Inside the NIH Grant Review Process Video Script -- FINAL 7/21/2009

Center for Scientific Review
National Institutes of Health
Department of Health and Human Services

Text:
The purpose of this program is to provide a basic understanding of National Institutes of Health Scientific Review Groups or grant review meetings. This presentation can be used in several ways, including complementing larger University forums on grantsmanship or during meetings of scientific societies.

On Camera Host

On Camera Host

Hello and welcome.

The staff of the NIH *Center for Scientific Review*, or CSR, has created this program to give you insight into what happens during an NIH *Scientific Review Group* meeting or *study section*.

We hope to convey the importance of preparing the best application possible to improve the chance your proposed research will get funded.

Thank you for watching and good luck.

Title Sequence:

Inside the Grant Review Meeting

Laura Moen: . . . one of my colleagues walked in and he said, what's that you have in your hand, you look as white as a ghost? And I said, I'm sure this is the summary statement telling me how the review of my application went … I looked at it and I just burst out

laughing, shrieking, jumping up and down…
it was really undignified.

Lee Mann: You're feeling somewhat angry and you feel rejected. What you have to understand is that the reviewers aren't critiquing you as a person. They're critiquing you as the investigator and they're critiquing the way you're presenting the idea.

NARRATOR

(*intonation segue from above*)
How well are you presenting your idea? How well executed is your application? What might reviewers think of it? Will it have enough scientific merit to be considered for an award of NIH research grant funds?

B Roll: Montage:

NARRATOR

This is a *behind the scenes* look at how the NIH establishes the scientific merit of applications for research grants.

Our purpose is to reduce misunderstanding and clarify ambiguities about the process.

B Roll

NARRATOR

In a typical year, the Center for Scientific Review at the NIH receives between 55 and 70 thousand grant applications. Only the top 20 to 30 percent eventually earn support.

While almost all applications are reviewed, the process is streamlined for efficiency and only the best applications are discussed at the review meeting

Graphic of scores

NARRATOR

The most well crafted applications, those that prompt high enthusiasm among reviewers, require just a

couple of minutes of discussion at the review meeting to confirm their excellence.

In contrast, applications with many flaws are often not discussed or scored at the meeting. These "unscored" applications will get full written critiques from two or more reviewers in their summary statement.

A subset of the above graphic focusing on the midrange.

NARRATOR

The applications that receive the most discussion fall into the midrange and display both strengths and weaknesses. About 10 to 15 minutes are devoted to these applications.

See: http://www.csr.nih.gov/Committees/meetings/meetings.asp

NARRATOR

Categorized by topic, applications are assigned to *study sections* or *Scientific Review Groups* for the first level of review.

Dean Brenner: I think part of the strength of our system in the United States is the concept of peer review. And what that means is that we're responsible for each other, in essence, we're responsible for the science, both to do it and do it well, and also to insure that it's being done well.

Study Section folks walking into the room, sitting down, Sharon and Dean having a tete-a-tete, head shots of each.

NARRATOR

The major goal of the *study section* is to ensure that all applications receive a thorough, fair, and objective review. One of the members of the study section, in

this case, Dr. Dean Brenner, acts as Chair and moderates discussion of scientific and technical merit.

A Scientific Review Administrator, like Dr. Sharon Pulfer, serves as the Designated Federal Official. This person has the overall responsibility for the operation of the peer review meeting and provides orientation and clarification of NIH policies and regulations.

To camera:

Sharon Pulfer: I want to welcome everyone to this scientific review group. I want to thank all of you for your participation and for taking the time from your very busy schedules to review these grant applications.

Sharon writes guidelines on easel paper as she talks to the group

NARRATOR

Dr. Pulfer begins by providing basic guidelines for the group. Principles encouraging confidentiality and discouraging conflict of interest are essential.

As far as conflict of interest goes, I'm gonna read this because it's really important. Conflict of interest in scientific peer review occurs when a reviewer has a professional, personal, or financial interest in an application. Most commonly that's when an application is submitted by either you, a relative, a close friend, or a collaborator. Or if you're listed on a budget page in any capacity.

