University of Southern California

Center for Education, Training, and Career Development (CETCD)
Southern California Clinical and Translational Science Institute (SC CTSI)

Clinical Sciences Center
2250 Alcazar Street, Room 2228
Los Angeles, CA 90089-9074
Tel: 323 442 4039   Fax: 323 442 2082   Email: cetcd@lists.sc-ctsi.org

Pre-doctoral Clinical and Translational Training Award

Application Guidelines for 2012

Applications for the Southern California Clinical and Translational Science Institute (SC CTSI) Pre-doctoral Clinical and Translational (PCT) Training Award are now being accepted. The SC CTSI is supported by an award from the National Institutes of Health with a thematic focus on research that will improve health of diverse populations in urban environments. The program for doctoral students comprises two years with one-year of funding coming from the National Institute of Health (NIH) TL1 Award. The students will be supported by their home department for the second year.

The PCT training award will support the research career development of promising doctoral students of the University of Southern California who wish to add to their doctoral training an emphasis on clinical and/or translational research. Candidates should be enrolled in a PhD program relevant to biomedical research and have an interest in conducting clinical/translational research in their chosen field. For purposes of this Award, translational research is considered broadly, including but not limited to:

- Bench research directed at developing new therapeutic or diagnostic tools;
- Human studies of disease mechanisms or diagnostic or therapeutic approaches, including clinical trials;
- Research into health care delivery, health outcomes and health economics; and
- Research into health behaviors and community health.

The deadline for submission of the application is 5:00pm on December 16, 2011. Incomplete applications will not be considered for funding. The scientific and scholarly merit of the applications will be determined by a scientific review panel, which will make recommendations to the CETCD leadership. The SC CTSI will fund up to four candidates for one year of the two year program. The CTSI will fund the most promising candidates and the award will begin July 2, 2012.

PCT Training Program Description & Requirements

Purpose: The program will provide multi-disciplinary, team-based clinical and translational research education to a select group of doctoral students. These students will acquire the scientific competencies necessary to perform clinical and translational research, including research in health problems of diverse populations. Students will have dual mentorship from their doctoral advisor and a clinical translational research mentor.

Eligibility: Students who are matriculated in a biomedical research-related PhD program or a joint professional degree/PhD program are eligible to apply. Applicants must have attained "Advanced to Candidacy" status according to the Graduate School at USC. We encourage applications from individuals in underrepresented minority groups. Please refer to the following web link for more information: web link: **http://grants.nih.gov/grants/guide/notice-files/NOT-RM-08-023.html**.

Training Experience: Students will complete their graduate requirements and receive their PhD from their home department. Their doctoral project has to involve some aspect of clinical and/or translational research. In addition, awardees will take coursework and co-curricular activities specific to the PCT training program. They may use these PCT training requirements to satisfy some of their department's degree requirements, where relevant. Completion of PCT training requirements will lead to either a Certificate in Translational Research or a Master of Science in Clinical and Biomedical Investigations.   Individuals who desire to obtain a <u>Master's Degree in Clinical and Biological Investigations</u> as part of their training plan must complete a separate application through the Department of Preventive Medicine. Also, PCT Trainees may structure an individual educational program by combining courses from the Master's, PHD program or with other courses from other programs. This fulfills the CETCD's mission in providing optimal training for each individual and their specific career objectives. Applicants wishing to pursue this last option should contact the PCT training program staff prior to developing their application for this award.

Each Trainee will work with his/her mentor to develop the planning, goals and execution of a career development plan and research project. Mentors must be accomplished investigators (i.e., federally funded) in clinical and translational research and must have a track record of success in training new investigators and fostering their success as independent researchers.

Key educational program elements will include:

All PCT Trainees are required to complete the following curriculum:

- **Clinical Translational Research Courses (1, 2, & 3):** CETCD has developed new Clinical Translational Research courses (CTR 1-3) totaling 12 units which are given under the Department of Preventive Medicine. These courses provide an overarching understanding and view of research from the clinical translational perspective. Using a new teaching and instructional method, the courses are taught in a problem-based fashion that requires Trainee's engagement and participation.

- **Directed Research:** A minimum of 6 months of practical research experience must be spent on a research project (PM590 – 3units).

- **Seminar Series:** These bi-weekly seminar series are an additional education component to the program. Sessions are intended to assist in developing leadership, scientific, and communication skills. Each session will consist of a different topic lead by an expert facilitator from the USC faculty, other universities, or other SC CTSI community partners.

