

Multidisciplinary K12 Career Development Program

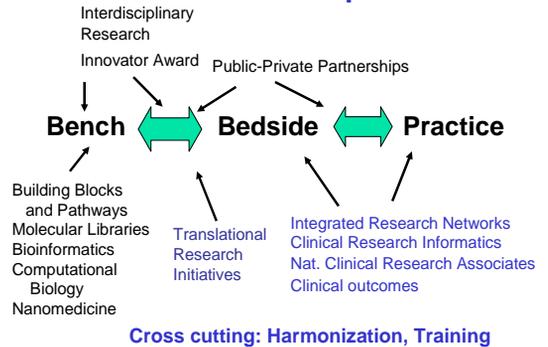
Pre-application Technical Meeting

Robert Star, MD
Joan Davis, MD, MPH

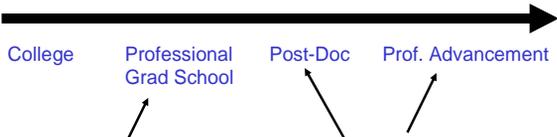
December 11, 2003



Re-engineering the Clinical Research Enterprise



NIH Clinical Research Career Development Programs



NIH Clinical Research Training Pgm; Multi-discip K12 Career Dev
Advanced Degree Programs Loan Repayment
Medical School Training Programs

Cross cutting: Trans-NIH Clinical Research Workforce Committee

Origins

Outside advice

Clinical Research Summit: Jan 30-31, 2003

Roadmap CR Workforce Implementation Committee

Duane Alexander and Andrew van Eschenbach, Chairs

25 Members

Subcommittee members:

- Joan Davis, NICHD
- Brian Kimes, NCI
- Barbara Mittleman, NIAMS
- Judy Salerno, NIA
- Walter Schaffer, OD
- Robert Star, NIDDK
- Judi Whalen, NICHD
- Linda Wright, NICHD

Trans-NIH Multidisciplinary K12 Career Development Program

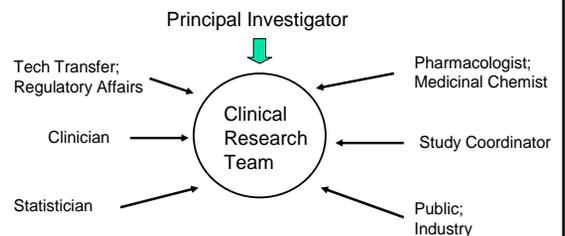
Goal

- Develop a national cadre of well trained clinical investigators
- Integrate clinical research training across an institution

Philosophy

- Improve viability of clinical research training pathway
- Formal training in the discipline of clinical research
- Clinical research apprenticeship performed in mentored multi-disciplinary team settings
- One stop shopping: Provide mortar to fill in gaps

Multidisciplinary Clinical Research Team To address a complex health problem



Members have unique skills and career paths
How to make each path viable?

Key features (at full implementation)

- 10 Training programs
- 20-25 Scholars per site; \$3.7 M/yr budget each
- Flexibility in % effort, salary up to NIH legislative cap
 - At least 75% effort for up to 5 years
 - Allow at least 50% effort for surgical specialties
- Core didactic courses, required the first year
 - Tuition support for advanced degrees
- Training in multi-disciplinary team settings
 - Project support for new studies: \$25K/year
- Faculty and mentor support to protect their time
- Shared research support facility: up to \$200K/year
- Annual meeting of Directors and Scholars at NIH

Program Director

- Senior faculty member or Director of a research center or multidisciplinary institute who possesses the scientific background, leadership, and administrative capabilities necessary to plan, direct, and manage the K12 program
- Strong and active track record in clinical research, clinical research training, and administration
- Leadership ability to work across professional and scientific boundaries
- 40% effort during planning phase; can split between two people (Co-PD)

Clinical Research (CR) Scholars

- Postdoctoral level health professionals and junior faculty from a variety of disciplines and clinical specialties (MD, DDS, PhD, PharmD, RN-PhD)
- Exposure to many disciplines
- Each yearly class should include CR Scholars whose backgrounds span at least two to three disciplines, specialty, and sub-specialty areas.
- When fully implemented, the Program should have CR Scholars in at least four disciplines or specialty and sub-specialty areas

Core didactic courses

- Course work in epidemiology, statistics, behavioral science, study design, regulatory compliance, bioethics, responsible conduct of research, mentoring, leadership and team building skills
- Curriculum may be individualized (allow different entry levels based on background/experience)
- Include regular journal clubs, seminars, grand rounds, etc. to facilitate the exchange of ideas, collaboration, and networking opportunities among CR scholars, mentors, and the Program Director
- Can use existing courses (K30, or other K12 programs), but fill in missing gaps or offer advanced courses

