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Walter E. Washington Convention Center





### The NIH Grant Peer Review Process

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Cancer Immunopathology and Immunotherapy Study Section

November 8, 2018

#### **Presenter Disclosure Information**

Denise R. Shaw, PhD

No relationships to disclose

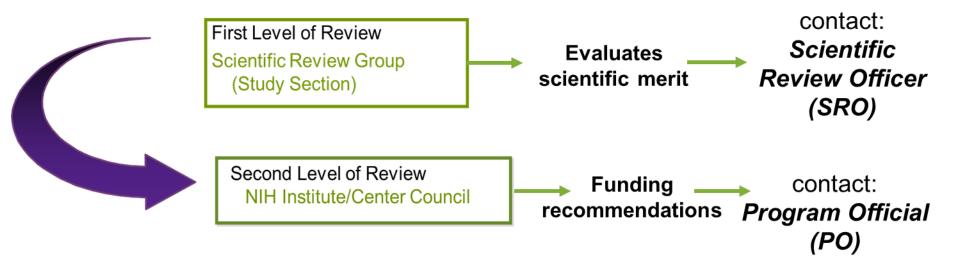


#### **Presentation Outline**

- Study section review versus funding decisions
- Application submission and review cycles
- Study section assignment
- Study section structure and review processes
- Results of study section review: the summary statement
- Ways to learn more about study section review



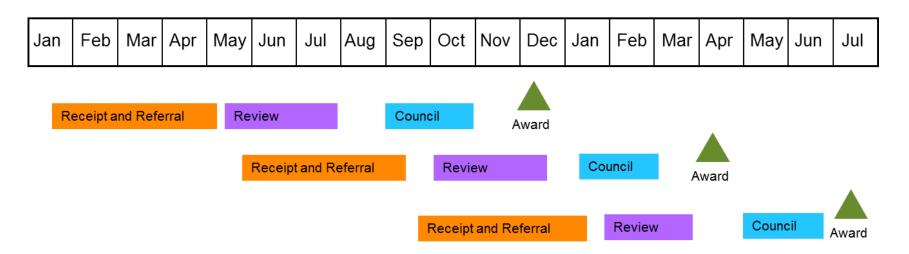
## **NIH Review of Grant Applications**





### **Overall Timeframe from Submission to Award**

There are three main overlapping cycles per year



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

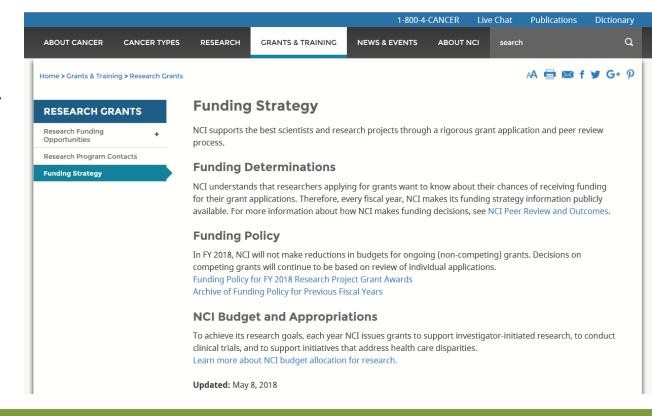


# Funding: It's Not My Job...

Check specific institute or center web pages for public statements of funding strategies

NCI (grants with CA numbers) is the largest NIH funder of cancer research projects







# Institutes Other that NCI May Support Cancer Immunology & Immunotherapy Projects

NIAID, National Institute of Allergy and Infectious Diseases (AI) <a href="https://www.niaid.nih.gov/grants-contracts/niaid-paylines">https://www.niaid.nih.gov/grants-contracts/niaid-paylines</a>

NHLBI, National Heart, Lung and Blood Institute (HL) <a href="https://www.nhlbi.nih.gov/node-general/fy-2018-funding-and-operating-guidelines">https://www.nhlbi.nih.gov/node-general/fy-2018-funding-and-operating-guidelines</a>

