



Guided Tour of the NIH Peer Review Process

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Cancer Immunopathology and Immunotherapy Study Section

Center for Scientific Review, National Institutes of Health

November 9, 2017

Presenter Disclosure Information

Denise R. Shaw, PhD

No relationships to disclose

Center for Scientific Review (CSR)

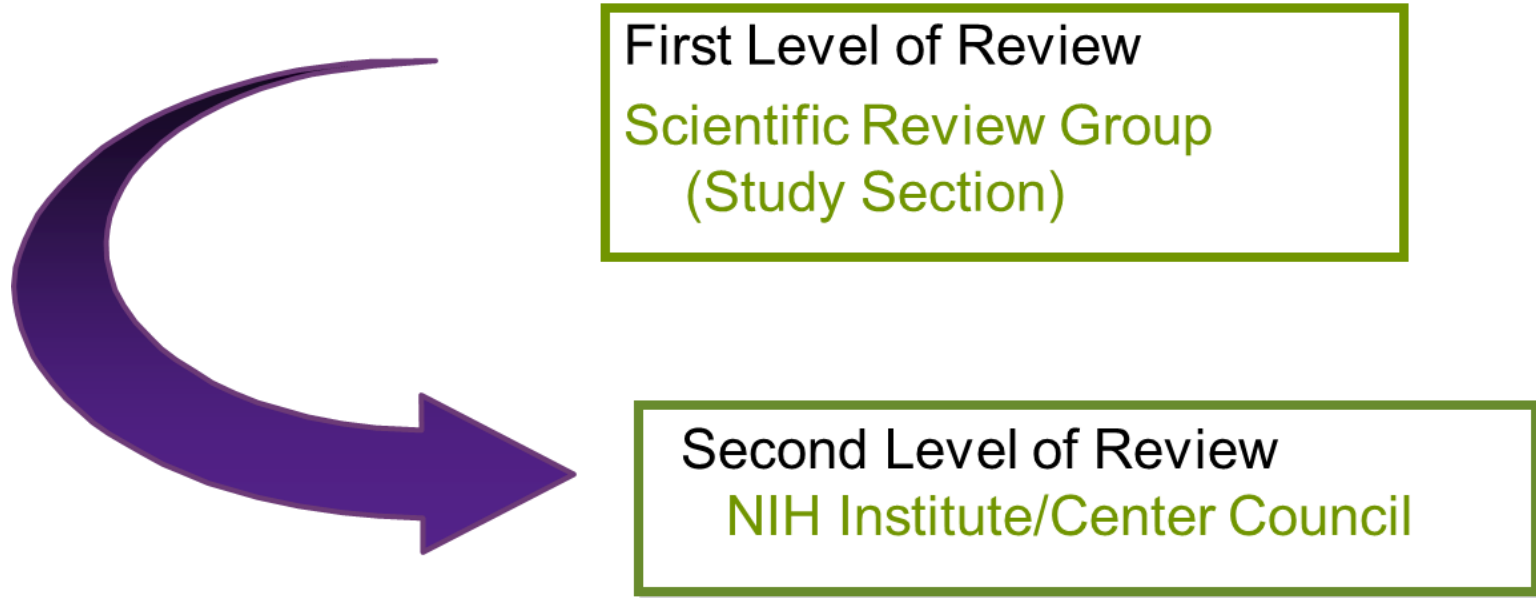
- **Serves as central receipt point for grant applications** submitted to NIH and some other DHHS agencies
- **Assigns applications to CSR review groups/study sections** or to an Institute (such as NCI or NIAID) scientific review group
- **Assigns applications to NIH Institutes/Centers** as potential funding components
- **Conducts initial scientific merit review of most** research applications submitted to the NIH in about 240 Study Sections and regularly recurring Special Emphasis Panels

CSR Peer Review – Fiscal Year 2016

- 92,000 applications received
- 60,000 applications reviewed
- 18,000 reviewers
- 247 Scientific Review Officers
- 1,600 review meetings

