

**Pre-Application Workshop for NICHD Program  
Announcements: “Vulvodynia – Systematic, Epidemiologic,  
Etiologic or Therapeutic Studies”**

**Highlights of the NIH Peer  
Review Process**

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# Topics for Discussion

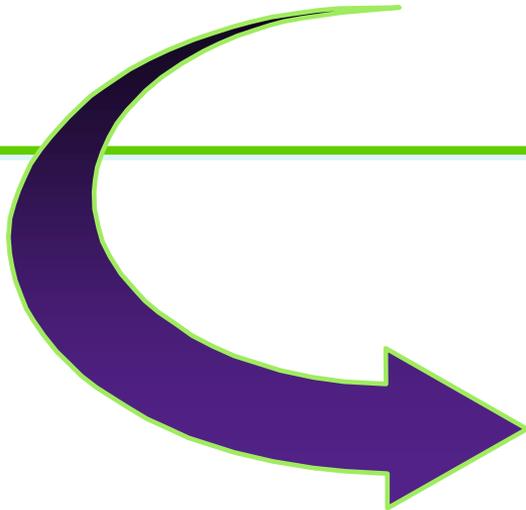
- ▶ **Overview of NIH Peer Review**
- ▶ Practical Review Considerations for Vulvodynia PARs
- ▶ Closing Remarks

# NIH “Dual” Peer Review System for Grant Applications

## First Level of Review

### Scientific Review Group (SRG)

- Provides Initial Scientific Merit Review of Grant Applications
- Makes Recommendations for Appropriate Level of Support and Duration of Award



## Second Level of Review

### Institute or Center Advisory Council

- Assesses Results of Initial Review
- Makes Recommendation to Institute Staff on Funding
- Evaluates Program Priorities and Relevance
- Advises on Policy

# Where Do We Find Reviewers?

- ▶ **Databases:** for publications, grant support, review service (IMPAC; QVR; PubMed; NSF Award Search; past review meeting rosters)
  - ▶ **Recommendations:** Professional Societies; Scientific Community Members; Journal Editors; Seminar Speakers; NIH Staff
  - ▶ **IT Tools:** Query View Reporting (QVR), Elsevier Reviewer Finder; Electronic Scientific Portfolio Assistant (e-SPA); many others
  - ▶ **Attendance at Conferences**
  - ▶ **Successful Applicants**
- 

# How Do We Assign Reviewers?

**A minimum of three reviewers are assigned to each application.**

- ▶ Spot-On Expertise
- ▶ Broad Expertise
- ▶ Community Members
- ▶ Outside Opinions
- ▶ Three “interactive” reviewers per application



# Public/Community Members in NIH Peer Review

- Why use Public Members?
- How are they identified?
- What is their role on the panel?
- How many are selected?
- How are they trained?



## Public/Community Members in Review (cont)

- ▶ Typically highly motivated and informed about “real world” (Impact) and situations of others in similar circumstances
  - ▶ May be patients, family members, caretakers, affiliated with allied professional areas
  - ▶ Have same role as other panel members to help evaluate merit of applications (e.g., voting rights)
  - ▶ Would typically be assigned as a 4<sup>th</sup> interactive reviewer
  - ▶ Receive orientation and training prior to meeting
- 

## Before the Initial Review Meeting

- ▶ Each application is assigned to 3 or more reviewers
- ▶ Reviewers assigned to an application will provide:
  - A preliminary **Overall Impact** score using the 1-9 scoring scale
  - **Criterion Scores** for each of the 5 “Core Review Criteria” using the 1 - 9 scoring scale
  - A preliminary written critique
  - Preliminary scores and critiques are posted on secure website (Internet Assisted Review site) usually >3 days pre-meeting

