

NIH Changes Meeting

Dr. Robyn Gershon
Associate Dean for Research Resources
December 8, 2009
11:45-1:15, Hess Commons



Columbia University
MAILMAN SCHOOL
OF PUBLIC HEALTH

Mailman School Research Resources Office

Updated Research Resources Website

http://www.mailman.hs.columbia.edu/

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Welcome to the Mailman School of Public Health

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President Clinton Joins ICAP to Observe World AIDS Day

As part of an all-day symposium sponsored by the Mailman School's **International Center for AIDS Care and Treatment Programs (ICAP)** on HIV and global health systems, President Bill Clinton, founder of the William J. Clinton Foundation, joined ICAP Director Wafaa El-Sadr and other HIV/AIDS experts for a panel discussion "Awareness, Access, Action: The Global and Domestic State of AIDS."

Co-hosted by ICAP and the Clinton Foundation, the event featured a far-ranging conversation that critically reviewed the challenges that remain almost thirty years after the HIV/AIDS epidemic was first identified.

[read more about the event and speakers >>](#)

News Headlines

- New England Journal of Medicine Perspective by Irwin Redlener, MD, Addresses Healthcare Reform
- Exposures to Metals and Diesel Emissions in the Air Are Linked to Respiratory Symptoms in Young Inner City Children
- Dr. Tomás R. Guilarte Named Chair of Environmental Health Sciences
- Stephen S. Morse Named Director of USAID Early Warning Project
- Study Links Factors to Choice of Infant Sleep Position

Updated Research Resources Website

The screenshot shows a web browser window with the URL <http://www.mailman.hs.columbia.edu/faculty-staff>. The page title is "SCHOOL OF PUBLIC HEALTH" and the navigation bar includes links for "HOME", "ABOUT US", "OUR FACULTY", "ACADEMICS", "RESEARCH & SERVICE", "DEPARTMENTS/CENTERS/PROGRAMS", "EVENTS", and "NEWS". The main heading is "FACULTY & STAFF" with a breadcrumb "Home » Faculty & Staff". A search bar is located in the top right, and a "Quick Links" section lists "Human Resources: Benefits", "5-Help Online", "Academic Calendar", and "CU Purchasing". An "Upcoming Events" section lists three events from 12/8/2009 to 12/9/2009. The main content area is titled "Faculty & Staff" and "Administrative Services", listing various services like Accounting, Auditorium Reservations, AP/CAR, Columbia HR, Columbia University Events Calendar, Computer Troubleshooting, Computing at CUMC, CUMC Events Calendar, DARTS, Effort Reporting, FFE, Events Calendar Submission, Mailman School HR (Login), Mailman School Subscriptions, Media Relations Assistance, Office of Finance & Administration (Login), Operations & Facilities (Login), Payroll, Policy Library, Printing Services, Purchasing, and Telecom. A left sidebar contains a "Faculty & Staff" menu with "Administrative Offices" highlighted by a red arrow.

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FACULTY & STAFF

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Quick Links

- Human Resources: Benefits
- 5-Help Online
- Academic Calendar
- CU Purchasing

Upcoming Events

- **12/8/2009 | 10am-3pm**
H&SS Sleep Short Course with Dr. Diane Lauderdale
- **12/9/2009 | 12-1pm**
HPM Brown Bag Seminars
- **12/9/2009 | 12-1pm**
HPM BROWN BAG SEMINARS

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Faculty & Staff

Administrative Services

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Auditorium Reservations	Mailman School HR (Login)
AP/CAR	Mailman School Subscriptions
Columbia HR	Media Relations Assistance
Columbia University Events Calendar	Office of Finance & Administration (Login)
Computer Troubleshooting	Operations & Facilities (Login)
Computing at CUMC	Payroll
CUMC Events Calendar	Policy Library
DARTS	Printing Services
Effort Reporting	Purchasing
FFE	Telecom

Faculty & Staff

- Administrative Directory
- Administrative Offices
- R2 Initiative
- Strategic Planning

Updated Research Resources Website

Please visit us at:

<http://www.mailman.hs.columbia.edu/faculty-staff/research-resources-r2-office>

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FACULTY & STAFF

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Research Resources (R2) Office

- Research Resources Guide
- Grant Resources
- Grant Library
- Training Resources
- Management Resources
- About Us
- Contact Us

R2 Initiative

The Research Resources (R2) Initiative was launched in November 2008 by Dr. Linda P. Fried. Under the guidance of Dr. Robyn Gershon, Associate Dean of Research Resources, and with the input of Mr. Anthony Pramberger, Ms. Rosa Rivera and the Office of Sponsored Projects Administration, Dr. Andrew Davidson, Dr. Melissa Begg, and Dr. Joseph Graziano, the Research Resources Initiative will oversee the implementation of a set of strategies recently identified by the faculty as necessary for a smooth and well functioning research infrastructure at the Mailman School.

News Headlines

- New England Journal of Medicine Perspective by Irwin Redlener, MD, Addresses Healthcare Reform
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- Dr. Tomás R. Guilarte Named Chair of Environmental Health Sciences
- Stephen S. Morse Named Director of USAID Early Warning Project
- Gene's Position in the Nucleus Can be Used to Distinguish Cancerous from Normal Breast Tissue

Contact Us

Dr. Robyn Gershon
Associate Dean for Research Resources Professor
Department of Sociomedical Sciences
Mailman School of Public Health

NIH/SF424 Changes are Coming

Changes to application formats will apply to all NIH applications due on or after Jan 25.

NIH Changes Meeting

Join us on Dec 8, 11:45 am, Hess Commons to discuss changes to formats and forms used for

Jr Faculty Grantwriting Group

First meeting: Wed, Jan 13. We ask members to bring a copy of your RFA and

Basic Overview of Application Changes

- **Most recent NIH notice on changes:** [NOT-OD-10-016](#)
(November 23, 2009)
- **Shorter page limits**
- **Research Plan**
 - Restructured “Research Strategy”
 - Aligned with new peer review criteria
- **Changes to Biosketch**
 - Requires Personal Statement
 - Publications limited to 15
- **Resources Section**

Modified instructions address:

 - Scientific environment
 - Institutional investment in Early Stage Investigators

Shorter Page Limits

- Introduction for either Revision or Resubmission Applications- **1 page**
- Specific Aims (all grant mechanisms)- **1 page**
- Biosketches- **remain 4 pages**
- Research Strategy (e.g., formerly the Background and Significance, Preliminary Studies, and Research Design and Methods sections)

Shorter Page Limits

Research Strategy:

- **6 pages:** **R03**, R13/U13, **R21**, R36, R41, R43, Fellowships (F), SC2, SC3
- **12 pages:** **R01**, single project U01, R10, R15, R18, U18, R21/R33, R24, R33, R34, U34, R42, R44, DP3, G08, G11, G13, UH2, UH3, SC1, X01
- **Other Activity Codes:** Follow funding opportunity Announcement (FOA) instructions
- **Complete Table of Page Limits:**
http://enhancing-peer-review.nih.gov/page_limits.html

Restructured Research Strategy

- **Revised Section**
- **“Research Strategy”**
 - Will replace:
 - “Background and Significance”
 - “Preliminary Studies/Progress Report”
 - “Research Design and Methods”
- **New Subheadings are now:**
 - Significance
 - Innovation
 - Approach

Significance

- Explain the **importance** of the problem or **critical barrier to progress** in the field that the proposed project addresses.
- Explain how the proposed project will **improve scientific knowledge, technical capability, and/or clinical practice** in **one or more broad fields**.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this **field will be changed** if the proposed aims are achieved.

Innovation

- Explain how the application **challenges** and seeks to **shift** current research or clinical practice paradigms.
- Describe any **novel** theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and **any advantage over existing** methodologies, instrumentation or intervention(s).
- Explain any **refinements, improvements, or new applications** of theoretical concepts, approaches or methodologies, instrumentation or interventions.

