

# Review of the Bioethics Education and Career Development Award Program

Program Evaluation SIG  
September 13, 2005



# Evaluation

- Evaluation/Review is routine, scheduled at 5 year intervals (schedule developed with FIC staff)
- FIC Framework for Evaluation (developed with FIC staff in 2001)
- Each category has suggested questions and metrics - Modified for specific program reviewed
- Expert panel (identified with PO) review matrix, review analyzed data, conduct interviews with stakeholders, write report

# FIC Framework for Evaluation

- Program Planning
- Program Management
  - Project selection
  - Recruiting talent
  - Program components and institutional setting
  - Human subjects and fiscal accountability
- Partnership & Communication
- Results (in relation to input and goals and objectives)

# Program Planning

## Questions:

- What is the planning process?
- Role of stakeholders?
- How are program modifications implemented?
- What are the goals?
- How do goals fit into the main institution and partner's strategic plan

## Metrics:

Program planning documents (Journals); evidence of stakeholder involvement (meetings, papers); goals (RFA); relevance of goals to institutions involved (interviews)

# Program Planning

- Information for this section was obtained by the panel from the briefing book, interviews and presentations
  - Lancet, October 2000 Report on Global Forum for Bioethics Research
  - Issues in Medical Ethics, April –June 2001
- Capacity building need identified
- Need for courses on international bioethics research identified
- Goals and Objectives developed

# Recommendations

## Program Planning

"FIC should reassess the program objectives and modify them to take into account its accomplishments to date, current needs in developing countries, and the changing environment at NIH."

PIs identify country needs in proposals (RFA)

FIC should consider NIH partner needs – enhance interactions in developing countries - new objective (data chart : NIH Investment abroad vs. Number of LT bioethics trainees)

Rename "Fogarty International Research Ethics Education and Career Development award"

# Program Objectives

Improve the quality of international ethics training by supporting the development of courses that will provide the skills necessary for teaching and research related to bioethics and the conduct of ethical medical research in developing countries (R25).

# Program Objectives

- Develop and provide intensive short courses specifically designed for individuals directly involved in human subjects research, ethical review, and conduct of clinical trials in developing countries

