HIV Research at NINR: Current State – Future Trends

Lyn Hardy, PhD, RN
Program Director, National Institute of Nursing Research

Reality

Only 1 OUT OF 4 HIV POSITIVE PEOPLE IN THE US ARE SUCCESSFULLY MAKING IT THROUGH THE HIV CARE CONTINUUM AND GETTING THE FULL BENEFITS OF TREATMENT
Objectives

• Overview of NINR – where we are today
• Current status of NINR’s HIV research
• Research goals of NIH Office of AIDS Research (OAR) and NINR
• Grantsmanship in the AIDs research arena

NINR Overview
To promote and improve health of individuals, families, communities, and populations.

NINR supports and conducts clinical and basic research and research training on health and illness across the lifespan.

NINR Mission

NINR Strategic Plan
NINR Website

Thematic Areas

- **Wellness & Health**
  - Immune Function
  - Health Promotion / Disease Prevention
  - Health Disparities / Environmental Influences
  - Women’s Health

- **Symptom Science**
  - Biology of Symptoms
  - Genetics

- **Self-Management & Chronic Disease**
  - Self management
  - Chronic disease
  - Caregiving

- **Technology & Training**

- **End-of-Life and Palliative Care Science**
### Wellness

*The most effective way to overcome the effects of illness is to prevent it from occurring in the first place:*

**Focus:**
- Promoting health and preventing illness across health conditions, settings, the lifespan, and in minority and underserved populations
- Understanding physical, behavioral, and environmental causes of illness,
- Assessing behaviors leading to healthy lifestyle choices,
- Developing evidence-based interventions to promote wellness

### Symptom Science

**Focus:**
- Chronic illnesses and adverse symptoms resulting from them
- New advances in genomics allowing nurse scientists to better understand the symptoms of chronic illness (e.g., pain, fatigue, and disordered sleep)
- Research developing improved, personalized strategies to treat and prevent the adverse symptoms of illness across diverse populations and settings
<table>
<thead>
<tr>
<th><strong>Self-Management &amp; Chronic Disease</strong></th>
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<tbody>
<tr>
<td><strong>Focus:</strong></td>
<td><strong>Cross-cutting area</strong></td>
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<tr>
<td>▪ Examining strategies to help</td>
<td>▪ Focus:</td>
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<tr>
<td>individuals with chronic</td>
<td>▪ Providing a foundation to</td>
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<td>conditions and their caregivers</td>
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<td>deliver personalized care</td>
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<td>and real-time health</td>
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<td>▪ Supporting research helping</td>
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<td>individuals from diverse</td>
<td>families, clinicians,</td>
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<td>backgrounds and their families</td>
<td>and communities</td>
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<td>▪ Developing effective approaches to</td>
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<td>self-management that can</td>
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<td>improve quality of life while</td>
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End-of-Life & Palliative Care Science

Focus:

- Assisting individuals, families, and health care professionals in managing symptoms of life limiting conditions and planning for end-of-life decisions
- Providing high-quality, evidence-based palliative care research as a critical component of maintaining quality of life at any stage of illness
- Addressing issues such as: relieving symptoms and suffering; and understanding decision-making by patients, caregivers, and providers

NIH Office of AIDS Research and NINR HIV Priorities
Office of AIDS Research (OAR)

- NIH Revitalization Act of 1993 require OAR to allocate all appropriated AIDS research funds to the Institutes and Centers according to the Trans-NIH Plan for HIV-Related Research
- Coordinates the scientific, budgetary, legislative, and policy elements of the NIH AIDS research program
- Sets scientific priorities
- Enhances collaboration
- Ensures that research dollars are invested in the highest priority areas of scientific opportunity

www.oar.nih.gov

Strategic Plan Areas

<table>
<thead>
<tr>
<th>OAR Priority Areas</th>
<th>NINR Priority Areas</th>
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<tbody>
<tr>
<td>Expanding basic discovery research</td>
<td>Health promotion disease prevention</td>
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<tr>
<td>Reducing new infections</td>
<td>Advancing quality of life through symptom and self-management</td>
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<tr>
<td>Improving disease outcomes</td>
<td>Improving disease outcomes</td>
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<tr>
<td>Reducing HIV-related disparities</td>
<td>End-of-life and palliative care</td>
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<tr>
<td>Translational research</td>
<td>Innovation</td>
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Merging Both Missions