Approach

- Include **Preliminary Studies/Progress Report**
- Describe the **overall strategy, methodology, analyses** to be used.
- Include how the **data** will be collected, analyzed, and interpreted and any resource sharing plans.
- Discuss **potential problems, alternative strategies, and benchmarks for success** anticipated to achieve the aims.
- If the project is in the early stages of development, describe any **strategy to establish feasibility**, and address the **management of any high risk aspects** of the proposed work.

Changes to Biosketches

- New Biosketch forms can be downloaded at:
<http://grants.nih.gov/grants/funding/phs398/phs398.html>
- New Section: **Personal Statement (Section A)**
 - Briefly describe why your experience and qualifications make **you particularly well-suited** for **your role** (e.g., PD/PI, mentor, participating faculty) in the project that is the subject of the application.
- Peer reviewed Publications
 - Limited to **15**
 - Can choose based on recency, importance to the field and/or relevance to proposed research

New Biosketch Sample

BIOGRAPHICAL SKETCH			
Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. DO NOT EXCEED FOUR PAGES.			
NAME Hunt, Virginia Lively		POSITION TITLE Associate Professor of Psychology	
ORA COMMONS USER NAME (if available, e.g., agency login) huntvl			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing. Include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MMYY	FIELD OF STUDY
University of California, Berkeley	B.S.	06/90	Psychology
University of Vermont	Ph.D.	05/96	Experimental Psychology
University of California, Berkeley	Postdoctoral	08/98	Public Health and Epidemiology

A. Personal Statement

The goal of the proposed research is to investigate the interaction between drug abuse and normal aging processes. Specifically, we plan to measure changes in cognitive ability and mental and physical health across a five-year period in a group of older drug users and matched controls. I have the expertise, leadership and motivation necessary to successfully carry out the proposed work. I have a broad background in psychology, with specific training and expertise in key research areas for this application. As a postdoctoral fellow at Berkeley, I carried out ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. At the Division of Intramural Research at the National Institute on Drug Abuse (NIDA), I expanded my research to include neuropsychological changes associated with addiction. As PI or co-Investigator on several previous university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work, and I have chosen co-investigators (Drs. Gryczynski and Newlin) who provide additional expertise in cognition, gerontology and genetics. In summary, I have a demonstrated record of successful and productive research projects in an area of high relevance for our aging population, and my expertise and experience have prepared me to lead the proposed project.

B. Positions and Honors

Positions and Employment

1998-2000	Fellow, Division of Intramural Research, National Institute of Drug Abuse, Bethesda, MD
2000-2002	Lecturer, Department of Psychology, Middlebury College, Middlebury, VT
2001-	Consultant, Coastal Psychological Services, San Francisco, CA
2002-2005	Assistant Professor, Department of Psychology, Washington University, St. Louis, MO
2005-	Associate Professor, Department of Psychology, Washington University, St. Louis, MO

Resources Section

- **Revised instructions:**
 - Describe how scientific environment...contributes to the probability of success.
 - **For Early Stage Investigators** , describe institutional investment in the success of the investigator (e.g., resources for classes, travel, training; collegial support; logistical support; financial support such as protected time for research with salary support).
 - R² office is working to create boiler plate for submissions from MSPH.
 - Describe any special facilities used for working with biohazards or other potentially dangerous substances.

What stays the same?

- Project Summary/Abstract (30 lines of text)
- Project Narrative (2 or 3 sentences)
- Cover Letter
- Budget Justification
- Bibliography/References Cited
- Inclusion Enrollment Report
- Targeted/Planned Enrollment Table
- Inclusion of Children
- Vertebrate Animals
- Multiple PD/PI Leadership Plan
- Consortium/Contractual Arrangements
- Letters of Support
- Resource Sharing Plan(s)

New Scoring Procedures and Review Criteria

- **Implemented Spring/Summer 2009**
 - Began with the May/June Review meetings

- **Core Review Criteria**

Reviewers score applications based on 5 criteria:

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

More information on New Review Criteria

- **More information:**
 - **NIH’s “Enhancing Peer Review” website:**
<http://enhancing-peer-review.nih.gov/>
 - **Guidance for Reviewers:**
http://enhancing-peer-review.nih.gov/guidance_reviewers.html

New Scores: 9-Point Scale

- **New scores range from 1-9 in whole numbers:**
 - 1= exceptionally strong application, essentially no weaknesses
 - 5= average score
 - 9= application with serious and substantive weaknesses, very few strengths
- **Final Scores:**
 - Represents overall impact of the application
 - Average of the overall impact/priority scores (1-9) given by reviewers, then **multiplied by 10**.
 - Low scores are good.
 - Percentiles– calculated across **all applications** (scores)
 - Paylines can be accessed at:
<http://www.einstein.yu.edu/ogs/NIHInfo/paylines.htm>

Interpreting New Scores

Impact	Score	Descriptor	Strengths/Weaknesses
High Impact	1	Exceptional	
	2	Outstanding	
	3	Excellent	
Moderate Impact	4	Very Good	
	5	Good	
	6	Satisfactory	
Low Impact	7	Fair	
	8	Marginal	
	9	Poor	

Non-numeric score options: NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND=Not Discussed

Upcoming R² workgroups and series

- Continuation of **Science Writing Workgroup**:
 - First Session: Wednesday, January 13th (1-2 pm)
 - Spring Semester: Will meet every other Wednesday
- **Grantwriting Workgroup**:
 - First Session: Wednesday, January 13th (12-1 pm)
 - Spring Semester: Will meet every Wednesday (12-1pm)
- **To Enroll**:
 - Please contact Halley Riley at her2109@columbia.edu

New R² Series for Junior Faculty Members

- **K Award Writing Group:**
 - First Session: January 21st, 1:00-2:30
 - MSPH 9th Floor Conference Room, Room 923
 - To join, please contact Halley Riley at her2109@columbia.edu.

Thank you!

R² Contact Information:

- **Website:**

<http://www.mailman.hs.columbia.edu/faculty-staff/research-resources-r2-office>

- **Office Phone:** 212-305-1186

- **Email:** her2109@columbia.edu (Halley Riley)

Table of Page Limits

Changes effective for due dates on or after January 25, 2010

Updated on November 2, 2009

Section of Application with Page Limits	
Section of Application with Page Limits	Page Limits *
Introduction to Revision Application For all Activity Codes	1 page
Introduction to Resubmission Application For all Activity Codes, EXCEPT Training T , D43 , D71 , K12 , and R25 applications	1 page
Introduction to Resubmission Application For institutional Training (T) , International Training (D43 , D71), Institutional Career Awards (K12), and Research Education Applications (R25)	3 pages
Introduction to Revision or Resubmission Applications For each project and core of multi-component applications	1 page
Specific Aims For all Activity Codes that use an application form with the Specific Aims section	1 page
Research Strategy For Activity Codes R03 , R13/U13 , R21 , R36 , R41 , R43 , Fellowships (F) , SC2 , SC3	6 pages
Research Strategy For Activity Codes R01 , single project U01 , R10 , R15 , R18 , U18 , R21/R33 , R24 , R33 , R34 , U34 , R42 , R44 , DP3 , G08 , G11 , G13 , UH2 , UH3 , SC1 , X01	12 pages
Research Strategy For each project and core of multi-component applications, such as Program Project/Center (P)	Generally 6 or 12 pages**
Research Strategy For all other Activity Codes	Follow FOA instructions
Combined: Research Strategy and first four items of Candidate Information For Individual Career Development Award (K) Applications	12 pages
Items 2-5 of Research Training Program Plan For Institutional Career Development and Research Training Applications, including K12 , T , D43 , and D71	25 pages
Research Education Program Plan For Research Education Grant Applications (R25)	25 pages
Commercialization Plan R41 , R42 , R43 , R44	12 pages
Biographical Sketch For all Activity Codes except DP1 and DP2	4 pages
Biographical Sketch For DP1 and DP2	2 pages

*FOA instructions always supersede these instructions.

