

# NUTS AND BOLTS (AND ELECTRONS) OF SECURING NIH FUNDING

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# MAJOR TOPICS

- Application Process
- Review Process
- Award Process
- Who to Contact & When



# APPLICATION PROCESS

- CSR receives all competing applications for NIH; for 2006 this will be nearly 80,000 applications.
- CSR receives competing small business applications for NIH, CDC, and FDA
  - Almost 7000 SBIR/STTR applications
  - Three dates a year for “unsolicited” applications”: new, resubmission/amended, renewal/competing continuation/Phase II
    - April 1, August 1, and December 1
    - May 1, September 1, and January 2 for AIDS applications
  - Requests for Applications (RFAs) have special receipt dates.



# HIGHLIGHTS OF ELECTRONIC SUBMISSION

- Registration – may take 4 weeks or longer
  - Grants.gov (organization – DUNS, CCR)
  - eRA Commons (individuals – Principal Investigator and Authorized Organization Representative/Signing Official)  
**There must be a different account for the PI and the AOR/SO (one account may NOT have both roles)**
- Submit combination of data forms and pdf attachments
- Validations by Grants.gov and eRA; may need to correct errors/warnings
- Assembled application image – two day window to check
- Application then available for assignment by DRR
- Use eRA Commons to track and get information (assignment, review outcome, Summary Statement)



# PREPARING AN APPLICATION

- Only the specific application package associated with an Funding Opportunity Announcement (FOA) can be used to apply. Be sure you have selected the correct FOA.
- Follow the instructions in the Application Guide and any specific requirements in the FOA.
- The credential field of the R&R Senior/Key Person Profile component **MUST** contain the PI's assigned eRA Commons User ID for NIH to process the application submission. (Omission is the most common error.)
- Attachments must be in PureEdge or PDF format.
  - **Do not** submit attachments in other formats such as Microsoft Word, Word Perfect, etc. (Second most common error.)
  - Do not put special characters in file names.
  - Disable all security features in the PDF document.
  - Do not send PDF documents with editable fields (fields that can be changed).



# TRACK THE PROGRESS OF THE APPLICATION IN eRA COMMONS

- Once the application has been submitted, Grants.gov and eRA Commons will send a series of status Email notifications.
  - Grants.gov will process the application and send an email within 2 business days after submission.
  - eRA Commons will process the application and send an email within 2 business days after availability in Grants.gov.
- Grants.gov sends notifications to the AOR only; eRA Commons sends notifications to the AOR/SO and the PI. A full list of notification messages can be found at:[http://era.nih.gov/ElectronicReceipt/submit\\_app.htm#4](http://era.nih.gov/ElectronicReceipt/submit_app.htm#4).
- Email can be unreliable – applicants should proactively check the status of their applications in eRA Commons after submission.



# ERRORS AND WARNINGS

- **Errors must be addressed** in order for application to complete submission process
- **Warnings** can be fixed at the applicant's discretion but **do not require action** for the application to move forward.
- After making all corrections, the entire changed/corrected application must be resubmitted through Grants.gov.
- Once all errors are corrected, a grant image is generated and made available for review by the PI and AOR/SO.
- Applications will move forward to the Division of Receipt and Referral after two business days.
- To make **corrections** to an application with warnings or to correct any other problems identified the AOR/SO must "**reject**" the application within the two business day period. Once the modifications are made the AOR/SO will submit the **changed/corrected** application through **Grants.gov**.



# WHERE TO GO FOR HELP

- General information on Electronic Submission and the SF424 (R&R): <http://era.nih.gov/ElectronicReceipt>
- Grants.gov registration, submission and Pure Edge questions:
  - <http://www.grants.gov/Customersupport>
  - Email [support@grants.gov](mailto:support@grants.gov)
  - Phone: 1-800-518-4726
- eRA Commons registration and post submission questions on Commons functionality
  - Support Page: <http://era.nih.gov/commons/index.cfm>
  - eRA Commons Help Desk
    - Web support: <http://ithelpdesk.nih.gov/eRA/>
    - E-mail: [commons@od.nih.gov](mailto:commons@od.nih.gov)
    - Phone: 1-866-504-9552 OR 301-402-7469
- Forms transition and questions on NIH's overall plan for electronic receipt - NIH Grants Information (GrantsInfo)
  - E-mail: [grantsinfo@nih.gov](mailto:grantsinfo@nih.gov)
  - Phone: 301-435-0714