# Program Objectives

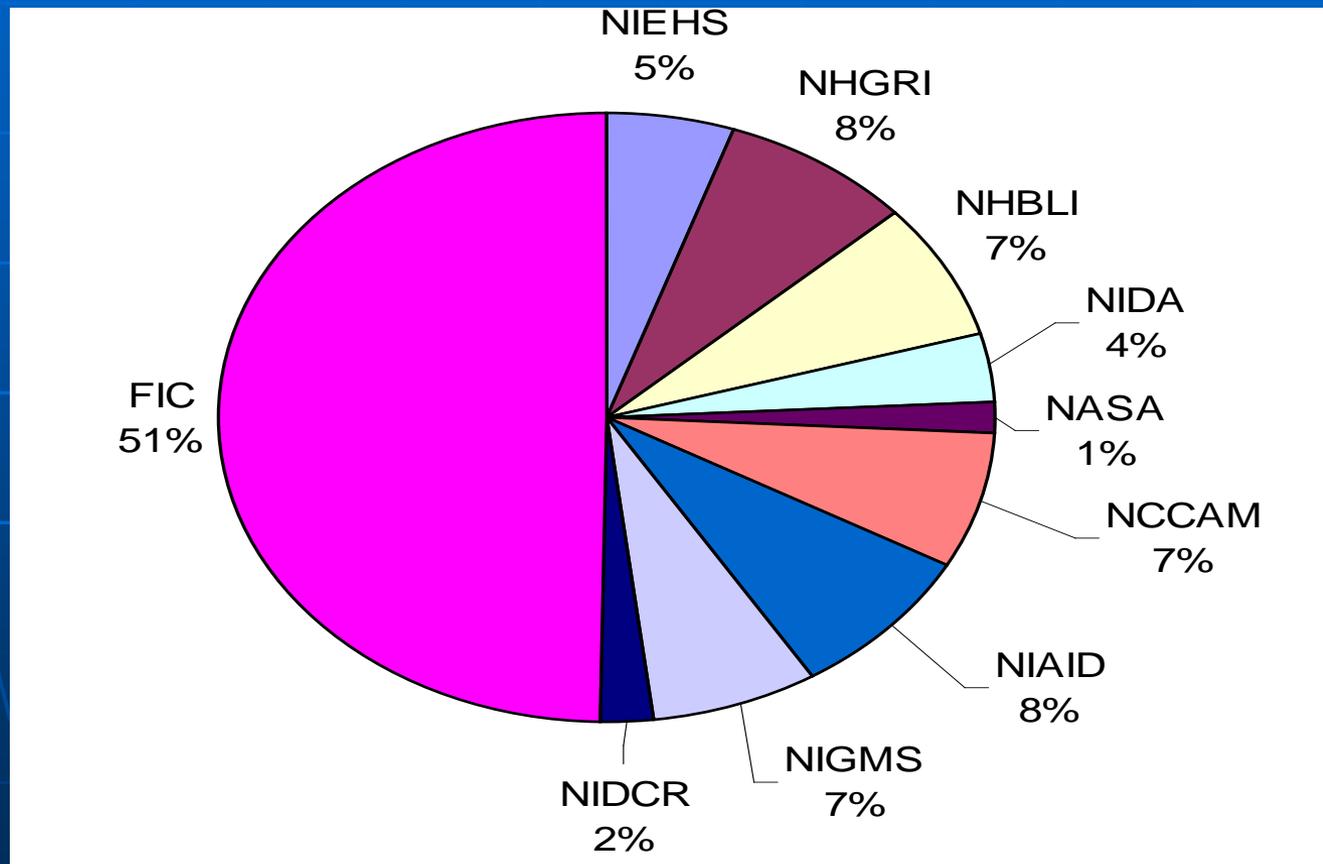
- Support the advanced training of developing country professionals who will assume the roles and responsibilities of bioethicists involved in ethical review or clinical trial design in research and clinical investigations at their home institutions.

# Results

- Inputs
- Outputs (with regard to inputs and objectives)
  - What new curriculum were developed?
  - New classes taught? Training implemented?
  - How many students were trained? Degree? Geographic area?
  - What publications have been produced? Which journals?
- Metrics: Funding; Pubs (progress reports, pub med), students (progress reports), curriculum (progress reports, request PI, interviews); countries involved; training (progress reports)
- Outcomes: Leadership roles of trainees, new IRBs, new bioethical policies, new grants and funding (progress reports and interviews)

