Peer Review Process for NIH Grant Applications

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Overview

- **How grants fit into NIH's mission**
- **Overview of peer review process**
- **Study sections that review statistical/quantitative methods grants**
- **Highlight a few issues**
  - **Recent changes to application instructions (*Human subjects)**
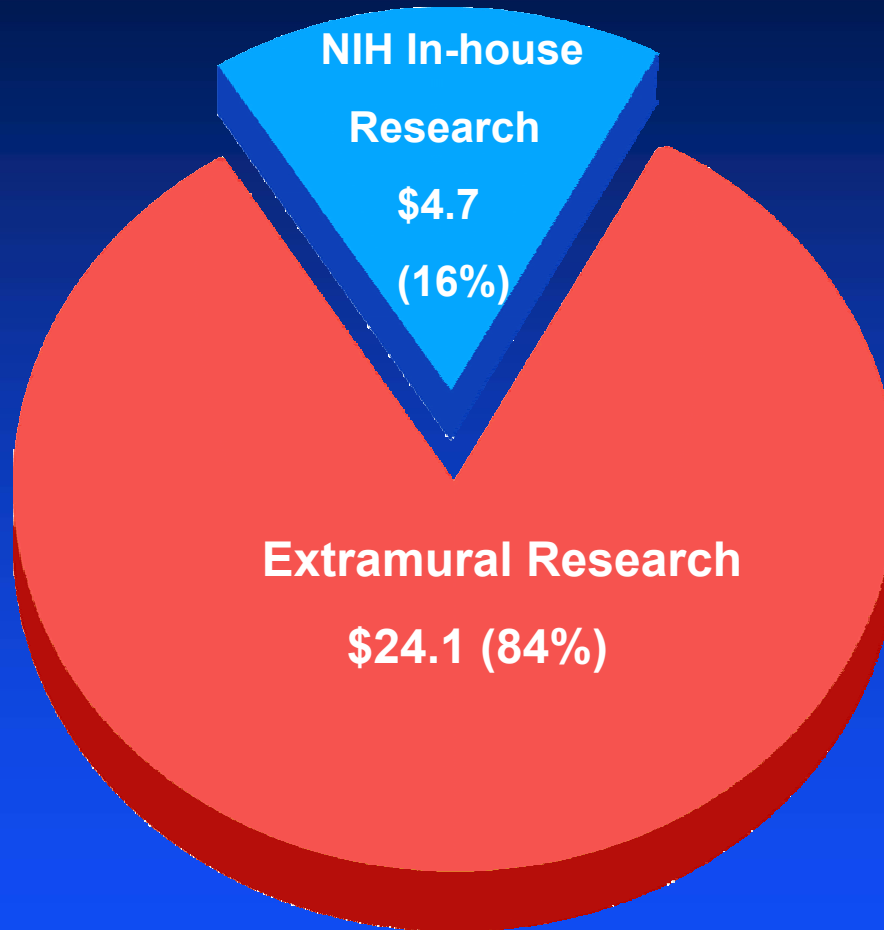 - **New directions for grant review**

National Institutes of Health

NIH Mission:

Promote biomedical and behavioral research to help improve the health of all Americans

Carried out through 27 Institutes and Centers

Allocation of FY 2005 NIH Budget (dollars in billions)

NIH In-house Research

$4.7

(16%)

Extramural Research

$24.1 (84%)