NIBIB, National Institute of Biomedical Imaging and Bioengineering (EB) <a href="https://www.nibib.nih.gov/research-funding-tabs-3">https://www.nibib.nih.gov/research-funding-tabs-3</a>

NINDS, National Institute of Neurological Disorders and Stroke (NS) <a href="https://www.ninds.nih.gov/Funding/About-Funding/NINDS-Funding-Strategy/NINDS-Funding-Strategy-FY-2018">https://www.ninds.nih.gov/Funding/About-Funding/NINDS-Funding-Strategy-Funding-Strategy-FY-2018</a>

NIDDK, National Institute of Diabetes and Digestive Diseases, (DK) <a href="https://www.niddk.nih.gov/research-funding/process/award-funding-policy">https://www.niddk.nih.gov/research-funding/process/award-funding-policy</a>

NIGMS, National Institute of General Medical Science (GM) https://www.nigms.nih.gov/research/pages/policies.aspx

NIDCR, National Institute of Dental and Craniofacial Research (DE) <a href="https://www.nidcr.nih.gov/about-us/strategic-plan">https://www.nidcr.nih.gov/about-us/strategic-plan</a>

NIEHS, National Institute of Environmental Health Sciences (ES)

https://www.niehs.nih.gov/funding/grants/priorities/strategies/index.cfm



## 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 ~240 standing Study Sections as well as recurring Special Emphasis Panels



### **CSR Peer Review – Fiscal Year 2017**

- 95,000 applications received
- 61,000 applications reviewed
- 18,000 reviewers
- 247 Scientific Review Officers (SROs)
- 1,600 review meetings









## **Types of Grants Reviewed in CSR - Overview**

- The vast majority of research project grants (R)
- Many of the fellowship (F) and NIH Director's award (D) mechanisms
- A minority of individual career development awards (K) and institutional training grants (T)
- Only a few program project/center grants (P) and cooperative agreements (U)



# The Funding Opportunity Announcement (FOA) may determine the locus of review

All NIH grant applications must be submitted under a currently-active FOA

- Program Announcement (PA, PAR, PAS)
- Request for Applications (RFA)
- Search for FOAs in the NIH Guide for Grants and Contracts (<u>https://grants.nih.gov/funding/index.htm</u>) or at <u>Grants.gov</u>



## **FOA Examples**

PA-18-484

## NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)

#### 2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) in accordance with NIH peer review policy and procedures, using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

PAR-18-560

National Cancer Institute's Investigator-Initiated Early Phase Clinical Trials for Cancer Treatment and Diagnosis (R01 Clinical Trial Required)

#### Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by NIH Center for Scientific Review (CSR), in accordance with NIH peer review policy and procedures, using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.



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

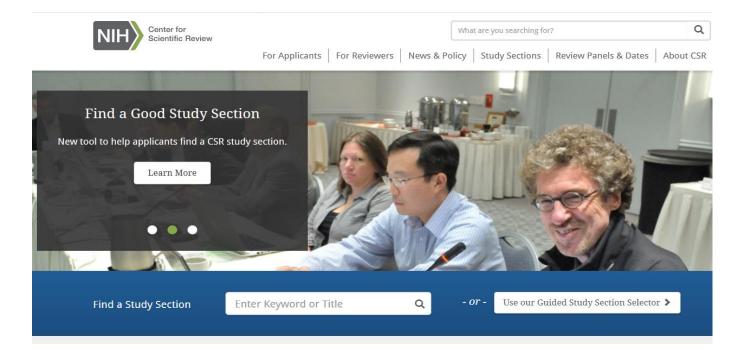
## Each IRG contains a cluster of study sections around a general scientific area.