**Each project or core will follow the page limit of the equivalent activity code. For example, if a project is equivalent to an R01, the project will be allowed 12 pages. Review the FOA and IC website for details.

This page was last reviewed on November 3, 2009

From: http://enhancing-peer-review.nih.gov/page_limits.html

Grant Pre-submission Checklist—Mailman School of Public Health

PI Responsibilities:

1. Preparatory Steps:

- Visit funding agency website and make sure you understand the goals, missions, and priorities of the agency to which you are applying.
- Principle Investigator (PI) must be registered with eRA commons:
<https://commons.era.nih.gov/commons/index.jsp>. Make sure profile is accurate and up to date.
- Start RASCAL Proposal Tracking Form at <https://www.rascal.columbia.edu/>.
- Make sure that Conflict of Interest Disclosure is up-to-date for all personnel involved with proposed project (update this within RASCAL).
- Make sure that all personnel involved with your proposed project have completed HIPAA and GCP Certifications (these can be completed using RASCAL's "Training Center" options).
- Contact all Approvers who must sign off on RASCAL proposal tracking form. Approvers can view the electronic proposal and make changes until you finalize it. Email a reminder (early on) to all those who will have to sign off on your proposal- alerting them that they will need to do this (give them an estimated date that they will have to sign off). Approvers include: co-investigators, your business officers/financial coordinators, department administrators (from both PI and co-investigators' departments), and department chairs (from the PI's department).
- When you are ready to submit your grant, you "Finalize" your RASCAL proposal. You CANNOT make changes to the proposal after you finalize it. The final RASCAL sign off occurs in the Sponsored Projects Office (i.e., Rosa Rivera's office) after the PI finalizes.

2. Final Text

- Make sure that font size and type meet requirements and are consistent throughout all text. For NIH and other PHS agencies, use Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger.
- Make sure page and margin size are correct and consistent. For NIH and other PHS agencies, use standard paper size (8 ½" x 11), use at least one-half inch margins (top, bottom, left, and right) for all pages, and do not include any information in the margins, including the PI's name or page numbers.
- Check formatting (e.g., subtitles, sections, spacing, references, labeling of figure, etc.) for consistency and clarity.
- Cover Letter: NIH strongly suggests that PIs include a cover letter indicating which Institute/Center you believe your grant should go to and requesting a specific review committee. More information about review committees can be found at NIH's Center for Scientific Review website:
<http://cms.csr.nih.gov/peerreviewmeetings/csrireqdescriptionnew/>.
- Specific Aims: Cannot be longer than 1 page.
- Compare list of collaborating organizations with letters of support received.
- Double check that text conforms to page limits. New page limits (as of January 25, 2010) will vary by grant type (e.g., R03/R21 Research Strategy- 6 pages, R01 Research Strategy- 12 pages).
- Compare project timeline with project period on budget—do they match?
- Reference page is a separate document and does not count toward page limit (for NIH and other PHS agencies). Make sure that all references in text are correct and that citations match.
- Make sure that all documents are converted to PDF before they are uploaded.

3. Budget

- Check that monetary values on budget pages and justification match.
- Check that correct indirect cost (IC) rate has been used. IC rate for FY 10 (July 1, 2009-June 30, 2010) is 60.3%. IC Rate for FY 11 (July 1, 2010 to June 30, 2011) is 61.0%.
- If there are subcontracts, make sure that the IC is applied only to the first \$25,000.

- Check that correct fringe rate has been used. Fringe rate for government grants and contracts for FY10 is 28.5%. More details about fringe rates are available at: http://finance.columbia.edu/controller/payroll/salary_fringe.html.
- Make sure that bottom line (total costs, both direct and indirect) correspond with the allowable costs in funding opportunity announcement.
- Make sure that person-months are correct. To calculate person-months for personnel on the budget, multiply months in project period (i.e., 12 months for a year-long project) by the percent effort for each personnel. For example, an individual who is on a year-long project for 20% effort will be on for 2.4 person months.

PI and Administrator Shared Responsibilities:

4. SF 424 Cover Page

- Make sure that Project Title is correct. For NIH and other PHS agencies, title can be no more than 81 characters, including spaces and punctuation marks.
- Double check that project period dates match budget.
- Check that Total Estimated Project Funding matches the budget pages.

5. Other Project Information

- Project Summary/Abstract (no more than 30 lines of text)
- Project Narrative (no more than 2 or 3 lines of text in lay language)
- Facilities and other Resources—Please make sure that resource page includes: Description of facilities to be used and their capacities (as relevant to the project); description of how the scientific environment in which the research will be done contributes to the probability of success of the project; for Early Stage Investigators, describe institutional investment in the success of the investigator). This is being prepared as a “boiler plate.”
- Check Bibliography and References Cited for any errors. This is a separate attachment.
- Make sure that all documents are converted to PDF before they are uploaded.

6. Research and Related (Senior/Key Personnel Profile)

- Check format of biosketches for all personnel. Make sure biosketches follow new formats for grants due after January 25, 2010. All biosketches must now include a “personal statement.”
- Make sure that all biosketches are up-to-date and relevant to the proposed project—especially personal statements.
- Make sure that there are no more than 15 publications listed in biosketches. Only include manuscripts that are published or in press (not submitted or in preparation).
- Note: Each *subcontract* needs to have a PI, if your submission has a subcontract make sure you designate one of the personnel as the PI on the contract.
- PIs must make sure that their business offices have their eRA Commons usernames to enter under “Credential, e.g., agency login.”

Administrator Responsibilities:

7. Budget Pages

- Check all numbers; compare with submitted budget.
- Check indirect cost rate.
- Upload Personnel Justification (for modular budgets) or itemized budget justification for all other budgets. (Mailman requires an itemized bullet for all grants). Note: subcontracts/consortiums need a separate justification.
- Double-check that person-months and percentage of time are equivalent.

8. PHS 398 Research Plan

Mailman Research Resources
December 2009

- Administrator uploads all applicable documents, in PDF form:
 - Introduction (for resubmissions only)
 - Specific Aims--no more than 1 page.
 - Research Strategy—check page limits.
 - Protection of Human Subjects (Contact CUMC IRB at 212.305.5883 for consultative services)
 - Inclusion of Women and Minorities (More information can be found here: http://grants.nih.gov/grants/peer/tree_minorities_clinical_research.pdf).
 - Target/Planned Enrollment Table (also check calculations).
 - Inclusion of Children (http://grants.nih.gov/grants/funding/children/pol_children_codes.htm).
 - Vertebrate Animals.
 - Multiple Project Director (PD)/PI Leadership plan.
 - Consortium/Contractual Agreement paperwork (required for subcontracts).
 - Letters of support—make sure that all letters are included.
 - Appendices (if applicable, include Appendix List).
 - Resource Sharing Plan (if applicable).

NIH R01 Cheat Sheet

For all new, revised, and resubmission applications due on or after **January 25, 2010**.

NOTE: Applicants who are eligible for continuous submission should use current forms and instructions for R01, R21, and R34 AIDS applications that would otherwise have been due on 1/7/10 through 2/7/10.

Applicants should use the MOST RECENT funding announcement. Your business office will download the new application forms for due dates on or after January 25, 2010.