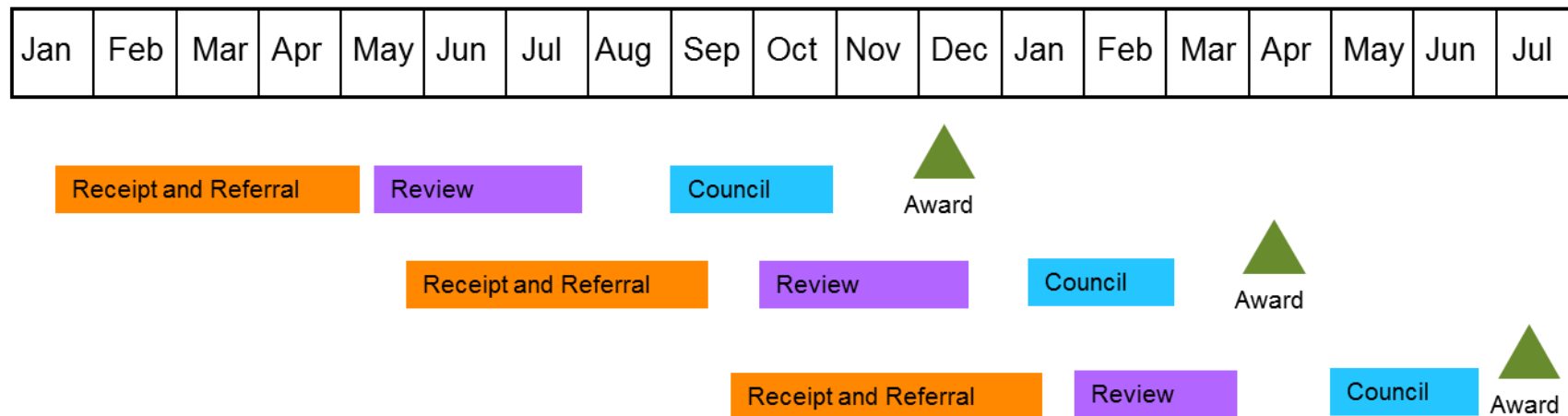


NIH Peer Review System for Grant Applications



Overall Timeframe from Submission to Award

There are three main overlapping cycles per year



<http://grants1.nih.gov/grants/funding/submissionschedule.htm>

Integrated Review Groups (IRGs) and SRGs (Study Sections)

Each IRG contains a cluster of study sections around a general scientific area.

- Brain Disorders and Clinical Neuroscience IRG [BDCN]
- Immunology IRG [IMM]
- Oncology 1 - Basic Translational IRG [OBT]
- Oncology 2 - Translational Clinical IRG [OTC]


- Basic Mechanisms of Cancer Therapeutics Study Section [BMCT]
- Cancer Biomarkers Study Section [CBSS]
- Chemo/Dietary Prevention Study Section [CDP]
- Cancer Immunopathology and Immunotherapy Study Section [CII]
- Clinical Oncology Study Section [CONC]
- Drug Discovery and Molecular Pharmacology Study Section [DMP]
- Developmental Therapeutics Study Section [DT]
- Radiation Therapeutics and Biology Study Section [RTB]

Find the Right Study Section for Your Application -- Method 1

Assisted Referral Tool (ART)

<https://art.csr.nih.gov/ART/selection.jsp>

Choose study section vs. IRG search.

 **Assisted Referral Tool (ART)**

Please make a selection:

- ☒ **Recommend study sections directly**
You will be given a list of the best matching of the 169 active SRG panels*.
- ☐ **Recommend IRG first followed by study sections**
You will first be given a list of the best matching Integrated Review Groups. You may then select the study sections within those IRGs to perform second-tier matching against the selected study sections.
- ☐ **Recommend SBIR/STTR Special Emphasis Panels**
If you are applying for a SBIR/STTR grant, select this option.

* Currently, the following SRGs are not available in ART:
CHSA, CHSB, ARM, and IPTA.

Continue


Find the Right Study Section for Your Application -- Method 1

Assisted Referral Tool (ART)

<https://art.csr.nih.gov/ART/selection.jsp>

Enter application title and text to get recommended CSR study sections for your project.

Click on the SRG to view study section descriptions. Click on roster to view current study section members.