- 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]



## Which Study Section Is Right for My Application?



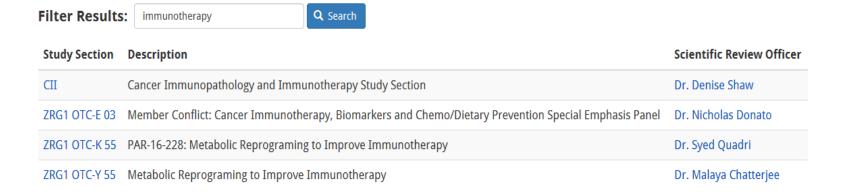
www.csr.nih.gov



## Find a Study Section – method 1



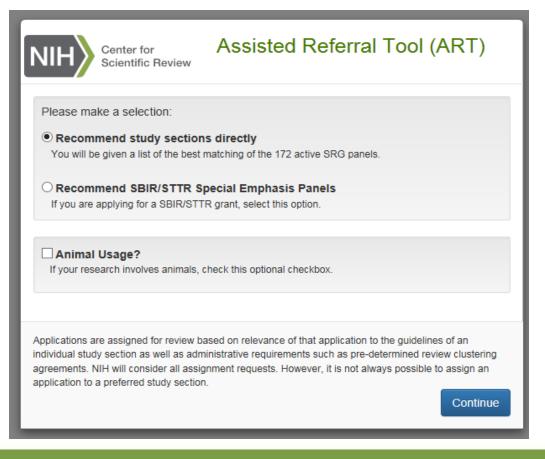
#### CSR SS Search





## Find a Study Section method 2

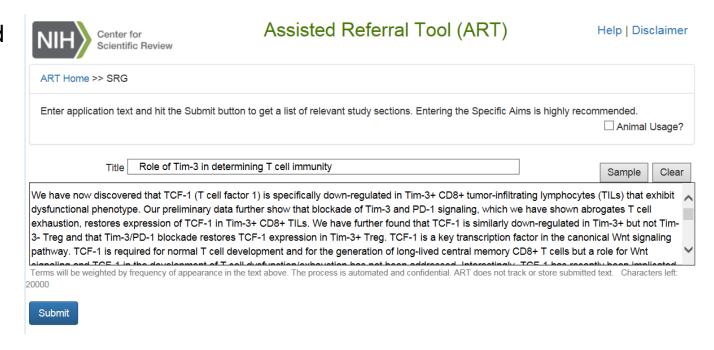
- or - Use our Guided Study Section Selector ➤





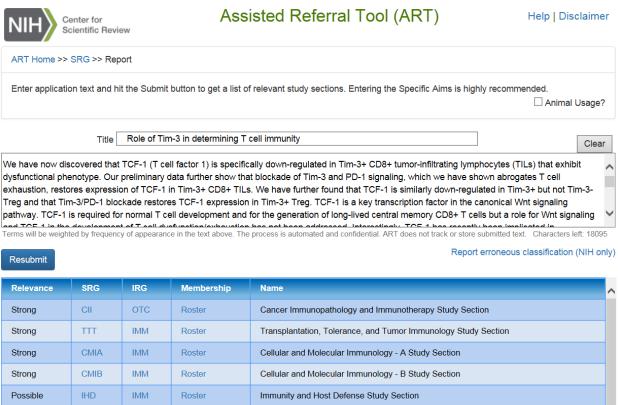
## Find a Study Section method 2

Enter project title and descriptive text from your application





Find a Study Section method 2





#### Find a Study Section (cont.)

# Click on the Study Section/SRG links to view study section descriptions.



- Tumor vaccines of all types (protein/peptide, viral, DNA/RNA dendritic cell, tumor cell) and formulations to induce or amplify tumor-specific immunity.
- Antibodies and antibody-like constructs that bind tumor cells or the tumor vasculature/microenvironment, to either directly modulate tumor cell biology (e.g., receptor agonists or antagonists), activate direct anti-tumor immune effector functions (complement, ADCC, phagocytosis), or deliver cytotoxic payloads (e.g., drugs, toxins, radionuclides, liposomes or nanoparticles).
- Antibody-based constructs and other strategies to deliver immune stimulatory signals or to block immune suppressive receptors and cytokines, in order to promote endogenous anti-tumor immunity.
- Hematopoietic stem cell transplantation (allogeneic, autologous) and adoptive cellular therapies (TILs, CAR- and TCR-engineered T cells, NK/NKT cells) using immune cells as cancer treatment; associated immune toxicities including graft-versus-host disease and cytokine release syndrome.