1. **R01 Standard Due Dates:** Cycle 1: February 5 (AIDS/ AIDS Related: May 7)
Cycle 2: June 5 (AIDS/ AIDS Related: September 7)
Cycle 3: October 5 (AIDS/ AIDS Related: January 7)
2. Check your announcement to see if standard due dates apply.
3. Check your announcement to see if single or multiple Principal Investigators (PIs) are allowed.
4. **Title-** Limited to **81 characters** (includes spaces and punctuation marks).
5. **Project Summary (Abstract)-**
 - No longer than **30 lines of text**.
 - Summary of the proposed activity suitable for dissemination to the public.
 - Briefly state the specific aims and research design.
 - Provide info on the significance (i.e., the gap the study is addressing and the public health significance).
6. **Project Narrative-**
 - No more than **2 or 3 sentences**.
 - Describe the **relevance to public health**.
 - Be succinct, use plain language appropriate for a lay audience.
7. **Biographical Sketch- CHANGES HAVE BEEN MADE TO BIOSKETCH FORMS**
 - Each biosketch is limited to **4 pages**.
 - Educational Block: begin with baccalaureate information.
 - **New Section-- "Personal Statement"** Briefly describe why your experience and qualifications make you particularly **well-suited for your role** on this project.
 - Include **no more than 15 publications** or manuscripts in press (NOT submitted or in preparation).
 - If you are citing NIH funded studies in your articles on your biosketch that fall under Public Access Policy (<http://publicaccess.nih.gov/>), provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or Pubmed Central (PMC) reference number (e.g., PMCID234567). More information can be found here: http://www.nlm.nih.gov/pubs/techbull/so08/so08_skill_kit_pmcid.html.

- The NIH Public Access Policy: applies to all peer-reviewed articles accepted for publication on or after April 7, 2008 and onward. See <http://publicaccess.nih.gov/> for more details.
- If the PMCID is not yet available because it is in process, then state “PMC Journal – In Process.” A list of the journals can be found here: http://publicaccess.nih.gov/submit_process_journals.htm.
- Research Support: List selected ongoing and completed (during the last three years) research projects (Federal or non-Federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and key personnel responsibilities that are relevant to the current application. *Do not include number of person months or total costs.*

8. Specific Aims:

- **1 page limit.**
- **Concisely** state the goals of the proposed research.
- Summarize the expected outcomes, including **impact** of research on fields involved
- **Succinctly** list objectives of proposed research (e.g., to test a hypothesis, create a novel design, solve a specific problem, etc.).

9. Research Strategy—**REVISED SECTION**

- Cannot exceed **12 pages** (for R01s; page limits for other grant types will vary).
- Includes: **Significance, Innovation, Approach.**

A. Significance:

- Explain the **importance** of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in **one or more broad fields.**
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this **field will be changed** if the proposed aims are achieved.

B. Innovation:

- Explain how the application **challenges** and seeks to **shift** current research or clinical practice paradigms.
- Describe any **novel** theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any **advantage over existing** methodologies, instrumentation or intervention(s).
- Explain any **refinements, improvements, or new applications** of theoretical concepts, approaches or methodologies, instrumentation or interventions.

C. Approach

- Include **Preliminary Studies/Progress Report** in “Approach” Section
- Describe the **overall strategy, methodology, and analyses** to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss **potential problems, alternative strategies, and benchmarks for success** anticipated to achieve the aims.

- If the project is in the early stages of development, describe any **strategy to establish feasibility**, and address the management of any **high risk aspects** of the proposed work.
- Point out any procedures, situations, or materials that may be **hazardous to personnel** and precautions to be exercised (<http://www.ehs.columbia.edu/>).

10. Other Sections:

- Cover Letter: NIH suggests **requesting a specific Institute/Center** and a **specific review committee**.
- Facilities and other Resources-- **Note: Changes have been made to the instructions for this section.** PIs must identify facilities used, their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe how the scientific environment in which the research will be conducted contributes to the probability of success. For Early Stage Investigators, describe **institutional investment** in the success of the investigator.
- Bibliography/References Cited
- Inclusion Enrollment Report
- Human Subjects Sections:
 - Protection of Human Subjects
 - Inclusion of Women and Minorities
 - Inclusion of Children
 - Targeted/Planned Enrollment Table
- Vertebrate Animals
- Select Agent Research. A full discussion on the use of Select Agents should appear in this section. **Note: Changes have been made to the instructions for this section.** PIs must now describe the biocontainment resources available at all performance sites.
- Multiple PD/PI Leadership Plan
- Consortium/Contractual Arrangements
- Letters of Support
- Resource Sharing Plan(s)

Additional NIH and Other PHS Agencies Instructions for a Biographical Sketch

Use the sample *format* on the [Biographical Sketch Format Page](#) to prepare this section for **all** (modular *and* other) grant applications. Include biographical sketches of all **Senior/Key Personnel and Other Significant Contributors**. The Biographical Sketch may not exceed four pages per person. This 4-page limit includes the table at the top of the first page. See the sample of a [completed Biographical Sketch](#).

If the individual is registered in the eRA Commons, include the Commons User Name. This data item is required for the PD/PI but is currently optional for all other Senior/Key Persons. In other federal forms this information is referred to as “Credential, e.g., agency login.” For information on the eRA Commons, see <https://commons.era.nih.gov/commons/index.jsp>.

Complete the educational block at the top of the format page beginning with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training, separately referencing residency training when applicable. For each entry provide the name and location of the institution; the degree received (if applicable); the month and year the degree was received, and the field of study. For residency entries, the field of study section should reflect the area of residency.

Following the educational block, complete sections A, B, C, and D as described below.

- A. Personal Statement.** Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PD/PI, mentor) in the project that is the subject of the application.
- B. Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.
- C. Peer-reviewed publications or manuscripts in press (in chronological order).** NIH encourages applicants to limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15. Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed research. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the Pubmed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate “PMC Journal – In Process.” A list of these journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm. Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of publicly available publications are not acceptable as appendix material).
- D. Research Support.** List both selected ongoing and completed (during the last three years) research projects (Federal or non-Federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of the Senior/Key Person identified on the Biographical Sketch. *Do not include number of person months or direct costs.*

Don't confuse “Research Support” with “Other Support.” Though they sound similar, these parts of the application are very different. As part of the biosketch section of the application, “Research Support” highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. In contrast, “Other Support” information is required for all applications that are selected to

Mailman Research Resources Office

NIH Changes Meeting: December 8, 2009

New Biosketch Instructions from SF424 (R&R) Application Guide for NIH and Other PHS Agencies

Pages I-69-I70

receive grant awards. NIH staff will request complete and up-to-date “other support” information from you after peer review. This information will be used to check that the proposed research has not already been Federally-funded.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Hunt, Virginia Lively	POSITION TITLE Associate Professor of Psychology		
eRA COMMONS USER NAME (credential, e.g., agency login) huntvl			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
University of California, Berkeley	B.S.	05/90	Psychology
University of Vermont	Ph.D.	05/96	Experimental Psychology
University of California, Berkeley	Postdoctoral	08/98	Public Health and Epidemiology

A. Personal Statement

The goal of the proposed research is to investigate the interaction between drug abuse and normal aging processes. Specifically, we plan to measure changes in cognitive ability and mental and physical health across a five-year period in a group of older drug users and matched controls. I have the expertise, leadership and motivation necessary to successfully carry out the proposed work. I have a broad background in psychology, with specific training and expertise in key research areas for this application. As a postdoctoral fellow at Berkeley, I carried out ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. At the Division of Intramural Research at the National Institute on Drug Abuse (NIDA), I expanded my research to include neuropsychological changes associated with addiction. As PI or co-Investigator on several previous university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work, and I have chosen co-investigators (Drs. Gryczynski and Newlin) who provide additional expertise in cognition, gerontology and geriatrics. In summary, I have a demonstrated record of successful and productive research projects in an area of high relevance for our aging population, and my expertise and experience have prepared me to lead the proposed project.