**Assisted Referral Tool (ART)**
[Help](#) | [Disclaimer](#)

ART Home >> SRG >> Report

Title

Novel immunotherapies for cancer are having a major clinical impact, in particular anti-PD-1 mAbs. However, the mechanisms that explain why a subset of patients responds to these therapies while other patients do not remain incompletely understood. Our preliminary data suggest that a baseline T cell-inflamed tumor microenvironment may be a predictive biomarker for response to multiple immunotherapies. Combination immunotherapies may push clinical efficacy in this subset of patients further.

Terms will be weighted by frequency of appearance in the text above. The process is automated and confidential. ART does not track or store submitted text. Characters left: 19504

Currently the following SRGs are not yet available in ART: [CHSA](#), [CHSB](#), [ARM](#), and [IPTA](#). Please consider these study sections if your application is in their respective areas.

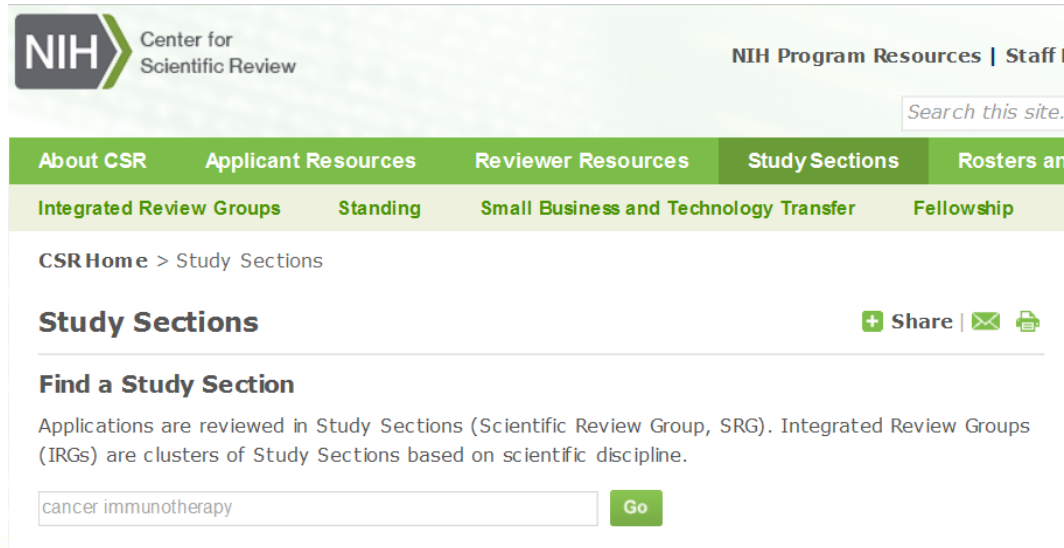
Resubmit

Relevance	SRG	IRG	Membership	Name
Strong	CONC	OTC	Roster	Clinical Oncology Study Section
Strong	CII	OTC	Roster	Cancer Immunopathology and Immunotherapy Study Section

Find the Right Study Section for Your Application -- Method 2

CSR website search for IRG, study section or simple scientific terms

<https://public.csr.nih.gov/StudySections/Pages/default.aspx>



The screenshot shows the NIH Center for Scientific Review website. At the top, the NIH logo and "Center for Scientific Review" are on the left, and "NIH Program Resources | Staff" is on the right. A search bar with the placeholder "Search this site." is on the right. Below the header is a green navigation bar with links: "About CSR", "Applicant Resources", "Reviewer Resources", "Study Sections" (highlighted), and "Rosters and Committees". Below this is a light green bar with sub-links: "Integrated Review Groups", "Standing", "Small Business and Technology Transfer", and "Fellowship". The main content area has a breadcrumb "CSR Home > Study Sections" and a heading "Study Sections" with a "+ Share" button and icons for email and print. Below the heading is the section "Find a Study Section" with a paragraph: "Applications are reviewed in Study Sections (Scientific Review Group, SRG). Integrated Review Groups (IRGs) are clusters of Study Sections based on scientific discipline." At the bottom is a search input field containing "cancer immunotherapy" and a green "Go" button.