# At the Initial Review Meeting: Discussions Focus on the Best Applications

- Reviewers typically discuss and score 50-60% of the applications (top tier based on preliminary postings) in regular study sections.
- Special emphasis panels may discuss more (or all) applications.
- Applications that are “Not Discussed” (ND) and thus not scored represent the lower tier in scientific merit by panel consensus.
- The panel will discuss any application a reviewer wants to discuss



## After the Initial Review, Summary Statements are prepared for each application

- ▶ Scores for each review criterion and Critiques from assigned reviewers
- ▶ Administrative notes, if any



### If your application is discussed, you also will receive:

- ▶ An overall impact/priority score and (possibly) a percentile ranking
- ▶ A resume and summary of the review discussion by the SRO
- ▶ Report of discussion of Additional Review Criteria and Review Considerations (protections, codes, etc)
- ▶ Budget recommendations, administrative notes, if any

# Topics for Discussion

- ▶ Overview of NIH Initial Peer Review
- ▶ **Practical Review Considerations for Vulvodynia PARs**
- ▶ Closing Remarks

## Vulvodynia Applications: PARs (R01, R03, R21)

- ▶ “PAR” implies special receipt dates and/or review conditions
  - can facilitate a “critical mass” of applications within a review locus
- ▶ A critical mass of applications in a specialty topic may facilitate the recruitment of a critical mass of appropriate reviewers

# Very Important! Electronic Submission Information

The screenshot displays the NIH Grants.gov website in a Microsoft Internet Explorer browser. The address bar shows the URL: <http://www.grants.nih.gov/grants/ElectronicReceipt/index.htm>. The page header includes the Office of Extramural Research logo and navigation tabs for Home, About Grants, Funding, Forms & Deadlines, Grants Policy, News & Events, About OER, and NIH Home. The main content area is titled "Applying Electronically" and provides information on the electronic submission process. A sidebar on the left lists various links such as "Prepare to Apply & Register", "Find Opportunity & Download Application Package", and "Submit, Track & View Application". A central section titled "Electronic Application Process" features a four-step flowchart: 1. Prepare to Apply & Register, 2. Find Opportunity, 3. Prepare Application, and 4. Submit, Track & View. Below the flowchart, there are links for "Process Overview" and "History of move from paper to electronic applications. (PDF - 31 KB)". A "News" section is also visible at the bottom of the page.

**Electronic Grants**

**Applying Electronically**

Most competing grant applications to NIH require electronic submission. Organizations submit applications via [Grants.gov](#), the online portal to find and apply for grants across all Federal agencies. Applicants must follow their application through to the [eRA Commons](#), NIH's electronic system for grants administration, to complete the submission process. If you can't view the application in the Commons, we can't review it!

**Important Reminder:** Organizations must register in both Grants.gov and eRA Commons to apply for most NIH grants. Registration can take four weeks or more to complete. [Start now!](#)

**Electronic Application Process**

- 1 Prepare to Apply & Register
- 2 Find Opportunity
- 3 Prepare Application
- 4 Submit, Track & View

[Process Overview](#)  
[History](#) of move from paper to electronic applications. (PDF - 31 KB)

**News**

<http://www.grants.nih.gov/grants/ElectronicReceipt/index.htm>

# PITFALL #1: Not Submitting Early

**NOT-OD-10-123:** NIH has eliminated **Error Correction Window** (e- and paper applications; Jan 25, 2011 receipt dates):

<http://grants.nih.gov/grants/guide/notice-files/not-od-10-123.html>

- Originally a temporary measure to facilitate the transition from paper to electronic submission
- Allowed applicants an opportunity **after the deadline** to correct missing or incorrect aspects of their applications
- Beginning on January 25, 2011, all applications submitted after 5 p.m. local time of the applicant organization on the due date will be subject to the **NIH Late Policy** and may not be accepted for review.

