



DEC 07 2007

TO: Raynard S. Kington, M.D., Ph.D.  
Deputy Director, NIH

FROM: Deputy Director for Management

SUBJECT: Proposed Modification of the NIH Title 42 Pay Model

As Chair of the NIH Compensation Committee, and at the request of the Deputy Director for Intramural Research, NIH, I am requesting your approval to modify the NIH Title 42 Pay Model to incorporate the newly established Intramural Professional Designation (IPD) of "Assistant Clinical Investigator" under Intramural (Clinical), Band II.

This new IPD will apply to talented investigators who intend to pursue advanced clinical research and are not quite ready for the Tenure Track. The creation of the Assistant Clinical Investigator IPD is based on the difficulty clinical researchers have in competing for tenure-track positions in the absence of a period of graduated independence. The creation of this new IPD represents a realignment of resources based on the potential for independent work (reviewed by a Board of Scientific Counselors). A draft definition of Assistant Clinical Investigator is proposed here:

An Assistant Clinical Investigator is an NIH employee on a time-limited appointment. Assistant Clinical Investigators are chosen through a selective, merit-based process that extends beyond the NIH. This position represents a commitment by the IC of independent resources, including salary, operating budget, personnel, and space, which should be documented in a letter of agreement filed with the Deputy Director for Intramural Research along with the candidate's CV. There also must be a mentoring plan. Research resources are adjusted based on scientific merit, based on recommendations of the BSC.

The assistant Clinical Investigator is a position designation for scientists whose abilities and focus in research make them candidates for tenure-track positions at NIH for which they may compete. As such, individuals in this position are on a career path that ultimately, if successful, may lead to formal consideration for tenure-track and tenure.

Assistant Clinical Investigators enter these positions following completion of clinical research experience as Clinical Fellows and Instructors, i.e., some form of

postdoctoral training or its equivalent. This training may have occurred inside or outside of NIH. Although there are no formal criteria for the length of postdoctoral training, training must be sufficient to allow for an evaluation of the scientist's potential for independent work.

Assistant Clinical Investigators are appointed for 3 years with 2 possible 1-year extensions. This time will allow the Assistant Clinical Investigator to establish himself or herself as a candidate for advancement.

To establish an equitable and consistent pay range for "Assistant Clinical Investigator" as compared to their peers who are similarly qualified and performing at comparable levels, your approval is requested to assign this IPD to Intramural (Clinical), Band II.

*Colleen Barros*  
Colleen Barros

✓  
Approved: \_\_\_\_\_

Disapproved: \_\_\_\_\_

Deputy Director, NIH

Date: \_\_\_\_\_

*[Handwritten signature]*

12/13/17

## **Revised Research Track to Support Careers in Clinical Research at the NIH**

**From the Clinical Careers Work Group of the NIH Advisory Board for Clinical Research  
August 2007**

In 1997, Dr. Stephen Straus chaired the NIH Committee on Recruitment and Career Development of Clinical Investigators. He introduced the subject by writing: At the NIH, the morale of clinical investigators has waned in recent years, and clinical investigators have begun to feel undervalued and under-supported. He continued, however, to acknowledge that the NIH, with its Clinical Center and large research portfolio has the ability to transcend these problems and to remain a bastion of clinical research excellence. The continuation of these efforts he initiated in the late 1990s is a tribute to his memory and dedication to the careers of present and future clinical researchers at the NIH. [<http://www1.od.nih.gov/oir/STRAUS/Report.html>]

A decade later, the NIH has a wonderful new Clinical Research Center, but clinical investigators face the same issues identified by Dr. Straus and his committee. Despite new hiring authorities, NIH salaries continue to lag behind those in academia for many specialties, the cost of conducting clinical research outpaces inflation, and careers of clinical researchers remain less defined than those of their laboratory research counterparts. Dr. Straus' committee explicitly noted that:

Staff Physician [Clinician] appointments are being used to circumvent the tenure process. More than half of Staff Physicians [Clinicians] spend less than the requisite 50% of their time on clinical service obligations; many of them control substantial independent budgets. Staff Physicians' [Clinicians'] appointments must be distinguished from tenured investigators' and both appointment mechanisms must be used properly.