NIH Center for Scientific Review

NIH Program Resources | Staff

Search this site.

About CSR Applicant Resources Reviewer Resources **Study Sections** Rosters and Committees

Integrated Review Groups Standing Small Business and Technology Transfer Fellowship

CSR Home > Study Sections

Study Sections + Share | Email Print

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.

cancer immunotherapy Go

Find the Right Study Section for Your Application -- Method 2

Study Section Search Page

Total Results:17

1. [OTC IRG - Cancer Immunopathology and Immunotherapy Study Section \[CII\]](#)

Description:CII - Cancer Immunopathology and Immunotherapy Study Section

Date:8/29/2017 5:57:35 PM

<http://public.csr.nih.gov/studysections/integratedreviewgroups/otcirg/cii>

CSR Meeting Rosters - CII

Click on **meeting dates** to view meeting rosters. Meeting rosters list all members present, whether permanent or temporary, and provide the total scope of expertise that may be present at the meeting on that date. The most current and two prior rosters are provided when available. Current rosters are posted 30 days before the meeting date and are tentative only, pending any last minute changes. The **View Membership Roster** link shows the membership roster of chartered members only.

View Membership Roster

Study Section Acronym	SRO	Meeting Rosters		
CII	Shaw, Denise	06/15/2017 (Roster)	03/02/2017 (Roster)	10/20/2016 (Roster)

Cancer Immunopathology and Immunotherapy Study Section [CII]

[Share](#) [Email](#) [Print](#)

The Cancer Immunopathology and Immunotherapy [CII] Study Section reviews applications addressing immunologic therapies of cancer, modulation of the innate and adaptive immune responses to cancer cells, and all antibody-based therapies including antibody-targeted delivery of therapy. The scope of projects includes in vitro studies, evaluation of immunotherapeutic strategies in preclinical animal models, and translational studies including pilot or phase I clinical trials.

Rosters

[CII Membership Roster](#)

[CII Meeting Roster](#)

Topics

- » Tumor vaccines of all types and dendritic cell-based therapies to induce or amplify tumor immunity
- » Therapeutic and diagnostic uses of antibodies and antibody fragments specific for either tumor cells, tumor vasculature/microenvironment, or immune cells in order to either alter immune responses to tumors, modulate tumor cell biology, or deliver therapeutic/diagnostic payloads (toxins, drugs, radionuclides, oligonucleotides, liposomes, nanoparticles, etc.)
- » Hematopoietic stem cell transplantation and adoptive cellular therapies using immune cells as cancer treatment
- » Modulation of tumor immune responses by gene therapy, cytokines, chemokines, growth factors, signal agonists and antagonists, or biological response modifying agents
- » Development and testing of methods and models of immune responses to cancer and assessing such responses in cancer patients
- » Mechanisms of tumor resistance and escape from immune recognition or killing including modulation of tumor antigen processing and presentation, alteration of susceptibility of tumors to innate and adaptive immune responses, tumor-induced immune suppression and tolerance

Closely Related

[Transplantation, Tolerance and Tumor Immunology Study Section \[TTT\]](#)
[Clinical Oncology Study Section \[CONC\]](#)
[Developmental Therapeutics Study Section \[DT\]](#)
[Radiation Therapeutics and Biology Study Section \[RTB\]](#)

Use the Optional Assignment Request Form

Request awarding component
(funding institute/center)

Request study section assignment

Identify conflicts

Suggest areas of expertise

[View Burden Statement](#) **PHS Assignment Request Form** OMB Number: OHS-0001 Expiration Date: 10/31/2018

Funding Opportunity Number:

Funding Opportunity Title:

Awarding Component Assignment Request (optional)

If you have a preference for an Awarding Component (e.g., NIH Institute/Center) assignment, please use the link below to identify the most appropriate assignment then enter the short abbreviation (e.g., NCI for National Cancer Institute) in "Assign to/Do Not Assign To Awarding Component" sections below. Your first choice should be in column 1. All requests will be considered, however, focus of review is predetermined for some applications and assignment requests cannot always be honored.

