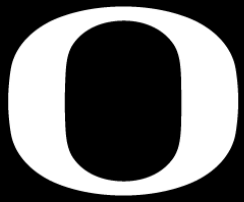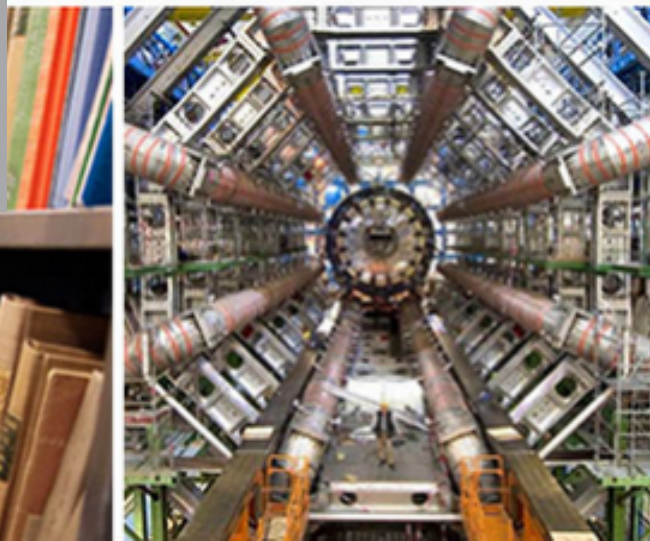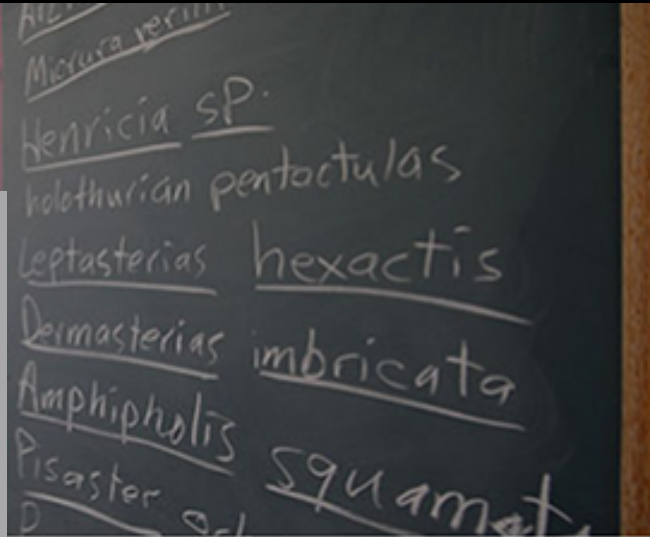# NIH Review Process

October 28, 2020

UNIVERSITY OF OREGON

Research Development Services

Research Development Services provides a variety of services for faculty seeking support for research, creative work, public service and scholarly projects

Agenda

- **Advocating for Review in application**
- **You've submitted….now what?**
- **Review Process**
- **Scoring Criteria**
- **Understanding Summary Statements**
  - **Planning for resubmission**
- **Early Career Reviewer Program**

