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Rigorous Resources for Rigorous Research



This past summer, NIH issued an [update](#) for applicants and reviewers on its two-year effort to enhance the reproducibility of its supported research. It came in response to recommendations of a congressionally mandated working group of the Advisory Council to the NIH Director. This group was charged with making recommendations on new ways to further enhance reproducibility of NIH-funded research.

The Upshot

An over-arching theme readily emerged,” said Dr. Mike Lauer, Director of the NIH Office of Extramural Research and Dr. Patricia Valdez, NIH Extramural Research Integrity Officer. “. . . no more forms or checklists. Instead, more resources!”

NIH Is Responding by--

- Highlighting Existing Resources and Products for Developing Better Proposals
- Clarifying What Is Meant by Scientific Premise
- Sharing Examples of Useful Authentication Plans
- Integrating Rigor into Training and the Responsible Conduct of Research
- Assessing Outcomes of Rigor Policies

[Get the details on Dr. Lauer's blog: Open Mike](#)

New Videos for Applicants



The NIH Center for Scientific Review has released two new videos to help new NIH grant applicants navigate NIH peer review: What Happens to Your NIH Grant Application and Top 10 Peer Review Q&As for NIH Applicants.

[What Happens to Your NIH Grant Application](#)

Most new NIH grant applicants can't attend one of our popular outreach presentations. So we created this video that gives viewers a front row seat to one of these presentations. PIs will get insights into how applications are processed and reviewed so they can better enhance and advance their applications in the peer review process.



[Top 10 Peer Review Q&As for NIH Applicants](#)

In this video, 10 experts from the NIH Center for Scientific Review answer the top 10 peer review questions applicants ask us.

More Videos

These videos are part of a [larger collection of CSR videos](#) developed to help applicants and reviewers better understand NIH peer review and enhance their grant applications and reviews.

Top 100 NIH Peer Review Q&As Web Page

NIH web pages are so packed with good information that sometimes it's hard to get what you need. A group of SROs on CSR's Communications Committee dove into the pool and came up with a list of the [Top 100 NIH Peer Review Q&As](#) so applicants and reviewers can get quick answers to important questions they might not even know to ask.

NY Times Highlights CSR Reviewer and Study Section Meeting – It’s Good News!



Staff at CSR was surprised to read an April 23, 2018, *New York Times* article* which reported an amazing story of personal and scientific discovery that featured one of our reviewers: Soo-Kyung Lee, Ph.D., a professor at Oregon Health Sciences University who has focused her research on FOX genes for more than 15 years.

Dr. Lee’s discovery began in 2012, when, as *Times* reporter Pam Belluck wrote, “Soo-Kyung traveled to Washington, D.C. to serve on a

National Institutes of Health panel reviewing grant proposals from brain development researchers.”

The Important Review Meeting

Dr. Lee had come to a meeting of the Neurogenesis and Cell Fate (NCF) Study Section with a heavier burden than most. Her daughter, Yuna, was suffering from a serious and mysterious illness. Several months after Yuna was born in 2010, she began to suffer from seizures, lack of weight gain and other developmental issues, and a myriad of other symptoms. The family received an initial diagnosis of Rett Syndrome, but it was far from certain.

As she often did at meetings, Dr. Lee described her daughter’s condition to her colleagues at a dinner organized by NCF’s Scientific Review Officer. By chance, Dr. Lee sat next to David Rowitch, M.D., Ph.D., Sc.D., then at the University of California San Francisco. They did not previously know each other, but his willingness to help made a crucial difference.

“He was very attentive,” recalled Dr. Lee, and he offered to show Yuna’s MRI to his UCSF colleague and leading expert in neuropathology Jim Barkovich, M.D.

The Surprising Diagnosis

Within just a few days of receiving the MRI, Dr. Rowitch wrote to share the preliminary conclusion. “It was eerie,” Dr. Lee said. Without knowing anything about Yuna beyond her MRI scan nor anything about Dr. Lee’s research, Dr. Barkovich thought the MRI showed a FOXG1 mutation.