# FY 2004-2005 Funding Sources for the Bioethics Program

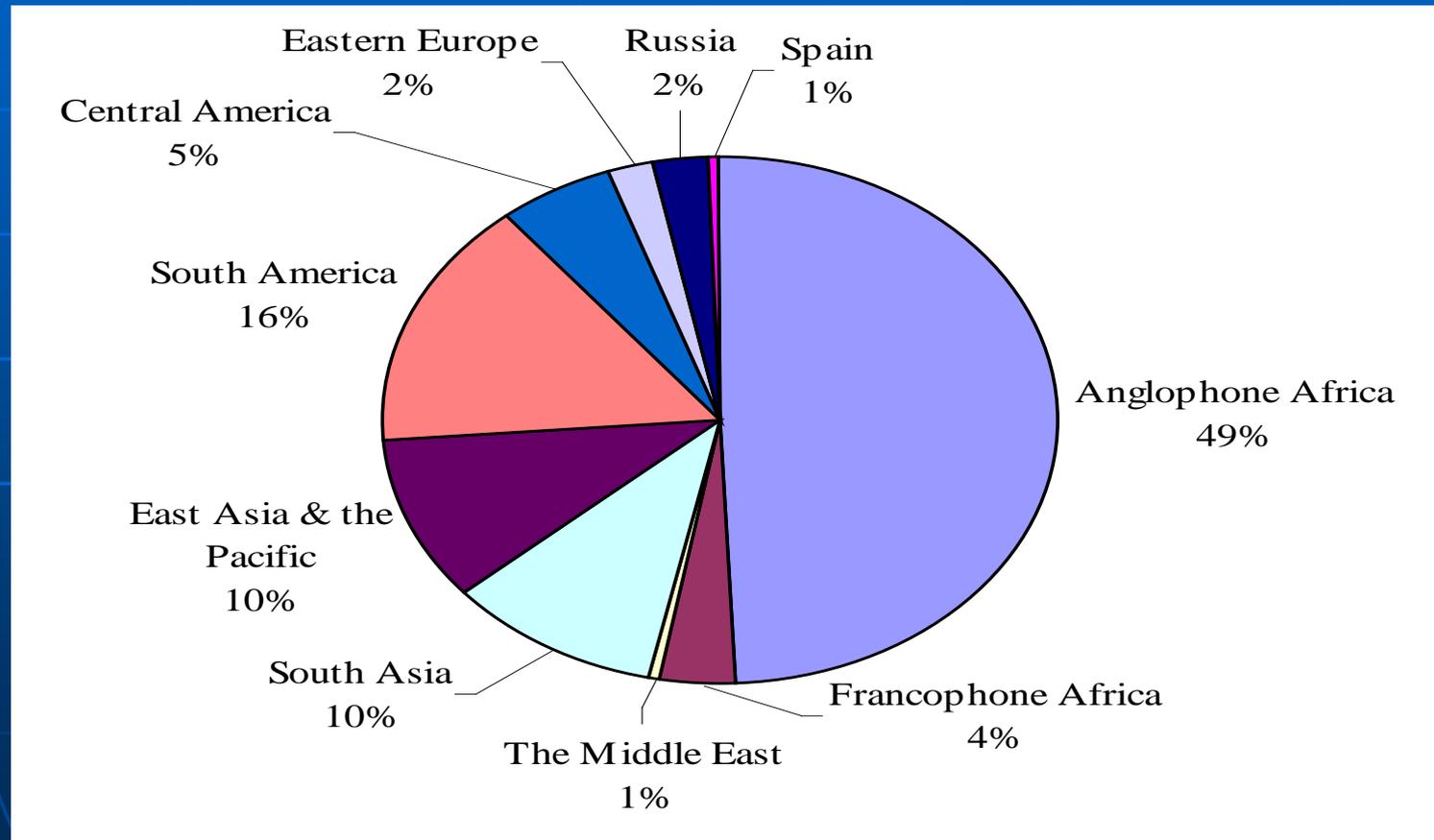
Total: \$3,407,340 (16 R25, 2 planning)



