### CSR Peer Review - Fiscal Year 2014

- 86,000 applications received
- 16,000 reviewers
- 237 Scientific Review Officers
- 1,500 review meetings



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## Applications Are Assigned by:

### **Referral Officers**

Professional scientists, most of whom also serve as scientific review officers of CSR study sections



### Your Application is . . .



- Checked for being on time, formatted correctly and complete
- Assigned to a Scientific Review Group
- Assigned to an NIH Institute or Center



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### **Applications Are Assigned to:**

- · Institutes or Centers based on-
  - Overall mission and guidelines of the Institute or Center
  - Specific programmatic mandates and interests of the Institute or Center
- Integrated Review Groups based on—
  - Specific review guidelines for each Integrated Review Group (IRG)



### **Assignment to CSR Study Sections**

### Within an IRG, applications are assigned to:

### **Standing Study Sections**

 When subject matter of application matches the referral guidelines for the study section or

### **Special Emphasis Panels (SEPs)**

- When the subject matter does not fit into any study section
- When assignment of an application to the most appropriate study section creates a conflict of interest
- When certain types of grants are sought (e.g., fellowships, SBIRs, AREAs)



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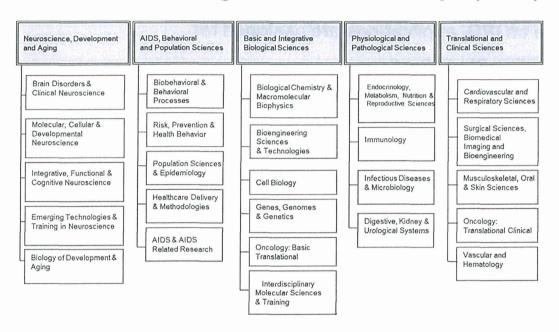
### **Assignment to Institutes**

# Applications are referred to an Institute or Center as the potential funding component.

- This assignment is based on a match between the research proposed and the overall mission of the Institute or Center.
- Dual assignments are made where applications are appropriate for more than one Institute or Center.



## **Divisions and Integrated Review Groups (IRGs)**





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## **The Study Section**



#### Division of Translational and Clinical Sciences

# Integrated Review Groups

Cardiovascular and Respiratory Sciences IRG

Musculoskeletal, Oral and Skin Sciences IRG

## Oncology Translational and Clinical IRG

Surgical Sciences, Biomedical Imaging & Bioengineering IRG

Vascular and Hematology

#### **Study Sections**

Basic Mechanisms of Cancer Therapeutics (BMCT) Cancer Biomarkers (CBSS)

Chemo/Dietary Prevention (CDP)

Cancer Immunopathology and Immunotherapy (CII) Clinical Oncology (CONC)

Drug Discovery and Molecular Pharmacology (DMP) Radiation Therapeutics and Biology (RTB)

Developmental Therapeutics (DT)
Cancer Diagnostics and Treatments SBIR (OTC-H)
Radiation Therapy and Biology SBIR (OTC-R)

Cancer Drug Development and Therapeutics SBIR (OTC-T)

Molecular Targets for Cancer Interventions (BMCT-C)



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### Help Your Application Get to the Right Study Section







#### Find a Study Section

Applications are reviewed in Study Sections (Scientific Review Group, SRG). Integrated Review Groups (IRGs) are clusters of Study Sections based on scientific discipline.

Enter Search Keywords



http://www.csr.nih.gov/



#### Integrated Review Groups: Oncology Translational and Clinical IRG [OTC]

#### Developmental Therapeutics Study Section [DT]

The Developmental Therapeutics [DT] Study Section reviews applications addressing the experimental therapy of neoplastic diseases in *in vitro* systems and *in vivo* model systems, including some early-stage, pilot clinical trials. The major emphasis of this study section is on the rational development of novel therapeutic strategies that have a significant potential for early translation to the clinic.

#### Roster

#### DT Membership Roster **DT Meeting Rosters**

#### Topics

- Evaluation of drug-delivery strategies (including nanoparticles, liposomes and other delivery vehicles) and gene therapy approaches involving non-immunologic targets for the treatment of cancer.
- Translational studies of novel antineoplastic agents and pre-clinical drug toxicity, pharmacokinetic/pharmacodynamic and biomarker studies of anticancer agents.
- Development of anti-angiogenic therapeutic strategies and rational combinations of cytotoxic drugs with novel agents including those targeting: growth factors, signaling, cell cycle regulation, angiogenic, and differentiation pathways.