**NIH Late Policy:** <http://grants.nih.gov/grants/guide/notice-files/not-od-11-035.html>

# **PITFALL #2: Post-Submission Application Materials may be Rejected**

- ▶ **NOT-OD-10-115 New NIH Policy on Post-Submission  
Application Materials**

*“Applies when unexpected events such as the departure of a participant, natural disaster, etc. has occurred, not to correct oversights/errors discovered after submission of the application”*

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-115.html>

## **PITFALL #2: Post-Submission Application Materials may be Rejected (cont) - A Notable Exception**

***Will NIH accept post-submission news of articles that have been accepted for publication and did not result from an unforeseen administrative issue?***

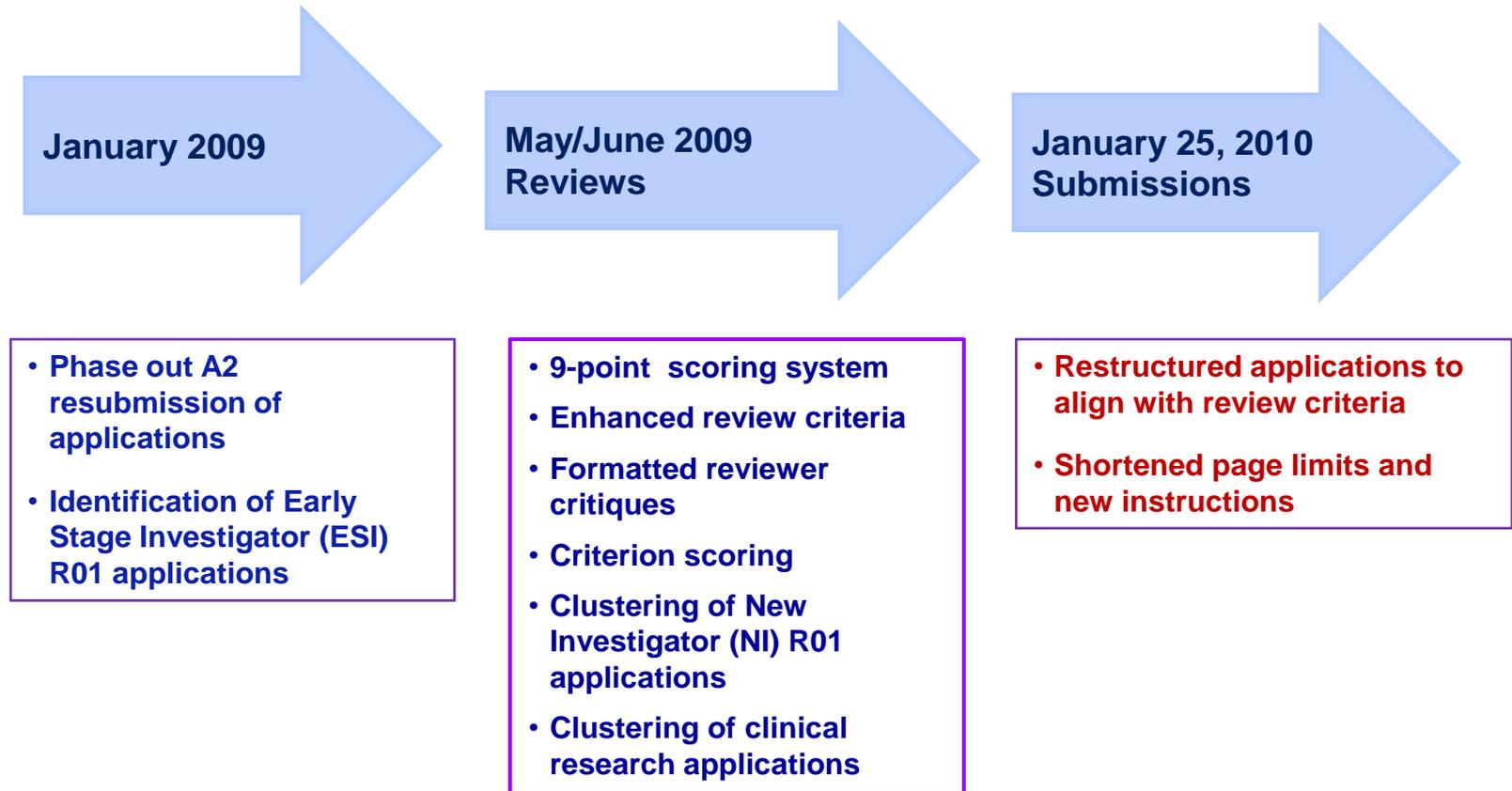
YES! NIH will accept news of all articles that were accepted for publication after the application was submitted and are relevant to the proposed project. **News of an article accepted for publication is considered another category of acceptable post-submission materials, separate from information being submitted from unforeseen administrative issues.)** For each article accepted, you may submit only the following: **Authors, institutional affiliations, title of the article, the journal that accepted it, and the expected time of publication.**