CR Scholar research projects

- Mentored research projects, Years 2-5
- On-going project under guidance of two mentors
- New research project to develop preliminary data
 - Institutional review by Multi-disciplinary Advisory Committee (MAC)
Must describe the process and review criteria, including the application, review, oversight, and evaluation procedures, and adherence to all Federal rules and guidelines regarding clinical research.
 - Funding pool: \$25K per year (can be up to \$50K)

Shared clinical research support facility

- To be used by CR Scholars for technical/other assistance ("research incubator")
- Should be dedicated shared facility – not part of an investigator's laboratory
 - Analyze infrastructure resources present/needed
 - May request these funds with strong justification
- Focus on training, developing protocols, research
 - Expertise in variety of clinical research/trial methods, descriptive and experimental methodologies, epidemiology, statistics, translation, informatics, etc.
 - Pool of study coordinators
 - Module for curriculum development and evaluation
- Initially \$100K per year; up to \$200K per year

Planning/Recruitment Phase

- Initial 6 months to set up needed infrastructure, and recruit first group of CR Scholars (\$250 K)
- Grant should list milestones needed to implement the program. ** Review criteria
- At 5 months, send progress report to NIH for administrative review
- If satisfactory progress, will get remaining funds (\$1M)

NIH involvement

- Planning meeting at NIH within 1 month
- Monthly phone calls
- Selection of scholars at site with final NIH approval (to ensure correct targeting and overall program balance)
- Annual meeting of Directors and Scholars at NIH
- Annual progress report
- Periodic site visits
- Tracking impact of program nationally

Application Format

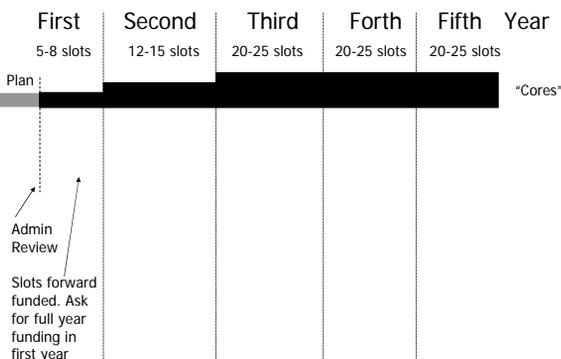
- Read carefully *special programmatic requirements, supplementary instructions, and review criteria*
- See web site: <http://www.nichd.nih.gov/RFA/HD-04-006/roadmap.htm>

- A. Lead Page
 B. Description, Performance Sites, and Key Personnel
 C. Table of Contents
 D. Detailed Budget Page for Initial Budget Period, separating the budget for the first 6 months (i.e., Planning Phase) from the second 6 months (i.e., initial implementation phase for 5-8 CR Scholars)
 E. Budget for Entire Proposed Period of Support that allocates the number of scholars to 12-15 in the second year and to 20-25 in the third, fourth and fifth years
 F. Biographical Sketches (not to exceed two pages per individual)
 G. Other Support
 H. Multi-disciplinary Clinical Research Career Development Program (no more than 40 pages)
- For Program Director, Co-director(s), Advisory Committee Members, Mentors, and Other Faculty of this Program
 - For the Program Director, Co-director(s), MAC members, Mentors, and Other Faculty of this Program
 - Multi-disciplinary Clinical Research Career Development Program (no more than 40 pages)
 - (1) Overall Aims
 - Approach/Meeting the Intent of this Initiative
 - Institutional Commitment
 - (2) Major Program Elements
 - Clinical Research Capability and Infrastructure
 - Program Leadership/Management
 - Include plans for Shared Clinical Research Support Facility
 - Program Leadership/Management
 - Multi-disciplinary Advisory Committee
 - Include plans for matching CR scholar to mentor
 - Include policies and procedures for the Research Project Support Program
 - Program Mentors/Team Leaders
 - Description of Clinical Core Requirements and Practicum research experiences
 - Interactions
 - (3) Candidate Pool and Recruitment Plans
 - (4) Evaluation/Tracking
 - (5) Funding Phase and Milestones

Tables

- Funded training and career development programs relevant to clinical research
- Existing funded clinical research support
- Clinical research infrastructure
- Expertise and training track record of program director, co-directors(s), MAC members, mentors, and other faculty.
- Clinical facilities, patients, and specialized populations

Budget – showing earliest start dates



First year budget

- \$250 K for first 6 months
 - 40% effort Program Director(s)
 - Costs to set up core curriculum, MAC
 - Find mentors, recruit CR Scholars
 - Administrative assistant, up to 0.5-1 FTE
- \$1 M for second 6 months
 - Core costs
 - Program director(s), 20% effort
 - Core curriculum costs
 - Shared research support facility 100K
 - Administrative assistant, up to 0.5-1 FTE
 - 5-8 CR Scholars – forward funded

