



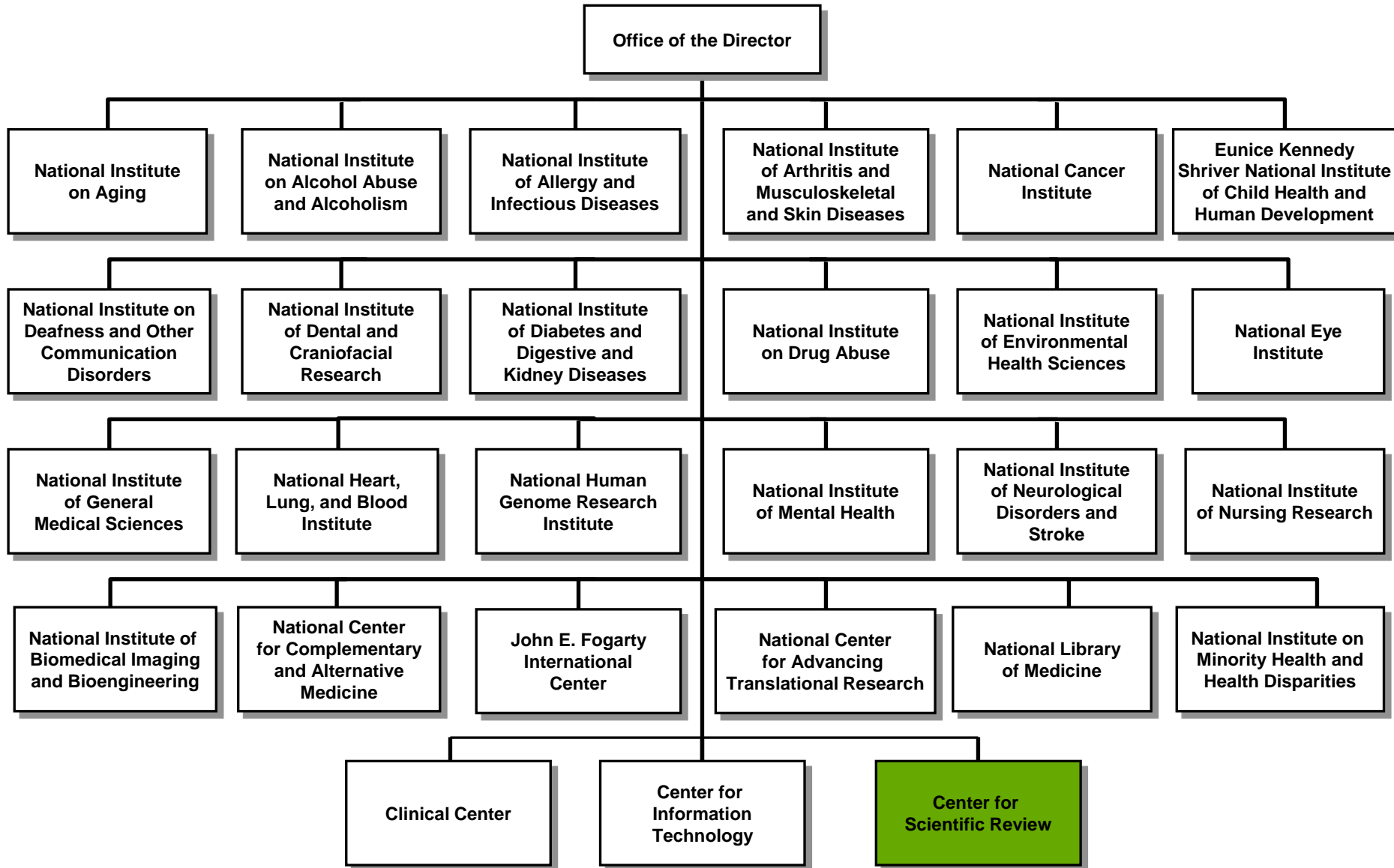
Center for
Scientific Review

Peer Review Process

(Policies for Gender and Diversity Groups Inclusion)

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National Institutes of Health



