NIH Funding Process and Research on Breastfeeding

State, Territory, Tribal Breastfeeding Coalitions:
Bi-Monthly Teleconference

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Outline

• The NIH and its organization, and a typical NIH Institute

• Budget and funding mechanisms, and determining funding priorities

• Grant application and funding process

• Breastfeeding-related topics with examples of funded, or ongoing studies
Where does NIH fit in the total scheme of Federal Government?

U. S. Department of Health and Human Services

The Secretary and the Deputy Secretary

- Administration for Children and Families (ACF)
- Administration on Aging (AaA)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Administration on Aging (AoA)
- Health Care Financing Administration (HCFA)
- Indian Health Services (IHS)
- National Institutes of Health (NIH)
- Centers for Disease Control and Prevention (CDC)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- Program Support Center (PSC)

Agencies Supporting Breastfeeding Research

The National Institutes of Health

- The NIH is one of agencies within the U.S. Department of Health and Human Services.

- Founded in 1887, the National Institutes of Health today is one of the world's foremost medical research centers, and the Federal focal point for medical research in the United States.

- NIH constitutes 27 Institutes and Centers and several Offices
NIH Mission

• To acquire new knowledge to help prevent, detect, diagnose, and treat diseases and disabilities, from the rarest to the commonest.

• To uncover new knowledge that will lead to better health for everyone.
NIH Mission (Continued)

- Conduct research in its own laboratories
- Support research of non-Federal scientists in this country and abroad, from universities, medical schools, hospitals, and research and for-profit institutions
- Help train research investigators
- Foster communication of medical and health sciences information to the scientific community and the general public

NIH Budget

- The NIH invests over $30.5 billion annually in medical research for the American people.

- More than 80% of the NIH's funding is awarded through almost 50,000 competitive grants to more than 325,000 researchers at over 3,000 universities, medical schools, and other research institutions in every state and around the world. (Extramural)

- About 10% of the NIH's budget supports projects conducted by nearly 6,000 scientists in its own laboratories, most of which are on the NIH Campus in Bethesda, Maryland. (Intramural)

- NIH maintains a strict separation between the two
NIH Budget

History of NIH Appropriations: 1996-2006

Allocation of NIH Appropriations
- Research Grants: 69%
- R&D Contracts: 9%
- Intramural: 10%
- RMS: 4%
- All Other: 8%

NIH Campus

Tonse Raju, NICHD/National Institutes of Health
NIH Organization

A Typical Institute
**NICHD Mission**

- To help people have healthy babies when they want them
- To avoid harm to women from the reproductive process
- To help all children reach adulthood able to achieve their full potential
- To optimize rehabilitation and achieve minimal disability
NIH Extramural Program

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>NIH Role</th>
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<tbody>
<tr>
<td>Grant</td>
<td>Patron (Assistance &amp; Encouragement)</td>
</tr>
<tr>
<td>Contract</td>
<td>Purchaser (Procurement)</td>
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<tr>
<td>Cooperative Agreement</td>
<td>Partner (Assistance with Substantial Program Involvement)</td>
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Some Research Grant Mechanisms*

- Research Project Grants: R01, R03, and R21
- Small Business Technology Transfer (STTR) & Small Business Innovative Research (SBIR) Research Grants (R41,R42, and R43,R44)
- Supplements to existing Research Grants
  - Minority supplement
  - Career reentry supplement
- Applications in response to “Program Announcements” (PA) & “Request for Applications”

*Complete listing at http://www.nichd.nih.gov/funding/funding-mechs.htm
What Determines Which Awards Are Made?

- Scientific merit
- Program Considerations
- Availability of funds

Determining Scientific Merit

Grant Applications & Funding Process
First Steps:
Scientific Research Idea & Putting Together a Good Application

Step 1: Researcher develops the idea & prepares a grant proposal

Step 2: School or University Submits it to CSR/NIH

Step 3: Center for Scientific Review Receives all applications

Step 4: Assigns to a Review Group or Study Section & an IC

Step 5: Study Section Evaluates the Science, Scores

Step 6: IC evaluates for programmatic relevance

Step 7: Advisory Councils and Boards recommend action

Step 8: Institute Director takes final action

Step 9: Applicant Institution receives the Funds

Step 10: The PI and her team conduct research

Review Process & Getting Funded

State Breastfeeding Coalitions Teleconference

2/9/2010

Tonse Raju, NICHD/National Institutes of Health
What are Study Sections?