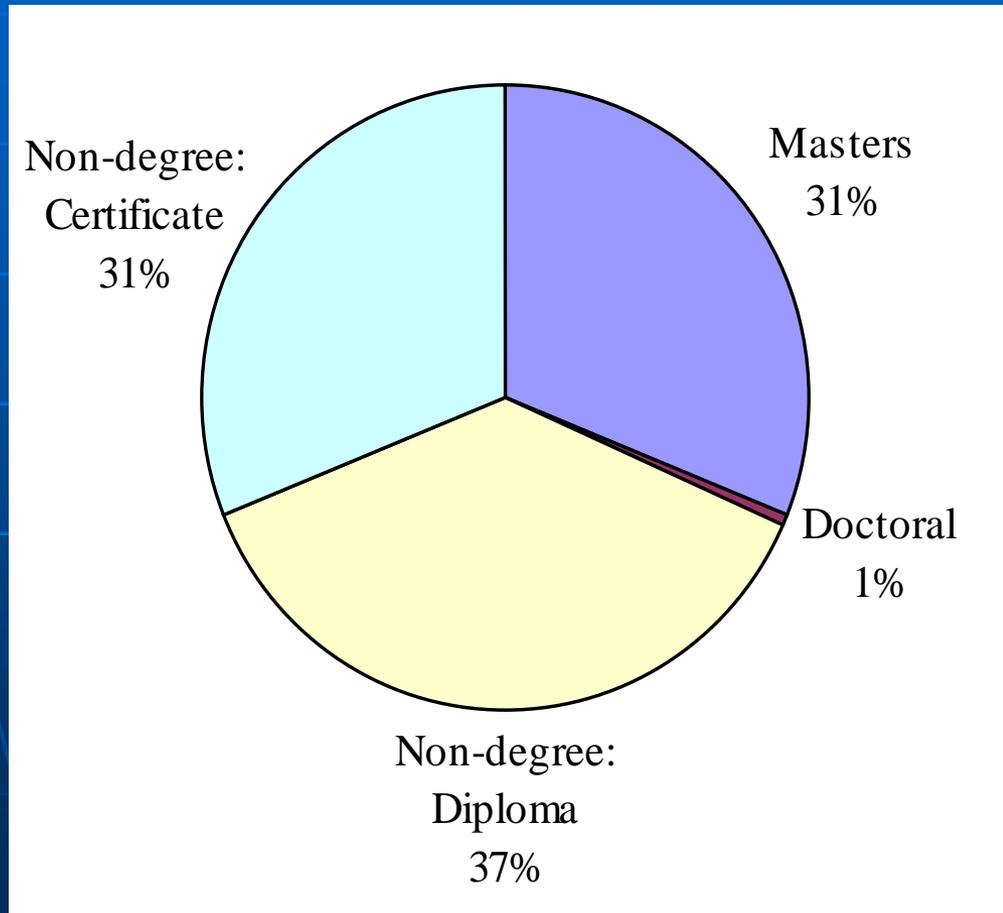
# Results (outputs)

- 167 long-term and 1406 short and medium term trainees graduated
- 38 different countries
- Diverse curricula developed related to bioethics and research ethics
- 81 publications; 54 presentations
- 27 short term and 28 medium term workshops held in all regions of the world

# Regional Distribution of Bioethics Long-Term Trainees (n=167)



# Training Conferred to Bioethics Long-Term Trainees (n=167)



# Results

- Outcomes (only 6 programs are 5 years old)  
Leadership roles of trainees, new IRBs, new bioethical policies, new grants and funding (progress reports and interviews)  
A graduate set up a national ethics review board in Nigeria, received Presidential medal  
A graduate is consultant to National Commission on Bioethics in Ecuador  
A graduate from India is a Steering committee member of the Asia Pacific Bioethics Network  
A graduate in S. Africa is the leader in ethics and law for an AITRP program.
- 98% of the long-term trainees return home

# Recommendations

## Results

- FIC and Bioethics PIs need to develop outcome metrics that will adequately describe the success and value of the accomplishments of their trainees, as well as the program accomplishments.

Suggestions:

Consultations and technical advice

Establishment of IRBs (local, national, international)

Invitations to participate in workshops & conferences

# Recommendations

## Results

- FIC should develop and implement a comprehensive trainee tracking system – track metrics, act as a resource (set-aside funds)
- FIC should consider how to provide bridge funding and career development grants to trainees who successfully complete the bioethics program (re-entry support-K01, Fogarty International Research Collaborative Award (FIRCA), Global Health Research Initiative Program for New Foreign Investigators (GRIP))

# Recommendations Management

- FIC in the review of proposals for the next RFA should work with the reviewing IC to substantially increase the number of peer reviewers from developing countries. Suggest a goal of 50% of the reviewers be from developing countries
  - Former bioethics program trainees
  - PIs not competing
  - Bioethics and research ethics experts

# Recommendations Management

- Interview grants mgmt & PO
- NIH should provide adequate staffing for this important program
- NIH should increase the flexibility of the current grants management mechanisms to better meet the needs of the foreign awardees.