The same concerns exist in 2007 and led the Clinical Careers Work Group of the Advisory Board for Clinical Research to develop a revised research track to honor and enhance the careers of independent clinical researchers and to foster their advancement to tenure.

### Blue Ribbon Panel on the Future of Intramural Clinical Research

This Blue Ribbon Panel was the next group to examine the issue of careers for clinical researchers at the NIH after it was established by NIH Director Elias Zerhouni in 2003. The Panel was chaired by Edward J. Benz, Jr., M.D., President, Dana-Farber Cancer Institute, and co-chaired by Joseph L. Goldstein, M.D., Professor and Chairman, Department of Molecular Genetics, University of Texas, Southwestern. It issued a report in January 2004. Among other conclusions, it believed that it is critical for the Intramural Clinical Research Program to develop novel programs that will attract clinical investigators to Bethesda, both as a training ground and as a place to conduct world class research. The Panel also advised that steps needed to be taken and methods developed to elevate the status of clinical research within the NIH enterprise.

Summary of the Panel's discussion and recommendation concerning the development of new training and career pathways in patient-oriented research.

The Panel specifically recommended that NIH strengthen career pathways and mentoring in the Intramural Clinical Research Program for patient-oriented research that would culminate in tenure. It concluded that "individuals in these pathways should be provided with the necessary infrastructure to achieve success as defined by clearly defined benchmarks. Clear distinctions should be made between the clinical service role and that of investigators with independent research resources."

The Panel also addressed the role of a staff clinician at NIH by noting that this role varies widely, from an individual doing service work to a young clinical investigator conducting research. It concluded that the recruitment, role, and review of staff clinicians should be redefined. The Panel

recommended that staff clinicians whose major focus is clinical research should be treated like other tenure-track scientists, recruited through an open search, and provided with independent research resources and an improved compensation package. The Panel suggested a possible separate, appropriate designation, such as clinical investigator, for these individuals, while reserving the Staff Clinician designation for those who truly function primarily in a service role.

NIH Follow-up Actions in Response to the Blue Ribbon Panel:

A. Benchmarks:

The Board of Scientific Directors approved revised guidelines for tenure that clearly enunciate the importance of team science that includes much of the clinical research conducted at NIH. Specific language includes phrases like:

- Clear evidence of distinct intellectual contribution to the outstanding research of a multidisciplinary team should be documented, such as: independent publication of methodological or seminal contributions to the candidate's specific research area.
- Letters of recommendation should address the distinct contribution of the individual within the larger context of the multidisciplinary team effort.
- Creative and unique contributions to team productivity should be documented in the reviews of advisory boards charged with program oversight and evaluations.

The full text of the revised tenure guidelines with the highlighted changes to reflect team science are found in Appendix A.

B. Creation of the Advisory Board for Clinical Research and a Working Group on Clinical Careers:

In response to the Blue Ribbon Panel Report, the Advisory Board for Clinical Research was created to replace the Clinical Center Board of Governors; one of its stated long-range goals is to develop new training and career pathways in patient-oriented research.

A Working Group, initially chaired by Dr. Lee Helman, and subsequently Dr. Lynnette Nieman, was established. Over time, members have also included Cliff Lane, M.D., Joan Reede, M.D., MPH, MS, Henry McFarland, M.D., Olufunmilayo Olapade, M.D., Monica Skarulis, and Stephen Straus, M.D. Richard Wyatt, M.D. and Frederick Ognibene, M.D. are principal staff for the group.

Thus, this Working Group set out to develop meaningful career pathways and selection mechanisms for outstanding tenure-track and tenured clinical researchers at the NIH and to describe a clear continuum in career track for the development of future independent tenured clinical researchers at the NIH from the student to Clinical Fellow to tenure-track Investigator to Senior Investigator.