The second issue is confidentiality. I need to remind you that everything associated with this meeting should be considered confidential. If applicants contact you, please refer them to me and let me know that they contacted you. All material should be left in this room. The only thing that you can take with you are your written reviews and any published manuscripts.

NARRATOR

She continues by reviewing standard criteria.

NARRATOR

Significance: Does this proposed study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

Innovation: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers, if any**?**

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support**?**

Human Subject and Vertebrate Animal Subjects: Has a compelling rationale for using humans or vertebrate animals as research subjects been presented? For Human Subjects, has the applicant addressed the adequacy of protection against risk, the potential benefits of the proposed research to the subjects and others, and the importance of the knowledge to be gained?

Back to B roll of the discussion of Sharon going over points; picture follows discussion.

NARRATOR

In general, those seeking support are asked to be both innovative and rigorous.

On Camera Host to camera.

On Camera Host

And the *Scientific Review Group*…what's asked of them?

Each one should be an expert in his or her field. Each, ideally, is conscientious, a thorough reader and listener, one who works well in groups, and carefully considers the advice that he or she is about to give.

An actual study section has twenty to thirty reviewers. For the purposes of this mock study section, we're using a smaller group of representative volunteers discussing representative grants.

As many of you know, a K08-Career Development application would not usually be reviewed alongside an R01 and an R03.

For our purposes, three actual grant applications, containing strengths and weaknesses, have been modified. These changes have been made for the sake of anonymity and to make this program as instructive and valuable as possible.

We've also edited and condensed the discussions to highlight those elements which will give you the most insight into the review process.

But, the overall flavor and tone are faithful to what you'd hear at a typical meeting. The discussions were not scripted. These volunteer reviewers were simply given the applications and asked to prepare to discuss them just as they would during their usual study section meeting.

The observers sitting in the background represent the program staff from Institutes that will consider funding the applications being discussed.

Dean Brenner: Our first grant review today is an R0-1 Muldoon. Primary reviewer, Andy Yeager.

NARRATOR

Three reviewers give their preliminary scores for this international, multi-center trial.

B Roll: Reviewers respond to the above question.

Andy Yeager: This is an application from a very talented and productive applicant and a very competent investigative team. The hypothesis that they're testing is that a selective inhibitor of cyclo oxygenase II, or Cox-2. This agent RK 42-B can inhibit recurrence of colonic polyps. A properly conducted trial of this sort could have substantial implications for prevention of colon cancer.

This may generate not only descriptive data but one hopes, some mechanistic data. They've chosen an appropriate target population – subjects who are at high risk for colon cancer. An appropriate, I think, time period, an intervention period of three years with placebo or the RK 42B. This really represents some innovation.

There are a few questions which is where I was a little less than enthusiastic. Is there a scientific rational for this intervention? Are the markers they're looking at appropriate?

The logistics of the trial, I think, require more information.

Dean Brenner: Howard.

Howard Kaufman: I agree pretty much with everything Andy said, but I was less enthusiastic for a few other reasons. First of all, this is clearly a strong group and they've done a lot of pre-clinical work in this area, and I thought that was a major strength of

the application. However, as Andy sort of eluded, their justification for picking this particular drug, I think was somewhat lacking.

And in fact, their own preliminary data in Table 2 where they actually use their drug compared to Solendac in looking in a rat model of a …it looks like there's really not much difference between these two groups. So, I thought they needed to really strengthen their rational for selecting this agent in the first place.

As far as the trial goes, I had some major issues there. This is a group that has not worked together in the past they really have no track record for doing a multi-institutional study; I felt they really didn't support the feasibility of quality control.

NARRATOR

Dr. Kaufman goes on to explain that much of the proposed methodology and database are not adequately described in the application. The presentation of models is confusing and insufficient. And so it is difficult to evaluate how the investigative team hopes to analyze results.

Howard Kaufman: In terms of accrual, they cite a number of centers and the numbers of patients that they've had, but they really don't justify these numbers; they don't really provide evidence that each of the sites can accrue patients appropriately for this trial.