B. Positions and Honors

Positions and Employment

1998-2000	Fellow, Division of Intramural Research, National Institute of Drug Abuse, Bethesda, MD
2000-2002	Lecturer, Department of Psychology, Middlebury College, Middlebury, VT
2001-	Consultant, Coastal Psychological Services, San Francisco, CA
2002-2005	Assistant Professor, Department of Psychology, Washington University, St. Louis, MO
2005-	Associate Professor, Department of Psychology, Washington University, St. Louis, MO

Other Experience and Professional Memberships

1995-	Member, American Psychological Association
1998-	Member, Gerontological Society of America
1998-	Member, American Geriatrics Society
2000-	Associate Editor, Psychology and Aging
2003-	Board of Advisors, Senior Services of Eastern Missouri
2003-04	NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer
2005-09	NIH Risk, Adult Addictions Study Section, member

Honors

2003	Outstanding Young Faculty Award, Washington University, St. Louis, MO
2005	Excellence in Teaching, Washington University, St. Louis, MO
2008	Award for Best in Interdisciplinary Ethnography, International Ethnographic Society

C. Selected Peer-reviewed Publications (Selected from 42 peer-reviewed publications)

Most relevant to the current application

1. Merrylye, R.J. & Hunt, V.L. (2004). Independent living, physical disability and substance abuse among the elderly. *Psychology and Aging*, 23(4), 10-22.
2. Hunt, V.L, Jensen, J.L. & Crenshaw, W. (2007). Substance abuse and mental health among community-dwelling elderly. *International Journal of Geriatric Psychiatry*, 24(9), 1124-1135.
3. Hunt, V.L, Wiechelt, S.A. & Merrylye, R. (2008). Predicting the substance-abuse treatment needs of an aging population. *American Journal of Public Health*, 45(2), 236-245. PMID: PMC9162292
4. Hunt, V.L., Newlin, D.B. & Fishbein, D. (2009). Brain imaging in methamphetamine abusers across the life-span. *Gerontology*, 46(3), 122-145.
5. Hunt, V.L. & Sher, K.A. (2009). Successful intervention models for older drug-abusers: Research across the life-span. *American Psychologist*, in press. NIHMSID: NIHMS99135

Additional recent publications of importance to the field (in chronological order)

1. Gryczynski, J., Shaft, B.M., Merrylye, R., & Hunt, V.L. (2002). Community based participatory research with late-life addicts. *American Journal of Alcohol and Drug Abuse*, 15(3), 222-238.
2. Shaft, B.M., Hunt, V.L., Merrylye, R., & Venturi, R. (2003). Policy implications of genetic transmission of alcohol and drug abuse in female nonusers. *International Journal of Drug Policy*, 30(5), 46-58.
3. Hunt, V. L., Marks, A.E., Shaft, B.M., Merrylye, R., & Jensen, J.L. (2004). Early-life family and community characteristics and late-life substance abuse. *Journal of Applied Gerontology*, 28(2),26-37.
4. Hunt, V.L., Merrylye, R. & Jensen, J.L. (2005). The effect of social support networks on morbidity among elderly substance abusers. *Journal of the American Geriatrics Society*, 57(4), 15-23.
5. Hunt, V.L., Pour, B., Marks, A.E., Merrylye, R. & Jensen, J.L. (2005). Aging out of methadone treatment. *American Journal of Alcohol and Drug Abuse*, 15(6), 134-149.
6. Hunt, V.L, Marks, A.E., Venturi, R., Crenshaw, W. & Ratonian, A. (2006). Community-based intervention strategies for reducing alcohol and drug abuse in the elderly. *Addiction*, 104(9), 1436-1606. PMID: PMC9000292
7. Merrylye, R. & Hunt, V.L. (2006). Randomized clinical trial of cotinine in older nicotine addicts. *Age and Ageing*, 38(2), 9-23. PMID: PMC9002364
8. Hunt, V.L., Jensen, J.L. & Merrylye, R. (2008). *The aging addict: ethnographic profiles of the elderly drug user*. NY, NY: W. W. Norton & Company.
9. Hunt, V.L. (2009). Contrasting ethnicity with race in the older alcoholic. *The Journals of Gerontology Series B: Psychological Sciences and Social Sciences*, in press. PMID: PMC Journal – In Process.
10. Hunt, V.L. (2009). Intervening successfully with the older methadone patient. *Journal of Applied Gerontology*, 13(4), 67-79.

D. Research Support

Ongoing Research Support

R01 DA942367-03 Hunt (PI) 09/01/07-08/31/12
Health trajectories and behavioral interventions among older substance abusers
The goal of this study is to compare the effects of two substance abuse interventions on health outcomes in an urban population of older opiate addicts.
Role: PI

R01 MH922731-05 Merryle (PI) 07/15/05-06/30/10
Physical disability, depression and substance abuse in the elderly
The goal of this study is to identify disability and depression trajectories and demographic factors associated with substance abuse in an independently-living elderly population.
Role: Co-Investigator

Faculty Resources Grant, Washington University 08/15/09-08/14/11
Opiate Addiction Database
The goal of this project is to create an integrated database of demographic, social and biomedical information for homeless opiate abusers in two urban Missouri locations, using a number of state and local data sources.

Completed Research Support

K02 AG442898 Hunt (PI) 09/01/06-
08/31/09
Drug Abuse in the Elderly
Independent Scientist Award: to develop a drug addiction research program with a focus on substance abuse among the elderly.
Role: PI

R21 AA998075 Hunt (PI) 01/01/04-
12/31/06
Community-based intervention for alcohol abuse
The goal of this project was to assess a community-based strategy for reducing alcohol abuse among older individuals.
Role: PI

Details of Application Changes for Research Grants and Cooperative Agreements (for due dates on or after January 25, 2010)

November 5, 2009

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Introduction

One of the priorities of the NIH Enhancing Peer Review initiative is to *Improve the Quality and Transparency of Review*. One of the goals associated with this priority is to shorten the Research Plan and align it with review criteria.

Restructured paper PHS 398 and electronic SF 424 (R&R) application packages and instructions will be required for all applications submitted for due dates on or after January 25, 2010. Changes were announced in [NOT-OD-09-149](#) and [NOT-OD-10-002](#).

This document provides details of applications changes to **Research Grants and Cooperative Agreements**. Details of application changes to other types of applications are provided via the [Restructured Applications page](#) of the [Enhancing Peer Review Web site](#).

Shortened Page Limits

Shortened page limits are provided at the [Table of Page Limits](#).

Alignment of the Application with Review Criteria

Many of the changes to the application were made to coordinate with review criteria used by reviewers in their assessment of scientific and technical merit. Table 1 shows the scored Enhanced Review Criteria for research grants and cooperative agreements, as announced in [NOT-OD-09-025](#), and the location in the application where a particular criterion is addressed.

Table 1: Enhanced Review Criteria for Research Grants and Cooperative Agreements

Enhanced Peer Review Criteria	Complementary Section of Restructured Application Forms and Instructions
Overall Impact. Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration	Entire application

Enhanced Peer Review Criteria	Complementary Section of Restructured Application Forms and Instructions
of the following five core review criteria, and additional review criteria (as applicable for the project proposed).	
Significance. Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?	5.5 Research Plan [PHS 398 and SF 424 (R&R)] 3. Research Strategy (a) Significance
Investigator(s). Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?	4.6 Biographical Sketch [PHS 398] 4.5 Senior/Key Person Profile [SF 424 (R&R)] Additional NIH & Other Agencies Instructions for a Biographical Sketch & 5.5 Research Plan [PHS 398 and SF 424 (R&R)] 12. Multiple PD/PI Leadership Plan
Innovation. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?	5.5 Research Plan [PHS 398 and SF 424 (R&R)] 3. Research Strategy (b) Innovation
Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?	5.5 Research Plan [PHS 398 and SF 424 (R&R)] 3. Research Strategy (c) Approach
Environment. Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the	5.5 Content of Research Plan [PHS 398 and SF 424 (R&R)] 11. Select Agent Research &

Enhanced Peer Review Criteria	Complementary Section of Restructured Application Forms and Instructions
project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?	<p>4.7 Resources [PHS 398] Resources Format Page</p> <p>4.4. Other Project Information Component [SF 424 (R&R)] Item 9. Facilities & Other Resources</p>

Tables 2 – 4 provide the text of the current application instructions in the right column, aligned with the corresponding restructured application instructions in the center column; revised text is indicated by **Emphasis**. The left column corresponds to the Enhanced Review Criteria from Table 1.