- Abscopal effects of local tumor treatments like radiation, intratumoral injections and mechanical ablation that promote systemic anti-tumor immune responses.
- Development and testing of methods and models of immune responses to cancer and assessing such responses in cancer patients
- Mechanisms of tumor resistance to immunotherapies and/or tumor escape from immune recognition and killing, including modulation of tumor antigen processing and presentation, alteration of tumor susceptibility to innate and adaptive immune responses, tumor-induced immune suppression, and immune effector cell tolerance/exhaustion.
- Predictive biomarkers of an individual patient's or tumor's clinical response to immunotherapies.

#### Cancer Immunopathology and Immunotherapy Study Section – CII

The Cancer Immunopathology and Immunotherapy (CII) Study Section reviews applications related to both active and passive immune therapies for cancer, including modulation of the innate and adaptive immune responses to cancer cells in situ (vaccines, immunostimulatory molecules, immune checkpoint blockade),



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adoptive transfer of autologous or allogeneic hematopoietic cells (TIL cell therapy, CAR- and TCR-modified T cells/NIK cells, hematopoietic stem cell transplantation including graft-versus-host disease), and antibodies/antibody derivatives that mediate tumor cytotoxicity either directly or by targeted delivery of toxic payloads. The scope of projects includes in vitro studies, evaluation of immunotherapeutic strategies in preclinical animal models, and translational studies including pilot or phase I/II clinical trials. CII is part of the Oncology 2 – Translational

The List of Reviewers lists all present, whether permanent or temporary, to provide the full scope of expertise present on that date. Lists are posted 30 days before the meeting and are tentative, pending any last minute changes.

Review Dates

- > List of Reviewers on 10/18/2018
- > List of Reviewers on 06/14/2018
- > List of Reviewers on 02/19/2018

#### Membership Panel

The membership panel is a list of chartered members only.

> View Membership Panel



#### Find a Study Section (cont.)

#### Shared Interests and Overlaps

There are shared interests with Transplantation, Tolerance and Tumor Immunology (TTT). Applications focused on hematopoietic stem cell transplantation for cancer therapy, graft-versus-host disease, tumor immune surveillance and tolerance, identification of new tumor antigens, and development of tumor vaccines may be assigned to either CII or TTT. Applications studying solid organ transplants and autoimmunity are more suitable for TTT.

There are shared interests with Tumor Microenvironment (TME). Applications proposing studies on tumor cell interactions with immune cells and the immune microenvironment that promote tumorigenesis may be assigned to TME. Applications focusing on tumor immunology, immunotherapy and responses to immunotherapy are suitable for CII.

There are shared interests with Clinical Oncology (CONC). Applications focused on clinical studies of cancer immunotherapies may be assigned to either CII or CONC. Clinical studies that focus on treatment modalities other than immunotherapy (e.g., surgery, chemotherapy, radiation therapy) may be more suitable for CONC.

There are shared interests with Clinical Neuroimmunology and Brain Tumors (CNBT). Applications studying the immunopathology and immunotherapy of central nervous system tumors (glioma, medulloblastoma, etc.) may be assigned to either CII or CNBT. Applications focused on immunological aspects of neural tissues and diseases unrelated to tumors should be assigned to CNBT.

There are shared interests with Developmental Therapeutics (DT) in the areas of drug delivery and gene therapy. In general, strategies relying on antibody-based targeted delivery are suitable for CII, as are approaches to deliver agents (drugs, genes) whose primary mode of anti-tumor activity is projected to be immunological.