I felt it would've been strengthened by either a more raw justification based on the literature or based on their own work in terms of how this drug may in fact be influencing a colorectal cell-proliferation. And so for that reason, I gave it the score that I did.

Dean Brenner: Thank you, Howard. Next, Donna?

Donna Neuberg: Well, I was globally all right with their sample size calculations within the context of the assumptions they made, but I thought that there were some inconsistencies that troubled me. I really

have to ask if their statistician is in close collaboration with the PI and really talking to them.

Now as I look more closely at that primary end-point, I got very confused. This study expects roughly 30 percent of the enrollies to be non-compliant and they blur the distinctions between non-compliance, non-adherence and dropouts. But basically, if you don't come back for your year three colonoscopies so they can check on recurrence of polyps, you're counted as a failure; they assume you have polyps.

The criteria, as Andy said, are either one polyp that is larger or two or more smaller polyps, but I would actually like to know how many polyps the people entering the trial had. And when I assess how many polyps you find at the end or how much... I think it's a much more complicated problem then they have any... given any indication of a statistical understanding for.

Reader 3, Sufan

Sufan Chien: I agree with the other reviewers, I just want to add one more comment. One of their major hypotheses is that RK-42B is protective because it decreases PGE2 production which in turn will decrease cell-proliferation, but their own data do not support this. In their preliminary study, PGE2 production will decrease, but cell, proliferation was not decreased; and in the application, they don't seem to have an alternative explanation. If this theory does not work out, what are they going to do? So that was my concern.

NARRATOR

The discussion is now opened so that other study section members can question the primary reviewers.

Gerardo Vasta: I just have a question, is it the fact that the effective dose of the drugs has not been defined yet, a major flaw, and that would suggest that the study is a little bit premature, I would say. I mean, wouldn't you go for a pilot study first in terms of the finding, which is the effective drug dose, and then go for the major long-term screening?

Andy Yeager: That's a valid comment.

Dan: I'm following up on Gerardo's comments. And Howard, did they really justify their dose with any rational, did they say that?

Howard Kaufman: I think they base a lot on the arthritis study and they take the dose from there...

Dan: But you have no idea whether the arthritis dose is going to be useful in the gut as an anti-proliferate?

Howard Kaufman: That's right.

Sufan Chien: Even at the highest dose.

Dean Brenner: Yeah. Well, for all you know, the highest dose might actually be worse, rather than better. Nora?

Nora Disis: If from what Howard said, there wasn't even that good of a justification of the drug itself considering that they looked at other inhibitors and they seemed to have similar effects in their animal models. So what I'm hearing is that there's problems with no justification of the drug, the dose and even the statistical design of the study; sounds pretty serious.

Dean Brenner: So, this looks like a big trial … this is not ready for prime time, huh?

Andy Yeager: I think this is going to need substantial reworking and adequate addressing of the comments, and I think some concerns that the study section brought up.

Dean Brenner: What are your thoughts about human subject protection, data safety monitoring?

Donna Neuberg: There's a plan, there's a Data Safety and Monitoring Committee identified, but the structure of the statistical considerations doesn't tell us just when they will be approached, when they will be invoked and what they're empowered to do. So I think more detail would be desirable.

Andy Yeager: In terms of participation of women and inclusion of minorities, this is very well addressed;

Andy Yeager: The other issue Dean, regarding participation of children. We know that children, adolescents who would fit the NIH defined criteria of being under age 21, do have a risk for colon cancer and this does exclude the known familial types of colon cancer; that is not adequately addressed. In fact, it needs to be indicated clearly that subjects in the pediatric age group would be eligible for this study, or adequate justification why they should be excluded; it's not as if this disease does not occur in that age group.

Dean Brenner: So that's going to affect the score some.

NARRATOR

In summary, the group noted investigators had not met the NIH requirements for detailed documentation of protection of human subjects nor did they justify the lack of participation of children.

Dean Brenner: Okay, then with that factored into your scores now, how do you want to restate your scores for final scoring?