**Health Promotion & Disease Prevention**
- Prevention of HIV infection in all age groups
- Define relationships between natural aging and HIV-induced pathological changes in multiple organ systems
- Interventions to reduce transmission

**Quality of Life Symptom Management**
- Improving disease outcomes
- Reduce HIV health disparities
- Study effects of treatment of long-term HIV disease and the natural aging process

**Palliative & End of Life Care**
- Caring for persons with HIV/AIDS

**Innovation**
- Novel and effective methods of HIV-1 prevention
- Methods to increase access to care in diverse populations

**Training**
- Provide training in HIV research with a multidisciplinary research approach

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**HIV Treatment Cascade**

(Gardner, et al., 2011, Clin Infect Dis; CDC-Hall, 2013)
HIV Treatment Cascade

Implementation Cascade for the Continuum of Care

Future Research Needs

Of those infected with HIV:
- 50% will over the age of 50 by the end of 2014
- 25% of persons are not virally suppressed
- 33% are on ART
- 66% are linked to care

How do you maintain a sense of wellness in this chronically ill population?
Current Status of NINR HIV Research

Data accessed from RePORTER 11/7/2013
Areas of NINR HIV/AIDS Research

Current NINR HIV award themes are:

- Prevention - 62%
- PCEOL - 19%
- Chronic Conditions - 12%
- Self-Management - 4%
- Health Disparities/ Health Literacy – 4%

Definitions:

- **Prevention** (for this analysis) - using methodologies to prevent HIV infection
- **Chronic Conditions** – using methods to treat or understand HIV sequelae
- **Self-Management** - using methods aimed at individual management of HIV infection

NINR HIV Research

- **Pathways to neurodegeneration: Effects of HIV and aging on resting-state functional connectivity**
  *Neurology*. Published online before print February 27, 2013; DOI 10.1212/WNL.0b013e318288792b

- **Motivational Groups Support Adherence to Antiretroviral Therapy and use of Risk Reduction Behaviors in HIV Positive Nigerian Women: A Pilot Study**
  Marcia McConnell Holsclaw1,2, James E. Essen1, Ernest Ekong2, Melinda Higgins1, Iya Teplinsky1, and Modupe Fajuluto Adewuyi1
  1NFL-Hodgson School of Nursing, Emory University
  2Institute of Community Health, University of Houston
  3Institute for Health Research and Development, Yaba, Lagos, Nigeria
More NINR HIV Research

- Mallory Johnson, PhD
  - Relationship dynamics and adherence
- Jared Baeten, MD, PhD
  - PrEP in serodiscordant couples

HIV Treatment Cascade

Implementation Cascade for the Continuum of Care

- Testing
- Diagnosis
- HIV Care
- Treatment
- Virologic Suppression
- Linkage
- Engagement/Retention

(Adapted from CDC, (2012). HIV in the United States: the stages of care)
Overview of NINR Supported Activity Codes

Research Program Grants

- **R01**
  - Supports discrete, specified projects
  - Must have completed pilot work
  - Application must tie together from theory to analysis

- **R21**
  - Exploratory/Developmental Grant
  - For innovative projects with high potential contribution to science

- **R15**
  - Academic Research Enhancement Award
  - Only eligible universities or colleges
  - Includes students
New Investigators/Early Stage Investigators

New Investigator (NI)
- A PD/PI who has not obtained a substantial NIH research grant

Early Stage Investigator (ESI)
- A New Investigator within 10 years of completing the terminal research degree or medical residency (or equivalent)

- Applies **only to R01 applications**

- New Investigators/Early Stage Investigators applications will be clustered together for review

Small Business Opportunities

- Innovative Research (SBIR)
- Research & development by small business

- Technology Transfer (STTR)
- Research & development by small business
Training & Education

Graduate Partnerships Program (GPP)  
NINR Summer Genetics Institute (SGI)

Individual Post-doc Awards (F32)  
Institutional Post-doc Awards (T32)  
R01 support under PIs  
NINR SGI  
Pathway to Independence Awards (K99/R00)

Career Development (K) Awards  
Individual Senior Fellow Awards (F33)  
NINR SGI

Individual Pre-doctoral Awards (F31)  
Institutional Pre-doc Awards (T32)  
R01 support under PIs  
NINR SGI

Career Development (K) Awards  
NIH Research Awards targeted to New Investigators  
NINR SGI

Bachelor’s Degree (senior year)  
Pre-Doctorate  
Post-Doctorate  
New Investigators  
Career Researchers

NINR Graduate Partnership Program

All doctoral coursework completed by August 2014.