# SUBMISSION TOPICS

- Late applications - NIH Guide Announcement:  
<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-06-086.html>
  - Advance approval is **not** given
  - Window of consideration
    - **1 week for expedited dates**
    - None for special dates (RFAs/PARs)
- Format requirements
  - Approved fonts: Arial, Helvetica, Palatino, or Georgia
  - 11 point, 15 cpi, 6 lpi, 1/2 inch margins
  - Applies to entire application; all pdf attachments
  - Use common sense; consider reviewers
- Omitted/additional information
  - Must contact Scientific Review Administrator after assignment
  - At this time do not have a means of submitting such information electronically



# COVER LETTER

The cover letter should be used for a number of important purposes:

- Suggest Institute/Center Assignment
- Suggest review assignment
- Identify individuals in conflict
- Identify areas of expertise needed to evaluate the application
- Discuss any special situations
- **Required** for a changed/corrected submission

But it is not appropriate to use the cover letter to suggest specific reviewers.



# POLICIES FOR APPLICATION SUBMISSION

- Duplicate applications are not allowed.
- Derivative applications should not be submitted.
- Organizations are responsible for assuring the materials submitted are original work, not used in previous applications.
  
- Resubmission/Amended Applications
  - Two resubmissions
  - No time limit
  - Must have received Summary Statement
  - Change in Content
  - Introduction/Mark Text
  
- Virtual A3 applications



# SBIR/STTR SPECIFIC POLICIES FOR SUBMISSION

- Must have received Phase I award to submit Phase II
- Fast Track applications must propose work and request \$ for Phase I (no leap frogging)
- Only one Phase II from an awarded Phase I
- Full Budgets (no modular budgets)



# THREE COMPONENTS OF EACH ASSIGNMENT

- Mechanism
  - SBIR/STTR
  - Phase I/Phase
  - Identify via FOA and SBIR/STTR Information
- Institute/Center for funding consideration
  - Dual Assignments by Referral or IC
- Review location



# INSTITUTE/CENTER ASSIGNMENTS

- Referral Guidelines for Funding Components of PHS
- ICs Shared Interests
  - Overall Mission
  - Specific Program Mandates
  - Establishment/Evolution Over Time
- Principal Investigator Requests
- IC requests
- Funding Opportunity Announcements
- Assignment History



# NIH FUNDING COMPONENTS: SBIR/STTR

- National Cancer Institute
- National Eye Institute
- National Heart, Lung, and Blood Institute
- National Human Genome Research Institute
- National Institute on Aging
- National Institute on Alcohol Abuse and Alcoholism
- National Institute of Allergy and Infectious Diseases
- National Institute of Arthritis and Musculoskeletal and Skin Diseases
- National Institute of Biomedical Imaging and Bioengineering
- National Institute of Child Health and Human Development
- National Institute on Deafness and Other Communication Disorders
- National Institute of Dental and Craniofacial Research
- National Institute of Diabetes and Digestive and Kidney Diseases
- National Institute on Drug Abuse
- National Institute of Environmental Health Sciences
- National Institute of General Medical Sciences
- National Institute of Mental Health
- National Institute of Neurological Disorders and Stroke
- National Institute of Nursing Research
- National Library of Medicine
- National Center for Complementary and Alternative Medicine
- National Center on Minority Health and Health Disparities
- National Center for Research Resources



# OTHER HHS FUNDING COMPONENTS: SBIR ONLY

- Centers for Disease Control
  - National Institute for Occupational Safety and Health
  - National Center on Birth Defects and Developmental Disabilities
  - National Center for Chronic Disease Prevention and Health Promotion
  - National Center for Environmental Health
  - National Center for Injury Prevention and Control
- Food and Drug Administration
  - Center for Biologics Evaluation and Research
  - Center for Drug Evaluation and Research
  - Center for Food Safety and Applied Nutrition
  - Center for Veterinary Medicine
  - Office of Orphan Products Development
- Participating components vary each year