Andy Yeager: Well, I was previously about 2.3. Having heard the elements of this discussion and these concerns that have been added in terms of human subjects, I'm going to come down; I'll be 2.7.

NARRATOR.

All reviewers present score each application on a five-point scale: a **"**priority" score of one is best; five is the worst.

NARRATOR.

These scores are based on relative scientific and technical merit and reflect each panelist's best expert judgment.

On Camera Host

The priority score is converted to a percentile ranking which reflects scoring behavior of the review group at this and two prior meetings.

All applications, even those that are 'streamlined' out of discussion, receive two to four critiques written by the assigned reviewers. The applications that are discussed and scored also receive a resume of the discussion written by the SRA after the meeting.

The scoring continues.

Dean Brenner: Two-seven. Howard?

Howard Kaufman: I think I'll stay at 2.6.

Dean Brenner: Two-six. Donna?

Donna Neuberg: I have not heard anything that would convince me to be more enthusiastic, so I'm going to stay at 2.9.

Dean Brenner: Two-nine. Sufan?

Sufan Chien: Two-seven.

Dean Brenner: Two-seven.

Sharon Pulfer: All right, right now, we need to change focus. We want you to take off your R01 hat and put on your K08 hat because we're going to review the Mentored Clinical Scientist Award.

Dean Brenner: Thank you, Sharon. We'll review KO8, Wayne Lawrence, I'm the primary reviewer and I gave it a 2.3. Sufan?

Sufan Chien: Two point one.

Dean Brenner: Two point one. Donna?

Donna Neuberg: Well, I'm a statistical reviewer and there aren't any, so I'll give it a 3.0.

Dean Brenner: Three-zero, okay. Gerardo?

Gerardo Vasta: I'll give it a 1.9.

Dean Brenner: One point nine. A little spread here. Okay, then I'll begin and go over this application.

NARRATOR

K08 grants support the development of clinician research scientists. In this case, the mock study section will examine the candidate's academic and clinical record. They will focus on his potential to develop as an independent researcher, in part, by critiquing his research plan and determining the level of institutional commitment to his work.

Currently a senior fellow, the candidate, Dr. Lawrence, is well trained and ready to move in a new academic direction – regional vascular permeability and blood flow in the kidney of patients with "square cell disease" during endotoxemia. His third journal article is about to be published and he is the recent recipient of an NRSA award.

Dean Brenner: …so that's quite an impressive productivity for a young guy just coming out of a fellowship, and it certainly tells us that he is moving in the direction of an academic career.

I think that this is really optimal for somebody like this as he will be able ultimately to move into more mechanistic approach into these important physiologic things that go on in the kidney

Dr. Mackenzie Lu's extremely well known in the area of blood flow physiology, particularly in the kidney, and appears to have been a really outstanding mentor for Dr. Lawrence.

NARRATOR

The young scientist has assembled an impressive team beyond Dr. Lu.

What he's going to do is he's really going to interact with them intensively. And I think that's a real strength to the application,

NARRATOR

But, Dr. Brenner has significant concerns.

He's not really thought about his outcome. I guess that's kind of a rookie mistake that we see on study sections, but maybe his mentor should have caught that.

There are also a lot of details that I'm looking for in this grant that are missing. For example, how is he going to make hypertonia exactly? What does he define as hypertonia and how rapidly is he going to run the gradient to increase the hypertonia?

Again, those kind of nitty gritty details that you really need to know to convince us that he's really thought this through.

Otherwise, as I noted, the mentors are very strong, the environment is really outstanding, there's a letter from the Chairman of his Department that I wish all my mentees would see which says, "We're going to promote him, we're certainly going to retain him, he's one of the most promising fellows we've seen."

NARRATOR

Dr. Brenner would really like to support the application, but has concerns about exactly how involved the mentor has been up to now – a point demonstrated by the weakness of the quantitative analyses.

Dean Brenner: So overall, I think it's a great program, great training environment, strong support, but there are some weaknesses in his scientific project that reduce my enthusiasm. Next review is Sufan.