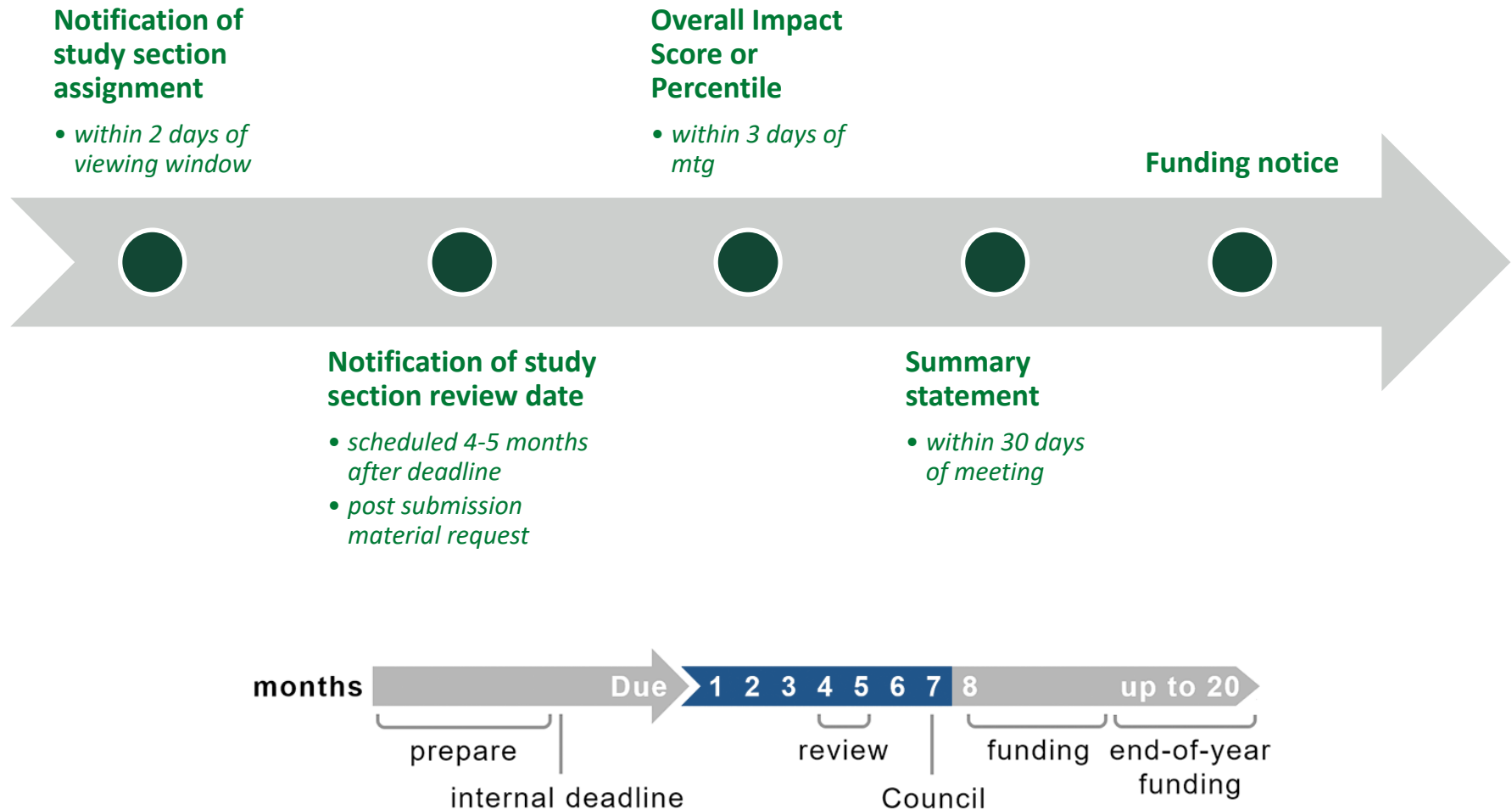# Advocating for Review in the Application

- **Talk to Program Officers!**
  - *But follow administrative guidance of SPS and NIH SF424*
- **Comply with ALL guidelines so your grant is not administratively rejected**
- **Be direct about the connection between your research and the mission/goals of your targeted IC**
- **PHS Assignment Request Form**
  - *NIH Assisted Referral Tool*
  - *Consider COI*

You've submitted your grant…now what?

Notification of study section assignment
- *within 2 days of viewing window*

Overall Impact Score or Percentile
- *within 3 days of mtg*

Funding notice

Notification of study section review date
- *scheduled 4-5 months after deadline*
- *post submission material request*

Summary statement
- *within 30 days of meeting*

months   Due   1 2 3 4 5 6 7   8   up to 20

prepare
internal deadline
review
Council
funding
end-of-year funding

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NIH multi-step process for review

Center for Scientific Review
- Receives proposals and assigns to institute/study section

Study Section or CSR
- Conducts Peer Review

Advisory Counsel / Boards
- Advises director based on peer review and IC goals

Institute Director
- Makes final decision

Some proposals aren't assigned a study section based on contact (i.e. fellowships, response to RFA, etc.

Some submissions are only administratively reviewed (i.e. supplements)

Sometimes a study section will review for funding under a different institute

Center for Scientific Review

Gateway for NIH applications and the review for scientific merit

- Administers the peer review process
- Assigns study sections (aka Scientific Review Groups, or SRGs)

Reviews ~75% of NIH applications

- Most R01s, fellowships, and small business applications
- Most NIH applications go to SRG including specific program projects, training grants, career development awards, RFAs

Scientific Review Officer

- Recruits qualified reviewers
- Ensures objective and fair initial peer review

Study Section (Scientific Review Group)

IC Study Sections	Evaluate and make recommendations based on review criteria
	Provide priority scores (or not discussed) and written critiques (summary statements)
	Do NOT make funding decisions
Special Emphasis Panels	Review groups formed ad hoc to review applications requiring special expertise or when a conflict of interest occurs.
	In lieu of study section
Scientific Review Officer	Recruits qualified reviewers
	Manages conflict of interest
	Ensures a fair and objective review