    In an effort for PCT Trainees to network with others, seminar sessions will periodically be open to the following USC programs/organizations:

    * Health, Technology, and Engineering program (HTE@USC)
    * 5th Year Medical Student Fellowship program
    * MD/PhD Program
    * Keck Postdoctoral Association

- **Work-in-Progress:** Approximately every six months, all PCT Trainees provide an update on their research. A work-in-progress will occur in place of a seminar session topic. This provides them

with an opportunity to receive feedback from respective colleagues in the program, mentors, the CETCD Leadership, and other audience members. **All mentors must attend this meeting.**

- **Annual Progress Reports and Performance Feedback:** The PCT Trainee must also complete an annual <u>progress report</u> describing the specific activities, career goals, accomplishments and whether the benchmarks established in the mentoring/educational plan have been reached. The annual progress report will include the following:

  * A statement on the progress toward each goal;
  * Listing and grades for formal coursework;
  * Progress in clinical research projects;
  * Scientific productivity, (manuscripts, abstracts, presentations, and grants);
  * Other activities;
  * Goals for the next 12 months; and
  * Summary of the interactions of the PCT Trainee with the mentors.

  Submission of the completed progress report is an absolute condition of the PCT Award.

- **Annual CTSA Conference:** Trainees are required to attend and present at the Annual National Pre-doctoral Clinical Research Training Program Meeting for TL1 Trainees at Washington University School of Medicine in St. Louis, MO. This provides an opportunity for the Trainees to meet colleagues from across the nation and present their work.

- Each CTSI PCT Trainee will have access to epidemiologic and biostatistical advice and the opportunity to receive extensive one-on-one tutorials on at least one manuscript and/or grant proposal.

- Trainees are expected to contribute to the goals of the CTSI by serving as role models for other pre-doctoral Trainees, clinical fellows, and teaching clinical and translational science methods to others in the PCT training program and in their home departments. Trainees are expected to interact from KL2 Scholars (post-doctoral awardees).

Transferability of the Award: This is an institutional career development award granted to USC, and it is non-transferable; Trainees who leave USC will not be able to continue receiving TL1/PCT funding from USC. Exceptions can be made for institutions that are closely affiliated with SC CSTI, such as Kaiser Permanente, and Children's Hospital Los Angeles.

Source of Funding: The award will provide the following financial coverage for one year:

- Full stipend coverage including benefits (e.g. health care costs). NIH will provide up to $21,600, and the remaining amount will covered through institutional funds.
- Tuition and fees of $12,115.25. This amount must be used toward the three Clinical Translational Research courses (12 units) as part of the program requirements.
- Research related funds of $4,200 to be used to cover the cost of books, supplies, and fees for seminars/conferences.
- Travel stipend (one time) of $1,500 to attend the annual National Pre-doctoral Clinical Research Training Program Meeting in St. Louis, MO.

The applicant's home department is expected to support the PCT Trainee for the second year of the program. They should spend at least 100% of their time on the proposed doctoral project and related

PCT curricular and co-curricular activities during both years of participation in the program. An applicant can receive this award only once. The award recipient will be required to actively participate in all PCT training activities for the duration of the training program. He/she will write a progress report at the end of each year for which CTSI funding was provided. Publications that result from this support will need to acknowledge the CTSA funding source.

The department chair/division chief must provide written assurance that they have research space, equipment, financial resources, and the interest required for training the candidate. The mentor must provide a statement that includes a description of the mentor plan and any sources of external support (Training Grant, NIH, American Cancer Society, etc.) available to them. Supplementation of the Award is permitted in accordance with the USC Graduate School guidelines. A primary mentor can sponsor only one application per year. Mentors who have received previous awards from the CTSI for their trainees must document that they have fulfilled their previous commitments (e.g., first author publications by previous trainees and grants).

Mentors: Developing a successful clinical research career requires strong relationships with mentors and a research team. Each Trainee must have a primary mentor and a co-mentor from a different discipline. The primary mentor should have sufficient independent research support to cover any costs of the proposed research project that exceed the Trainee research funds provided by the PCT award. PCT's primary mentor will receive a small percentage of salary support for their mentoring efforts and additional financial support for their research expenses related to the PCT Trainee.

i. ***Primary mentors*** are expected to be in the same area of the applicant's field of clinical or translational research and a member of the faculty in the applicant's unit. Under the guidance from the primary mentor, the applicant will prepare a proposal that describes the research project to be undertaken. A Principal Investigator (primary mentor) can sponsor only one application per year. Primary mentors, who have received previous awards from the CTSI for their trainees, must document that they have fulfilled their previous commitments (i.e., first author publications by previous trainees and grants). The primary mentor is responsible for:

- Guiding and encouraging the design and execution of an original, high quality, research project.
- Providing guidance and supervision to assure that projects are moving satisfactorily on the path to presentations, publications, grant applications, and preparation of a final report.
- Providing opportunities and helping the Trainee develop creative and independent careers in research, as well as providing advice on career direction, national networking, and academic promotion.
- Being familiar with faculty, resources and databases at USC, and having resources including research staff to assist the Trainee in his/her research.
- Assure that the Trainee's time of 100% effort is protected and fully available for their training and research as required by the program.
- Meeting with the Trainee at least monthly, both individually and in conjunction with other members of the research team. Primary mentors are required to meet with their Trainee and other mentors as a group at least twice a year.
- Attend Trainee's Work-in-Progress sessions scheduled every 6 months.
- Attend additional mentoring workshops as scheduled by the CETCD Office.

If the primary mentor is providing research space and/or financial support, he /she may submit a separate letter addressing this resource component.

ii. ***Co-mentors*** will be responsible for working with the primary mentor on the responsibilities mentioned above, and will provide guidance in one or more complementary areas of expertise. It

4

is highly desirable that the co-mentor be a faculty researcher in another discipline who can provide translational input into the applicant's project.

iii. ***Department or Division Chair*** must provide written assurance that they have research space, equipment, financial resources, and the interest required for training the candidate. This statement by the department or division chair must include any sources of external support (for example: Training Grant, NIH, and American Cancer Society) available to them. Supplementation of the Award is permitted in accordance with the USC Graduate School guidelines.   Each Trainee is also expected to meet periodically with her/his division chief/department chair who will oversee the Trainee's departmental interactions and academic advancement. The department/division chair must ensure that they will uphold the required protected time of 100% for PCT Trainees.

Please note the Director of the PhD program is not the department/division chair unless he/she holds both positions with the department. If the primary mentor is providing research space and/or financial support, he/she may submit a separate letter in place of the department chair/division chief.

Selection Committee members may also serve as mentors but during the selection of the candidate, these individuals will be excused from the discussion and vote.

Trainee Selection Process: A campus-wide Selection Committee will review the Trainee's application. Selection criteria focus on five major areas:

i. ***Track record*** or candidate's ability in the areas of expertise and prior training; publications; funded grants to be attached to the application.
ii. ***Research plan's*** scientific value, potential clinical and or translational importance and feasibility.
iii. ***Educational and mentoring plan's*** quality, appropriateness, multidisciplinary mentors, and plan for additional didactic and/or other training at USC or elsewhere.
iv. ***Resources*** and commitment provided by the home department, and suitable /available clinical and laboratory infrastructure.
v. ***Career potential*** or likelihood that the candidate will develop a career as an outstanding investigator who will lead multidisciplinary teams and potentially impact on health.

Application Advice: Before submission, candidates should check with their department chairs to ensure that the department will provide any stipend support and effort not covered by the CTSI. Note that these funds may not be derived from Public Health Service (i.e. NIH) fund sources.

Please contact the CETCD's administrative staff, Jeanne Dzekov and Amy Zhu, at cetcd@lists.sc-ctsi.org or via phone at (323) 442-4039 about the submission process and paperwork.

Application Instructions

To be completed by the Applicant:

The following application process and format must be adhered to:

1. **Letter of Intent**
   The information in the letter of intent allows us to better plan the review process, and assist potential applicants as necessary. *Deadline for submission is due by 5:00pm on November 18, 2011. Please submit the letter of intent to CETCD's Program Administrator, Jeanne Dzekov at dzekov@usc.edu*. This letter must not exceed 2 pages in length and should contain:

   - Applicant's contact information;
   - A brief paragraph describing what you hope to achieve through participation in the program
   - A paragraph describing educational and mentoring goals;
   - A brief paragraph describing the research including the project title that you would like to perform as a part of the program;
   - The name, contact information, and specialty of the primary mentor and co-mentor; and
   - Applicant's curriculum vitae and bibliography.