- The Study Sections are review groups, convened by the Center for Scientific Review (CSR)
- The review group members are from the scientific community at large—they are NOT NIH personnel
- >17,000 scientists from US and abroad serve in various Study Sections
- There are ~150 permanent Study Sections and >300 ad-hoc (Special Emphasis Panel) Study sections
- The CSR maintains the review process independent of the funding NIH Institute or Center

Applications Submitted to NIH

- Each year, >80,000 grant applications are submitted.
- Most are now submitted electronically.
- CSR Referral Officer assigns the application to the most appropriate Study Section for review
Study Section Meeting Process

• A typical Study Section includes 10-20 members, and meets 3 times a year.
• Each Study Section may review ~50-75 applications
• Scientific review officer (SRO) runs the meeting

Review Criteria & Process

• The applications are reviewed using the criteria:
  – Significance
  – Investigators
  – Innovation
  – Approach
  – Environment

• Additional review criteria
  – Protection of study participants and researchers
  – Animal care

• Additional review considerations: Budget

• All applicants receive a detailed review notes, called “Summary Statements” (formerly called the “pink sheets”)
Overall Impact or Priority Score

- About 50% (the bottom-half) of applications are not discussed (ND) and do not receive an impact score
- Others are discussed
- All discussed applications receive an impact score from 10-90
- Approximate impact gauge:
  - 10 to 30 = high impact
  - 40 to 60 = moderate impact
  - 70 to 90 = low impact

Impact/Priority Score is affected by the Strengths and Weaknesses

- Based on the magnitude of impact on the science from the studies
- Presence (or absence) of weaknesses
  - Minor weakness: easily addressable weakness that does not substantially lessen impact
  - Moderate weakness: lessens the impact
  - Major Weakness: severely limits the impact
After the Study Section Review. . .

- The funding NIH Institute or Center receives the priority score or percentile ranking
- The Program Officers determine scientific merit and mission relevance
- Competitive applications are sent to the National Council for second level of review
- The Director makes the funding decisions based on:
  - The Council recommendations
  - Programmatic relevance
  - Available funds

Common Features of Successful Applications

- New or original ideas
- Great scientific and/or clinical rationale
- Clearly stated knowledge gaps to be filled in by the study
- Investigators’ expertise in conducting the study and available resources
- Focused research plan and rigorous study design
- Clearly provided “experimental” or study details
- Convincing argument about the public health need for the study with proper end points and appropriate citations
- Showing that work can be done in the proposed time span by this team
- Clear future directions
Common Problems in Unsuccessful Applications

- Lack of new or original ideas
- Absence scientific rationale
- Lack of experience in the methodology
- Questionable experimental approach
- Diffuse, superficial, or unfocused research plan
- Lack of sufficient experimental detail
- Lack of knowledge of published relevant work
- Unrealistically large amount of work
- Uncertainty concerning future directions

18 of 24 Funding NIH Components Support Various aspects of Breastfeeding Research

- NIA
- NI AID
- NI AMS
- NCI
- NI CHD
- NI DCD
- NI DCR
- NI DDK
- NI DA
- NI EHS
- NEI
- NI GMS
- NHLBI
- NI MH
- NI NDS
- NI NR
- NHGRI
- NI BIB
- FIC
- NCCAM
- NCRR
- NCMHD
- NLM
- CC
- CIT
- CSR
NIH Entities Supporting various aspects of Breastfeeding Research

1. National Cancer Institute
2. National Heart, Lung, and Blood Institute
3. National Institute on Alcohol Abuse and Alcoholism
4. National Institute of Allergy and Infectious Diseases
5. National Institute of Arthritis and Musculoskeletal and Skin Diseases
6. Eunice Kennedy Shriver National Institute of Child Health and Human Development
7. National Institute on Deafness and Other Communication Disorders
8. National Institute of Dental and Craniofacial Research (NIDCR)
10. National Institute on Drug Abuse (NIDA)
11. National Institute of Environmental Health Sciences (NI EHS)
12. National Institute of General Medical Sciences
13. National Institute of Mental Health (NIMH)
14. National Institute of Neurological Diseases and Stroke (NI NDS)
15. National Institute of Nursing Research (NINR)
16. National Center for Complementary and Alternative Medicine (NCCAM)
17. National Center on Minority Health and Health Disparities (NCMHD)
18. National Center for Research Resources (NCRR)

Examples of Research on Diverse Aspects of Breastfeeding, Human Milk and Lactation