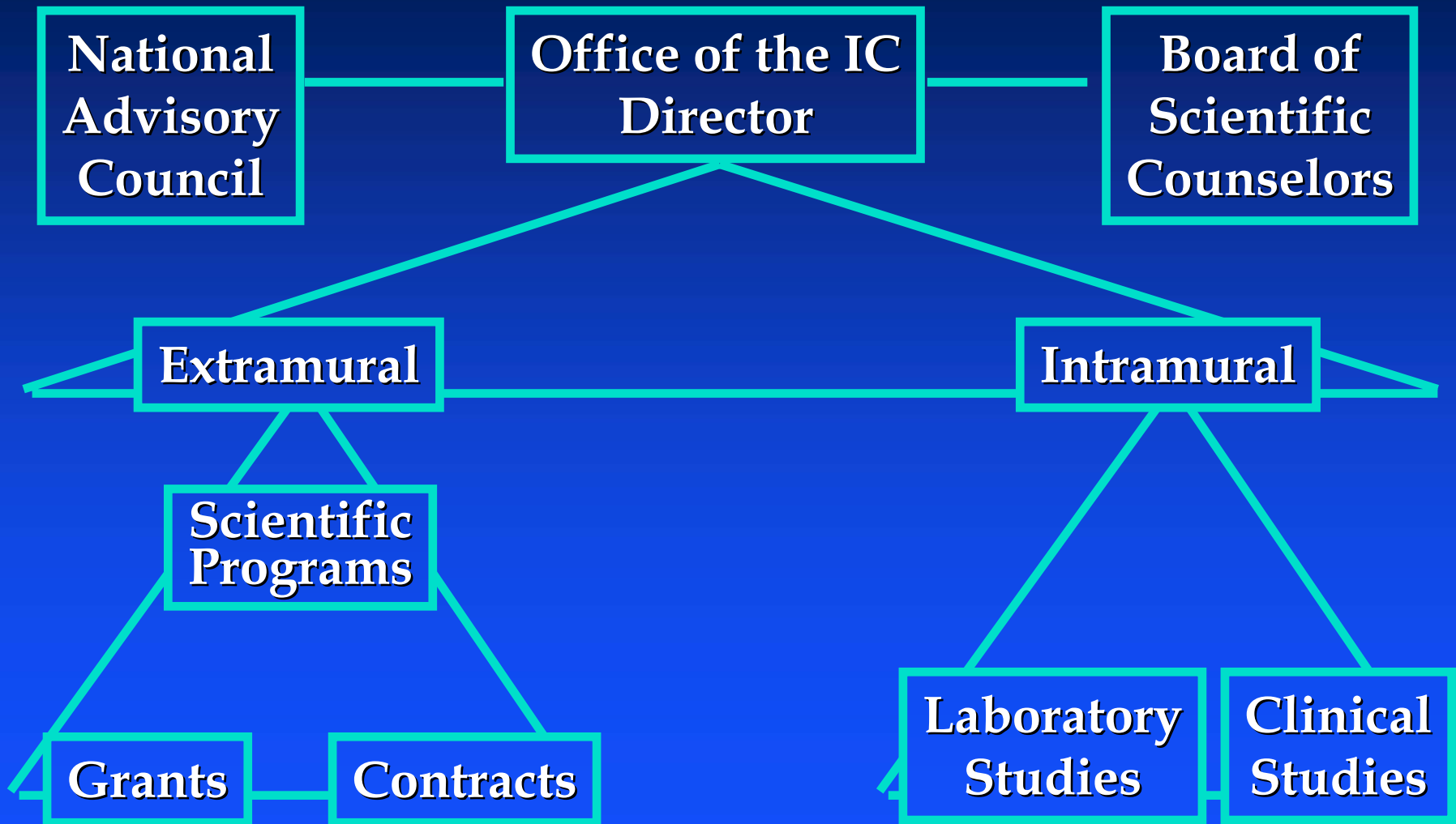**24/27 Institute/Centers award extramural funds**

Extramural Funding Mechanisms

- **Grants**
  - Unsolicited
  - In response to RFA, Program Announcement (PA, PAR, PAS)
- Cooperative agreements
- Contracts

Grant Mechanisms

- **R series (research projects)**
  - **R01 -individual research**
  - **R03- small, short-term**
  - **R21- exploratory/developmental**
  - **R15 – certain inst. with little NIH funding**
- **Other series**
  - **F (fellowship)**
  - **T (Training)**
  - **P (Large program projects/centers)**

Dual Review System for Grant Applicatio[n]