#### **Use the Optional Assignment Request Form**

Request IC assignment (funding institute/center)

PHS Assignment Request Form ONE trumper 0825-0001 View Burden Statement Expression 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., fill) (institute/Center) assurpment, please use the kink below to identify the most appropriate assurpment then enter the short abbreviation (e.g., NC) for National Carcer (institute). In "Assign turbo Not Assign To Awarding Component" sections percei. Your first choose should be in column 1. All requests will be considered, however, locus of review is predetermined for some applications and assignment requests cannot always be honored

information about Awarding Components can be found here: Iddgs Uguarts rift gov/glants/yrs, assignment, information html//warding Components

Do filed Assign to Asserting Component

Study Section Assignment Request (optioned)

Assists to Awarding Component

If you have a preference for a study section assignment, please use the link below to sterrify the most appropriate study section then enter the short attace-valon for that study section in Vissign to/Do not Assign to Study Section" sections below. Your first choice should be in column 1. All requests will be considered, however, loous of review is predetermined for some

For example, you would enter "CAMP" if you wish to request posignment to the Cencer Molecular Pathobiology study section or enter "ZRS1 HCMR" if you wish to request assignment. to the Healthcare Delivery and Methodologies SBRISTTR panel for informatios. Be cereful to accordinly cepture all formatting (e.g., spaces, hyphere) when you type in the request.

information about Study Sections can be found feere intigat/grants.nls govignostating\_assignment\_information.nlm#Study Section

Request study section assignment



Assign to Study Section City 20 characters allowed Do Not Assign to Shuty Section only 20 characters allowed

#### PHS Assignment Request Form

**Identify conflicts** 



identify Scientific areas of expertise needed to review your application (optional)

List individuals who should not review your application and why (ortional)

Suggest areas of expertise

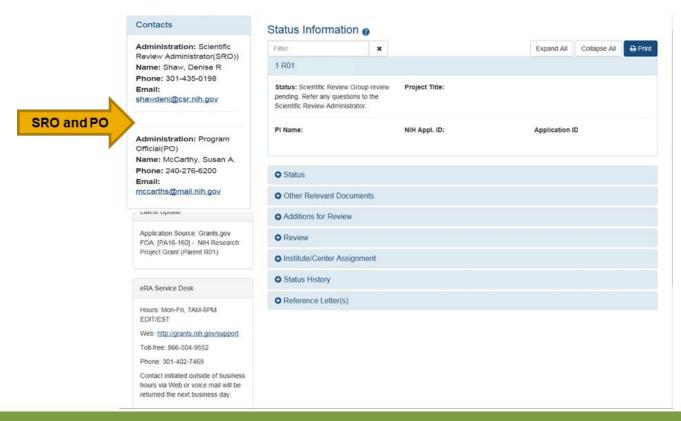


Note: Please do not recycle owners of individuals

Only 1000 characters allowed

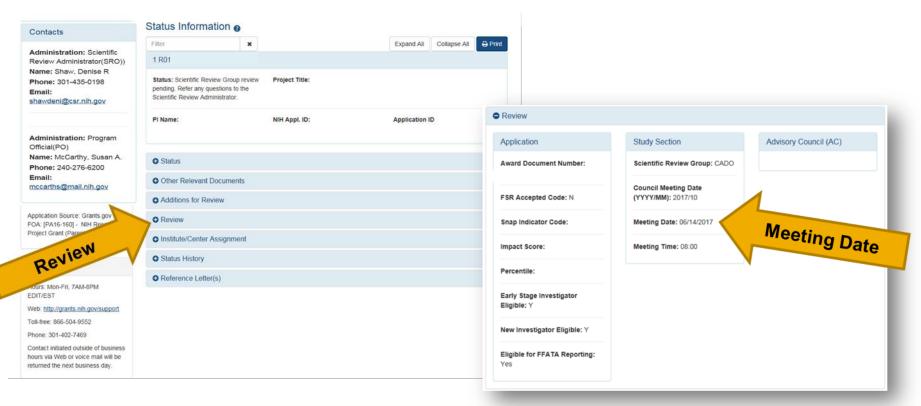


## Check the Status of Your Application in NIH eRA Commons





### Check the Status of Your Application in NIH eRA Commons





#### **Peer Review in CSR**

- CSR Study Sections are managed by a Scientific Review
  Officer (SRO), 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



