How to successfully submit a grant application to US federal funding agencies

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A pessimist sees the difficulty in every opportunity; an optimist sees the opportunity in every difficulty

Winston Churchill

General Information on the National Institutes of Health (NIH)

- The NIH is made up of 27 different Institutes or centers. Each component has its own specific research agenda, often focusing on particular diseases or body systems.
- All but three of these components receive their funding directly from Congress, and administrate their own budgets.
- The NIH invests nearly \$27 billion dollars annually (2018) in medical research.
- More than 80% of the NIH's funding is awarded through about 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every state and around the world.
- 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.

NIH Institutes, Acronyms, and Budget (2016-2018 in billions of dollars)

	2016	2017	2018
National Cancer Institute (NCI)	5,206	5,505	4,474
National Heart, Lung and Blood Institute (NHLBI)	3,109	3,110	2,535
National Institute of Dental and Craniofacial Research (NIDCR)	413	415	321
National Inst. of Diabetes & Digestive & Kidney Diseases (NIDDK)	1,964	1,955	1,600
National Institute of Neurological Disorders and Stroke (NINDS)	1,693	1,693	1,356
National Institute of Allergy and Infectious Diseases (NIAID)	4,797	4,621	3,783
National Institute of General Medical Sciences (NIGMS)	2,509	2,509	2,186
Natl. Inst. of Child Health & Human Development (NICHD)	1,338	1,337	1,032
National Eye Institute (NEI)	707	715	550
National Institute of Environmental Health Sciences (NIEHS)	693	692	534
National Institute of Environmental Health Sciences *	77	77	60
National Institute on Aging (NIA)	1,596	1,597	1,304
Natl. Inst. of Arthritis & Musculoskeletal & Skin Diseases (NIAMS)	541	541	418
Natl. Inst. on Deafness and Communication Disorders (NIDCD)	422	422	326
National Institute of Mental Health (NIMH)	1,517	1,545	1,245

NIH Institutes, Acronyms, and Budget (2016-2018 in billions of dollars)

	2016	2017	2018
National Institute on Drug Abuse (NIDA)	1,049	1,075	865
National Institute on Alcohol Abuse and Alcoholism (NIAAA)	467	467	361
National Institute of Nursing Research (NINR)	146	146	114
National Human Genome Research Institute (NHGRI)	513	518	400
Natl. Institute of Biomedical Imaging and Bioengineering (NIBIB)	343	346	283
Natl. Institute on Minority Health and Health Disparities (NINHD)	280	279	215
Natl. Center for Complementary and Integrative Health (NCCIH)	130	131	102
National Center for Advancing Translational Sciences (NCATS)	684	684	557
Fogarty International Center	70	70	
National Library of Medicine (NML)	395	394	373
Office of the Director	1,571	1,620	1,452
Buildings and Facilities	129	129	99
National Institute for Research on Safety and Quality (NIRSQ)			379
Total, Program Level	32,358	32,593	26,920

State of Israel 2019 budget: 116 billion dollars

What Happens to a Proposal from the Time of Submission to Funding?

Routing of a grant

- ✤ At the submission deadline the grant is referred to the Center for Scientific Review (SCR) (!!!)
- Officers assign the grant to an Institute (specific division) and a Study Section (Intervene)
- At the division, a program director is assigned to the grant and follows it through (Contact-PD)
- Applications are reviewed in study sections. Each grant receives a written critique and a score (Contact- SRO).
- Scores and summary statement are referred to Council, where funding decisions are made (Intervene).
- If funding is approved, there are some negotiations about budget details and start time.
- For funded grants: Yearly reports and final termination report are requested (Patents).

Study Sections

- The Center for Scientific Review (CSR) assigns grant applications to study sections groups of 20–40 scientists focused on a particular research field who are charged with reviewing applications.
- Each study section is managed by a CSR's Scientific Review Office (SRO), who makes initial contacts with scientists, asking them to become members of a study section.
- The SRO assigns grant applications to specific members of a study section and organizes review meetings, where applications are reviewed and scored.
- Reviews of investigator-initiated research applications (R01, R03, R21, R15, and Ks) are done by chartered study sections which have both regular and temporary members.
- Other types of Study Sections: Special Emphasis Panels, Fellowships, SBIR (small business innovation research), and STTR (technology transfer research).