CR Scholar

- Salaries set by institution; appropriate to background and experience
- Rough estimates
 - \$60-100K Salary
 - \$10-15K Benefits
 - \$25 K Research project support
 - \$10 K Mentors
 - \$ 5 K Tuition
 - \$ 5 K Misc (travel, etc)

Review Criteria

- Overall approach
 - Approach/meeting the intent of this initiative
 - Institutional commitment
- Major program elements
 - Clinical research capability and infrastructure
 - Program leadership/management
 - Multidisciplinary advisory committee
 - Program mentors/team leaders
 - Didactic core requirements
 - Interactions
- Scholar pool and recruitment plans
- Evaluation/tracking
- Planning phase

Institutional commitment

- Letters from high-ranking institutional officials
 - Integral component of the institution's broader vision
 - How are institutional barriers for clinical research and clinical researchers are being addressed
 - Guarantee protected time for the CR Scholars.

Important facts

- Letter of intent: February 23, 2004
- Application due: March 23, 2004
- New RFA Number: RM-04-006
- List serve
 - list.nih.gov/archives/clinrescareers.html
- Web site with FAQ
 - www.nichd.nih.gov/RFA/HD-04-006/roadmap.htm
- Table formats
- See web site **soon**

Contacts

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Questions

Only one entity from a university may apply to this program

- The Clinical Research Career Program should integrate existing clinical research training/career development programs and infrastructure within a university
- The program should perform effectively as one activity across institutional boundaries
- The application may come from any division, faculty, center, school, or hospital affiliated with the university
- Multiple applications will be returned without further consideration by the NIH. This includes any related not-for-profit organizations

Collaborating institutions

- Collaborating institutions may be included to supplement training activities in needed areas
- Encourage collaborations with minority institutions

What if we have another K12 program

- Show have sufficient resources (mentors, pool of potential CR Scholars, CR infrastructure) to support concurrent K12 programs
- Address how the K12 programs interact
 - How are the programs different? How will you decide who (i.e., mentors, Scholars) is in which program? Will the programs be separate and distinct programs that avoid overlap in terms of coursework and/or research topics?
- May use RM courses for other K12 pgms

What if the institution has a K30 or similar program

- Explain how the K30 or existing curriculum will interact with the Trans-NIH K12
 - Will the two programs be distinct? Will you use some of the K30 courses in the K12 program, then use K12 funds to develop new courses?

Can the program have a focus?

- The program must not be restricted to a single problem or disease (e.g. cardiovascular disease, cancer, diabetes, etc.). *Consider Roadmap Intra-disciplinary P20 center*
- The program should be dispersed across multiple health conditions
- During the practicum phase, we expect that an individual CR scholar's research projects may be focused on a single disease or health problem. However, the program should have a broad focus and representation from multiple disciplines and specialties

CR Scholar Applicant already in another K12 program

- The Scholar may transfer to the RM K12. However, the cumulative length of time under all K12 program should be ≤ 5 years
- Since the minimum amount of time any one Scholar may spend in this RM K12 program is two years, Scholar may not have had more than three years of support under the previous K12 program
- The applicant would need to justify why then need additional mentored research training or training in a team context

Are CR Scholars eligible to apply for individual K awards such as the K08 and K23?

- Yes, but this would require a very strong justification to convince peer reviewers of the need for additional mentored training
- Upon completing their training on the K12, CR Scholars should be prepared to submit a K22, R-type or U-type grant application (e.g. R03, R21, R01, U01, etc.)

NIH defines human clinical research as (from PHS 398)

1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Patient-oriented research includes:
 - Mechanisms of human disease
 - Therapeutic interventions
 - Clinical trials, or
 - Development of new technologiesExcluded from this definition are in vitro studies that utilize human tissues that can not be linked to a living individual.
2. Epidemiologic and behavioral studies
3. Outcomes research and health services research

Second year budget Rough estimates

2.17 M for

Core costs

- Program director(s) 20% effort
- Core curriculum costs
- Shared research support facility, 150K
- Administrative assistant: up to .75-1.25 FTE

12-15 CR Scholars

- Research project support 25K per scholar

Third year budget Rough estimates

3.7 M for

Core costs

- Program director(s) 20% effort
- Core curriculum costs
- Shared research support facility, 200K
- Administrative assistant, up to 1-1.5 FTE

20-25 CR Scholars

- Research project support, 25K per scholar

New NIH policy

To facilitate transition to independent NIH research support, all K award recipients can hold R, P, or U grants in last two years of their career award

- Permits candidates to continue to benefit from the protected time offered by the K award.
 - Will reduce percent effort on K12 award
 - Total level of research effort must not drop below 75%
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- See Grants.nih.gov/grants/guide/notice-files/NOT-OD-04-007.html