Post Submission Materials **FAQs**:

[http://grants.nih.gov/grants/funding/post\\_submission\\_faq.htm](http://grants.nih.gov/grants/funding/post_submission_faq.htm)



# “Enhancing Peer Review”: Implementation Overview and Timeline



# What are the Major Changes in Application Forms?

## *Summary:*

- ▶ Shortened page limits
  - ▶ Application reorganized to align with review criteria
  - ▶ New Research Strategy section
  - ▶ Biosketch limits publications; includes personal statement re: ability to do the research
  - ▶ Facilities and Resources focuses that specifically contribute to accomplishment of the research
- 

# Shorter Page Limit Guide

Section of Application	Page Limits
<b>Introduction for Resubmission Application</b>	<b>1</b>
<b>Specific Aims</b>	<b>1</b>
<b>Research Strategy:</b> <b>R03</b> , R13/U13, <b>R21</b> , R36, R41, R43, Fellowships (F), SC2, SC3	<b>6</b>
<b>Research Strategy:</b> <b>R01</b> , single project U01, R10, R15, R18, U18, R33, R24, R34, U34, R42, R44, DP3, G08, G11, G13, UH2, UH3, SC1	<b>12</b>
<b>Biographical Sketch</b>	<b>4</b>

**The Research Strategy includes Tables, Figures, Diagrams, and Charts**

## **PITFALL #3: Violating page limits (“overstuffing” the application)**

“Overstuffing” means circumventing page limits for limited sections (e.g., Research Strategy) by adding unallowable material in the unlimited sections (e.g., Appendix).

- Reviewers need not consider any text that is inappropriately included in a section of the application that has no page limits, and SRO may include an Administrative Note in the summary statements as a warning.
- NIH may withdraw egregious violations from review and funding consideration.

NOT-OD-11-080: Reminder: Compliance with NIH Application Format and Content Instructions : <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html>

# Enhanced Peer Review: Review Criteria are Aligned with Restructured Applications

## Overall Impact

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

## New Review Criteria Order

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

**Additional Review Criteria** (considered in determining overall impact score but not given separate scores)

- ▶ Protections for Human Subjects
  - ▶ Inclusion of Women, Minorities, and Children
  - ▶ Vertebrate Animals
  - ▶ Biohazards
  - ▶ Resubmission Application
  - ▶ Renewal Application
  - ▶ Revision Application
- 

**Additional Review Considerations:** non-scored; not considered in Overall Impact/Priority Score

- ▶ Budget and period of support
  - ▶ Select Agent Research
  - ▶ Applications from Foreign Organizations
  - ▶ Resource Sharing Plans
- 

# Scoring Scale

- ▶ **Overall Impact Score** using 1-9 scale
- ▶ **Criterion Scores** using 1-9

## All applications receive scores:

- ▶ **Discussed** applications receive an overall impact score from each eligible (i.e., without conflicts of interest) panel member and these scores are averaged to one decimal place, and multiplied by 10. The 81 possible priority scores thus range from 10-90.
- ▶ **Not Discussed and Discussed** applications receive initial criterion scores from each of the assigned reviewers as additional feedback.