# Recommendations

## Partnership and Communication

- Experts interviewed Partners (focus group)
- FIC needs to better communicate with partners inside and outside NIH about the program and its accomplishments. Furthermore, Bioethics trainees and PIs need to be informed about other NIH programs and researchers whose needs overlap with their interests and skills and who offer opportunities to have a wider impact.

# Conclusion

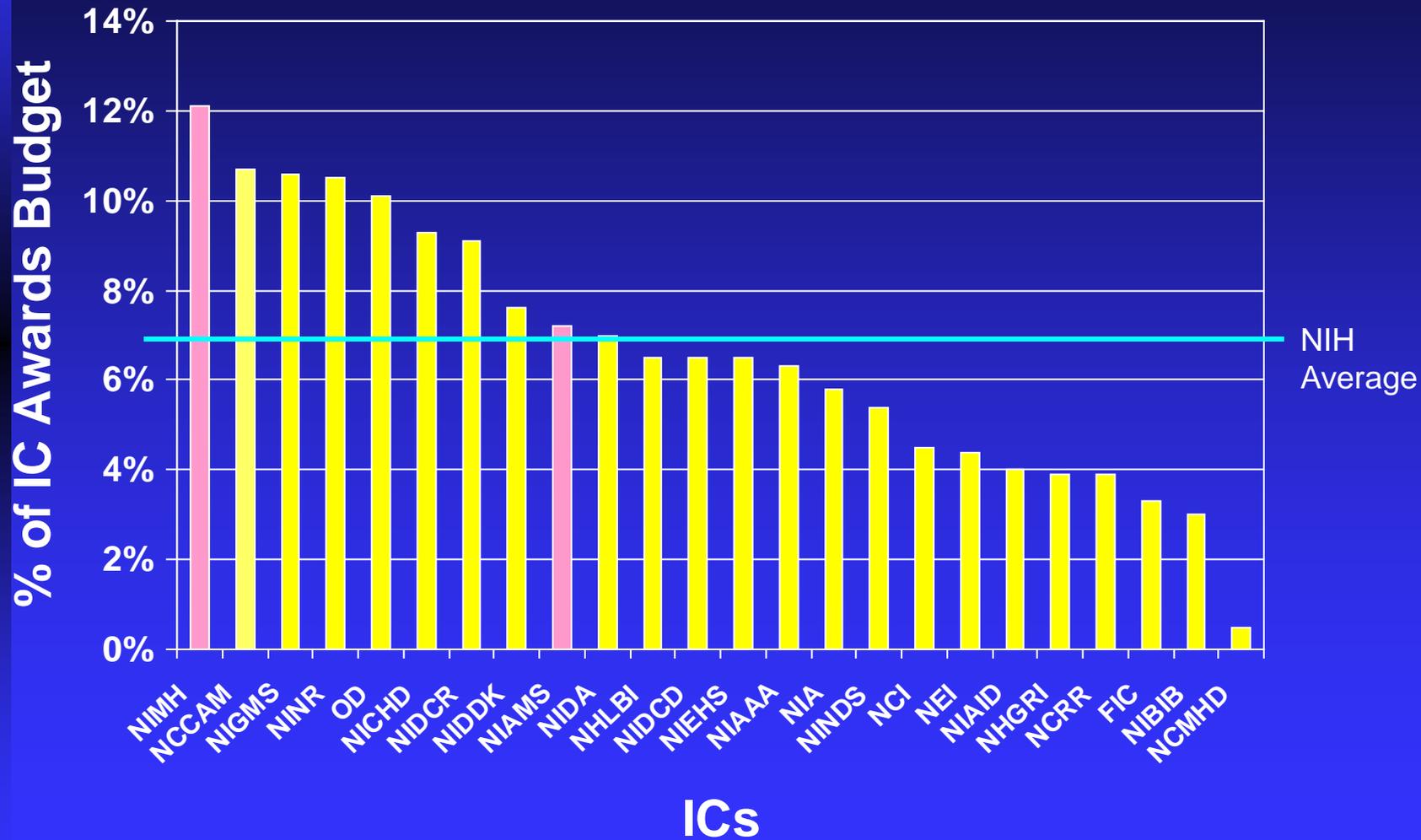
- The FIC Bioethics program has already made an outstanding contribution to developing capacity in research ethics in the developing world. It has demonstrated the innovation to fund in an area with no significant previous commitments. The continues to be a real and demonstrated need for such training worldwide.