Its first approach was to develop and recommend to the ABCR three nationally advertised, 3-5 year intramural training programs in clinical, basic and translational research, with central funding and administration, to provide salary and independent research support for post-doctoral clinicians. In an era of flat and constrained budgets, this approach for new funding was not promulgated, pending a mechanism to fund these programs. [MEC Minutes, November 7, 2006, [http://intranet.cc.nih.gov/mec/agendas\\_minutes/minutes/2006/mec\\_minutes\\_11-07-06.htm](http://intranet.cc.nih.gov/mec/agendas_minutes/minutes/2006/mec_minutes_11-07-06.htm)]

The Working Group then undertook to describe carefully-articulated intramural clinical research career pathways. Problems included the perception that clinical investigators cannot be tenured and possibly that flat resources and ethics issues are a disincentive to hire clinical investigators.

In response to the former, a flow chart depicting Intramural Professional Designations (IPDs) was created to delineate the presence or absence of independent resources (Appendix B). The chart shows comparable extramural titles in parallel to IPDs. It is important that significant independent

resources be reviewed by BSCs, and the chart is meant to realign who is to be reviewed and who is not. There is need for a new IPD for pre-tenure track clinical researchers, designated Assistant Clinical Investigator (subject to a search to identify the best candidates), who would be entitled to independent resources.

The title of Assistant Clinical Investigator is presently used for an advanced Clinical Fellow, but would become a position comparable extramurally to an assistant professor. The advanced Clinical Fellow could be designated as an Instructor or another appropriate term and would not likely require the creation of a new IPD. The IPDs of Clinical Fellows, Tenure-track Investigators, and Tenured Senior Investigators are attached to this document (Appendix C).

This new IPD will apply to talented investigators who intend to pursue advanced clinical research and are not quite ready for the Tenure Track. The creation of the Assistant Clinical Investigator IPD is based on the difficulty clinical researchers have in competing for tenure-track positions in the absence of a period of graduated independence. The creation of this new IPD represents a realignment of resources based on the potential for independent work (reviewed by a Board of Scientific Counselors). A draft definition of Assistant Clinical Investigator is proposed here:

An Assistant Clinical Investigator is an NIH employee on a time-limited appointment. Assistant Clinical Investigators are chosen through a selective, merit-based process that extends beyond the NIH. This position represents a commitment by the IC of independent resources, including salary, operating budget, personnel, and space, which should be documented in a letter of agreement filed with the Deputy Director for Intramural Research along with the candidate's CV. There also must be a mentoring plan. Research resources are adjusted based on scientific merit, based on recommendations of the BSC.

The assistant Clinical Investigator is a position designation for scientists whose abilities and focus in research make them candidates for tenure-track positions at NIH for which they may compete. As such, individuals in this position are on a career path that ultimately, if successful, may lead to formal consideration for tenure-track and tenure.

Assistant Clinical Investigators enter these positions following completion of clinical research experience as Clinical Fellows and Instructors, i.e., some form of postdoctoral training or its equivalent. This training may have occurred inside or outside of NIH. Although there are no formal criteria for the length of postdoctoral training, training must be sufficient to allow for an evaluation of the scientist's potential for independent work.

Assistant Clinical Investigators are appointed for 3 years with 2 possible 1-year extensions. This time will allow the Assistant Clinical Investigator to establish himself or herself as a candidate for advancement.

As for Staff Clinicians, some would be hospitalists (primarily a service role). A small number could have independent resources for the time being, and some could move into Assistant Clinical Investigator, tenure, or tenure track positions after an appropriate search. At present, approximately 25% of Staff Clinicians have independent resources, and not all are reviewed by BSCs. The new IPD of Assistant Clinical Investigator would give status to early independent clinical researchers and allow resources to be assigned.

This concept was endorsed by NIH leadership, including the Scientific Directors (June 6, 2007), the Medical Executive Committee, (June 19, 2007) and the Intramural Working Group (June 13, 2007\*); the ABCR also endorsed this approach.