# INITIAL REVIEW GROUP ASSIGNMENT

- SBIR/STTR Special Emphasis Panels:  
[http://www.csr.nih.gov/Roster\\_proto/sbir\\_section.asp](http://www.csr.nih.gov/Roster_proto/sbir_section.asp)
- Principal Investigator requests; generally always show application to requested IRG
- CSR practice is that if request cannot be honored, accepting/welcoming IRG must communicate with PI.
- Previous assignment history
  
- IRG considerations:
  - Conflict of Interest
  - Workload



# REFERRAL OUTCOME

- Principal Investigator and Organization access information in the eRA Commons
- Application Number
  - Mechanism
  - Phase I/Phase II/Resubmission
- Institute/Center for Funding Consideration
  - General contact number for primary
  - Dual assignments
- Special Emphasis Panel or Study Section
  - SRA address, telephone number, etc.
  - Scientific Review Administrator is main point of contact throughout review stage



# ASSIGNMENT ISSUES – PRINCIPAL INVESTIGATOR

- Verify correct mechanism
- Concerns regarding review
  - Contact SRA
  - Contact DRR
- Concerns regarding IC assignment
  - Contact DRR
- Request for change in writing to DRR (fax 301-480-1987)
- More efficient to include cover letter with submission



# NIH DUAL PEER REVIEW

- Scientific Review Group
  - Evaluate scientific and technical merit
  - Recommend level of support, duration
  - Does **not** make funding decisions
- Advisory Council
  - Reviews the review
  - Funding recommendations to Institute/Center
  - Evaluate priorities/relevance
  - Advise on Policy
- Funding decision made by Institute/Center



# PEER REVIEW IN CSR

- Scientific Review Groups/Study Sections/Review Committees/Special Emphasis Panels - Small Business applications are reviewed in Special Emphasis Panels.
- Scientific Review Administrator is responsible for the management of the meeting.
- Chair and 10 - 24 members who are from academia and small businesses
- 40 - 100 applications are reviewed at each study section meeting (face to face meeting).
- CSR is experimenting with review platforms – video conferences, asynchronous extended discussion, and others.



# SCIENTIFIC REVIEW ADMINISTRATOR

- Performs administrative and technical review of applications to ensure completeness
- Selects reviewers based on broad input
- Assigns reviewers (generally at least two reviewers and one reader per application)
- Manages review meeting/Designated Federal Official
- Prepares Summary Statement
- Provides requested information about review recommendations to Institutes/Centers and advisory councils



# CRITERIA FOR SELECTION OF PEER REVIEWERS

- Demonstrated scientific expertise
- Doctoral degree or equivalent
- Mature judgment
- Work effectively in a groups
- Breadth of perspective
- Impartiality
- Interest in serving
- Adequate representation of women and minority Scientists
- Geographic distribution
- Small Business representation



# REVIEW MEETINGS

- Closed to the public
- Introductions
- SRA instructions: Confidentiality, conflict of interest, new NIH policies, procedures
- Streamlining
  - Bottom half
  - Not discussed
  - Must be unanimous/any member can request discussion



# REVIEW MEETINGS (cont).

Individual review of top half applications

- Conflicts excused
- Assigned reviewers/readers: preliminary scores, evaluations
- General discussion, including human subjects, vertebrate animals, biohazard issues
- Private assignment of priority score
- Discussion of budget, data sharing, resource sharing issues

“Mock” Study Section video

<http://cms.csr.nih.gov/ResourcesforApplicants/InsidetheNIHGrantReviewProcessVideo.htm>



# REVIEW LOGISTICS

- Reviewers receive applications and assignments one to two months in advance of meeting.
- Reviewers post preliminary scores and critiques on a secure web site in advance.
- Reviewers may see other critiques only after their own are posted.
- May be telephone conference call for streamlining in advance of meeting
- Are not aiming for consensus but outliers must explain their views
- Critiques are modified in light of discussion.
- SRA prepares Resume and Summary of Discussion.