# 9-Point Score Scale Descriptors

Impact	Score	Descriptor	Additional Guidance
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses

# Summary Statements

**Review Group:** VIRB  
Virology - B Study Section

**Meeting Date:** 10/08/2009  
**Council:** JAN 2010  
**Requested Start:** 04/01/2010

**RFA/PA:** PA07-070  
**PCC:** M34A

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**Project Title:** [REDACTED]

**SRG Action:** Impact/Priority Score: 29    Percentile: 12

**Human Subjects:** 10-No human subjects involved

**Animal Subjects:** 10-No live vertebrate animals involved for competing appl.

## **CRITIQUE 1:**

Significance: 2  
Investigator(s): 1  
Innovation: 2  
Approach: 2  
Environment: 1



## **CRITERION SCORES**

### **Overall Impact:**

#### **Strengths**

- The principal investigator is highly qualified for the proposed studies and has a long track record of outstanding productivity in the field.
- There is extensive and high-quality preliminary data that support key aspects of the research plan.

# Topics for Discussion

- ▶ Overview of NIH Peer Review
- ▶ Practical Review Considerations for Vulvodynia PARs
- ▶ **Closing Remarks**

# Challenges in Initial Review of Vulvodynia Applications

- ▶ **A multifactorial, poorly defined pain syndrome** that may argue for a multidisciplinary approach in research and in peer review
- ▶ **Complexity of the problem** complicates recruiting reviewers with the appropriate breadth/depth of expertise
- ▶ **Probability of achieving a “critical mass” of applications** in PARs (R03, R21, R01)
- ▶ **How to identify, recruit and effectively involve Public/Community Members**
- ▶ **SROs will avail of venues that maximize recruitment of best qualified reviewers**
  - In-Person Meeting of Review Panel ✓
  - Telephone Conference Call ✓
  - Videoconference ✓

# Closing Reminders and Suggestions:



- Please do not suggest reviewers. You may include a COVER LETTER indicating *areas of expertise involved* in your project.
- Ensure that you have followed the specific instructions and noted any different characteristics in each PAR.
  - e.g., for R03 or R21 applications: preliminary data are not required, but if provided they *will* be evaluated by the review group as part of the scientific merit.
  - e.g., R03 Appendix materials may include ONLY pre-printed questionnaires or surveys. No publications or figures are allowed in the Appendix for PAR-10-191 applications.
- Be aware of *No Tolerance* for violations of Page Limits

## Closing Reminders and Suggestions (cont):



- Do not include inappropriate material in non-limited sections (e.g., Appendix).
- Do include a Personal Statement in the Biosketch (lack of adherence is not illegal but may affect reviewer's evaluations of "Investigator" criterion).
- Heed Allowance of Post-Submission Application Materials: NOT-OD-10-115 (July 23, 2010): usually resulting from unforeseen administrative issues only; one exception is news of publication.
- Submit on time; no allowance for Late Submission for these PARs.
- Direct any peer review questions to the Scientific Review Officer listed in eRA Commons.

***Bonne Chance!***



# For additional information: some useful links



- ▶ NIH Office of Extramural Research Website: <http://grants.nih.gov/grants/oer.htm>
- ▶ Global Office of Extramural Research **FAQs**: [http://grants.nih.gov/grants/frequent\\_questions.htm](http://grants.nih.gov/grants/frequent_questions.htm)
- ▶ Grant Application Submission **FAQs**: <http://grants.nih.gov/grants/ElectronicReceipt/faq.htm>
- ▶ Post Submission Materials **FAQs**: [http://grants.nih.gov/grants/funding/post\\_submission\\_faq.htm](http://grants.nih.gov/grants/funding/post_submission_faq.htm)
- ▶ NIH Late Policy: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-035.html>
- ▶ Enhancing Peer Review: <http://enhancing-peer-review.nih.gov>