Dr. Gottesman also distributed a draft of this flow chart to the Chairs of the NIH BSCs at their annual meeting in June 2007. He told them it corrects a lack of intermediate positions between

fellowship and tenure-track status for physician scientists. He added that once this intermediate position is formalized, they as BSCs should begin seeing candidates for review.

Pay Proposal for new Assistant Clinical Investigator and Instructor:

Assistant Clinical Investigators would be paid using the same pay table as for tenure-track Investigator (Clinical) and Staff Clinicians. Salaries are highly dependent on medical specialty or unique combination of medical specialties, and this proposal gives maximum flexibility to the ICs in setting salaries for Assistant Clinical Investigators. The full NIH Title 42 pay model in its current state of development is found in Appendix D and at the following site:

<<http://www1.od.nih.gov/oir/sourcebook/personnel-appt/Title42PayRanges2007.pdf>>

“Instructors” would continue to be paid on the Clinical Fellow scale based on PYG. The recognition of conferring the title “Instructor” would be used at the discretion of the IC to adjust pay upwards.

**Appendix A**  
**Criteria for Tenure at the NIH**  
**[with Highlighted Changes that Accommodate Team Science]**

- ! High quality, originality and impact of scientific contributions to a specific field and biomedical research more generally
  - quality of studies, including scientific rationale and methodological rigor
  - innovation and originality in the form of new ideas, approaches, discoveries and paradigms that open lines of further inquiry, including discovery and development of technological approaches, as well as design, development and implementation of clinical trials and population studies
  - scientific, clinical and/or public health impact of published work
  - upward trajectory of research contributions expected following tenure
  - for members of multidisciplinary teams, continued high quality, original research following tenure is expected even if the multidisciplinary team disbands
  
- ! Independent creative effort
  - independent research as evidenced by primary and senior authorship on original research publications
  - for team research, clear evidence of distinct intellectual contribution to the outstanding research of a multidisciplinary team, such as: independent publication of methodological or seminal contributions to the candidate's specific research area; where possible, explicit in-print acknowledgement of unique creative contributions in multi-author publications and/or selection for presentation of team findings at national and international scientific conferences; members of research teams should demonstrate peer recognition of their specific contributions and some publications should highlight their distinctive research; creative and unique contributions to team productivity should be documented in the reviews of advisory boards (internal, scientific, BSC) charged with program oversight and evaluations
  
- ! Productivity relative to resources
  - quality and quantity of publications (e.g., an original paper in a high-impact journal is considered more consequential than several papers in specialty, lower-impact journals; for members of multidisciplinary teams, primary or senior authorship on key publications from the team or middle-authorship in a paradigm-shifting paper from the team)
  - reputation of journals in which peer-reviewed papers are published, including specialty journals appropriate to the candidate's field
  - patents, CRADAs, bioinformatics tools for public use or public release of widely-used software even if not published in conventional journals, that constitute significant contributions to science
  - timely deposition of data (in particular, large data sets) in freely available, public databases; recognition given to high-quality data made available electronically to the research community, in some cases not directly linked to conventional journal publication(s)
  
- ! National/international recognition and leadership
  - peer recognition for developing an important body of work with a unifying theme, evidenced in letters of recommendation from the leaders in the field; for team research, the letters should address the distinct contribution of the individual within the larger context of the multidisciplinary team effort
  - invited lectures and review or commentary publications
  - membership on editorial boards or as invited journal reviewer
  - participation in grant review panels for NIH or other funding organizations
  - ability to forge multidisciplinary partnerships, taking advantage of the breadth

- and depth of the NIH scientific and clinical environment
  - honors and awards
  - election to scientific societies
- IC programmatic need that evidences distinct and important contributions to the mission of the NIH may be considered

- ! Mentorship abilities and activities
  - success in training and mentoring junior colleagues at all levels as evidenced by their professional progress, competitive funding and/or publications

