



# NIH Genes and Environment Initiative Exposure Biology Program

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## Cooperative Agreements & Review Issues

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# NIH Genes and Environment Initiative Exposure Biology Program

## Cooperative Agreements

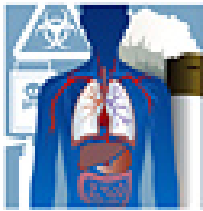
- **The cooperative agreement (U01 or U54) is an assistance mechanism in which substantial NIH programmatic involvement with the awardees is anticipated**
- **NIH role is to support and stimulate the activities of the program by working with the awardees in a partnership role**
- **It is NOT to assume direction, responsibility for research or play a dominant role in the program**



# NIH Genes and Environment Initiative Exposure Biology Program

## Need for Cooperative Agreements

- **GEI is a high visibility program under the direction of the Office of the Secretary of DHHS**
- **There is a multi-layer committee structure**
- **Frequent interactions with grantees to facilitate transfer of information and reporting of results**
- **Product driven – opportunity to promote research products to next stage through collaborations and supplementation**
- **To assure results need to move forward together**



# NIH Genes and Environment Initiative Exposure Biology Program

## PI rights and responsibilities (Extramural and Intramural)

- **Design and develop experimental approaches and conduct research**
- **Set project milestones**
- **Opportunities for collaboration**
- **Participate in group activities**
  - **Voting member of steering committee (SC)**
  - **Develop and adhere to common guidelines**
    - ...Progress reporting
    - ...Publications
    - ...Data sharing



# NIH Genes and Environment Initiative Exposure Biology Program

## NIH staff role

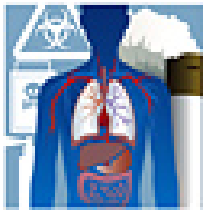
- **Two NIH staff members may work with every awardee**
  - **Program Director** – responsible for normal stewardship and administration of award
  - **Project Scientist** – extramural staff selected because of content area expertise and experience
    - ...Technical assistance, advice and coordination
  - In some instances the **PD** and **PS** may be the same person
- **Facilitate not direct**



# NIH Genes and Environment Initiative Exposure Biology Program

## NIH staff responsibilities

- **Project Scientists** participate as **Steering Committee** members in:
  - The process of setting research priorities
  - Setting and monitoring program milestones
  - Determining opportunities to enhance product development and implementation
  - Program coordination
  - Assisting the development of guidelines, QA/QC, other issues that arise
  - Data analysis, interpretation and co-authorship when warranted
- **Multiple Project Scientists** can be members of **Steering Committee** and subcommittees - **NIH** has one vote



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## Collaborative responsibilities (Extramural and Intramural)

- **Grantee meetings twice a year**
- **Steering committees may meet during grantee meetings and more frequently by teleconference as needed**
- **Steering Committee**
  - **Develop policies, guidelines, and procedures**
  - **Define and monitor program milestones and annual goals**
  - **Create subcommittees as needed**
  - **Liaison with other GEI committees as needed**

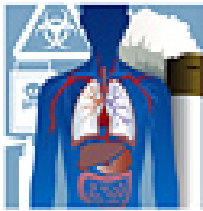


# NIH Genes and Environment Initiative Exposure Biology Program

## Review of applications

- **Lead ICs will conduct reviews by convening special emphasis panels**
- **Intramural applications will be reviewed using same criteria as extramural applications but in a separate meeting**





# NIH Genes and Environment Initiative Exposure Biology Program

## Review Criteria

### U01 and U54 subprojects

- **Significance**
- **Approach**
- **Innovation**
- **Investigators**
- **Environment**

### U54 Facility Cores

- **Utility of Core Members in the Program**
- **Quality of service provided**
- **Cost effectiveness and efficiency**
- **Qualification of personnel involved**
- **Justification of requested items within the Core**
- **Core must provide services for two or more research projects**



# NIH Genes and Environment Initiative Exposure Biology Program

## Review Criteria

### U54 Administrative Core

- Evaluate the qualifications and effectiveness of the leadership
- Evaluate the Core's plans for monitoring the research productivity and the management of resources
- Evaluate the Core's plans for promoting collaborative activities among the research projects

### U54 Overall program

- At least three meritorious research projects
- Significance of the overall program (Impact)
- Synergy and cohesiveness of the program
- Innovative use of new, existing, emerging concepts & approaches
- Experience and qualification of the Research Team
- Environment