The extreme rarity of the mutation (affecting only about 300 people worldwide) had prevented Dr. Lee from linking her research to her daughter’s condition. Her colleagues similarly doubted the coincidence, but a sequencing of Yuna’s FOXG1 gene confirmed

Dr. Barkovich's initial hypothesis. Still not totally convinced, Dr. Lee reviewed the raw data herself.

"I was half glad, half sad," she said. "I was glad because, after so many years of a quest for the cause of her syndrome, we finally got the results." Her understanding of FOXP1 led to sadness, however, as she knew far better than most people the long-term severity of this mutation.

How Things Have Changed



Since that fateful study section conversation in 2012, Yuna has made some progress through therapy and other supports. Without having to focus so much on the cause, "it gives me great pleasure to actually get to know my daughter and who she really is," said Dr. Lee. She had previously anguished whether an inherited disorder or something she had done during her pregnancy caused her daughter's condition. The Lees now have a younger child—knowing the cause of Yuna's condition, however difficult, proved an enormous relief.

In addition, the discovery "changed my research in a very profound way," Dr. Lee said. Yuna has a proportionally thin corpus callosum structure (the structure that connects the brain's left and right sides). Dr. Lee redirected her research to the connection between FOXP1 and the corpus callosum. She now is further studying the role of FOXP1 in brain development, funded by the National Institute of Neurological Disorders and Stroke.

"One of the Most Important Jobs I Have to Do"

While this is an amazing example of a life-changing connection sparked at a peer review meeting, it is far from unique. Review meetings -- particularly face-to-face meetings -- allow scientists in different fields to mix together and enable newer scientists to mix with senior scientists. There are many positive interactions and wonderful opportunities to learn new things during the meetings, as well as at breaks or meals.

After the *Times* article appeared, Dr. Lee received emails from other parents, including scientists whose own children's conditions have redirected their research. She connects with them to share information and encouragement. She has remained on the NCF study section, despite a full schedule of professional and personal demands. "It [peer review participation] has helped me a lot as a scientist," she said. "I take this as one of the most important jobs I have to do." – by *Paula Whitacre*

[Visit Dr. Lee's My Fox Girl Web Site to Learn More](#)

* "[Infinitesimal Odds: A Scientist Finds Her Child's Rare Illness Stems From the Gene She Studies](#)," Pam Belluck, *New York Times*, April 23, 2018, Page D1.

When Is an NIH Warning Not Really a Warning?



The short answer for NIH applicants is: NEVER! Here is what you need to know about the warnings and errors you may get when you submit your applications.

Red Lights: Your application undergoes over 800 electronic checks (called validations) on its way from your computer to the NIH. When something is very wrong, you will get an error message during the submission process telling you that your application was rejected. Think of it as a red traffic light. To get the green light for your application to go ahead in the review and funding processes, you must fix the error(s) and submit again—before the deadline.

Yellow Lights: Other times, your application passes all the electronic validations required for a successful submission, but something may not be quite right. In that case, your application comes all the way through to eRA Commons, but you get a warning. Please slow down and take a close look at that warning (yellow light) to see whether it is important for your application. Some warnings are general, such as reminders to all applicants to use a new application form set when a form change has happened, but some warnings may be specific to your application and might even have a critical impact on our ability to review it.

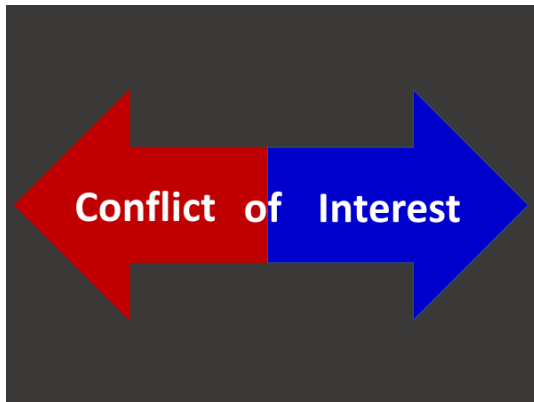
Real Risks of Running Yellow Lights: Every council round, CSR's Division of Receipt and Referral hears from applicants who did not heed the warnings and have ended up with downstream problems, sometimes resulting in withdrawal of their application. Sometimes, we even hear that the organization's own grants office told their principal investigators to ignore any warnings they receive. If it wasn't an important notification, NIH would not include it in the warnings we give you during submission. While not all warnings require action on your part, some do, and some may be critically important for the success of your application.