! High ethical standards and integrity in directing and conducting research

- ! NIH citizenship and collegiality
  - IC or NIH-wide activity or committee participation (e.g., Scientific Interest Group, IRB, ACUC, WSAs, Faculties, etc.), clinical service and other activities that promote the scientific enterprise at the NIH and more broadly

#### Documentation to Assess Fulfillment of the Criteria for Tenure

- Updated and accurate C.V. and bibliography, including all necessary information that addresses the criteria for tenure
- Letters of recommendation from the leaders in the field (at least 6 from non-collaborators)
- BSC reports, with particular emphasis on the most recent one (must be within the past 2 years for the Central Tenure Committee); for team research, also include relevant sections of reports prepared by program-specific internal oversight and scientific advisory board(s) documenting creative and distinct contributions to team productivity
- Recommending memorandum from the Laboratory/Branch Chief, team leader or Scientific Director, through IC Director, specifically addressing the recommendation for tenure
- Report of the IC Promotion & Tenure Committee (only for tenure-track candidates)
- Report of the DDIR-approved Search Committee (only for outside candidates)
- The 5 publications that the candidate considers most important
- Description of future research plans by the candidate (no more than 5 pages)
- Detailed description of the resources (budget, personnel, space, other) available to the candidate from the beginning of the tenure track to date, with a timeline of changes during the tenure track (only for tenure-track candidates); for team research, also include a summary of resources made available to the candidate as part of the team program





**Appendix C**  
**Selected Intramural Professional Designations**

[from <http://www1.od.nih.gov/oir/sourcebook/prof-desig/intradesigns.htm>].

1. Clinical Fellow

A Clinical Fellow is a doctoral-level health professional with interest in biomedical research relevant to NIH program needs, who is employed on a time-limited appointment renewable subject to the five-year/eight-year rule. Clinical Fellows participate in protocol-based clinical research as well as laboratory research. Scientists with considerable experience beyond postdoctoral training (PGY-9 equivalent or beyond) may be designated Senior Clinical Fellows provided they fulfill the competitive selection requirements.

The purpose of a Clinical Fellowship is to provide junior-level physicians experience in biomedical research relevant to NIH's program needs. This position has both clinical and laboratory components, with some time spent in direct patient contact supporting the performance of clinical protocols and the rest in laboratory research related to these protocols. In some cases, Clinical Fellows may receive approved credit towards residency training, advanced subspecialty training, or Board certification.

To be eligible for the Clinical Fellowship, a candidate must be a graduate of an accredited medical or osteopathic school and have satisfactorily completed an internship approved by the Council on Medical Education and Hospitals, the American Medical Association, or the American Osteopathic Association. The candidate must have demonstrated outstanding scholastic achievement and the ability to conduct successfully, with minimal supervision, pre-established programs in both clinical and laboratory research.

Initial appointments are approved by the IC Scientific Director for 2 to 3 years. The maximum length of this fellowship is 8 years - the duration is determined by the length of time spent at NIH in all fellowship capacities - unless the scientist is approved for tenure-track or another permanent NIH appointment. (5/8 year Duration policy).

Because Clinical Fellows perform services for NIH in addition to the research experience, these positions apply against the IC's FTE ceiling. Appointments are made either through the Civil Service/Title 42 or the PHS Commissioned Corps. Title 38 provisions may be applicable.

More detailed information about the program and application process is available through the Office of Intramural Training and Education web site on: <http://www.training.nih.gov/>

2. Staff Clinician

A Staff Clinician is an NIH employee on a time-limited, renewable appointment or, by exception, on a permanent appointment for retention and recruitment reasons. The Staff Clinician is a physician or dentist who spends a majority of his/her time providing critical patient care services but who may also be the principal investigator on clinical protocols, under the supervision of a Senior Investigator.

The Staff Clinician is expected to provide clinical leadership and the highest level of clinical care. Performance will be evaluated on the level and quality of the clinical activities. Staff Clinicians in general will not receive resources to conduct independent laboratory or clinical research, and do not have oversight of independent resources.. However ICs may provide resources for research on a case-by-case basis. Such research must be sponsored and supervised by a tenured or tenure-track investigator

and undergo review by the IC Board of Scientific Counselors (BSC). Appointments are made following a recommendation by the Medical Executive Committee and approval by the NIH Associate Director for Clinical Research.