Table 2a: Instructions for Selected Sections of the Research Plan (Introduction, Specific Aims, and Research Strategy)

Paper applications: Section 5.5 of the PHS 398

Electronic applications: Section 5.5 of the SF 424 (R&R) PHS 398 Research Plan Component

	Restructured Application Instructions (New Language)	Current Application Instructions
	<p>5.5.1 Introduction (Resubmission or Revision Applications only)</p> <p>See specific instructions in 2.7 Resubmission Applications and 2.8 Revision Applications on the content of the Introduction. First time (new) applications should not include an Introduction unless specified in the FOA.</p> <p>The Introduction is limited to one page unless specified otherwise in the FOA.</p>	<p>5.5.1 Introduction (Resubmission or Revision Applications only)</p> <p>All Resubmission and Revision applications must include an Introduction. The Introduction may not exceed three pages for Resubmission applications, or one page for Revision applications. See specific instructions in 2.7 Resubmission Applications and 2.8 Revision Applications on the content of the Introduction. Place the Introduction at the very beginning of the Research Plan.</p>
	<p>5.5.2 Specific Aims</p> <p>State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.</p> <p>List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.</p> <p>Specific Aims are limited to one page.</p>	<p>5.5.2 Specific Aims</p> <p>List the broad, long-term objectives and the goal of the specific research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology. One page is recommended.</p>

	Restructured Application Instructions (New Language)	Current Application Instructions
	<p>5.5.3 Research Strategy</p> <p>Organize the Research Strategy in the specified order and using the instructions provided below. Start each section with the appropriate section heading—Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References cited section (Item 5.5.5).</p> <p>Follow the page limits for the Research Strategy in the Table of Page Limits, unless specified otherwise in the FOA.</p>	
<i>Significance</i>	<p>(a) Significance</p> <ul style="list-style-type: none"> • Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. • Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. • Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved. 	<p>5.5.3. Background and Significance</p> <p>Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. If the aims of the application are achieved, state how scientific knowledge or clinical practice will be advanced. Describe the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive this field. Two to three pages are recommended.</p>
<i>Innovation</i>	<p>(b) Innovation</p> <ul style="list-style-type: none"> • Explain how the application challenges and seeks to shift current research or clinical practice paradigms. • Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s). • Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions. 	

	Restructured Application Instructions (New Language)	Current Application Instructions
<i>Approach</i>	<p>(c) Approach</p> <ul style="list-style-type: none"> • Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 5.5.15, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate. • Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. • If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work. • Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of Select Agents should appear in 5.5.11 below. <p><u>Preliminary Studies for New Applications.</u> For new applications, include information on Preliminary Studies as part of the Approach section. Discuss the PD/PI's preliminary studies, data, and/or experience pertinent to this application. Except for Exploratory/Development Grants (R21, R33), Small Research Grants (R03), Academic Research Enhancement Award (AREA) Grants (R15), and Phase I Small Business Research Grants (R41/R43), preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project. Early Stage Investigators should include preliminary data. (However, for R01 applications, reviewers will be instructed to place less emphasis on the preliminary data in applications from Early Stage Investigators than on the preliminary data in applications from more established investigators.)</p>	<p>5.5.5 Research Design and Methods</p> <p>Describe the research design conceptual or clinical framework, procedures, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 17, include how the data will be collected, analyzed, and interpreted as well as the data-sharing plan as appropriate. Describe any new methodology and its advantage over existing methodologies. Describe any novel concepts, approaches, tools, or technologies for the proposed studies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.</p> <p>Although no specific number of pages is recommended for the Research Design and Methods section, be as succinct as possible. There is no requirement that all 25 total pages allotted for items 2-5 be used.</p> <p>5.5.4. Preliminary Studies/Progress Report</p> <p><i>(a) Preliminary Studies.</i> For new applications, use this section to provide an account of the PD/PI's preliminary studies pertinent to this application, including preliminary experience with and outreach to the proposed racial/ethnic group members. This information will also help to establish the experience and competence of the investigator to pursue the proposed project.</p> <p>Peer review committees generally view preliminary data as an essential part of</p>

	Restructured Application Instructions (New Language)	Current Application Instructions
<i>Approach</i>	<p><u>Progress Report for Renewal and Revision Applications.</u> For renewal/revision applications, provide a Progress Report as part of the Approach section. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes resulting from significant budget reductions. A list of publications, manuscripts accepted for publication, patents, and other printed materials should be included in 5.5.5; do not include that information here.</p>	<p>a research grant application.</p> <p>Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project.</p> <p><u>(b) Progress Report for Renewal and Revision Applications.</u> A Progress Report must be provided for Renewal and Revision applications. Provide the beginning and ending dates for the period covered since the project was last reviewed competitively. Summarize the previous application’s specific aims and the importance of the findings. Provide a succinct account of published and unpublished results, indicating progress toward their achievement. Discuss any changes in the specific aims as a result of budget reductions.</p>

Table 2b: Instructions for the Select Agents Research Section of the Research Plan

Paper applications: Section 5.5.11 of the PHS 398


Electronic applications: Section 5.5, Item 11 of the SF 424 (R&R) PHS 398 Research Plan Component

	Restructured Application Instructions (New Language)	Current Application Instructions
<i>Environment</i>	<p>5.5.11 Select Agent Research</p> <p>Select Agents are hazardous biological agents and ...</p> <p>3. Provide a description of all facilities where the Select Agent(s) will be used.</p> <ul style="list-style-type: none"> • Describe the procedures that will be used to monitor possession, use and transfer of the Select Agent(s). • Describe plans for appropriate biosafety, biocontainment, and security of the Select Agent(s). • Describe the biocontainment resources available at all performance sites. 	<p>5.5.11 Select Agent Research</p> <p>Select Agents are hazardous biological agents and ...</p> <p>3. Provide a description of all facilities where the Select Agent(s) will be used.</p> <ul style="list-style-type: none"> • Describe the procedures that will be used to monitor possession, use and transfer of the Select Agent(s). • Describe plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Table 3: Instructions for the Resources Section

Paper applications: Section 4.7, Resources Format Page of the PHS 398

Electronic applications: Section 4.4, Item 9 of the SF 424 (R&R)

	Restructured Application Instructions (New Language)	Current Application Instructions
<i>Environment</i>	<p>This information is used to assess the capability of the organizational resources available to perform the effort proposed.</p> <ul style="list-style-type: none"> Identify the facilities to be used (laboratory, clinical, animal, computer, office, other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project. Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements. For Early Stage Investigators, describe institutional investment in the success of the investigator, e.g., resources for classes, travel, training; collegial support such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESIs project, and availability of organized peer groups; logistical support such as administrative management and oversight and best practices training; and financial support such as protected time for research with salary support. 	<p>4.4 Other Project Information Component [SF 424 (R&R)]</p> <p>Item 9 – Facilities & Other Resources</p> <p>This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project. Please click the add attachment button to the right of this field to complete this entry.</p> <p> No special form is required but this section must be completed and attached for submissions to NIH and other PHS agencies unless otherwise noted in an FOA. If there are multiple performance sites, then resources available at each site should be described. In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment, or subject populations or employ useful collaborative arrangements. If research involving Select Agent(s) will occur at any performance site(s), the biocontainment resources available at each site should be described.</p>