• Mammary gland biology and lactation
  – Anatomy of mammary gland formation
  – Physiology of lactation,
  – psychological aspects of lactation/breastfeeding

• Breastfeeding, feeding of human milk and child health
  – Allergy asthma, and atopic dermatitis
  – Respiratory disorders and AOM
  – Neonatal NEC
  – Diarrhea
  – Infant IQ
  – Childhood and adolescent obesity
  – Adult disorders
  – Growth and development
Examples of Research on Diverse Aspects of Breastfeeding, Human Milk and Lactation (2)

- Breastfeeding and Mothers’ health
  - Breast, ovarian, and uterine cancers
  - Depression
  - Psychological health
  - Obesity
  - Biology of resilience
  - Bone turnover
  - Oral contraceptive, and other medications
- Epidemiology of breastfeeding and support for breastfeeding
  - Efforts to enhance breastfeeding among minority ethnic groups
- Breastfeeding in special populations (preterm), late preterm, cleft lip, cleft palate
- Physiology of suck, swallow, deglutition, and digestion
- Health disparity
- Breastfeeding and HIV
- Prescription Drugs, Drugs of abuse and Pollutants and breastfeeding
  - Antipsychotic drugs
  - Lead, mercury
  - Alcohol, drugs of abuse
- Breastfeeding and over-the-counter medication use (NCCAM)

Breastfeeding Support Research

  - Grant Support:
    - 1P60 MD 000516-05/MD/NCMHD NIH HHS/United States
    - R01 HD04976301A2/HD/NICHD NIH HHS/United States
    - PI Karen Bonuck
  - Testing routine prenatal care versus two interventions (lactation consultant, and focused education to the healthcare workers)
Breastfeeding Support for Mothers of Infants with Cleft Palate

The wide varieties of CLP are reflected in, from right to left, a unilateral cleft lip, a bilateral cleft lip and finally a cleft palate with intact lip.

SBIR Project:
PI: Peter Jardine

(left): A sequence of actions for breastfeeding in a schematic CLP Device. Figure 3(a): Detailed Schematic of a CLP feeding appliance featuring a stiffened upper silicone section, to mimic the hard palate. (b): In order to generate a seal, a thin breast seal surface is compressed onto the breast using a silicone/foam breast shield.
Breastfeeding Support for Mothers of Infants with Cleft Palate

Initial form of the CLP appliance.

Other Examples

• R01HD050758-03 PI: OKEN, EMILY  *BREASTFEEDING PROMOTION RCT AND CHILD METABOLIC SYNDROME*  HARVARD PILGRIM HEALTH CARE, INC.

• K23HD057232-02 PI COLAIZY, TARAH TRINITY  *CLINICAL EPIDEMIOLOGIC AND BIOLOGIC STUDIES OF DONOR HUMAN MILK AND BREASTFEEDING*  UNIVERSITY OF IOWA

• F31NR011562-01 PI: RADTKE, JILL V.  *BREASTFEEDING THE LATE PRETERM INFANT: A GROUNDED THEORY STUDY*, UNIVERSITY OF PITTSBURGH
Other Examples (2)

- 1R13HD024549-01 INTERNATIONAL CONFERENCE--BREASTFEEDING AND NUTRITION PI: ATKINSON, STEPHANIE MCMASTER UNIVERSITY
- 1R13ES015475-01 BREAST MILK: PHYSIOLOGY, BIOCHEMISTRY AND OUTCOMES, PI: MORROW, ARDYTHE L. CHILDREN'S HOSPITAL MED CTR (CINCINNATI)
- 1U13DP000677-01 2008 NATIONAL CONFERENCE OF STATE BREASTFEEDING COALITIONS NAYLOR, AUDREY U.S. BREASTFEEDING COMMITTEE, INC.
- NICHD Inter-Agency Contract (to FDA) INFANT FEEDING PRACTICES STUDY II

The Sources for Obtaining More Information:

Databases

- NIH Funded-Grants’ Database:
  - Research Portfolio on-line Reporting Tool (RePort)

- NIH Institute’s website (supporting breastfeeding research) for specific types of research being supported
- PUBMED text-search: “Breastfeeding and NIH” to see published studies acknowledging NIH support
- Note: Federal support is not consistently reported by the researchers; yet, ~150 hits for 2009 alone.
RePORTER satisfies a legislative mandate included in the NIH Reform Act of 2006 to provide the public with an electronic system to search NIH research projects using a variety of codes, including public health area of interest, and provide information on publications and patents resulting from NIH-funded research.
Thank you