Information about Awarding Components can be found here: https://grants.nih.gov/grants/assignment_information.html#AwardingComponents

	1	2	3
Assign to Awarding Component	<input type="text"/>	<input type="text"/>	<input type="text"/>
Do Not Assign to Awarding Component	<input type="text"/>	<input type="text"/>	<input type="text"/>

Study Section Assignment Request (optional)

If you have a preference for a study section assignment, please use the link below to identify the most appropriate study section then enter the short abbreviation for that study section in "Assign to/Do Not Assign to Study Section" sections below. Your first choice should be in column 1. All requests will be considered, however, focus of review is predetermined for some applications and assignment requests cannot always be honored.

For example, you would enter "CAMP" if you wish to request assignment to the Cancer Molecular Pathobiology study section or enter "ZRS1 HCMR" if you wish to request assignment to the Healthcare Delivery and Methodologies SBIR/STTR panel for informatics. Be careful to accurately capture all formatting (e.g., spaces, hyphens) when you type in the request.

Information about Study Sections can be found here: https://grants.nih.gov/grants/assignment_information.html#StudySection

	1	2	3
Assign to Study Section	<input type="text"/>	<input type="text"/>	<input type="text"/>
Do Not Assign to Study Section	<input type="text"/>	<input type="text"/>	<input type="text"/>

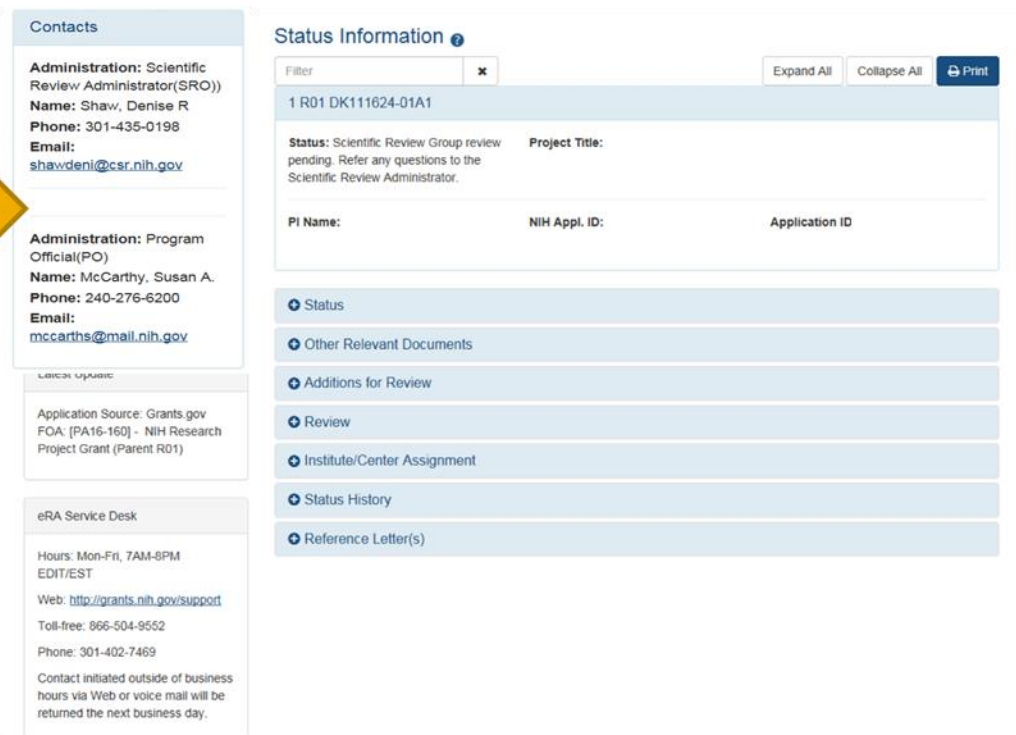
PHS Assignment Request Form

List Individuals who should not review your application and why (optional) Only 1000 characters allowed

Identify Scientific areas of expertise needed to review your application (optional)
Note: Please do not provide names of individuals

	1	2	3	4	5
Expertise	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Check the Status of Your Application in NIH eRA Commons