2. **Application Form**

   a. To begin the application process, please go to the CETCD's home page located at:

      http://www.sc-ctsi.org/index.php/resources/education

   b. Download the following documents:
      - **Application Guideline**: Read the guidelines <u>thoroughly</u> before you begin filling out the application form.
      - **Area of Expertise Coding List**: Read guidelines for more information when to use and complete the application appropriately.

   c. Click on indicated link from the CETCD home page to access the online application form, or you may go to the link directly: **https://redcap.sc-ctsi.org/surveys/?s=9HSgtK**

   Please <u>complete all</u> the sections of the application form:

   Section 1: Basic Data
   Please note all elements of this section must be completed in order to process all awardee paperwork in a timely manner. In some cases, applicants may already have an eRA Commons user name through the Department of Health and Human Services. If an eRA Commons user name has already been obtained, please enter the user name in the area provided in this section. If you do not have an eRA Commons user name, you may go to the following link for more information: **http://era.nih.gov/commons/faq_commons.cfm#I1**. The area of expertise must be completed with the appropriate code. The coding list for the area of expertise can be downloaded off the CETCD website at **http://www.sc-ctsi.org/index.php/resources/education**.

   Section 2: Additional Information required by the NIH
   Please note this section is optional.

   Section 3: Educational /Academic Honors/Work Experience

Section 4: Letters of Recommendations

Please complete the contact information for Primary Mentor, Co-mentor, and Division Chief/Department Chair in the application. Primary and co-mentors will need to provide the applicant a PDF copy of their letter of recommendation, NIH Biosketch, and list of previous mentees in order to complete the PCT application submission process. The department chair/division chief must complete the letter of recommendation component, but does not need to submit an NIH Biosketch or list of previous mentees.

Supporting documents to be completed by the Mentors and Division Chief/Department Chair:

a. Letters of recommendations (maximum 2 pages) should be provided to the applicant as a PDF file by the:

- Primary mentor,
- Co-mentor, and
- Division Chief or Department Chair.

   Primary mentor and co-mentor should be able to comment on the applicant's qualifications relevant to the study of clinical/translational research and their commitment to a career in clinical or translational research as well as describing the qualifications of the applicant to conduct the proposed research project. Elaborate on the potential of the candidate to perform the research project and understand its implications for human disease and improvement of human health, particularly on urban populations. Elaborate on the commitment of the applicant to clinical and translational research and how this award would benefit him/her in continuing an independent career in this field. The Mentors should also describe their qualifications to mentor the applicant, and elaborate how this research project fits in with research conducted by the Mentor's. If the primary mentor is providing research space and/or financial support, he /she may submit a separate letter addressing this resource component. Mentors must ensure that they will uphold the required protected time of 100% effort for PCTs to spend on clinical/translational research and training activities while in the program.

   Division chief or department chair should be able to comment on the resources that they will provide to support the candidate's research for the years the candidate is in the program. Please be specific as to amount of space, number and kind of staff, clinical and lab resources, and dollars they will make available to the Trainee (this has an important impact on funding decision).   The division chief or department chair also needs to indicate their commitment to ensure that they will uphold the required protected time (100% effort for PCTs) for the candidate while in the program. If the primary mentor is providing research space and/or financial support, the department chair/division chief still must submit of letter of recommendation stating his/her support for the applicant.

b. A copy of each mentor's NIH style biosketch (no more than 4 pages, follow NIH guidelines for format and content) must be uploaded as a PDF file within the appropriate section of the online application. This is not a required element for the department chair/division chief.

c. A list of previous Scholars who worked with each mentor over the past ten years. Provide up to 5 publications of the mentees as a primary author. Include information on their current positions. This information must be uploaded as a PDF file within the appropriate section of the online application. This is not a required element for the department chair/division chief.

Section 5: Proposed Mentoring Plan

In a collaborative effort with mentors, please provide up to a one page outline/timeline with the following components as part of the mentoring plan:

a. Description of career development goals including timeline and strategy proposed to meet the goals (e.g., communications skills (written, oral, multidisciplinary interaction, teaching, and research skills). Please include information on the frequency, duration, and when mentoring meetings will be initiated.

b. Specific benchmarks and anticipated completion of research project, and

c. Expectations regarding submission of application for extramural funding, manuscripts, and meeting presentations.

Section 6: Proposed Educational Plan

Please provide a one page statement on applicant's plans for educational development during the award (intention to pursue a Master of Science in Clinical and Biological Investigations, or other coursework, tutorials, or training). Include and describe structured activities, such as course work or technique workshops as well a specific benchmarks, and anticipated dates of completion. This portion of the application needs to include didactic courses that will be incorporated into the career development and mentored research experience. Also, explain how this educational plan will facilitate overall long-term career development goals.