Sufan Chien: Yes, I agree with Dr. Brenner. I think that all these studies are feasible and the experiments are within the expertise of the PI and co-investigators.

One is the studies in AIM-1 would not add much new information to our knowledge. For the number one study, it will determine the extent of increase of vaso occlusion induced by endotoxin; and this effect actually has already been reported in previous publications.

Dean Brenner: Thank you. Donna?

Donna Neuberg: Well, you've challenged me here to provide a statistical review of an application. And while I think it's actually a good application, I am concerned that the applicant neither addressed his statistics in this application, nor is he entirely aware of his need of statistics…

He does say, and this is his only... as close as he gets to this, that Dr. Dale who developed the transgenic knockout mouse model for Square Cell Disease will train him in how to properly design and interpret studies that use genetically altered mice. So I think there's that appreciation, but "What kind of differences am I going to be able to detect."

NARRATOR

Like other panelists, Doctor Neuberg has some enthusiasm for the application, but believes the researcher doesn't understand how statistical thinking applies to his work. She also thinks presentation of the markers chosen for the study is superficial and, in general, lacks detail. Dr. Vasta has a similar opinion.

Gerardo Vasta:: I'm also concerned about the lack of detail in some experimental aspects particularly in how their re-agents will be used and what kind of reagents will be used; the source of the LPS for instance are in the toxins, what doses are going to be used. The fact that they're going to be using antibodies against the human homologs of the mouse, for instance, integrin as target for inhibition of adhesion.

Gerardo Vasta: And finally, I think the major weakness of the proposal is the fact that opposed to measuring expression or release of some of these cytokines or chemokines or surface expression of these adhesive molecules, I think the problem of this application is that you're not attempting... the applicant is not attempting to figure out how they work, how they interrelate to each other and in what sequence.

Gerardo Vasta:: I think the role of the mentor and the co-mentor in this case is also to help the applicant to identify a new area that's going to lead him to scientific independence. So they're going to still contribute in the scientific aspect, but it will also lead him to develop himself as an independent scientist.

Dean Brenner: Donna?

Donna Neuberg: Well, I just want to respond to Herardo. You have a very good critique of this application, but you gave it the best score. . I'm looking to be talked into a better score. I'm wondering why you were so enthusiastic when you had so many critical things to say.

Gerardo Vasta:: Well, the main reason for my score is the focus on the training environment. I think, again, the mentor and co-mentors are absolutely outstanding and the institution is outstanding and it shows tremendous commitment to his particular project.

So I would like to give a very encouraging score at the same time a very strong message that the experimental plan has to be detailed, has to be concise, has to be well-crafted, basically.

Dean Brenner: So to summarize, I think the committee seems to be swayed more by the excellence of the applicant and the high quality environment and the kind of plan that he wishes to take over the deficiencies that we see in the application.

…so I certainly move my score up to about 1.8 at this time. Sufan, where do you go?

Sufan Chien: Two point zero.

Dean Brenner: Two point zero. Donna?

Donna Neuberg: I'll come down to a 1.9.

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As you can see, the discussion actually brought the scoring recommendations of the panel closer together. This resulted in a better score for the applicant, a score that reflects the strength of Dr. Lawrence's training environment.

Sharon Pulfer: All right, we need to shift gears again and the next application was submitted in response to a specific program announcement.

…the main thing you have to keep in mind that these are for preliminary studies, so the budget is capped and also the time is limited to two years. So please keep all these things in mind when we start the review.

Dean Brenner: Thank you, Sharon. This is a grant from Thomas Westcott; it's an R03. Nora, you're a primary, can you give me levels of enthusiasm?

Nora Disis: One point eight.

Dean Brenner?: One point eight. I'm at 2.5, I'm secondary. Donna, where are you?

Donna Neuberg: Two point seven.

Dean Brenner?: Two point seven. Andy, where are you?

Andy Yeager: I'm about 2.2.

Dean Brenner: Two point two, okay, Nora, go ahead.

Nora Disis: So, let me tell you why I liked this proposal. This is a very simple Phase 1 study of a cancer vaccine, immunizing patients with advanced

stage CEA over-expressing tumors.