Details - Study Section Review

Reviewer Assignments

- Minimum 3 reviewers per proposal
- Based on scientific content, expertise and considerations of conflict of interest

Top 50% of proposals are discussed in study section:

- 9 hour day of review; each proposal gets ~13-14 minutes

In discussion:

- Reviewers with conflicts leave room
- Assigned reviewers present initial scores
- Primary reviewer explains project; strengths/weaknesses
- Other assigned reviewers follow
- Open discussion
- Assigned reviewers present score following discussion
- Indication of voting out of range

REVIEW CRITERIA AT A GLANCE – RESEARCH

	Research/Research Center (R, DP, RC, P, U01 etc.)	Conferences and Scientific Meetings R13/U13	SBIR/STTR (R41, R42, R43, R44)	Academic Research Enhancement Award (AREA)(R15)	Institutional R25
Parent Announcements (CT = Clinical Trials)	R01 CT Not Allowed R01 CT Required R01 BESH* R03 CT Not Allowed R21 CT Not Allowed R21 CT Required R21 BESH*	R13 CT Not Allowed	R41/R42 CT Not Allowed R41/R42 CT Required R43/R44 CT Not Allowed R43/R44 CT Required	Issued through Program Announcements (PARs)	Issued through Program Announcements (PARs)
Overall Impact	*Overall Impact*	*Overall Impact*	*Overall Impact*	*Overall Impact*	*Overall Impact*
Scored Review Criteria (Scored individually and considered in overall impact score) PAR & RFA: May add questions to each scored criterion or additional criteria	*Significance* *Investigator(s)* *Innovation* *Approach* *Environment*	*Significance* *Investigator(s)* *Innovation* *Approach* *Environment*	*Significance* *Investigator(s)* *Innovation* *Approach* *Environment*	*Significance* *Investigator(s)* *Innovation* *Approach* *Environment*	*Significance* *Investigator(s)* *Innovation* *Approach* *Environment*
Additional Review Criteria (Not scored individually, but considered in overall impact score) PAR & RFA: May add new criteria or questions to each additional criterion	**Clinical Trials only:** *Study Timeline* **All:** *Protections for Human Subjects* *Inclusion* *Vertebrate Animals* *Biohazards* Resubmission Renewal Revision	Appropriate Representation *Protections for Human Subjects* *Inclusion* *Vertebrate Animals* *Biohazards* Resubmission Renewal Revision	**Clinical Trials only:** *Study Timeline* **All:** Phase II Fast Track *Protections for Human Subjects* *Inclusion* *Vertebrate Animals* *Biohazards* Resubmission Renewal Revision	**Clinical Trials only:** *Study Timeline* **All:** *Protections for Human Subjects* *Inclusion* *Vertebrate Animals* *Biohazards* Resubmission Renewal Revision	*Protections for Human Subjects* *Inclusion* *Vertebrate Animals* *Biohazards* Resubmission Renewal Revision
Additional Review Considerations (Not scored individually and not considered in overall score)	**All:** Applications from Foreign Organizations Select Agents Resource Sharing Plans Authentication of Key Biological and/or Chemical Resources *Budget & Period of Support*	Provision of Family Care Facilities Applications from Foreign Organizations Select Agents Resource Sharing Plans *Budget and Period of Support*	Select Agents Resource Sharing Plans Authentication of Key Biological and/or Chemical Resources *Budget & Period of Support*	Select Agents Resource Sharing Plans Authentication of Key Biological and/or Chemical Resources *Budget & Period of Support*	Recruitment & Retention Plan to Enhance Diversity Training in the Responsible Conduct of Research Select Agents Resource Sharing Plans *Budget and Period of Support*

Scoring Criteria

Review FOA: relevant criteria listed here

- Sent to reviewers; guides discussions; format for critiques in summary statement

Scored Criteria: 1 = exceptional; 9 = poor

- Significance
- Approach
- Innovation
- Investigator(s)
- Environment
- Protection of human subjects/Vertebrate Animals/Biohazard*

Additional Review Criteria

Reviewers will evaluate additional items while determining scientific and technical merit and in providing an overall impact score, **BUT** will not give *separate scores* for these items.

- Study Timeline (specific to applications involving clinical trials)
- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Biohazards
- Resubmission
- Renewal
- Revision

Priority/Impact Score

Overall Impact:
The likelihood that a project will have a sustained and powerful influence on science (and/or clinical practice and/or technological developments?)

Overall Impact	High	Medium	Low
Score	1 2 3	4 5 6	7 8 9

Evaluating Overall Impact:
Consider the 5 criteria: significance, investigator, innovation, approach, environment (weighted based on reviewer's judgment)

e.g. Applications are addressing a problem of high importance 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 low or no 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.