SRO and PO

Contacts

Administration: Scientific Review Administrator(SRO))
Name: Shaw, Denise R
Phone: 301-435-0198
Email: shawdeni@csr.nih.gov

Administration: Program Official(PO)
Name: McCarthy, Susan A.
Phone: 240-276-6200
Email: mccarths@mail.nih.gov

Application Source: Grants.gov
FOA: [PA16-160] - NIH Research Project Grant (Parent R01)

eRA Service Desk

Hours: Mon-Fri, 7AM-5PM
EDIT/EST
Web: <http://grants.nih.gov/support>
Toll-free: 866-504-9552
Phone: 301-402-7469
Contact initiated outside of business hours via Web or voice mail will be returned the next business day.

Status Information

Filter ✕

Expand All Collapse All Print

1 R01 DK111624-01A1

Status: Scientific Review Group review pending. Refer any questions to the Scientific Review Administrator. **Project Title:**

PI Name: **NIH Appl. ID:** **Application ID**

- Status
- Other Relevant Documents
- Additions for Review
- Review
- Institute/Center Assignment
- Status History
- Reference Letter(s)

Check the Status of Your Application in NIH eRA Commons

Contacts

Administration: Scientific Review Administrator(SRO))
Name: Shaw, Denise R
Phone: 301-435-0198
Email:
shawdeni@csr.nih.gov

Administration: Program Official(PO)
Name: McCarthy, Susan A.
Phone: 240-276-6200
Email:
mccarths@mail.nih.gov

Application Source: Grants.gov
FOA: [PA16-160] - NIH Research Project Grant (Parent)

Hours: Mon-Fri, 7AM-8PM
EDIT/EST

Web: <http://grants.nih.gov/support>

Toll-free: 866-504-9552

Phone: 301-402-7469

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Status Information ?

Filter x

Expand All Collapse All Print

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PI Name: **NIH Appl. ID:** **Application ID**

- Status
- Other Relevant Documents
- Additions for Review
- Review
- Institute/Center Assignment
- Status History
- Reference Letter(s)

Review

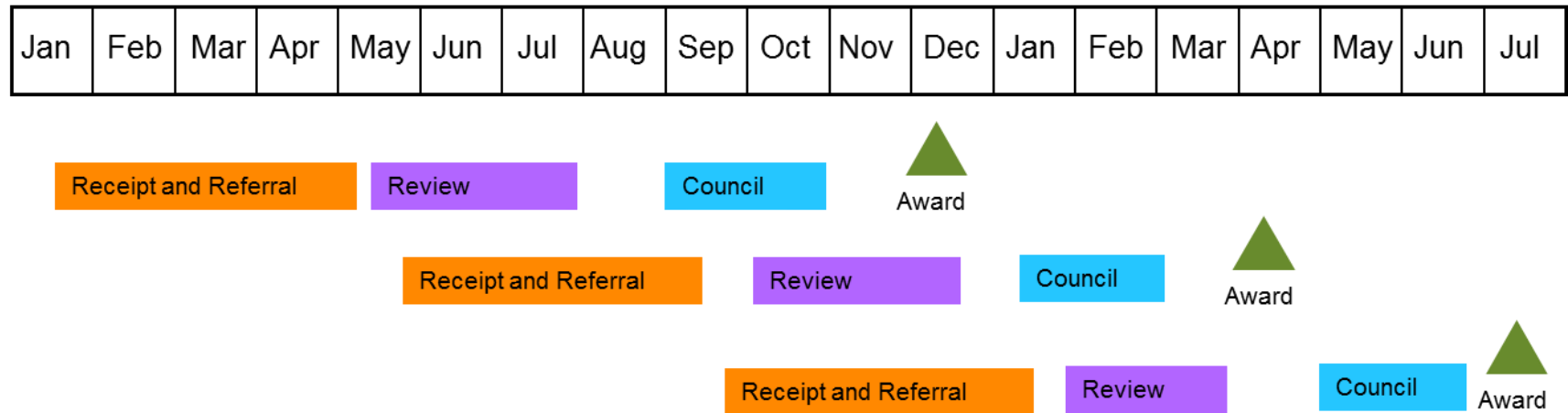
Review

Application	Study Section	Advisory Council (AC)
Award Document Number:	Scientific Review Group: CADO	
FSR Accepted Code: N	Council Meeting Date (YYYY/MM): 2017/10	
Snap Indicator Code:	Meeting Date: 06/14/2017	
Impact Score:	Meeting Time: 08:00	
Percentile:		
Early Stage Investigator Eligible: Y		
New Investigator Eligible: Y		
Eligible for FFATA Reporting: Yes		