## **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



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

- Each application is assigned to 3 or more reviewers (who are not in conflict) 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 Criteria 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

Criterion Scores for each of the 5 core review criteria

 Overall Impact/Priority Score is based on but not a sum of the core criterion scores plus additional criteria



## **Scoring**

#### **5 Core Review Criteria**

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

Assessment of the likelihood

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

**Overall Impact** 

Scored from 1-9

Each scored from 1-9

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



## 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 Official not the SRO with any questions or concerns regarding scores or summary statements.



#### Program Officer

SUMMARY STATEMENT PROGRAM CONTACT:

Susan McCarthy Ph.D. 240-276-6200

mccarths@mail.nih.gov

( Privileged Communication )

Release Date: 10/03/2014

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

Revised Date: 10/03/2014

**Summary Statement** 

Principal Investigator

SMITH, JANE PHD

Applicant Organization: STATE UNIVERSITY

Review Group: CII

Cancer Immunopathology and Immunotherapy Study Section

Meeting Date: 09/29/2014 Council: JAN 2015

RFA/PA: PA13-302 PCC: 2PIM

Requested Start: 04/01/2015

Dual IC(s): Al

Human and **Animal Subjects** status

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

Impact Score and Percentile (if applicable)

Project	Direct Costs	Estimated
Year	Requested	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.

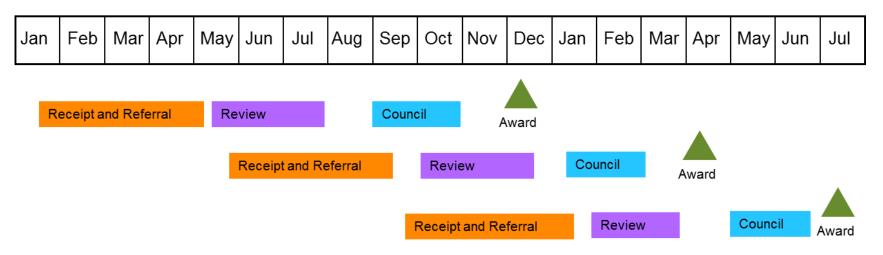
NEW INVESTIGATOR

New and Early Stage Investigator status



### **Overall Timeframe from Submission to Award**

There are three main overlapping cycles per year



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





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CSR Advisory Council Meeting Sept. 24, 2018 Dr. Alexei Kondratvev Named Chief of CSR's Integrative

## **CSR Applicant Resources**

#### www.csr.nih.gov



#### What Happens to Your NIH Grant Application

Video



#### **Application Process**

CSR does not award funding but instead handles review of proposals. Please visit the NIH for an overview of the grant process.



#### Planning & Writing

Guidance to assist you in planning and preparing a proposal.



#### **Application Deadlines**

Standard receipt dates for grant proposals



#### Submission & Assignment

How proposals are assigned to a review



#### Initial Review, Results, & Appeals

What happens in the review process?



#### **Become a Reviewer**

- Check Out Our Early Career Reviewer Program: <a href="www.csr.nih.gov/ecr">www.csr.nih.gov/ecr</a>
- 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 <u>csrvolunteer@mail.nih.gov</u>





## **Take Home Messages**

- Understand the NIH peer review system before beginning to prepare your grant application submission.
- Take advantage of NIH and CSR internet and staff resources to answer questions about your planned application before submission.
- Work with your institution's grant office to ensure timely submission of your application.
- After receiving a summary statement, carefully consider all aspects of the study section's evaluation; discuss with the designated PO.
- Serving as a study section reviewer is a great way to gain insights into how to improve your own grant applications.