	Restructured Application Instructions (New Language)	Current Application Instructions
<i>Environment</i>	<ul style="list-style-type: none"> If there are multiple performance sites, describe the resources available at each site. Describe any special facilities used for working with biohazards or other potentially dangerous substances. <i>Note: Information about Select Agents must be described in the Research Plan, 5.5.11 (Select Agent Research).</i> 	<p>4.7 Resources [PHS 398]</p> <p>RESOURCES FORMAT PAGE</p> <p>Follow the sample format and instructions on the Resources Format Page when completing information on resources available for the project. If there are multiple Project/Performance Sites the resources available at each site should be described. In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations, or employ useful collaborative arrangements. If research involving Select Agent(s) will occur at any Project/Performance Site(s), the biocontainment resources available at each site should be described.</p>

Table 4: Instructions for the Biographical Sketch

Paper applications: Section 4.6 of the PHS 398 Section 4.6

Electronic applications: Section 4.5 of the SF 424 (R&R)

	Restructured Application Instructions (New Language)	Current Application Instructions
<i>Investigator(s)</i>	<p>Following the educational block, complete sections A, B, C and D:</p> <p>A. <i>Personal statement. Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PD/PI, mentor) in the project that is the subject of the application.</i></p> <p>B. <i>Positions and Honors. List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.</i></p>	<p>Complete the educational block at the top of the format page, and complete sections A, B, and C:</p> <p>A. <i>Positions and Honors. List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.</i></p>

	Restructured Application Instructions (New Language)	Current Application Instructions
<i>Investigator(s)</i>	<p>C. NIH encourages applicants to limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15. Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed research. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm. Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of publicly available publications are not acceptable as appendix material.)</p> <p>D. Research Support. List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). Begin with the projects that are most relevant to the research proposed in the application. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.</p>	<p>B. Selected peer-reviewed publications or manuscripts in press (in chronological order). Do not include manuscripts submitted or in preparation. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm. Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of publicly available publications are not accepted as appendix material.)</p> <p>C. Research Support. List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). Begin with the projects that are most relevant to the research proposed in the application. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.</p>

NOTE: This document provides only the details of application changes that are related to Peer Review Enhancements. Other application changes for due dates on or after January 25, 2010 include those [required by the Federal Funding Accountability and Transparency Act \(FFATA\)](#).

New Outline and Review Criteria for NIH Grant Proposals

Starting in 2/2010

Created by Dr. John Santelli, Department of Population and Family Health

Outline of Grant Proposals	Enhanced Peer Review Criteria
<p>Introduction (Resubmission or Revision Applications only)</p> <ul style="list-style-type: none"> • See specific instructions in 2.7 Resubmission Applications and 2.8 Revision Applications on the content of the Introduction. First time (new) applications should not include an Introduction unless specified in the FOA. • The Introduction is limited to one page unless specified otherwise in the FOA. 	
<p>Specific Aims</p> <ul style="list-style-type: none"> • State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. • List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology. • Specific Aims are limited to one page. 	
<p>Research Strategy</p> <ul style="list-style-type: none"> • Organize the Research Strategy in the specified order and using the instructions provided below. • Start each section with the appropriate section heading—Significance, Innovation, Approach. • Experimental details should be cited using the Bibliography and References Cited section (see Item 5.5.5) and need not be detailed in the Research Strategy. • Follow the page limits for the Research Strategy in the Table of Page Limits, unless specified otherwise in the FOA. 	
<p>Significance</p> <ul style="list-style-type: none"> • Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. • Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. • Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved. 	<p>Significance.</p> <ul style="list-style-type: none"> • Does the project address an important problem or a critical barrier to progress in the field? • If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? • How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
<p>Innovation</p> <ul style="list-style-type: none"> • Explain how the application challenges and seeks to shift current research or clinical practice paradigms. • Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s). • Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions. 	<p>Innovation.</p> <ul style="list-style-type: none"> • Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? • Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? • Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
<p>Approach</p> <ul style="list-style-type: none"> • Describe the overall strategy, methodology, and analyses to be 	<p>Approach.</p> <ul style="list-style-type: none"> • Are the overall strategy, methodology, and

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<p><i>used to accomplish the specific aims of the project. Unless addressed separately in Item 5.5.15, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.</i></p> <ul style="list-style-type: none"> • <i>Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.</i> • <i>If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.</i> • <i>Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of Select Agents should appear in 5.5.11 below.</i> 	<p><i>analyses well-reasoned and appropriate to accomplish the specific aims of the project?</i></p> <ul style="list-style-type: none"> • <i>Are potential problems, alternative strategies, and benchmarks for success presented?</i> • <i>If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?</i> • <i>If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?</i>
<p>Preliminary Studies for New Applications.</p> <ul style="list-style-type: none"> • <i>For new applications, include information on Preliminary Studies as part of the Approach section. Discuss the PD/PI's preliminary studies, data, and/or experience pertinent to this application.</i> • <i>Except for Exploratory/ Development Grants (R21, R33), Small Research Grants (R03), Academic Research Enhancement Award (AREA) Grants (R15), and Phase I Small Business Research Grants (R41/R43), preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project.</i> • <i>Early Stage Investigators should include preliminary data. (However, for R01 applications, reviewers will be instructed to place less emphasis on the preliminary data in applications from Early Stage Investigators than on the preliminary data in applications from more established investigators.)</i> 	
<p>Environment. <i>This information is used to assess the capability of the organizational resources available to perform the effort proposed.</i></p> <ul style="list-style-type: none"> • <i>Identify the facilities to be used (laboratory, clinical, animal, computer, office, other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project.</i> • <i>Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.</i> • <i>For Early Stage Investigators, describe institutional investment in the success of the investigator, e.g., resources for classes, travel, training; collegial support such as career enrichment</i> 	<p>Environment.</p> <ul style="list-style-type: none"> • <i>Will the scientific environment in which the work will be done contribute to the probability of success?</i> • <i>Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?</i> • <i>Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?</i>

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<p><i>programs, assistance and guidance in the supervision of trainees involved with the ESIs project, and availability of organized peer groups; logistical support such as administrative management and oversight and best practices training; and financial support such as protected time for research with salary support.</i></p> <ul style="list-style-type: none"> • <i>If there are multiple performance sites, describe the resources available at each site.</i> • <i>Describe any special facilities used for working with biohazards or other potentially dangerous substances. Note: Information about Select Agents must be described in the Research Plan, 5.5.11 (Select Agent Research).</i> 	
<p>Biosketch <i>Following the educational block, complete sections A, B, C and D:</i></p> <p>A. <i>Personal statement. Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PD/PI, mentor, participating faculty) in the project that is the subject of the application.</i></p> <p>B. <i>Positions and Honors. List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.</i></p> <p>C. <i>NIH encourages applicants to limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15. Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed research. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm . Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of publicly available publications are not acceptable as appendix material.)</i></p> <p>D. <i>Research Support. List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). Begin with the projects that are most relevant to the research proposed in the application. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.</i></p>	<p>Investigator(s).</p> <ul style="list-style-type: none"> • <i>Are the PD/PIs, collaborators, and other researchers well suited to the project?</i> • <i>If Early Stage Investigators or New Investigators, do they have appropriate experience and training?</i> • <i>If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?</i> • <i>If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?</i>
<p>Progress Report for Renewal and Revision Applications.</p> <ul style="list-style-type: none"> • <i>For renewal/revision applications, provide a Progress Report as part of the Approach section. Provide the beginning and</i> 	

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ending dates for the period covered since the last competitive review.