Meeting Date

Overall Timeframe from Submission to Award

There are three main overlapping cycles per year



<http://grants1.nih.gov/grants/funding/submissionschedule.htm>

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 by the SRO as needed.
- About 60-100 applications are normally reviewed at each study section meeting.

How Reviewers Are Selected for Study Section Service

- Demonstrated scientific expertise and 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

Before the Study Section Meeting

- Each application is assigned to 3 or more reviewers 5-6 weeks before the meeting
- Reviewers assess each application by providing:
 - A preliminary Overall Impact score
 - Criterion scores for each of the 5 core review criteria
 - A written critique
- Reviewers have access to other reviewer critiques and scores before the meeting to prepare for meeting discussions

9-point scoring 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

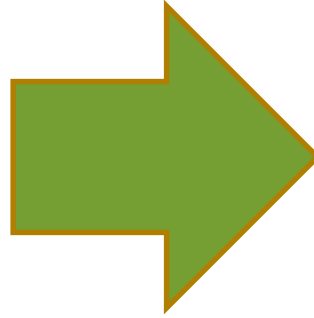
Impact	Score	Descriptor
High Impact	1	Exceptional
	2	Outstanding
	3	Excellent
Medium Impact	4	Very Good
	5	Good
	6	Satisfactory
Low Impact	7	Fair
	8	Marginal
	9	Poor

Scoring

5 Core Review Criteria

- **Significance**
- **Investigator(s)**
- **Innovation**
- **Approach**
- **Environment**

Each scored from 1-9



Overall Impact

Assessment of the likelihood for the project to *exert a sustained, powerful influence on the research field(s) involved*

Scored from 1-9

There is no mathematical relationship between the 5 criterion scores and Overall Impact score

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

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 (e.g., R21s) may be clustered

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 members without a conflict are invited to join the discussion and then vote on the final overall impact score



Scoring of Discussed and Not Discussed Applications

- Reviewers discuss about half of the applications, beginning with the best.
- The panel will discuss any application any reviewer wants to discuss.
- Discussed applications receive an overall score from each panel member (excluding conflicts). The scores are averaged to one decimal place, and multiplied by 10. The 81 possible priority scores thus range from 10-90.
- All applications receive criterion scores. Not discussed applications will receive initial criterion scores from the three assigned reviewers.

After the Meeting

The SRO checks final overall impact scores and releases them for posting to the application eRA Commons site

- Scores are available to applicants generally within 3-4 days after the meeting.

The SRO compiles reviewer critiques and, for discussed applications, writes a Summary of Discussion for the summary statement

- Summary statements are released for posting in the application eRA Commons site generally within 30 days after the meeting.
- Applicants should contact their assigned Program Officer – not the SRO – with any questions or concerns regarding scores or summary statements.

Program Officer

PROGRAM CONTACT:
Susan McCarthy Ph.D.
240-276-6200
mccarths@mail.nih.gov

SUMMARY STATEMENT
(Privileged Communication)

Release Date: 10/03/2014
Revised Date: 10/03/2014

Application Number: 1 R01 CA#####-01A1

Principal Investigator

SMITH, JANE PHD

Applicant Organization: STATE UNIVERSITY

Review Group: CII

Cancer Immunopathology and Immunotherapy Study Section

Meeting Date: 09/29/2014

RFA/PA: PA13-302

Council: JAN 2015

PCC: 2PIM

Requested Start: 04/01/2015

Dual IC(s): AI

Project Title: Improving Cancer Immunotherapy

SRG Action: Impact Score: 21 Percentile: 7

Next Steps: Visit http://grants.nih.gov/grants/next_steps.htm

Human Subjects: 10-No human subjects involved

Animal Subjects: 30-Vertebrate animals involved - no SRG concerns noted

Human and
Animal Subjects
status

Impact Score and Percentile
(if applicable)