Most Staff Clinician appointments are made in Title 42. With regard to guidance concerning the possible use of permanent appointments for Staff Clinicians, there are three situations in which use of a permanent mechanism (General Schedule Civil Service or Commissioned Corps) might be necessary or appropriate, based on the needs of the Institute. (1) For recruitment of Staff Clinicians from outside the NIH: After an appropriate search has occurred, using the same process currently used to identify tenure-track candidates, the Scientific Director could request to the Deputy Director for Intramural Research that a permanent mechanism be used for the recruitment, based on the long-term necessity of the program/project, the likelihood that the candidate's skills will be relevant for the foreseeable future, and the difficulty in recruiting the candidate to the NIH using Title 42 at an appropriate salary. (2) For retention of Staff Clinicians already at the NIH: In exceptional circumstances, based on a long track record at NIH of high quality research or clinical support, productivity, and adaptation to changing programs, projects, and technologies, a Staff Clinician could be given a permanent appointment. This would require review by an Institute Promotion and Tenure Committee, followed by the request of the Scientific Director, through the IC Director, to the Deputy Director for Intramural Research for approval. (3) For scientists already at the NIH in a permanent GS position, appointment to a Staff Clinician position would be in a permanent GS position. Permanent appointments into Title 5 are made under special circumstances, when issues of recruitment or retention are involved. Use of a permanent mechanism requires approval by the Deputy Director for Intramural Research.

### 3. Investigator (tenure-track)

An Investigator is an NIH employee, who is a tenure-track scientist on a time-limited appointment. Investigators are selected by a competitive national search. A tenure-track position represents a commitment by the IC of independent resources, including salary, operating budget, personnel, and space. Research resources are adjusted based on scientific merit.

Investigator is a position designation for scientists whose abilities and focus in research make them candidates for permanent staff positions among the NIH independent scientists. As such, individuals in this position are embarked on a career path that, if successful, will lead to formal consideration for tenure.

Investigators enter tenure-track positions following completion of advanced research experience, i.e., some form of postdoctoral training or its equivalent. Such training may have occurred inside or outside of NIH. While there are no formal criteria for the length of postdoctoral training, training must be sufficient to allow for an evaluation of the scientist's potential as a tenure-track scientist.

The length of a tenure-track position may be up to 6 years (8 years for clinical and epidemiology investigators) to allow the Investigator to establish himself or herself as an independent scientist. (See the Timetable under the Tenure Program.)

In creating a tenure-track position, the Scientific Director (SD) solicits recommendations from senior institute scientists, Special Interest Groups, IC Promotion and Tenure Review Panel, and/or the IC Board of Scientific Counselors. (For further information see Search Process for Tenure and Tenure-Track Investigators.)

#### 4. Senior Investigator

A Senior Investigator is an NIH employee who has been granted tenure by the Deputy Director for Intramural Research (DDIR), after review and recommendation by the NIH Central Tenure Committee or the Senior Biomedical Research Service Policy Board. Tenure at the NIH is the commitment of salary to an independent Senior Investigator. Tenured Senior Investigators are granted independent resources (personnel, budget and space) by their Institute, and are required to have regular outside, expert review by Boards of Scientific Counselors. Resources may be adjusted up or down by the Institute, based on productivity and the quality of their work, as determined by these and other reviews.

Post-tenure evaluations of Senior Investigators are conducted annually by the Laboratory/Branch Chief or Scientific Director and every four years by the IC Boards of Scientific Counselors.

Tenure includes assurance of continuing salary even if scientific resources are cut back. The renewal of Senior Investigators is assumed, regardless of personnel mechanism, except in cases of malfeasance or if the Senior Investigator fails to remain a productive member of the scientific community. The amount of research support, however, must depend on the quality of science as determined by the BSC and other reviews.

**Appendix D**