  Development and application of mathematical and computational methods for the investigation of combination chemotherapy using small molecules and other modalities.
- Therapeutic approaches involving biologic response modifiers either alone or in combination with novel or conventional drugs for cancer treatment.
- Early-stage, pilot clinical trials of novel anticancer therapeutic and drug-delivery strategies involving pharmacokinetic, pharmacodynamic, toxicologic, or pharmacogenomic endpoints

#### Closely Related

Basic Mechanisms of Cancer Therapeutics Study Section [BMCT]
Gene and Drug Delivery Systems Study Section [GDD]
Cancer Immunopathology and Immunotherapy Study Section [CIII]
Drug Discovery and Molecular Pharmacology Study Section [DMP]
Clinical Oncology Study Section [CONC]



### Peer Review in CSR

- CSR Study Sections are managed by a Scientific Review Officer (SRO) who is a doctoral-level professional, whose scientific background is close to the focus of the study section.
- Each CSR standing study section has 12-25 regular members who are from the scientific community.
- Temporary members are recruited as needed.
- About 60-100 applications are normally reviewed at each study section meeting.



#### Role of the Scientific Review Officer

# Designated Federal Official with overall responsibility for the review process

- Performs administrative and technical review of applications to ensure completeness and accuracy
- · Selects reviewers based on broad input
- Manages study section meetings
- Prepares summary statements



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### **Extramural Support Assistant**

- Assists Scientific Review Officer with administrative and technical review of applications
- Makes preparation for study section meetings and project site visits
- Shares administrative responsibilities at meetings
- Prepares preliminary summary statements for Scientific Review Officers



### How Reviewers Are Selected for Study Section Service

- Demonstrated scientific expertise/research support
- Doctoral degree or equivalent
- Mature judgment
- Work effectively in a group context
- · Breadth of perspective
- Impartiality
- · Representation of women and minority scientists
- Geographic distribution



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### Where Do We Find Reviewers?

- CSR Registry for Volunteer Reviewers
- Successful applicants
- Recommendations from reviewers and NIH staff
- NIH RePORTER (<a href="http://projectreporter.nih.gov/reporter.cfm">http://projectreporter.nih.gov/reporter.cfm</a>)
- Internet
- Scientific conferences



### **Before the Study Section Meeting**

- Each application is assigned to 3 or more reviewers 5-6 weeks in advance
- Reviewer assess each application by providing:
  - A preliminary Overall Impact score
  - Criterion Scores for each of the 5 Core Review Criteria
  - A written critique



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### **Reviewer Conflicts of Interest (COI)**

#### What Constitutes a Reviewer COI?

- Institutional
- Family member/close friend
- Collaborator
- · Longstanding scientific disagreement
- Personal bias
- Appearance of conflict

http://grants.nih.gov/grants/peer/peer\_coi.htm



### Confidentiality

- Review materials and proceedings of review meetings represent privileged information for reviewers and NIH staff.
- At the end of each meeting, reviewers must destroy or return all review-related material.
- Reviewers should not discuss review proceedings with anyone except the SRO.
- Questions concerning review proceedings should be referred to the SRO.
- Applicants should never communicate directly with any members of the study section about an application.



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### Role of Study Section Chair

- Partners with their Scientific Review Officer to conduct the meeting
- · Guides and summarizes study section discussion
- Ensures all study section member opinions are given careful consideration
- Manages scientific discussions at the meeting, e.g., timeliness and thoroughness



### **The Study Section Meeting**



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### At the Meeting

#### Order of Review

- The average of the preliminary Overall Impact score from the assigned reviewers determines the review order
- Discussions start with the application with the best average preliminary Overall Impact score

#### Clustering of Review

- New Investigator R01 applications are clustered
- Clinical applications & other mechanisms may be clustered (n ≥ 10)

#### **Not Discussed Applications**

- About half the applications will be discussed
- Applications unanimously judged by the review committee to be in the lower half are not discussed



## At the Meeting: Application Discussion

- Any member in conflict with an application leaves the room
- Reviewer 1 introduces the application and presents critique
- Reviewers 2 and 3 highlight new issues and areas that significantly impact scores
- All eligible members are invited to join the discussion and then vote on the final overall impact score



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### **CSR Study Sections: The Meeting**



- Each CSR standing Study Section has ~12-22 regular members plus temporary reviewers from the scientific community
- About 70-100 applications are usually reviewed by each study section in 1-2 day meetings





### **Discussions Focus on the Best Applications**



- Reviewers typically discuss the top half of the applications
- The panel will discuss any application a reviewer wants to discuss



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### Your Scientific Review Officer



# During and After the Review Meeting

- Manages the meeting
- Prepares summary statements
- Provides information to NIH Institutes and Centers