Center for Scientific Review

Referral

- Central receipt point for most PHS Grant Applications
- Institute/Center assignment (potential funding component)
- Assignment to Scientific Review Group in CSR or in an Institute

Scientific Review

- Approximately 240 CSR chartered study sections and regularly recurring Special Emphasis Panels that primarily review:
 - Research Grant Applications
 - Fellowship Applications
 - Academic Research Enhancement Award Applications
 - Small Business Innovation Research Applications

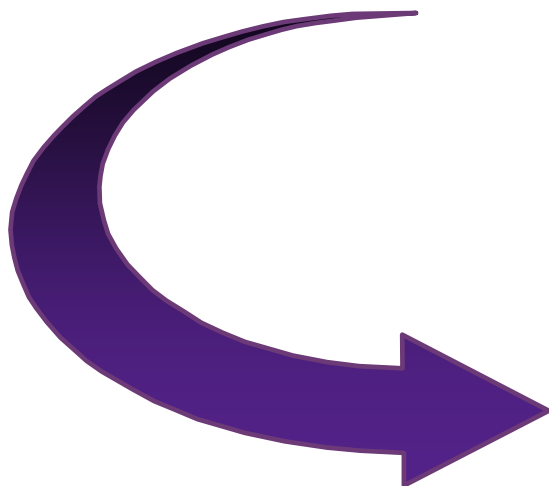
CSR Mission



To see that NIH grant applications receive fair, independent, expert, and timely reviews – free from inappropriate influences – so NIH can fund the most promising research.

Overall Peer Review Process

NIH Peer Review System for Grant Applications



First Level of Review
Scientific Review Group
(Study Section)

Second Level of Review
NIH Institute/Center Council



Discussions Focus on the Best Applications

- Reviewers typically discuss about half the applications
- The panel will discuss any application any reviewer wants to discuss



Review Criteria

- Overall Impact
 - Assessment of the likelihood for the project to *exert a sustained, powerful influence on the research field(s) involved*
- Core Review Criteria
 - Significance
 - Investigator(s)
 - Innovation
 - Approach
 - Environment

Review criteria each scored from 1 - 9

Additional Criteria Contribute to Overall Impact Scores

- Protections for human subjects
- Inclusions of women, minorities, and children
- Appropriate use of vertebrate animals
- Management of biohazards

Review Guidelines for Women and Minority Groups inclusion in NIH Sponsored Research