Examples of Integrated Review Groups (total of 25)

Biological Chemistry and Macromolecular Biophysics Biology of Development and Aging Brain Disorders and Clinical Neuroscience Bioengineering Sciences and Technologies Cell Biology Cardiovascular and Respiratory Sciences Vascular and Hematology Digestive, Kidney and Urological Systems Endocrinology, Metabolism, Nutrition and Reproductive Sciences Genes, Genomes, and Genetics Infectious Diseases and Microbiology Integrative, Functional and Cognitive Neuroscience Immunology Interdisciplinary Molecular Sciences and Training Molecular, Cellular and Developmental Neuroscience Musculoskeletal, Oral and Skin Sciences Oncology 1 – Basic Translational Oncology 2 – Translational Clinical Surgical Sciences, Biomedical Imaging and Bioengineering

The Endocrinology, Metabolism, Nutrition and Reproductive Sciences IRG

Reviews applications that address molecular, cellular, and higher order hormoneregulated processes in physiology and pathophysiology.

Study Sections

- Molecular and Cellular Endocrinology Study Section (MCE)
- Integrative and Clinical Endocrinology and Reproduction Study Section (ICER)
- Cellular, Molecular and Integrative Reproduction Study Section (CMIR)
- Pregnancy and Neonatology Study Section (PN)
- Cellular Aspects of Diabetes and Obesity Study Section (CADO)
- Integrative Physiology of Obesity and Diabetes Study Section (IPO)
- Clinical and Integrative Diabetes and Obesity Study Section (CIDO)
- Integrative Nutrition and Metabolic Processes Study Section (INMP)
- Diabetes, Metabolism, Nutrition and Obesity Small Business (ENMR (10))
- Reproductive Sciences Small Business (EMNR (11))
- Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group Fellowship Panel (F06)

Types of Research Grants

Research Grants (R series)

- RO1: Main type, 3-5 years, no restriction on budget (usually 250K/year)
- R03: Small grants, 2 years, 50K/year
- R13: Support for conference
- R15: Enhancement award for undergraduate and graduate students
- R21: Exploratory, 2 years, 275K/year
- ✤ R24: Resource-related research projects
- ✤ R25: Education projects
- ✤ R34: Clinical Training
- R41/R42: Small business feasibility, 1 year, 150K/year, 3 phases, up to 1 million
- ✤ R43/R44: Small business innovative research, 6 months, 150K, up to 1 million
- R56: High priority short term projects
- Career Development Awards (K series)
- Research Training and Fellowships (T & F series)
- Program Project/Center Grants (P series)
- Research Project Cooperative (U01 series)

Foreign Applicants

- The peer review of applications from foreign institutions is the same as that for applications from U.S. institutions and is described in the NIH Grants Policy Statement Chapter 2.4.
- The following are assessed as part of the review process and award decisions for applications from foreign institutions:
- Whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources.
- Whether the proposed project has specific relevance to the mission and objectives of the IC and has the potential for significantly advancing the health sciences in the United States

Grant Review Process

- Before the meeting: Selecting grants for review
- ✤ At the meeting: Order of Review
- The Critique: Primary, secondary and tertiary reviewers Preliminary overall impact score
- The Scoring: A 9-point rating scale (1 = exceptional; 9 = poor)
- 1. Significance
- 2. Investigator(s)
- 3. Innovation
- 4. Approach
- 5. Environment
- Overall Impact (voting and consensus)
- Percentile
- Information for applicants
- Funding level : Best kept secret

The Advisory Council/Board

- Council of potential awarding Institute/Center (IC) does the second level of review.
- Membership is composed of scientists from the extramural research community and public representatives.
- Members are chosen by the IC and are approved by the Department of Health and Human Services. Some members are appointed directly by the President of the United States.
- NIH program staff consider the overall impact scores given by the study section, percentile rankings, and summary statements in light of the IC priorities.
- Council members have access to applications and summary statements pending funding for that IC in that council round.
- The Advisory Council/Board also considers the Institute/Center's goals and needs and advises the Institute/Center director concerning funding decisions.
- The Institute/Center director makes final funding decisions based on staff and Advisory Council/Board advice.

DOD – Congressionally Directed Medical Research Programs (CDMRP)

- Mostly funding Specific Disease- or Condition related studies: e.g., breast cancer, prostate cancer, autism, PTSD, Gulf war illness, etc.
- The annual funding of the various programs depends on the success by different lobby groups to obtain congressional funding.
- The first program in 1993 was on breast cancer (250 million dollars).
- Very strict adherence to rules of formatting, content and timing.
- More complex structure of proposals: many more components than NIH.
- The review and scoring systems are very similar to those in NIH.
- ✤ At the study section meeting: presence of "consumers".
- Two tier funding decision: Scientific review and then council.
- Very elaborate annual reporting system for funded grants.