Section 7: Proposed Research Plan

a. <u>Personal/Career Development Statement by the Applicant</u> (one page): A personal statement by the applicant describing his/her career goals, future commitment to clinical translational research, and how this research project would help him/her to achieve these goals. Elaborate on future goals, not on the past. Stress the new, enhanced research skills and knowledge that will be acquired as a result of the proposed award. Address how this award will allow you to accomplish your career/training goals. If an applicant has considerable research experience in the same areas as the proposed research, reviewers may find that the program will enhance their research career.

b. <u>Project Title</u>

c. <u>Research Project Address CTSI's Translational Priority Areas:</u> Please check at least one of the boxes provided on the application. The research project should address at least one of CTSI's translational priority areas.

d. <u>Structured Abstract:</u> The abstract is a summary of the proposed research project. The following sections must appear as part of the structured abstract (350 word limit):

   -*<u>Background</u>:* Provide background information on the research topic.

   -*<u>Research Question/Hypothesis</u>:* Concisely state the study hypothesis.

   -*<u>Design</u>:* Describe the study as retrospective or prospective. Identify the study design. Interventional studies should be listed as a randomized clinical trial, non-randomized clinical trial, interventional case series, or interventional case report. Observational studies should be listed as a case control study, cross-sectional study, cohort study, or observational case

series. A perspective, meta-analysis, or auto-designation study should be indicated, as appropriate.

   -*Participants/Animal:* State the number of persons/animals and/or the number of controls if a separate control group is included.

   -*Methods/Approach:* Concisely, describe the principal treatment(s), procedure(s), test(s), or observation(s) to be performed in order to answer the research question.

   -*Main Outcome Measures*: Defines the main parameter(s) being measured (e.g., intraocular pressure, vision, electroretinography, inflammation, etc.).

   -*Innovation:* Briefly summarizes the anticipated research results or innovative contributions/impact.

e. Specific Aims (one page): State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology that can be developed to improve health or health care.

f. Research Strategy (no more than four pages): Organize the Research Strategy in the specified order and using the instructions provided below. Start each section with the appropriate section heading *(Significance, Innovation, and Approach)*. Study details should be cited using the Bibliography and References Cited section and need not be detailed in the Research Strategy.

   -*Significance/Relevance*: 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. State the relevance to health problems in general and to health problems in urban settings where relevant.

   -*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.

   -*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. 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.

g. <u>Preliminary Data</u> (no more than two pages): Include relevant preliminary data (graphs, tables, micrographs, etc.) that support the hypothesis and are in line with the Specific Aims. **Note:** The purpose of preliminary data is to demonstrate, where relevant, work that the candidate has already initiated on his/her research project, but not to demonstrate full competency in the applicants' research approach. If no preliminary data is available, relevant data from outside sources maybe used for this section. Please reference outside sources under the cited literature section of the application.

h. <u>Literature cited</u>: Authors, title, journal, volume, pages, and year. Do not exceed 25 references. Cited Literature must be specifically related to the applicant's research.

i. <u>NIH Bio Sketch</u> of the applicant (four pages)-Please refer to NIH website link for format and additional information: **http://grants.nih.gov/grants/funding/phs398/biosketch.pdf**.

j. <u>Reprints</u>: Please provide PDF copies of the first page of the reprints of applicant's previous publications related to applicant's current research proposal. The first page of the reprint must include the abstract.

Section 8: Applicant's Proposed Budget

Please complete all budgetary information under the corresponding application type (KL2 or PCT). All questions pertaining to current award status and financial aid must be completed as well.

Section 9: Signature Page

Applicant and mentors' signatures must be obtained to complete the submission process. The signature page can be found on the last page of the application. Please download the signature page form. Once signatures have been obtained, please upload a PDF copy of the signature page to complete the submission process.

The deadline for submission of the application is at 5:00pm on December 16, 2011. Incomplete applications, applications that do not adhere to the requirements, and/or applications submitted after the deadline shall not be considered for review.

Please complete and upload all required documents within the appropriate sections of the online application form at https://redcap.sc-ctsi.org/surveys/?s=9HSgtK.

Receipt, Review, and Award Schedule

Call for Applications/Application Format Available	September 2011 – December 16, 2011
Deadline for Letter of Intent	November 18, 2011 (5:00pm)
Deadline for Application Submission	December 16, 2011 (5:00pm)
Notification of Interview Appointment	February 8 – 10, 2012
Interviews of selected Applicants & their Mentors	February 13 – 23, 2012
Initial Notification of Awards	March 1 – 2, 2012
Trainee's NIH Appointment Process	March 5, 2012 – June 29, 2012
Appointment Start Date	July 2, 2012