. Radiation [ ]  No [ ]  Yes8a. If “Yes,” Approval Date       |  |
| 9. DATES OF PROPOSED PERIOD OF  SUPPORT *(month, day, year—MM/DD/YY)* | 1. COSTS REQUESTED

Direct Costs ($)      |  |
| From | Through |  |  |
| 07/01/2015 | 06/30/2016 |
| 12. The undersigned reviewed this application for a CCTST research award and are familiar with the policies, terms, and conditions of UC and/or CCHMC concerning research support and accept the obligation to comply with all such policies, terms, and conditions. |
| Primary Applicant:       | Division Chair of Primary Applicant:       |
| Signature of Primary Applicant | Date: | Signature of Division Chair of Primary Applicant | Date: |
| Affiliate applicant:       | Division Chair of Affiliate Applicant       |
| Signature of Affiliate Applicant | Date: | Signature of Division Chair of Affiliate Applicant:  | Date: |
| Date Application Received by CCTST: | Received By: |

|  |  |
| --- | --- |
| Principal Investigator/Program Director (Last, First, Middle): |       |
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| **Scientific Abstract**: Using technical language, briefly describe the proposed project in 200 words or less. |
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|       |
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| **Lay Abstract**: Using non-technical language, briefly describe the proposed project in 100 words or less. |
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| Principal Investigator/Program Director (Last, First, Middle): |       |
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| DETAILED BUDGET FOR BUDGET PERIODDIRECT COSTS ONLY | FROM | THROUGH |
| 07/01/15 | 06/30/16 |
| PERSONNEL *(Applicant organization only)* |  | % |  | DOLLAR AMOUNT REQUESTED *(omit cents)* |
| NAME | ROLE ONPROJECT | TYPEAPPT.*(months)* | EFFORTONPROJ. | INST.BASESALARY | SALARYREQUESTED | FRINGEBENEFITS | TOTAL |
|       |  |       |       |       |       |       |       |
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| SUBTOTALS |       |       |       |
| CONSULTANT COSTS      |       |
| EQUIPMENT *(Itemize)*      |       |
| SUPPLIES *(Itemize by category)*      |       |
| TRAVEL      |       |
| PATIENT CARE COSTS | INPATIENT |       |       |
| OUTPATIENT |       |       |
| ALTERATIONS AND RENOVATIONS *(Itemize by category)*      |       |
| OTHER EXPENSES *(Itemize by category)*      |       |
| SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD | $ |       |
| CONSORTIUM/CONTRACTUAL COSTS | DIRECT COSTS |       |
| FACILITIES AND ADMINISTRATIVE COSTS |       |
| TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 10, Face Page)* | $ |       |
| Principal Investigator/Program Director (Last, First, Middle): |       |
|  |
| BUDGET JUSTIFICATION |
|  |
|       |
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| Principal Investigator/Program Director (Last, first, middle):       |
| **BIOGRAPHICAL SKETCH**Provide the following information for the key personnel in the order listed for Form Page 2.Follow the sample format for each person. **DO NOT EXCEED FOUR PAGES.** |
|  |
| NAME      | POSITION TITLE      |
| EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)* |
| INSTITUTION AND LOCATION | DEGREE*(if applicable)* | YEAR(s) | FIELD OF STUDY |
|       |       |       |       |
|       |       |       |       |
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**NOTE: The Biographical Sketch may not exceed four pages. Items A and B (together) may not exceed two of the four-page limit. Follow the formats and instructions on the attached sample.**

1. **Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

1. **Selected peer-reviewed publications (in chronological order).** Do not include publications submitted or in preparation.

1. **Research Support.** Listselected ongoing or completed (during the last three years) research projects (federal and non-federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and your role (e.g. PI, Co-Investigator, Consultant) in the research project. Do not list award amounts or percent effort in projects.

|  |
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| **Principal Investigator/Program Director (Last, first, middle):** |
| **OTHER SUPPORT** |

Provide active support for all key personnel. **Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards.** Training awards, prizes, or gifts do not need to be included.

There is no "form page" for other support. Information on other support should be provided in the *format* shown below, using continuation pages as necessary. ***Include the principal investigator's name at the top and number consecutively with the rest of the application.*** The sample below is intended to provide guidance regarding the type and extent of information requested. Refer to the specific instructions in Section I.

For information pertaining to the use of and policy for other support, see “Policy and Additional Guidance.”

**Format**

|  |
| --- |
| **NAME OF INDIVIDUAL**ACTIVE/PENDING  |
| Project Number (Principal Investigator) SourceTitle of Project *(or Subproject)*The major goals of this project are… | Dates of Approved/Proposed ProjectAnnual Direct Costs | Percent Effort |
| OVERLAP *(summarized for each individual)* |

ACTIVE

PENDING

OVERLAP

|  |  |
| --- | --- |
| Principal Investigator/Program Director (Last, First, Middle): |       |
|  |
| RESOURCES |
| FACILITIES: Specify the facilities to be used for the conduct of the proposed research. Indicate the performance sites and describe capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Under “Other,” identify support services such as machine shop, electronics shop, and specify the extent to which they will be available to the project. Use continuation pages if necessary. |
| Laboratory:      |
| Clinical:      |
| Animal:      |
| Computer:      |
| Office:      |
| Other:      |
| MAJOR EQUIPMENT: List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.      |