# Evaluation of Research Training and Career Programs at NIMH



**NIMH**  
National Institute  
of Mental Health

# NIH FY 2004 Training & Career Funds (Fs, Ts, Ks)



Funds As a Percent of IC Awards Budget (incl. AIDS)

# Research Training at NIMH

<u>Mechanism</u>	<u>FFTP</u>	<u>Budget</u>
Institutional (T32, T34)	1194	\$ 47.7 M
Fellowships (F30, 31,32)	329	\$ 12.0 M
Mentored K (K01,08,12,23, 25)	401	\$ 60.0 M
<hr/>		
Total Training:	1,924	\$119.7 M
vs.		
Total RPG Competing:	628	\$185 M

\* FY 2004 Budget

# The Pipeline vs the Payline: Do we have the right balance?

Payline:

New RPGs = 628  
for new RPGs = \$185M

Pipeline:

Training FTTPs = 1,923  
\$ for training = \$119M



Total Extramural Research (- contracts) Budget = \$1, 091M

# What are the outcomes of research training?

- What happens to the trainees?
- Are they in science?
- Are they in research?
- Are they PIs on NIH grants?

# Feasibility Study

- Conducted by WESTAT
- Supported through funds from the Office of Evaluation, Office of the Director, NIH
- In partnership with NIDA and NINDS

# Feasibility Study Key Research Questions

- What are the outcomes of interest to assess research training success?
- What data sources exist to evaluate these outcomes? Is there a need for primary data collection?
- If so, what is the best way to collect this data?

# Feasibility Study Methodology

## ■ Interviews:

- ◆ NIMH, NIDA, and NINDS Institute Directors and Training Program Officers
- ◆ NIH officials overseeing training and evaluation activities
- ◆ NIH staff responsible for maintaining NIH databases
- ◆ Institutional Training Program Directors and other extramural scientists familiar with NIMH, NIDA, and NINDS training programs

## ■ Literature Reviews

## ■ Pilot testing of proposed methodology

# Feasibility Study Findings

- Outcomes of Interest Identified in 3 Domains:
  - ◆ Role
    - ◆ Conducting research; Administering research; Science-related role; Non-science related role
  - ◆ Setting
    - ◆ Academia; NIH; Other Gov't; Industry; Research Institute; Health Care.
  - ◆ Source of funding
    - ◆ NIH; Other Gov't; Private Foundation; Industry.