- *Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement.*
- *Explain any significant changes to the specific aims and any new directions including changes resulting from significant budget reductions.*
- *A list of publications, manuscripts accepted for publication, patents, and other printed materials should be included in 5.5.5; do not include that information here.*

Scoring System and Procedure

REVIEWER TRAINING SUMMARY PAGE

- The NIH grant application scoring system is being implemented to improve rating reliability, encourage use of the full scoring range, and provide quantitative feedback on all applications, both discussed and not discussed.
- The NIH grant application scoring system uses a 9-point rating for the impact/priority score with 1 = Exceptional and 9 = Poor.
- Ratings are in whole numbers only (no decimal ratings).
- Assigned reviewers also provide ratings for each review criterion [e.g. Significance, Investigator(s), Innovation, Approach, Environment] using the same 9-point scale.
 - These criterion ratings are provided in the summary statement for applications, both discussed and not discussed.
 - Criterion ratings should be considered in determining the overall impact/priority score, but reviewers should determine the relative importance of each criterion for the science or work being proposed.
- Reviewers should use the full range of the rating scale and spread their scores to better discriminate among applications.
- Discussed applications will receive impact/priority scores from all eligible reviewers (e.g., without conflicts of interest). Individual reviewer scores will be averaged and the result multiplied by 10 to determine the final impact/priority score (range of 10 to 90).
- Scores will be percentiled to the appropriate base (e.g. study section base if the number of applications ≥ 25 ; CSR all base, or IC all base if < 25) and reported in whole number percentiles. Until a new base has been established from three rounds of reviews, percentiles will be based only on the current round of applications (reviews for October 2009 Council) or the prior and current rounds (reviews for January 2010 Council).

DETAILED INSTRUCTIONS

Rationale for the New NIH Grant Application Scoring System

The prior scoring system of 1.0 to 5.0 in 0.1 increments served NIH well for many years, but its weaknesses became increasingly evident as the quality and quantity of applications increased and NIH budgets to fund grant applications tightened. The new scoring system is being implemented to address the following issues:

- For even the most experienced reviewers, it is difficult to make 41 reliable discriminations of application merit. Based on measurement science, prior experience, and feedback from various constituencies, a 9-point rating scale with descriptors associated with each rating option was adopted.
- Reviewer ratings became increasingly positive, compressing the score range, and effectively reducing the usefulness of scores for NIH funding decisions. In the new scoring system, the descriptors associated with each rating were designed to encourage use of the full scoring range.
- To provide additional feedback to applicants, program staff, and other consumers of the summary statement, assigned reviewers also provide rating of the specific review criteria using the same 9-point scale.

The NIH Grant Application Scoring System

The NIH scoring system uses a 9-point rating scale from 1 = Exceptional to 9 = Poor for the overall impact/priority score as well as the individual review criteria. Ratings are provided only in whole numbers, not decimals. In addition to the descriptors associated with each rating, two additional rating guides (see below) are provided:

- For the impact/priority score, the far left column provides guidance for assigning scores to applications based on the project's likelihood to have a sustained, powerful influence on the research field(s) involved:
 - 1 to 3 = high impact
 - 4 to 6 = moderate impact
 - 7 to 9 = low impact
- For the impact/priority score and for the individual criterion scores, the far right column provides a graphical guide of how strengths and weaknesses are considered in assigning a rating. A score of 1 indicates an exceptionally strong application (or exceptionally strong significance, investigators, innovation, approach, environment) with essentially no weaknesses. A score of 9 indicates serious and substantive weaknesses with very few strengths. For the impact/priority score rating, strengths and weaknesses across all of the review criteria should be considered. For each criterion rating, the strengths and weaknesses within that review criterion should be considered. In considering strengths and weaknesses, reviewers should consider the relative importance of the strengths and weaknesses noted, not simply the number of strengths and weaknesses.

9-Point Score Chart

Impact	Score	Descriptor	Strengths/Weaknesses
High Impact	1	Exceptional	
	2	Outstanding	
	3	Excellent	
Moderate Impact	4	Very Good	
	5	Good	
	6	Satisfactory	
Low Impact	7	Fair	
	8	Marginal	
	9	Poor	

Non-numeric score options: NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND=Not Discussed

Additional Guidance on Strengths and Weaknesses

The graphical representation of strengths and weaknesses (the far right column) is provided to illustrate the relative balance of strengths and weaknesses associated with each rating score. Reviewers should consider not only the relative number of strengths and weaknesses noted, but also the importance of these strengths and weaknesses to the criteria or to the overall impact when determining a score. For example, a major strength may outweigh many minor and correctable weaknesses. The table below provides additional guidance to assist reviewers in determining their ratings.

Score	Descriptor	Additional Guidance on Strengths/Weaknesses
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
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
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

Minor Weakness: An easily addressable weakness that does not substantially lessen impact

Moderate Weakness: A weakness that lessens impact

Major Weakness: A weakness that severely limits impact

Distribution of Scores

With 9 possible rating discriminations, it is imperative that reviewers distribute or spread their scores as widely as possible among applications. The descriptors associated with each rating were designed to encourage the spreading of scores. Therefore, although score distributions may vary by study section, reviewers should use the full range of 1 to 9; the expectation, however, is that there will be few 1s and few 9s.

Because the new scoring system was designed to encourage greater spreading of scores, it is not appropriate to simply convert scores from the old rating scale to the new rating scale. For example, a rating of 2.0 in the former scoring system does not have the same meaning as a 3 in the new scoring system. A rating of 3 in the new scoring system indicates an excellent application of high impact that is very strong with only some minor weaknesses, considerably better than what is typically indicated by a 2.0 rating in the former scoring system.

Highly rating all applications greatly diminishes the ability of a reviewer or study section to communicate the impact of an application. Therefore, reviewers who carefully consider the rating guidance provided in determining their scores improve not only the reliability of their scores, but also improve their ability to communicate the impact of the applications reviewed.

Scoring and Not Discussed Applications

Most study sections discuss only a percentage (usually 50%) of applications assigned to the study section. Typically, these applications have preliminary scores in the better half of the scoring range. Following discussion, however, reviewers should feel free to assign the score that they believe best represents the impact of the application, and not feel constrained to limit their score to the upper half of the score range if they do not feel such a score is justified. For example, if the assigned reviewers initially score an application as 4, 5, and 6, and subsequent discussion reveals a serious weakness that will substantially lessen the project's impact, then it is appropriate for reviewers to give a higher (worse) score.

Scoring Range

After discussion, the assigned reviewers state their final scores, defining the score range. Based on the discussion, all eligible reviewers also score the application. If reviewers wish to score outside the score range of the assigned reviewers, they should declare that they intend to score outside the range and briefly describe the reason. Any score outside the range of the assigned reviewers should be declared, even if the range is a single score (i.e. all assigned reviewers give the same final score). It is important that all points of view and opinions of reviewers are discussed; therefore, reviewers should feel free to score outside the range based on their determination of the overall impact of the application.

Additional Guidance on Criterion Scoring

Assigned reviewers provide both preliminary impact/priority scores and criterion scores (ratings of each review criteria). These criterion scores are included in the summary statement to give applicants of both discussed and not discussed (i.e. streamlined) applications a sense of how consideration of the review criteria influenced the overall evaluation of the application. However, because the relative importance of each individual criterion to the overall score differs for each application, reviewers should not use a formula of weighted or unweighted averages across applications to determine the overall impact/priority score. In addition, unrated criteria such as human subjects, vertebrate animal care, and RFA-specific criteria also should be considered in determining the overall

impact/priority score. Therefore, each review criterion should be weighed differently for each application depending on how important each review criterion is to the work being proposed. As a result, a reviewer may give only moderate scores to some of the review criteria but still give a high overall impact/priority score because the one review criterion critically important to the research is rated highly; or a reviewer could give mostly high criterion ratings but rate the overall impact/priority score lower because the one criterion critically important to the research being proposed is not highly rated.

Final Impact/Priority Scores and Percentile Scores

Discussed applications will receive impact/priority scores from all eligible reviewers. Individual reviewer scores will be averaged and the result multiplied by 10 to determine the final impact/priority score (range of 10 to 90) reported in the summary statement.

Scores will be percentiled to the appropriate base (e.g. study section base if the number of applications ≥ 25 ; CSR all or IC all base if < 25) and reported in whole number percentiles. Until a new base has been established from three rounds of reviews, percentiles will be based only on the current round of applications (reviews for October 2009 Council) or the prior and current rounds (reviews for January 2010 Council).