First Level of Review

Scientific Review Group

- Provides Initial Evaluation of Scientific Merit
- Rates Applications and Makes Recommendations Regarding Budget and Duration
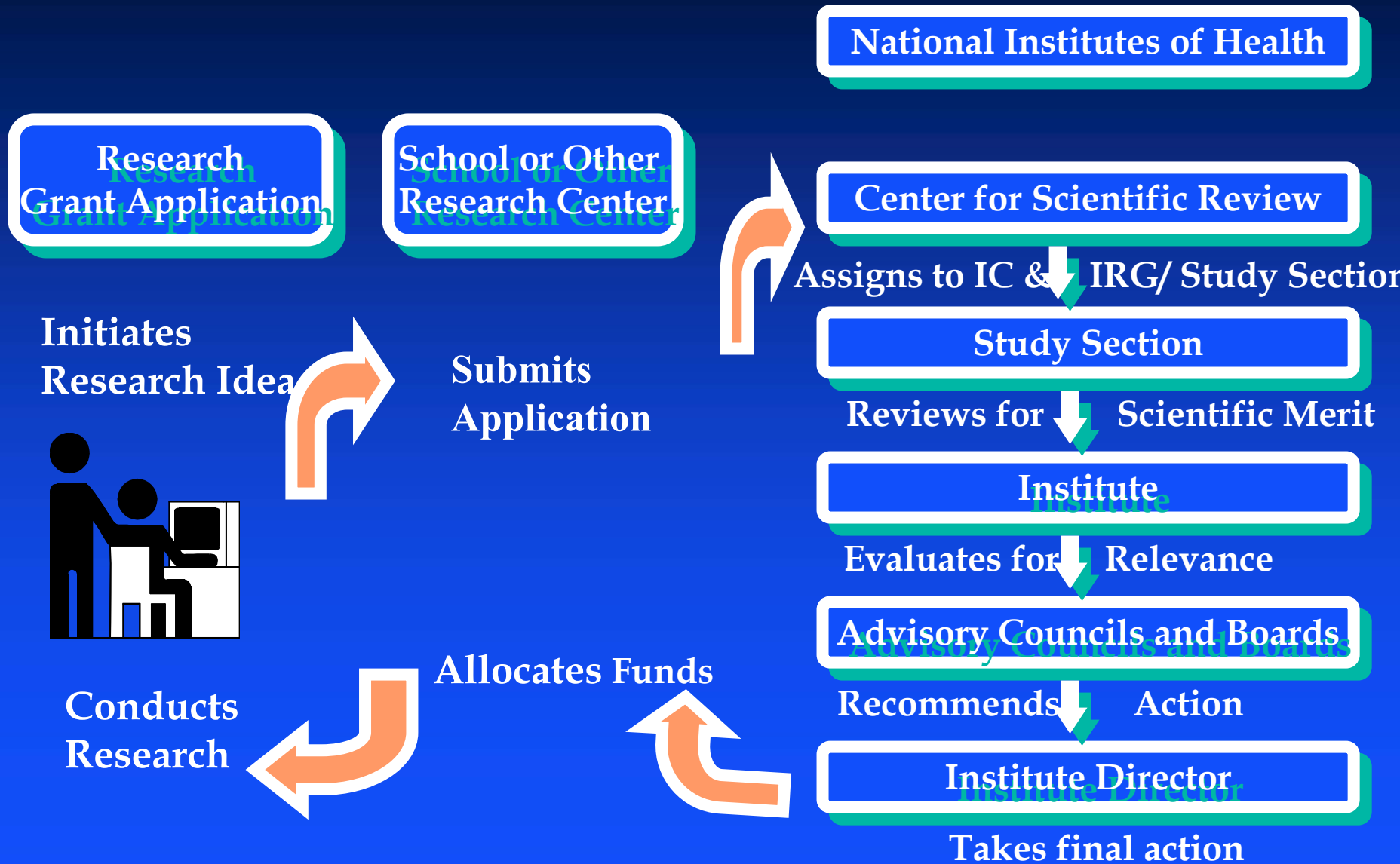
Second Level of Review

Council

- Assesses Quality of SRG Review
- Makes Recommendation to Institute on Funding
- Evaluates Program Priorities and Relevance
- Advises on Policy

Review Process for a Research Grant

Research Grant Application

School or Other Research Center

National Institutes of Health

Center for Scientific Review

Assigns to IC & IRG/ Study Section

Study Section

Initiates Research Idea

Submits Application

Reviews for Scientific Merit

Institute

Evaluates for Relevance

Advisory Councils and Boards

Allocates Funds

Recommends Action

Conducts Research

Institute Director

Takes final action

Typical Timeline for a New Individual Research Project Grant Application (R01)

There are three overlapping cycles per year:

- –Submit in February (June, October)
  - –Review in June (October, February)
    - –Council in September (January, May)
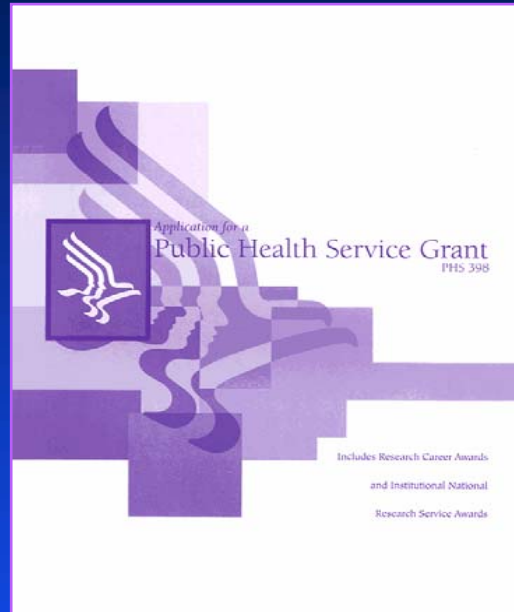   - –Earliest award in December (April, July)

Cycle 1----
Cycle 2----
Cycle 3----

Pre-submission

- **Follow instructions (PHS 398) – format, sections, length, deadlines**

- **PI can talk to program official before submission**

- **PI can request the funding institute and review by a specific study section**

PHS Research Grant Application Kit (form PHS 398)

Recent changes:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-039.html

READ the Instructions:

http://grants.nih.gov/grants/funding/phs398/instructions2/phs398instructions.htm

Upon Receipt:

- **Unique application number assigned**

    1 R01   CA09999-01A1

- **Assigned to institute and study section**

    - **70% applications reviewed in one of ~ 250 study sections in Center for Scientific Review (CSR)**

- **PI is notified**

Scientific Review Groups or Study Sections

- **Objective, fair, and competent review of scientific and technical merit**

- **Scientific Review Administrators:**
  - **Organize the review meeting**
  - **Ensure procedures and policies are followed**
  - **Communicate results of review**

What Study Sections Review Statistical Grants?

- **Biostatistical Methods and Research Design (BMRD)**

- **SSPS – econometrics, survey methods**

- **GCAT – microarray, pop genetics, gene mapping**

- **BDMA – comp biol, bioinform, basic science**

- **MABS- modeling complex bio systems (cellular/molec level)**

- **BCHI – large clinical data base development, data mining**

What Does BMRD Review?

- Development of quantitative methods and/or assoc. technologies to address statistical/mathematical problems, research design, or methodological issues

- Relevant to biomedical/clinical, behavioral, social sciences (clinical and pop-based science)

- Ex: sample selection, bias, survey methods, study/trial design, measurement, psychometrics, analysis, modeling
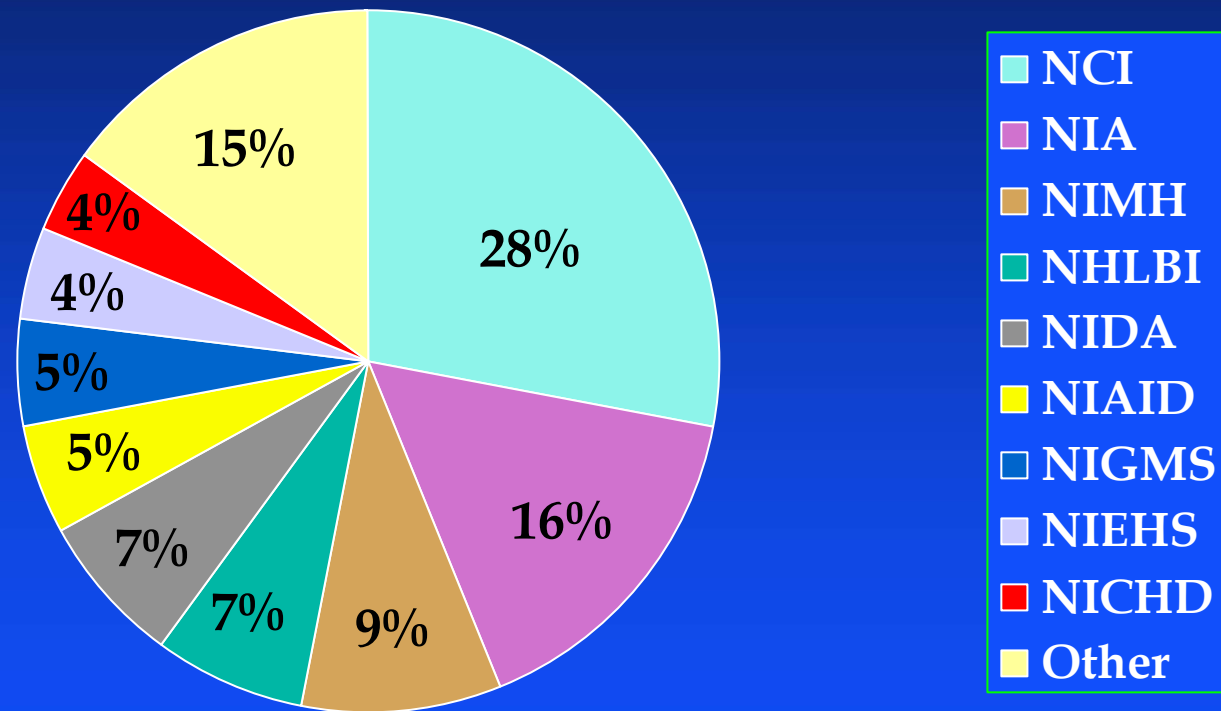
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BMRD Study Section

