

Clinician Scientist Research Award R50 PAR Concept

Office of Cancer Centers
and Coordinating Center for Clinical Trials

Background

- Outstanding clinical investigators at academic institutions carry out activities that are critical to the success of NCI clinical trials
- Research activities include accruing patients, developing national trials, and providing leadership for the clinical trials infrastructure of institutions
- Clinical duties and requirements to generate clinical revenue make it difficult for clinician investigators to dedicate the necessary time to clinical research activities
- Encouraging a career path in academia with stable funding is vital to retaining these clinician scientists

Purpose of the Clinician Scientist Research Award

- Provide a career path and stable salary support for outstanding clinician scientists who want to focus on the design and conduct of NCI-funded clinical trials but who do not seek independent research funding

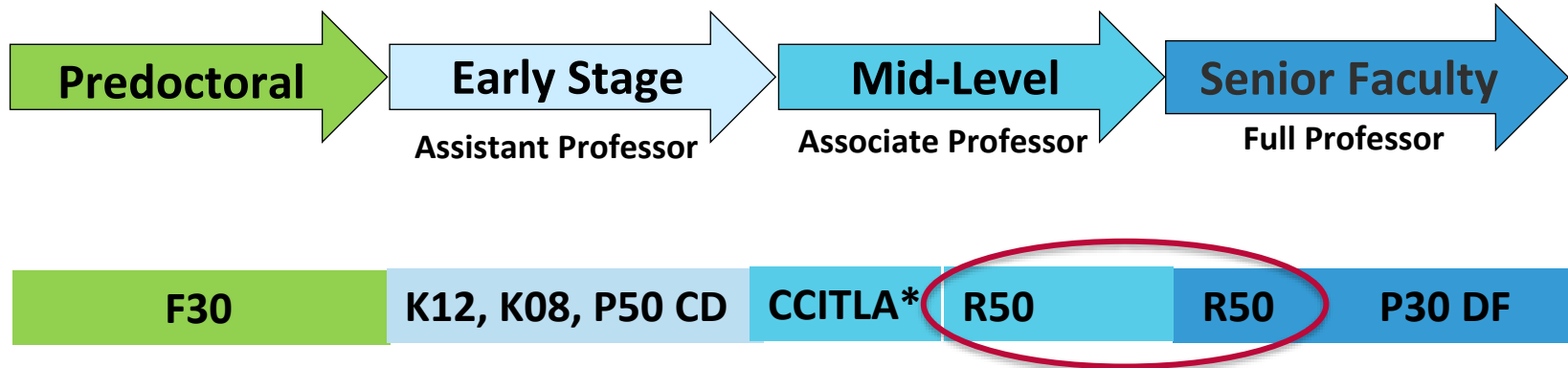
Portfolio Analysis

- There are no mechanisms currently offered by NCI that provide a clinical career path with *sustained* salary support
- Related mechanisms:
 - Cancer Clinical Investigator Team Leadership Award (CCITLA)
 - P30 Developmental Funds – Clinical Staff Investigator
 - K12 and K08 – Early-stage clinician scientist *mentored* research training
- Research Specialist R50 award mechanisms are for laboratory or core-based scientists

CCITLA

- Provides *recognition and limited support* for outstanding mid-level clinical investigators at NCI-designated Cancer Centers who are actively engaged in NCI-funded collaborative clinical trials
- Administrative supplement to P30 grant; not individual award
- \$60,000 per year for 2 years (~15% effort); *non-renewable*
- 8 to 12 awards per year; 132 awardees since 2009
- 96% of recipients who have completed award (n=114, 2009-2018) are still in academic clinical research positions

NCI Grant Funding for Clinician Scientists



*CCITLA would switch towards earlier stage
CD=Career Development; DF=Developmental Funds

R50 Proposed Eligibility

- Clinician scientists who have a clinical degree (M.D., D.O., D.D.S., D.M.D., O.D., D.C., PharmD., N.D., D.V.M.), possess active licensure, and are actively practicing in an oncology clinical setting
- Individuals with a Ph.D. or other doctoral degree in clinical disciplines with direct patient contact such as clinical psychology, nursing, clinical genetics, speech-language pathology, audiology, or rehabilitation
- Cannot hold R01, P01, or other significant NIH funding (not including R03, R21, or K awards at time of award)
 - P30 funding or P50 Career Development awards, or national network funding allowable
 - Past funding will not affect eligibility

Application Requirements

- 20% to 40% effort; maximum NCI funding cap of 50%
- NIH biosketch, letter of institutional support, 3 letters of recommendation
- Engaged in the conduct of NCI-funded cancer clinical trials at an academic medical center
- Track record of involvement in cancer clinical trial-related activities
- Any academic institution that carries out significant NCI-funded clinical trial activity is eligible

Clinical Activities in Support of NCI-Funded Trials

- Accrual to NCI-funded clinical trial networks
- Development of national trials
- Leadership in NCI networks, such as the NCTN steering committees, national or site Principal Investigator of trials, etc.
- Leadership in the institution's clinical trials infrastructure
 - Examples: Directing and participating in activities of the clinical trials office, institutional review board, protocol review, and audit and data safety monitoring committees
- Leadership of the institution's disease- or modality-based groups
- Special activities to ensure the inclusion of underserved populations in the institution's clinical trials

Budget

- Anticipate ~ 26 awards total in the first year
- Estimated total cost per award of \$115,000 (average effort of 30%)
- \$3M total cost the first year
- 5-year total cost - \$15M
- Anticipate fewer awards in years 2 and 3 as with existing R50 PARs

Evaluation

- **Initial effectiveness:** number of applications, the strength of the applications as judged by peer-review, and the number of awards ultimately funded
- **Long term:** Increase in accrual to NCI-funded clinical trials, participation and leadership in institutional committees, publications of the awardees, and retention of awardees in clinical research
- Awardee and institutional assessment of the value of the mechanism

Updates in Response to BSA Feedback

- Scope and eligibility:
 - Clinician scientists can be engaged in any part of the spectrum of NCI-funded clinical trials (early phase, late phase, cancer control etc.)
 - Not intended for clinician scientists that focus on industry trials
 - Ph.D. clinician scientists must have direct patient contact
- Total NCI grant effort capped at 50%
- R50 is a renewable mechanism
- Each institution or cancer center will be limited to three applications in a calendar year (one per receipt date)
- Language to improve the diversity of the research workforce will be included in the funding announcement

Appreciation

- Henry Ciolino (OCC)
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- Debbie Jaffe (CCCT)



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