Project Year	Direct Costs Requested	Estimated Total Cost
1	250,000	412,435
2	250,000	412,435
3	250,000	412,435
4	250,000	412,435
5	250,000	412,435
TOTAL	1,250,000	2,062,174

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

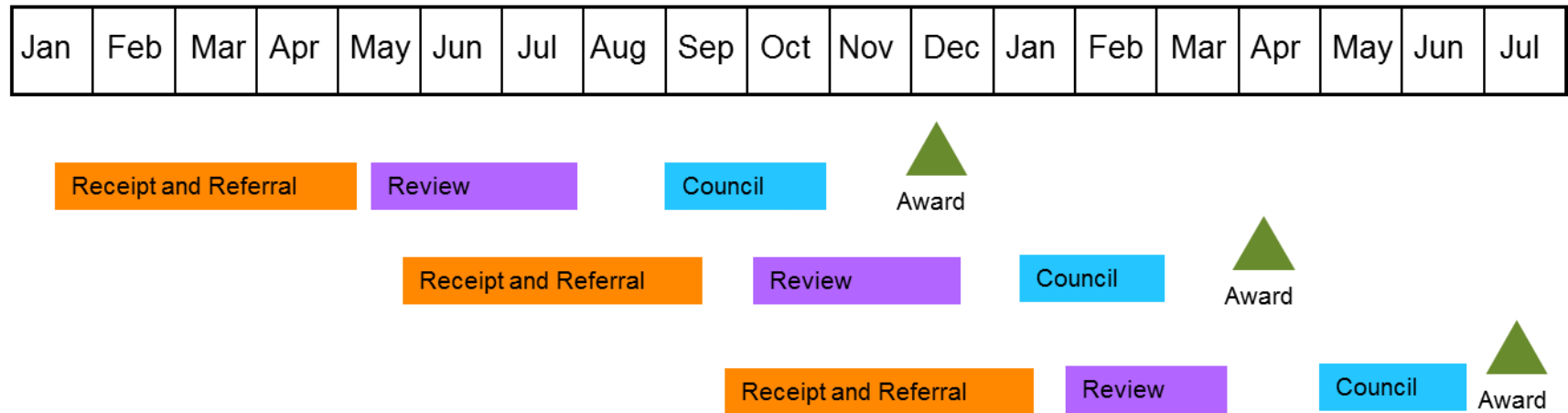
NEW INVESTIGATOR

New and Early Stage Investigator status

Summary Statement

Overall Timeframe from Submission to Award

There are three main overlapping cycles per year



<http://grants1.nih.gov/grants/funding/submissionschedule.htm>

CSR Applicant Resources

<https://public.csr.nih.gov/ApplicantResources/Pages/default.aspx>

NIH Peer Review Revealed

Provides a front-row seat to a peer review meeting.



Ways to Successfully Navigate NIH Peer Review and Get a Grant

View Webinars for R01, R15, Fellowship and SBIR/STTR applicants



FAQs

» For Applicants

NIH Tips for Applicants

Reviewers give applicants practical advice and insights.



Grant Process

Planning, Writing, & Submitting
Receipt & Referral

Peer Review

- Initial Level of Review

Policy Changes

- » Reminder: NIH Natural Disaster Policy - Hurricane Irma
- » Notice of Assistance Available to Institutions Impacted by Hurricane Harvey
- » Reminder: NIH Natural Disaster Policy - Hurricane Harvey
- » New Appendix Policy Related to Clinical Trial Applications Due on or After Jan. 25

Become a Reviewer

- **Check Out Our Early Career Reviewer Program:** www.csr.nih.gov/ecr
- **Contact a CSR Scientific Review Officer:** Send them your CV
- **Let Us Try to Find a Good Review Group for You:** Send your CV to csrvolunteer@mail.nih.gov