Second Level of Review

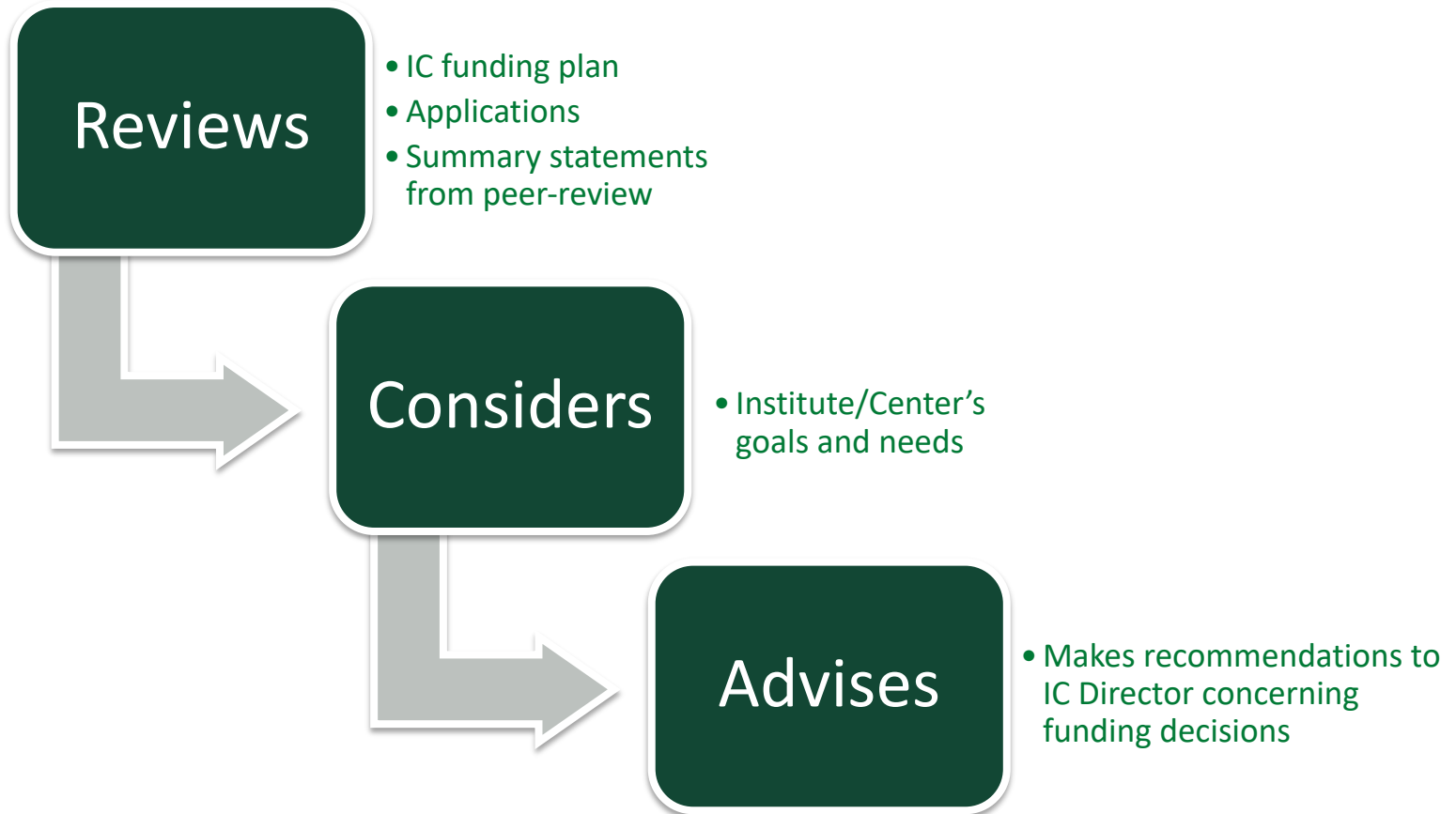| National Advisory Councils or Boards | Advisory Council/Board are connected to the potential awarding Institute/Center |
| | Composed of both scientific and public representatives |
| | Chosen by IC for their expertise, interest, or activity in matters related to health and disease |

Details - Second Level of Review

Advisory Board/Council...