When you go back to the first aim which is looking at the immune responses, it was really beautiful in the fact that he's looking at very highly quantitative assays.

This applicant is actually using some new strategies; one is called L.E. Spot (ph.) and the other is Intracellular Flow Cytommetry (ph.) looking at intracellular cytokine (ph.) production and being able to quantitate out; numerically, CD-4 and CDAT cells that responding to antigen. These are new techniques and although in this mechanism you don't really have to have a lot of preliminary, he actually presents a significant amount of preliminary data demonstrating that he can do these techniques.

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Actually, the R03 mechanism doesn't call for preliminary data to support the research proposed. The Chairman might have taken the opportunity to guide the discussion away from this point. Or, the SRA might remind reviewers that preliminary data are helpful, but not critical for R03s.

Nora Disis: And what I really liked about the application is that throughout these very complex scientific studies, he had a lot of troubleshooting; what he would expect, not being able to get responses, what he'd see next. So clearly, even though this investigator has never published on these techniques, he really reflects through the writing in potential pitfall sections exactly what problems he proposes to encounter.

NARRATOR

Dr. Disis continues her commentary. Some major downsides of Westcott's plan include deficiencies in structure, poor definition of assays, statistical weaknesses, and incomplete clinical trial data.

Disis: I think by far the weaknesses for me were the statistics; he didn't have the clearest statistical definition of what would be considered a positive immune response; again, there was some overlap with the assays on exactly what assays will be done. And in terms of the clinical trial, which I understand he has to do on advanced staged cancer patients, these are patients that are more likely to be immuno-suppressed so they'd be the exact category of patients where you wouldn't really expect to see an immune response.

Dean Brenner: Thank you, Nora. I agree with everything you say, and in fact, I just weighed it differently than you did. I think this was an extraordinarily novel and important approach. One of the things that we have in treating solid tumors and particularly adenocarcinoma of the colon, there's a lack of good therapeutic alternatives, and this is a very innovative, important therapeutic alternative.

So why did I give it a 2.5 given all the things you've said, and it gets to the clinical trial. I really don't think he sat down and figured out what he was really after.

…he's treating a cohort of subjects who might not have that and so he's going to get false data.

I gave him a huge amount of credit for breaking molds and presenting something that I think could very well change though the way that we approach colon cancer after surgery, but I don't think this is the way to go about it in the Phase 1. And I think he really needs to rethink that and that's why I gave him the 2.5. Donna?

Donna Neuberg: Well, I actually am very gratified to see the effect of including a statistician on the review for each of these grants, because between Nora and you, Dean, I don't have to say a lot of this stuff because it would be repetitious. I was basically concerned that the application itself does not have statistics in it, that the statistics in the clinical trial are only in the appendix in the clinical trial.

Dean Brenner: Andy

Andy Yeager: I think much of what I had made some notes on in my read, have already been stated very well. This is a novel approach, an extremely well-qualified investigator, and my enthusiasm for all of that was quite high. That, on the other hand, was counter-balanced by what others have already indicated are some problems, some flaws in the design of the clinical trial.

Dean Brenner: Discussions? Nora.

Nora Disis: Okay, one of the things that I think we often go over in these review groups, is that when we review these biologics, especially in terms of cancer vaccines, we're used to looking at purified materials like peptides and things along these lines. This is going into a totally different concept…

. . . I'd look at this, not so much as a Phase 1 study, but as a feasibility study allowing him to get the data to come back and write the real grant with the real patients. The same thing when we talk about putting parameters on these immune monitoring things; I kind of gave him a buy because these haven't been used extensively in humans before.

Dean Brenner: Other questions or comments?

Howard Kaufman: Yeah, I had an opportunity to read this grant and I liked it because I felt it was very responsive to the program announcement in terms of being at trial that was not just a clinical trial; although I do see the weaknesses in the trial, but that there would be an ability to get a lot of immunologic information out of the trial.