Once accepted, the fellow’s dissertation research is begun and completed at NIH in collaboration with the dissertation committee at home institution.
Timeline: New R01 Applications

<table>
<thead>
<tr>
<th>Receipt Date</th>
<th>Scientific Review</th>
<th>Council Review</th>
<th>Award Date</th>
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<tbody>
<tr>
<td>February 5</td>
<td>June</td>
<td>October</td>
<td>December</td>
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<tr>
<td>June 5</td>
<td>October</td>
<td>January</td>
<td>April</td>
</tr>
<tr>
<td>October 5</td>
<td>February</td>
<td>May</td>
<td>July</td>
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Timeline: HIV/AIDS Applications

<table>
<thead>
<tr>
<th>Receipt Date</th>
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<tbody>
<tr>
<td>May 7</td>
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<tr>
<td>June 5</td>
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<tr>
<td>October 5</td>
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</tbody>
</table>
### Timeline: New K Series, R03, R21, R15 Applications

<table>
<thead>
<tr>
<th>Application Type</th>
<th>Receipt Date</th>
<th>Scientific Review</th>
<th>Council Review</th>
<th>Award Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>K Series</td>
<td>February, June, October</td>
<td>June/July Oct/Nov Feb/March</td>
<td>Aug/Oct January May</td>
<td>December April July</td>
</tr>
<tr>
<td>R21, R15 (25th)</td>
<td>February, June, October</td>
<td>June/July Oct/Nov Feb/March</td>
<td>Aug/Oct January May</td>
<td>December April July</td>
</tr>
<tr>
<td>F Series</td>
<td>April, August, December</td>
<td>June/July Oct/Nov Feb/March</td>
<td>Aug/Oct January May</td>
<td>Sept/Dec April July</td>
</tr>
</tbody>
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**Your NIH Application: What Does it Mean?**
Decoding Your NIH Grant Number

<table>
<thead>
<tr>
<th>Application Type</th>
<th>Activity Code</th>
<th>Institute Code</th>
<th>Serial Number</th>
<th>Support Year</th>
<th>Extension</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>R01</td>
<td>NR</td>
<td>12345</td>
<td>01</td>
<td>A1</td>
</tr>
</tbody>
</table>

- 1 = new
- 2 = renewal
- 3 = supplement
- 5 = non-competing continuation
- R = Research project
- P = Program project or Center
- T = Training (institutional)
- F = Fellowship (individual)
- K = Career Development
- U = Cooperative agreement
- NR = NINR Unique, up to six digits
- Support Year = Years of Continuous Funding
- A1 = Resubmission

Overview

NIH Scientific Review of Grant Applications

Assignment Process
- Where reviewed?
- What study section?
- Who reviews?

Communication Process
- Release of scores
- Release of statements

Initial Review Process
- Critique presentation
- Discussion
- Scoring of application
- Confidentiality

Second Level Review
- Council review
- Council recommendations
- Confidentiality

Notice of Grant Award

Applicant

Grant Application Kit

Scientific Review Group

Funding Institute/Center

Summary Statement
### Where are NIH Applications Reviewed?