- **21 regular members**
  - Active, productive researcher in field
  - Work effectively in group context
  - Impartial
- **4-year terms**
- **Cover major topical areas**
- **Diversity: institutional, geographic, gender, racial/ethnic**

Institutes Sponsoring BMRD Grants

Legend:
- NCI
- NIA
- NIMH
- NHLBI
- NIDA
- NIAID
- NIGMS
- NIEHS
- NICHD
- Other

Pie chart values: 28%, 16%, 9%, 7%, 7%, 5%, 5%, 4%, 4%, 15%

20/24 Funding institutes have had grants reviewed in BMRD

Pre-review Activities

- **Recruit additional reviewers (temporary members) to cover expertise**

- **Assign applications; each has 3-4 reviewers (expertise, conflict, continuity)**

- **Provide review materials, training, information on policies and procedures**

- **Arrangements for review meeting**

What happens in the study section meeting?

- **Closed**
- **Orientation**
- **Determine streamlined proposals**
- **Review**
  - Discussion of scientific merit, human subjects, inclusion
  - Everyone scores
    - ◆ Scores range from 1.0-5.0 (best – worst)
  - Budget

Streamlining

- Those applications that the entire group agrees would fall below the median score

- Streamlined proposals are not scored or discussed

- Summary statement with reviewer's written critiques are provided

- Make more efficient use of time at meetings

Post-meeting

- Scores – averaged, multiplied by 100, percentiled (based on current and 2 previous rounds)

- Scores and Percentiles – available on NIH Commons or from PO- DON'T CALL ME

- Summary statements – available within 6-8 weeks

- Funding decisions are made by Institutes with input from Advisory Council

Human Subjects and Inclusion

- **New guidance on research involving the use of "coded, private information"**

  http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf

- **Changes reflected in new PHS 398 instructions**

- **http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-020.html**

Human Subjects

- **Definition:**

  …living individual about whom an investigator obtains either (1) data through intervention or interaction with the individual, or (2) identifiable private information….

- **Not human subjects – non-living, or non-identifiable information (must document)**
  - **No code key**
  - **Provided w/ agreement to not release identifying info**
  - **Policies prohibiting release (Census data)**
  - **No investigator has access to key or identifiers**

Human Subjects

	Previous	New
1/Simulated data, non-human, not at indiv level	No HS	No HS
2/ Collecting data thru interaction/intervention	HS	HS
3/ Existing private info w/ ID		
No access to ID	E4	No HS
1+ investig w/ access	HS	HS

Research involving Human Subjects must address:

- **Risks to subjects**

- **Protections**

- **Potential benefits**

- **Importance of knowledge to be gained**

- **Inclusion of women, minorities, and children (less than 21 years)**

What's new

- **CSR has a new Director:**

  Dr. Antonio Scarpa

- **Speed up review and feedback process**
- **Greater use of electronic technology**
  - **Applications on CD for reviewers**
  - **electronic submission**
  - **NIH Commons – scores, summaries, posting reviews and materials**
  - **"on-line" meetings**

Useful web sites

- NIH site: http://www.nih.gov/
- Office of Extramural Research:
  http://grants1.nih.gov/grants/
- Program Announcements:
  http://grants.nih.gov/grants/guide/pa-files/index.html
- CSR site: http://www.csr.nih.gov/
- NIAID's "All About Grants" tutorials:
  www.niaid.nih.gov/ncn/grants/default.htm

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