NARRATOR

Others on the panel reinforce that it's important for applicants not to overstate goals. Is this an appropriate phase one study, or an appropriate pilot study?

Dean Brenner: Can you restate your scores now?

Nora: I'm just going to put one last plea. I think this

is a feasibility study and some of the things have been discussed are not a fatal flaw, so I'm going to stick with the 1.8.

Dean Brenner: One point eight. Thank you.

Dean Brenner: Well, I'm going to stick with a 2.5 because I believe there is a fatal flaw. He needs to write a pilot and this isn't ready for prime time.

On Camera Host

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Sometimes, reviewers disagree on the relative weight of each criterion for scientific and technical merit. How does innovation balance approach? This can result in divergent overall scores, as we'll see.

Dean Brenner: Two point five. Donna?

Donna Neuberg: I agree it's a feasibility study. I'd like to see it come back as one; 2.2.

Dean Brenner: Andy?

Andy Yeager: I'm staying at 2.2.

Dean Brenner: Okay, mark your score sheets, thank you very much.

Chuck Selden: There's a percentage of grants that we discuss in detail where the strengths and weaknesses are balanced against each other and… the fact that three or four reviewers are assigned to each application means that there will be different opinions and different personal preferences as to how much weight to give one aspect or another of an application.

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The discussions are over for the day. All applicants, even those whose applications were not discussed, will receive a full written critique comprised of the comments and recommendations of members of the *study section.*

Scores will serve as a guide to the staff of the funding institutes who make the funding decisions, based on research needs and priorities, as advised by their National Advisory Councils.

So, what can you do to improve your chances that your application will receive an enthusiastic recommendation for funding?

Be clear

Michael Small: there has to be a very clear picture of the background you have and the fact that you understand, for instance, building the proper controls, that you've considered alternative hypotheses and alternative approaches to solving problems.

Be innovative

Dean Brenner: I don't look for correct answers, I look for innovative answers, I look to see whether an investigator's able to pick new things and interpret them and go in a direction that it might lead them despite the fact that their pre-conceptions might be different.

Focus on key questions

Michael Small: I think we can't over stress the importance of having as convincing a research plan as possible, but one that focuses on the key questions and sort of the proof of what I call the proof of principle ...

Be convincing and thorough

NARRATOR

Applicants should strongly state the contribution their study will make to the field, demonstrate a thorough knowledge of their subject and the literature, show careful consideration of animal and human subjects, present a well-thought out budget, and reveal their own enthusiasm for the work in focused, thorough, and clear language.

Don't wait to the last minute.

Chuck Selden: The best advice I have is don't' wait till the last minute and finish your grant application.

Organize to communicate.

Mike Sayre: Many times, we have issues of grantsmanship where someone has a really great idea, but they just don't know to organize it in a way that they can sell it to people who aren't in love with that idea.

Follow instructions to the tee

Lee Mann: If you follow the design of the PHS398 and follow it to a tee, you'll be much more successful than other people. So, that's important.

Proof a hard copy.

Chuck Selden: If it looks great on the computer, read it again in a print because things will not always be the same.

Ask knowledgeable others to critique a draft.

Lee Mann: You need someone who can be honest with you, be honest as the critique you're going to get back after the grant submission. And by having people do it before you submit the grant, you're just doing yourself a favor in what the critique is going to be later.

Ask people at NIH to help

Laura Moen: Don't be afraid to call people at the NIH and ask for information. I think that was probably the most important thing I learned.

Use the program administrators as a resource

Laura Moen: If you have questions of whether or not an institute would be interested in your project, call the program administrator there and if you don't know who to call at that particular institute, most of the information is available on web pages.

Submit again…

Lee Man: If you're not successful the first time, you're allowed two more submissions and people should use those two submissions if they're getting positive feedback from the critiques.

Analyze the critique

Mike Sayre: Keep trying. If you get a score that the Institute decides is not fundable, read the critiques, carefully, think about it for a while, try to step back outside of your own perspective and take a broader view of it, and then come back with a stronger application.