Getting a Green Light: Submitting your application well before the deadline is always a good idea. But the bottom line is that the time to correct errors (and warnings, if you need to) is before the 5 PM local (applicant organization) time submission deadline. Corrected applications submitted after that time are considered late, and they may only be accepted if they fall into one of the situations covered by [our late policy](#).

Learn More About this Key Part of the Submission Process

- [Submit, Track, and View Your Application](#)
- [How We Check for Completeness](#)
- [Submit a Changed/Corrected Application](#)

Going All Electronic: Pre-and-Post-Meeting Conflict of Interest Certification in IAR this Fall



Any time a reviewer has a real or apparent conflict of interest (COI) with a grant application or R&D contract being reviewed, the reviewer needs to reveal the conflict by signing the pre- and post-meeting COI certifications in eRA's Internet Assisted Review (IAR) module.

Signing the pre-meeting COI certification, as well as the post-meeting COI certification, is essential to ensuring that the NIH peer review process is fair, impartial and conducted with integrity. The certifications need to be signed even if there is no conflict.

What's Changing

Currently, a reminder pops up in IAR if a reviewer has forgotten to sign the pre-meeting COI certification. But starting this fall, a hard system check will prevent a reviewer from submitting critiques, criterion scores and overall impact scores if the pre-meeting COI certification has not been electronically signed.

This move is to ensure that reviewers electronically sign the pre-meeting COI certification early in the process, well before they get to the actual review meeting.

Similarly, the post-meeting COI certification must be electronically signed at the time reviewers complete their participation in the study section meeting. Paper certifications will no longer be accepted.

Other Changes Coming to the COI Certifications this Fall

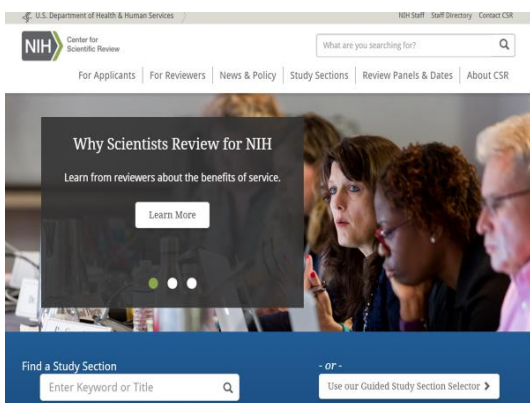
- The language of the pre- and post-meeting certifications will be updated, so reviewers should read it carefully before certifying at the bottom of the screen.

- Reviewers will be presented with the appropriate information, depending on whether grant applications or R&D contract proposals are being reviewed and whether the reviewer is a federal/non-federal employee. If the information is not correct, reviewers should contact their Scientific Review Officer (SRO).
- A recertification will be required if an additional conflict is discovered before the meeting or under other scenarios (meeting date changes and certifications reflect the previous date, etc.).
- The COI screens will include a history of the certifications, including date certified and name of the reviewer who certified.

Ask your SRO if you have any questions about pre- and post-meeting COI certification.

These changes are scheduled to be implemented around the end of October.

CSR Launched New Internet Web Site



Our public [Web site](#) has been redesigned!

Much of the content and layout is similar to the prior iteration but has been refined to better serve the needs of applicants and reviewers and to be in keeping with the style of www.nih.gov.

The new design and content were based on extensive testing with applicants and reviewers, feedback from CSR staff, and usability data that helped us determine what

information applicants and reviewers are seeking and to better position that information.

Webmasters who use CSR links may need to update some of them. The URL for the landing page of the web site is the same (<https://public.csr.nih.gov>) as before but links for material deeper within the site have changed.

We welcome your suggestions and edits. We will continue to refine the site. Please send your comments to Dr. Kristin Kramer, Web Coordinator and Scientific Review Officer: kramerkm@csr.nih.gov.

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Send comments or questions: PRN@csr.nih.gov

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