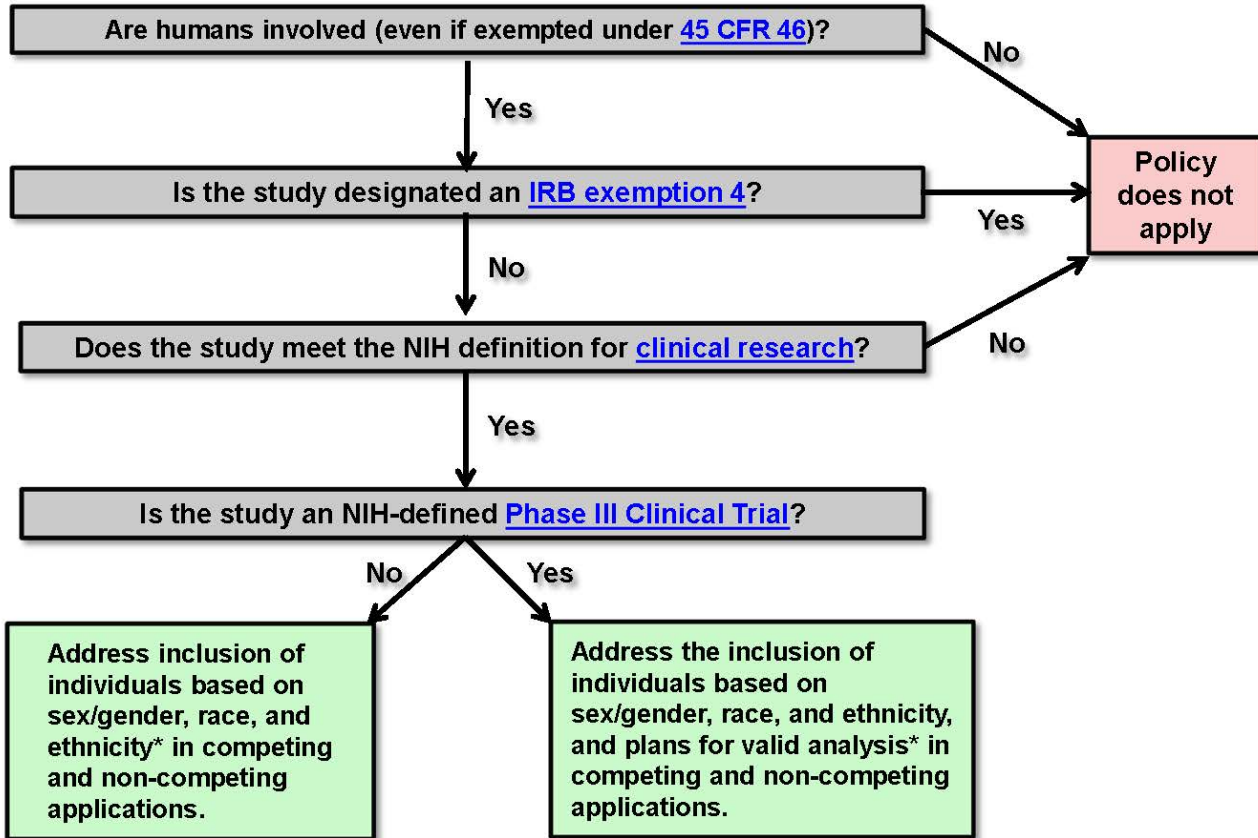
Peer Review of Inclusion

- The assessment of scientific and technical merit of applications by the SRG must include:
 - ❖ an evaluation of the proposed composition of the study population in terms of women, minorities, and children
 - ❖ appropriateness to the scientific objectives of the study
- If the representation of gender, minorities, or children is inadequate to answer the scientific question(s) addressed and the justification for the selected study population is inadequate:
 - ❖ reviewers will consider these factors as a scientific weakness or deficiency in the study design and will be factored into the overall impact score

Brief Overview of Inclusion Policy

- Inclusion of women and minorities in NIH funded or supported clinical research is mandated by law (42 USC 289a-2)
- Purpose of the policies:
 - To ensure that the sex/gender, race, ethnicity, and age of study participants reflects the population needed to accomplish the scientific goals of the study
 - Cost is not an acceptable reason to exclude certain groups
- Inclusion of children mandated by NIH policy
 - Child currently defined as under 21 (for purposes of inclusion policy)
- What is subject to the policies?
 - All studies that meet the NIH definition of clinical research

Decision Tree for Monitoring Inclusion Based on Sex/Gender, Race, and Ethnicity in Research



*Refer to [application instructions](#), the relevant Funding Opportunity Announcement, and the [inclusion policy page](#) for additional guidance.

NIH definition of clinical research:

- (1) **Patient-Oriented Research:** Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual (e.g., IRB E4).
- **Patient-oriented research includes**
 - (a) mechanisms of human disease
 - (b) therapeutic interventions
 - (c) clinical studies
 - (d) development of new technologies
- (2) Epidemiologic and Behavioral Studies
- (3) Outcomes Research and Health Services Research

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title:

Total Planned Enrollment:

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino			
Not Hispanic or Latino			
Ethnic Category: Total of All Subjects *			
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
Racial Categories: Total of All Subjects *			

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects"

Planned Enrollment Report

This report format should NOT be used for collecting data from study participants.

Study Title:

Domestic/Foreign: (D/F drop down)

Comments:

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native					
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American					
White					
More Than One Race					
Total					



Summary: Who is responsible for monitoring implementation

- Investigators
 - NIH staff
 - Scientific Review Officers
 - Program Officers
 - Grants Management
 - Peer reviewers
 - Advisory Councils
 - Institute/Center Directors
- } NIH Inclusion Policy Office
Office of Extramural Research

The goal of NIH inclusion policies is to ensure that the right people are in the study. Reviewers focus on whether the inclusion plans are acceptable in the context of the science proposed. Concerns are considered a bar to funding and must be resolved prior to award.