And don't give up

Laura Moen: All I can say is that sometimes you have to be extremely persistent. 10:15:08 What about when your research project wasn't going well and the experiments just didn't seem to be working right. Did you go away and give up in disgust? Of course not.

Donna Neuberg: I think you heard in our review process that often we see weaknesses and still score a grant well because we think it has promise.

Laura Moen: We would love to give money to people with good ideas. We can't just give money to people who tell us they have good ideas. A peer review committee is essential to that process.

On camera conclusion

On Camera Host

You should now have a basic understanding of how NIH Peer review meetings work.

Since we originally produced this video, NIH and CSR introduced several new policies and initiatives that will affect the application submission and review processes. Many of these changes arose from an NIH-wide effort to enhance our peer review process.

One high-profile change is that applicants can now submit most applications electronically using the SF424 R&R form through grants.gov. It is still best to submit your application early to avoid problems.

If you submit your application on time, you have a short window to address any error or warning notices from our system.

Once it is error free, an image of it is assembled. You'll then have another short window to view it. For any changes made beyond the application due date, the NIH late application policies apply.

After the viewing window expires, the system won't allow any further modifications to your application and you'll only be able to send a limited number and certain type of supplemental and corrected pages to the Scientific Review Administrator. We now call these individuals Scientific Review Officers, or SROs.

If accepted, these pages will be uploaded as an addendum in the "Additions for Review" section of your electronic grant application folder.

Another big change is the new NIH policy that you can only submit an application twice – the original and a single resubmission or amended application. The goal here is to fund high-quality applications sooner.

If you do not receive funding after two submissions, the project must be significantly re-designed before submitting a new application. You'll find more about this policy on our Web sites.

NIH also is moving to create shorter applications, starting in calendar year 2010. The policy is still being finalized so please check our Web sites for more information.

CSR now uses alternative electronic review platforms for about 20 percent of the applications. These include online discussion boards and video enhanced discussions to make it easier to recruit reviewers.

We've also changed elements of our review process to more efficiently identify the most promising applications.

One of the most significant review changes is the new 9-point scoring system with "1" for exceptional and "9" for poor. Reviewers now assign scores for each of the five core review criteria and an overall impact/priority score for discussed applications.

High impact applications will be scored 1 for exceptional, 2 for outstanding or 3 for excellent. Moderate impact applications will be scored 4 for very good, 5 for good or 6 for satisfactory. Low impact applications will be scored 7 for fair, 8 for marginal or 9 for poor.

The NIH now asks reviewers to focus more on the impact of the proposed research rather than on details related to the experimental approach.

The format for summary statements has also changed. Reviewers now use standardized electronic templates that focus on strengths and weaknesses for each main review criterion.

The NIH has instituted several special initiatives for investigators. Multiple PI's can now be designated on certain types of applications.

This change helps these researchers receive appropriate credit for their collaboration and allows them equal access to critical NIH information related to their grants.

NIH also recently modified its policy for new investigator applications to facilitate earlier transitions to independence. New Investigators within ten years of completing their terminal research degree—or within ten years of completing their medical residency—will be designated Early Stage Investigators (ESIs). This designation will be

determined by your career dates in your Commons account, so be sure they are correct.

Check your career dates in your Commons account.

Extensions can be made for military service, clinical training, family care responsibilities, etc.

New Investigator R01 applications (including the ESI subset) will be reviewed in clusters, if possible, and reviewers are instructed to make appropriate allowances for these applicants in terms of their career stage.

The different NIH Institutes and Centers may set different paylines for these applications to ensure that an appropriate number are funded.

Another change has occurred in CSR review groups. Applications are now reviewed in order, using the preliminary scores reviewers assigned to them before the meeting. Applications that are clustered – such as new investigator applications – are also reviewed in order.

If you would like more information on the NIH review process, a list of resources is available on the Web. You can also consult the "Additional Resources" section on the "Inside the NIH Grant Review Process" CD or the CSR Web site.

Thank you from all of us…. and good luck.

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Get More Information
http://grants.nih.gov
http://www.csr.nih.gov
http://enhancing-peer-review.nih.gov