### Your Application Could Be Reviewed Electronically

# Electronic reviews are used to facilitate reviewer participation

#### **Electronic Review Platforms**

- Telephone Assisted Meetings
- Internet Assisted Meetings
- Video Assisted Meetings





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### **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



### 9-Point Scoring Scale

Impact	Score	Descriptor
High Impact	1	Exceptional
	2	Outstanding
	3	Excellent
Medium Impact	4	Very Good
	5	Good
	6	Satisfactory
Low Impact	7	Fair
	8	Marginal
	9	Poor



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### **Overall Impact:**

The likelihood for a project to exert a <u>sustained</u>, <u>powerful</u> influence on research field(s) involved

Overall Impact	High	Medium	Low
Score	1 2 3	4 5 6	789

### Evaluating Overall Impact:

Consider the 5 criteria: significance, investigator, innovation, approach, environment (weighted based on reviewer's judgment) and other score influences, e.g. human subjects

e.g. Applications are addressing a problem of high importance/interest in the field. May have some or no technical weaknesses.

e.g. Applications may be addressing a problem of high importance in the field, but weaknesses in the criteria bring down the overall impact to medium.

e.g. Applications
may be addressing
a problem of
moderate
importance in the
field, with some or
no technical
weaknesses

e.g. Applications
may be addressing
a problem of
moderate/high
importance in the
field, but
weaknesses in the
criteria bring down
the overall impact
to low.

e.g. Applications may be addressing a problem of <u>low</u> or <u>no</u> importance in the field, with some or no technical weaknesses.



5 is a good medium-impact application, and the entire scale (1-9) should always be considered.

### **Scoring**

#### 9-point score scale is used to provide:

- Criterion Scores for each of the 5 core review criteria
- Overall Impact/Priority Score based on but not a sum of the core criterion scores plus additional criteria

#### All applications receive scores:

- Not discussed applications will receive only initial criterion scores from the three assigned reviewers.
- Discussed applications also receive an averaged overall impact score from eligible (i.e., without conflicts of interest) panel members. These scores will be averaged to one decimal place, and multiplied by 10. The 81 possible priority scores will thus range from 10-90.



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# 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



### **Summary Statement**

# Feedback to the applicant and the assigned NIH Institute(s) or Center(s) that may fund it.

- Essentially unedited critiques
- Scores for each review criterion
- Administrative notes if any

### Additional information for discussed applications

- Summary of review discussion
- An overall impact/priority score and percentile ranking
- Budget recommendations



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### What Reviewers Look for in Applications

- Significance and impact
- Exciting ideas
- Clarity
- Ideas they can understand -- Don't assume too much
- Realistic aims and timelines -- Don't be overly ambitious
- Brevity with things that everybody knows
- Noted limitations of the study
- A clean, well-written application

Insider's Guide to Peer Review for Applicants: <a href="http://www.csr.nih.gov/applicantresources/insider">http://www.csr.nih.gov/applicantresources/insider</a>



### **Common Problems in Applications**

- · Lack of new or original ideas
- Absence of an acceptable scientific rationale
- Lack of experience in the essential methodology
- · Questionable reasoning in experimental approach
- Uncritical 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



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### **Decision making process**

In the end, with notable transparency

- Study sections focus on scientific and technical merit; SRO provides summary statements with scores and written critiques to institutes, advisory councils, and applicants (60-100 application/meeting)
- Councils must review/recommend applications to be paid (often vote en bloc; an appeal venue)
- Awards are made by Institute Directors (scientific merit (90%), also programmatic priorities and availability of funds)





#### View the Videos



- NIH Peer Review Revealed
- Jumpstart Your Research Career with CSR's Early Career Reviewer Program
- NIH Tips for Applicants
- What Happens to Your NIH Grant Application

http://www.csr.nih.gov/video/video.asp



### Meet the Experts in NIH Peer Review Webinars



### For Researchers Seeking:

- R01 Grants
- Fellowship Awards
- AREA/R15 Grants
- Small Business Grants

www.csr.nih.gov/webinar



### NIH Peer Review Information on the Web

### National Institutes of Health: http://www.nih.gov

- Office of Extramural Research http://www.nih.gov/grants/oer.htm
- Grants Policy http://www.nih.gov/grants/policy/policy.htm
- Electronic Submission
   http://era.nih.gov/ElectronicReceipt

### Center for Scientific Review: http://www.csr.nih.gov

- Resources for Applicants
   <a href="http://www.csr.nih.gov/ResourcesforApplicants">http://www.csr.nih.gov/ResourcesforApplicants</a>
- CSR Study Section Descriptions http://public.csr.nih.gov/StudySections
- CSR Rosters and Meeting Dates
   http://public.csr.nih.gov/RosterAndMeetings



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# The NCI Grants Process

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