# REVIEW CRITERIA

Specifically tailored for small business applications:

- Significance
- Approach
- Innovation
- Investigator
- Environment

Overall evaluation – weigh as appropriate, consider impact on scientific field



# SIGNIFICANCE

Does the proposed project have **commercial potential** to lead to a **marketable product, process or service**? Does this study address an important problem? What may be the anticipated **commercial and societal benefits** that may be derived from the proposed research? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? Does the application **lead to enabling technologies** (e.g., instrumentation, software) for further discoveries? Will the technology have a **competitive advantage** over existing/alternate technologies that can meet the market needs?



# APPROACH

Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Is the proposed plan a sound approach for establishing **technical and commercial feasibility**? Does the applicant acknowledge potential problem areas and consider alternative strategies? Are the **milestones and evaluation procedures** appropriate?



# INNOVATION

Are the aims original and innovative?  
Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?



# INVESTIGATORS

Is the PD/PI appropriately trained and capable of coordinating and managing the proposed SBIR? Are the investigators well suited to carry out this work? Does the investigative team bring complementary and integrated expertise to the project (if applicable)? Is the work proposed appropriate to the experience level of the PD/PI and other researchers, including consultants and subcontractors (if any)? **Are the relationships of the key personnel to the small business and to other institutions appropriate for the work proposed?**



# ENVIRONMENT

**Is there sufficient access to resources (e.g., equipment, facilities)?** Does the scientific and technological environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?



# SPECIAL REVIEW CRITERIA

- Resubmissions
  - Responses to comments from the previous review
  - Improvements in application
- Phase II Applications
  - Progress in Phase I – objectives met, feasibility demonstrated
  - Commercialization Plan
  - Commercial potential
- Fast Track Applications
  - Measurable goals/milestones
  - Commercialization Plan
  - Commercial potential
  - Funding commitments/resources



# ADDITIONAL REVIEW CRITERIA

- Protection of human subjects from research risk
- Inclusion of women, children and minorities
- Care and use of vertebrate animals
- Biohazards

Problems in these areas will have a deleterious impact on the review outcome/score



# OTHER REVIEW CONSIDERATIONS

- Budget – amount, duration
- Plans for Data Sharing if required
- Plans for Resource Sharing

These do not contribute to the score



# REVIEW OUTCOME

- Not recommended for further consideration – rare, usually due to serious ethical or safety concerns
- Deferral – also rare, study section does not have sufficient information to make a determination
- Unscored/bottom half
- Scored; normally between 100 and 300



# SUMMARY STATEMENT

- Unscored/Priority Score
- Overall Resume and Summary of Discussion if scored
- Essentially unedited critiques
- Budget recommendations
- Administrative Notes
- Available in Commons only to Principal Investigator



# ADVISORY COUNCIL/BOARD AND FUNDING

- Second required step in dual peer review process
- Most applications considered in en bloc action; a few are specifically discussed (budget change, deferral)
- Funding decisions made by Institute/Center Director/staff based on
  - Scientific merit
  - Program considerations
  - Availability of funds
- Institute/Center assignment may be changed for funding to make best use of set aside funds.
- Specifics may vary by fiscal year and Institute/Center.



# AWARD PROCESS

- Involves interaction with
  - Program Director
  - Grants Management Specialist
- Need to address Just in Time issues (human subjects protection, vertebrate animal welfare, etc.)
- May be other considerations (biohazards, select agents, etc.)
- Budget negotiations, contractual arrangements, etc.



# WHO TO CONTACT & WHEN

- Your computer – make use of websites, FAQs, etc.
- Prior to submission
  - Grants Info
  - Division of Receipt and Referral  
301-435-0715 301-480-1987 (fax)
  - NIH Small Business office
  - CSR Scientific Review Administrators  
[http://www.csr.nih.gov/Roster\\_proto/sbir\\_section.asp](http://www.csr.nih.gov/Roster_proto/sbir_section.asp)
  - Institute/Center Program Staff; <http://www.nih.gov/icd/>
- Submission
  - Grants.gov
  - eRA Commons
- Review – Scientific Review Administrator\*
- Post Review – Program Director\*
- Award – Program Director\* and Grants Management Specialist\*

\* Contact information is available on the eRA Commons



# QUESTIONS

Your turn.