



**RFP: C-DOCTOR ITP Team Awards for the
Clinical Translation of Tissue Regeneration Technologies
Targeting Dental, Oral, or Craniofacial Indications**

Background:

The Center for Dental, Oral, Craniofacial Tissue and Organ Regeneration (C-DOCTOR) combines customized product development advice, core resources, and funding to help drive promising dental, oral and craniofacial tissue engineering and regenerative medicine (TE/RM) technologies toward human clinical trials. This resource center was established through NIH/NIDCR RFA-DE-17-001 and operates with funding and programmatic oversight from the NIDCR.

C-DOCTOR provides clinical, scientific, industrial and regulatory expertise to advance promising strategies for regeneration and reconstruction of dental, oral, and craniofacial tissues to clinical trials by facilitating access to a diverse network of experts and resources from eight renowned centers of translational research excellence - UCSF, USC, UCLA, UCB, UCD, UCSD, City of Hope, and Stanford. Within this context, C-DOCTOR will nurture an active, close collaboration with Interdisciplinary Translational Project (ITP) Teams to foster pre-clinical refinement of TE/RM products, optimal alignment with unmet clinical needs, market potential, and anticipated patient value.

The current request for proposals (RFP) will support one year awards for ITP teams to access C-DOCTOR resources for studies to refine their Target Product Profile and Product Development Plan. The programmatic goals for these grants are to: 1) attract existing and new technologies that address unmet clinical needs and have a strong commercial case; and 2) enhance ITP value and success probability through collaboration with C-DOCTOR faculty and advisors. ITP teams that have successfully met their milestones can apply for future C-DOCTOR funding to support aggressive pre-clinical development and commercial partnering that enable an IND/IDE submission to the FDA.

Selected ITPs will work closely with C-DOCTOR resource directors to address pitfalls, alternative approaches, and countermeasure strategies. They will be matched with appropriate experts and resources available within the C-DOCTOR network, which include: animal models; biochemistry; biomarkers, functional testing, and histology; biomaterials and biomechanics; biomedical informatics; biostatistics; cell/GMP manufacturing facilities; clinical research planning; commercialization; drug discovery, delivery, and toxicology; genomics; imaging; and regulatory science and reimbursement. Please see [our website](#) for further information about available resources.

Award Process:

The C-DOCTOR award process is supported by a panel of expert advisors from academia, clinical practice, regulatory science, and industry. Successful applicants progress through four distinct selection processes to receive critical feedback, expert consulting, and funding for their ITP.

The first stage involves a two-page pre-proposal that provides an overview of the ITP team, the TE/RM strategy, the unmet clinical need, and potential for clinical adoption (see details below).

For the second stage, a select number of ITPs will be invited to submit a five-page proposal (in February 2018) that will be reviewed by the C-DOCTOR expert panel and NIDCR program staff to help highlight research progress to date (e.g. robustness of pre-clinical data), validity of the models and appropriateness of outcome measures, as well as remaining key gaps that need to be addressed to strengthen their likelihood of securing IND/IDE approval from the FDA to launch clinical trials, and future commercialization and clinical adoption.

In the third stage, the C-DOCTOR Resource Core Director and Operations team will provide help to high-scoring ITPs in order to address gaps that were identified by the review panel and work to refine their budgets. These finalists will be invited to present their proposals in front of the C-DOCTOR team, advisors, and NIDCR program staff prior to the final funding decision by the C-DOCTOR Leadership Council.

Eligibility:

ITPs from *both the public and private sectors* are invited to address unmet clinical needs in the following areas:

- vascularized and innervated craniofacial bone and musculoskeletal complex
- periodontium
- tooth
- cartilage
- salivary gland
- temporomandibular joint (TMJ)
- skin and soft tissue scarring

Faculty in all series and ranks at any U.S. or foreign institution, and individuals from U.S. companies of any size can apply.

Only projects with a clear clinical indication (or use case) and early target validation or proof-of-concept data will be eligible for consideration. We expect applicants to provide *in vivo* evidence of efficacy for the intended craniofacial indication. The therapeutic area can cover priority areas listed above, or other unmet medical needs in dental, oral and craniofacial tissue engineering and regenerative medicine. If patents or patent applications have not been filed, there should be a strong potential for obtaining defensible intellectual property. A list of awardees from the Spring 2017 cycle is available on [our website](#).

Note that the Michigan-Pittsburgh-Wyss Regenerative Medicine Resource Center (MPWRM) is also accepting applications through a companion RFP at this time. However, you may only submit to **one** center on this cycle. Please refer to the center websites, [c-doctor.org](#) and [doctrc.org](#), respectively, for further information that may help you to decide which opportunity to pursue.

Pre-proposal application:

Please submit your ITP project pre-proposal online via <https://cdoctor.submittable.com/submit> by **January 12 (5 p.m. PST)**.

- **Proposal narrative (2 pages).** Please use the provided template available [here](#). The narrative should address:
 - Significance
 - Unmet clinical need, total addressable market, potential for clinical adoption
 - Innovation and Impact including:
 - Current stage of technology, early target validation or proof-of-concept data
 - Competition
 - How is the clinical need currently addressed?
 - Work plan strategy and Aims
 - Studies proposed to enhance commercialization potential
- **Biosketches:** Provide NIH-style biosketches for PI and any co-PIs, as a single PDF. Use PHS 398 NIH Biographical Sketch Format Page form (5-page maximum per person) found at <https://grants.nih.gov/grants/forms/biosketch.htm>.
- **Budgets:** Budgets are not required for pre-proposals. Full application budgets for initial awards will be up to \$150,000 in total costs for one year, to be used for C-DOCTOR Resource Services and/or work conducted in the investigators' laboratories, and will not include PI salary. Each project will receive free mentoring and project management support. If you are affiliated with a company or a non-C-DOCTOR university, or if you plan to have subawards, the total direct cost may decrease. Contact [Dr. Dezba Coughlin](#) for further information.

Contact Info: For more information, please contact Dr. Dezba Coughlin (dezba.coughlin@ucsf.edu) or Dr. Bridget Samuels (bdsamuel@usc.edu).