<table>
<thead>
<tr>
<th>WHERE</th>
<th>MECHANISM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Center for Scientific Review</td>
<td>• Research Projects (R01, R21, R03)</td>
</tr>
<tr>
<td>(CSR)</td>
<td>• AREA (R15)</td>
</tr>
<tr>
<td></td>
<td>• Small Business Innovation Research (R41, R42, R43, R44)</td>
</tr>
<tr>
<td>NINR</td>
<td>• Pre- and Post-doctoral Fellowships (F31, F32, F33)</td>
</tr>
<tr>
<td>(Office of Review)</td>
<td>• Career Development Awards (K’s)</td>
</tr>
<tr>
<td></td>
<td>• Institutional Training Grants (T 32)</td>
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<td>• Special Initiatives (RFAs, PARs)</td>
</tr>
</tbody>
</table>

### Impact Scoring Criteria

- Significance
- Investigators
- Innovation
- Approach
- Environment
Other Criteria: Factored into Overall Impact

- Protection of Human Subjects
- Vertebrate Animal Welfare
- Inclusion of Women, Minorities and Children
- Biohazards

Scoring of Criteria and Overall Impact

- Applications scored on each review core criterion using a scale of 1-9.
- The overall impact of the application is determined by using the same scale of 1-9.
- The impact score is not the average of the criterion scores.
### NIH Scoring Scale: Additional Guidance

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Strengths/Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Impact</td>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong/no weaknesses</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong/negligible weaknesses</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td>Very strong/some minor weaknesses</td>
</tr>
<tr>
<td>Moderate Impact</td>
<td>4</td>
<td>Very Good</td>
<td>Strong/numerous minor weaknesses</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td>Strong/ at least 1 moderate weakness</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths/some moderate weaknesses</td>
</tr>
<tr>
<td>Low Impact</td>
<td>7</td>
<td>Fair</td>
<td>Some strengths/ at least 1 major weaknesses</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td>Few strengths/few major weaknesses</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td>Very few strengths/many major weaknesses</td>
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### Additional Scoring Guidance

- Minor Weakness: *Does not lessen* impact
- Moderate Weakness: *Lessens* impact
- Major Weakness: *Severely limits* impact
“There is no amount of Grantsmanship that will turn a bad idea into a good one… but there are many ways to disguise a good idea”

Dr. William F. Raub
Deputy and Acting Director NIH (1986-1991)
2 Level System for Application Review

1st Level
Scientific Review Group (SRG)
- Independent outside reviewers
- Evaluate scientific merit & significance
- Recommend length and level of funding

2nd Level
National Advisory Council
- Assesses Quality of SRG Review
- Makes Recommendation to Institute Staff on Funding
- Evaluates Program Priorities and Relevance
- Advises on Policy

Things to Consider

- Significance What will it mean to the science?
- Investigators Who’s on your team?
- Innovation What makes this new?
- Approach Your methods
- Environment Your University

Specific Aims Page Cover Letter
NINR Program Directors

Contact NINR Program Directors for Assistance

- Common Topics:
  - Ideas for research proposals
  - Questions regarding FOA's
  - Guidance with application preparation
  - Questions regarding population tracking
  - Any issues regarding your funded application
  - General concerns/comments

Funding Opportunities
NINR Funding Opportunities

- Symptom Management in HIV-Infected Individuals with Comorbid Conditions (R01) Announcement Number: PA-13-210/211
- Multidisciplinary Studies of HIV/AIDS and Aging (R01) Announcement Number: PAR-12-175
- HIV/AIDS Testing and Follow-up Among the Underserved in the United States (R21) Announcement Number: PA-11-119

NIH Common Fund Opportunities

- Provides a mechanism for exceptional, early career scientist to forgo traditional post-doctoral training
- Applicants must be within a year of their terminal research degree/clinical residency
- Up to $300K/yr. for 5 years

http://commonfund.nih.gov/earlyindependence/
Summary

- NINR is committed to funding novel, cutting edge, patient oriented HIV/AIDS research
- NINR’s mission is consistent with that of OAR as we strive for health promotion, disease prevention, and quality of life in this population
- Your thoughts and concerns, as HIV nurse scientists and care providers, make a difference

Thoughts to Leave You With

“We live in a completely interdependent world, which simply means we cannot escape each other. How we respond to AIDS depends, in part, on whether we understand this interdependence. It’s not someone else’s problem. This is everybody’s problem.”

Bill Clinton

“It’s not the years in your life that count, it’s the life in your years.”

Abraham Lincoln

We all make a difference in this fight!
The Ultimate Reality

Only 1 OUT OF 4 HIV POSITIVE people in the US are successfully making it through the HIV CARE CONTINUUM and getting the full benefits of treatment.

Thank you! Questions?