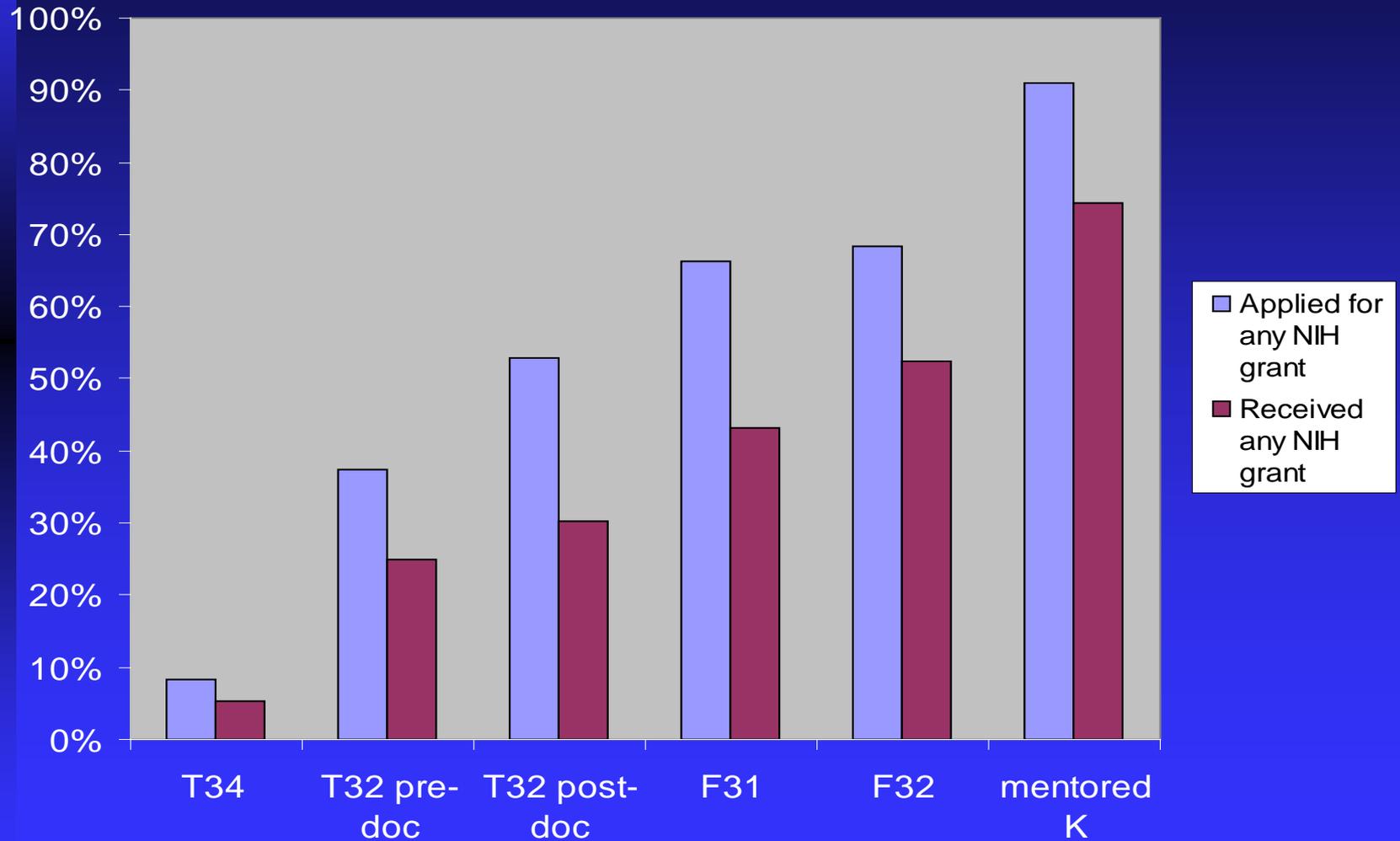
# Feasibility Study Findings (cont.)

- NIH databases are limited to:
  - ◆ Role: Conducting research as a P.I.
  - ◆ Setting: Varies
  - ◆ Source of funding: NIH
- Missing: Many roles, settings, and sources of funding.