Reviews
- IC funding plan
- Applications
- Summary statements from peer-review

Considers
- Institute/Center's goals and needs

Advises
- Makes recommendations to IC Director concerning funding decisions

Final Step

IC Directors	Make final funding decision
	Only applications that are recommended for approval by **both** the SRG and the Advisory Council may be recommended for funding.
Summary Statement	Details the review process
	Provided to applicants for feedback

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Details - Summary Statement

PROGRAM CONTACT: Stuart Moss
(301) 435-6979   mossstua@mail.nih.gov

SUMMARY STATEMENT (Privileged Communication)
Release Date: 03/27/2016

Application Number: 1 R21 HDXXXXX-01
Principal Investigator   CURIE, MARIE, PHD
Applicant Organization: University of Paris
Review Group: CMIR *Meeting Date:*   03/23/2016
RFA/PA: PA11-261
Council: MAY 2014 PCC: RS -SM
Requested Start: 07/01/2016
Project Title: The Effect of Radium on the Testis

SRG Action: **Impact/Priority Score: 30 Percentile: 22 #**
Human Subjects: 10-No human subjects involved
Animal Subjects: 30-Vertebrate animals involved –no SRG concerns noted

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Summary Statement

RESUME AND SUMMARY OF DISCUSSION:

Written by the SRO based on the final outcome of the discussion, summarizes strengths & weaknesses mentioned by all reviewers, highlights areas of concurrence & disagreement between reviewers.

CRITIQUE 1

Significance: 3

Investigator: 1

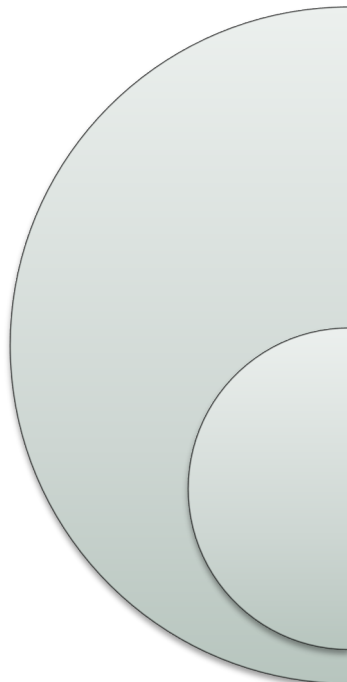**Innovation: 1**

Approach: 4

Environment: 1

Overall Impact:

Written by the individual reviewer to summarize their opinion on the overall strengths and weaknesses of the application.

Options if Your Application Isn't Funded: Planning for Next Steps

Be Resilient!

- Funding competition is fierce
- Most grants require multiple submissions before they are funded

Unsuccessful? Spend some time identifying what went wrong

- First, assess the reviewer critiques
- Then, decide on next steps

Assessment and Decision

Assessment Stop 1: Your Summary Statement

- Are the application's problems fixable?
- Was it reviewed by the right study section?

Assessment Stop 2: Your Program Officer

- Ask about chances for special funding
- Ask for help understanding your summary statement and give more insights into the review meeting
- Get their take on reviewer enthusiasm for your ideas

Decision Stop 1: Were They the Right Reviewers?

- Did the reviewers' expertise fit your topic?
- Were they knowledgeable about your methods?
- Did they understand the rationale for your research?

Decision Stop 2: Is It Worth Fixing?

- No amount of revising can fix deal-breaking flaws such as an unexciting topic
- But an application that piques interest, but has flaws, can be fixed

Common Fixable Problems

Poor writing, formatting, or presentation	• **Solution:** Rewrite; get help with writing, editing, formatting, and presentation.
Insufficient information, experimental details, or preliminary data	• **Solution:** Assess what's missing; add it to the Research Plan.
Significance not convincingly stated.	• **Solution:** Show the importance to IC's mission, your area of science, and public health.
Research not shown to be feasible by the proposed staff	• **Solution:** Recruit collaborators and consultants with the required expertise onto your project.
Insufficient discussion of obstacles and alternative approaches	• **Solution:** Describe what you'll do if you get negative results or an approach doesn't pan out. Include decision trees

Hard to fix Problems

Some applications may not be worth revising or will need major overall

Low-impact research topic

Philosophical issues, e.g., the reviewers do not think the work is important

Hypothesis is not sound or not supported by the data

Work has already been done

Methods proposed were not suitable for testing the hypothesis

Early Career Reviewer Program

Career Advancement

- Help emerging researchers advance their careers by exposing them to experience in peer review that may make them more competitive as applicants

Training

- Educate qualified scientists without prior CSR review experience to develop critical and well-trained reviewers

Broaden Review

- Enrich the existing pool of reviewers by including scientists from less research-intensive institutions

Work with RDS

Contact us for supporting the development of your proposals.

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