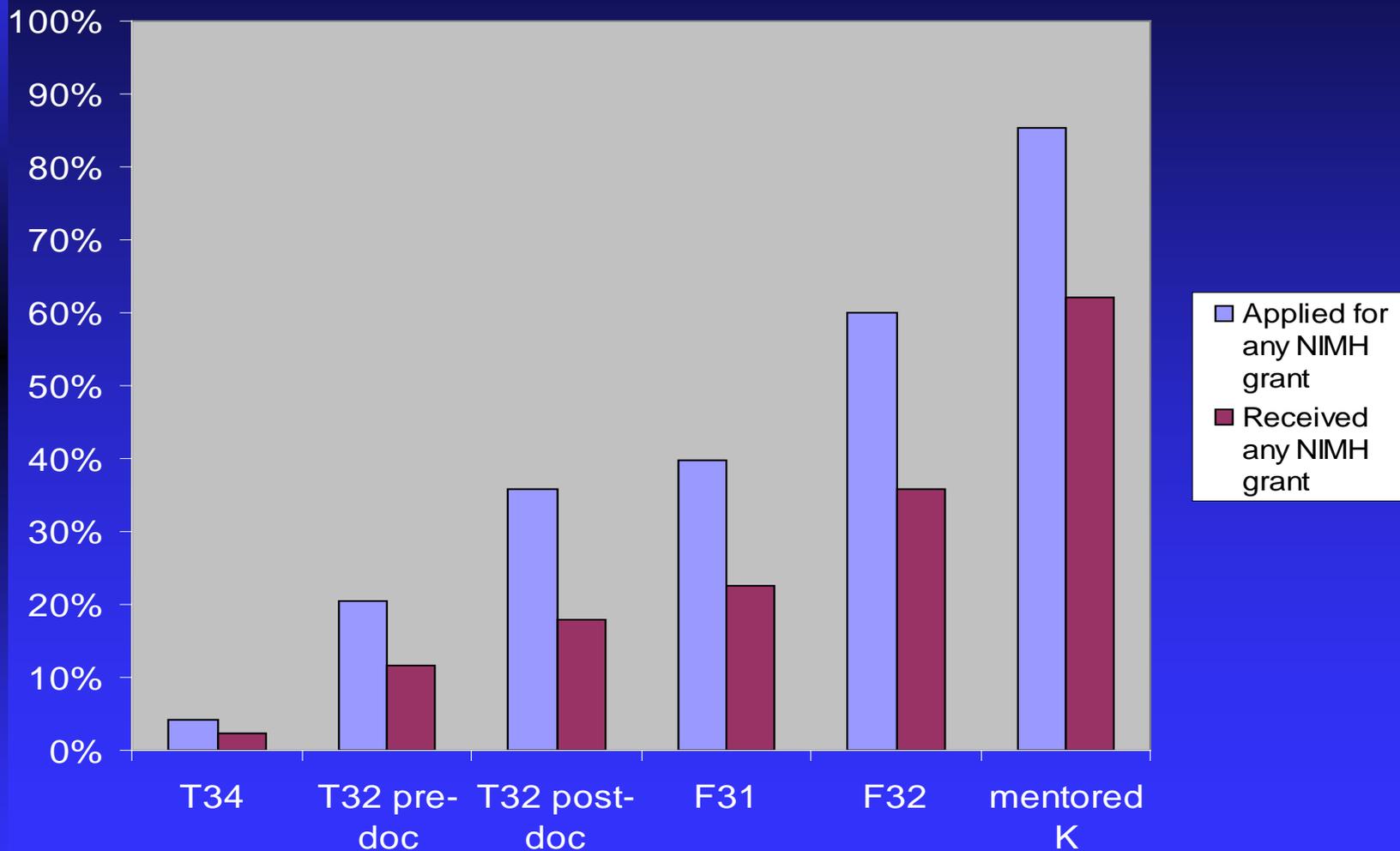
# In-House Limited Evaluation

- Conducted by OSPPP
- Limited to capturing whether trainees have applied/received NIH grants only (no contracts)
- Limited to 3 years of data:
  - ◆ T34: 1988-1990
  - ◆ T32: 1990-1992
  - ◆ F31 & F32: 1990-1992
  - ◆ Mentored Ks: 1995-1997

# Percent of Trainees Who Applied/Received an NIH Grant



# Percent of Trainees Who Applied/Received an NIMH Grant



# Limits of NIH Databases

- Not captured:
  - ◆ Co-PIs
  - ◆ Teaching
  - ◆ Mentoring
  - ◆ Other funding sources

# Can We Assess Training Outcomes in a Cost-effective Manner?

## ■ Yes:

- ◆ Sampling
- ◆ Web searches
- ◆ PubMed Searches
- ◆ Potential supplemental data collection via institutional training directors

# Next Steps

- Large-scale evaluation
- WESTAT proposed design
  - ◆ 18 months
  - ◆ \$493,000