Deborah Maloney, MSM, CRA, Executive Director, Center for Veterans Research and Education, Minneapolis, MN, USA
Katie Knight, CPRA, Grants Manager, University of Kansas Medical Center, Kansas City, KS, USA
POST SUBMISSION ACTIVITIES

• What’s happening after submission?
• Post Submission Materials
• Just in Time process
• Non-standard terms and conditions
• Compliance
• F&A Costs Questions
• Special Situations
What’s Happening at NIH?

NATIONAL INSTITUTES OF HEALTH

• Receipt and Referral: checks for completeness, determines area of research and assigns application to a specific NIH I/C
• Peer Review Process
  • Level One: Scientific Review Groups
    • Peer review roles & Mtg Overview
    • Scoring
    • Summary Statement
    • Appeals
  *Just in Time requests initiated based on score

• Level Two: Advisory Council/Board
  • NIH program staff examine applications, their overall impact score, program needs and make recommendations for funding
  • I/C Director makes final funding decision

• Post Review
  • Not Funded? - Resubmit
  • Fundable Score? - The Grant Management Specialist will be in contact with any additional information request.
What’s Happening at NSF?

NATIONAL SCIENCE FOUNDATION

- Cognizant Program Officer receives proposal and conducts a preliminary review to ensure completeness and conformance. 3 external reviewers are then identified.

- External reviewers evaluate based on Merit Review Principles.

- NSF Program Officer analyzes input and makes recommendations to Division Director.

- Division Director review of recommendation

- Award recommendation?

- Application is submitted to Division of Grants and Agreements for award processing.

Dear Applicant,

You are receiving this letter because your application has been assigned to the NST-2 study section and will be reviewed on October 25, 2018. Please read this entire email as it addresses many questions I commonly receive both before and after the study section meets (you may want to save this email and revisit it after your scores are released to you).


Should you choose to send post submission materials, you must adhere to the following points:

- Submission deadline is 11:59 PM Eastern Time on September 25, 2018.
- Email post submission materials directly to me (webbere@ninds.nih.gov) via your institution’s signing official. Copying your institution signing official is not sufficient, the email must come from the signing official.
- The applicant must be copied on the email.
- The subject line of the email must include the grant number and the last name of the applicant.
- If you are sending news of an article that has been accepted for publication, then you may submit only the following: authors, institutional affiliations, title of the article, the journal, and citation (if available). Do NOT include a copy of the article or an abstract.
  - If the article is not currently visible online (e.g., if I will not be able to confirm this is an accepted publication by searching the journal’s site or PubMed), then please also include the email/letter from the journal confirming acceptance as a separate file.
  - This must be an accepted publication, not merely submitted/under review.
- MS word or pdf formats are acceptable; file size not to exceed 25 MB.

Scores will be posted 1-2 business days after the review meeting concludes. Please note that this means your scores may not be released until Monday, October 29th. Applications reviewed at this study section do not receive a percentile, only a priority score. Some of these applications also may be unscored (not discussed). For an understanding of that and additional general information on the NIH Peer Review process, I recommend looking through the information provided on the following two sites: https://grants.nih.gov/grants/peer-review.htm and https://www.niaid.nih.gov/grants-contracts/peer-review.

Summary statements are typically released within 4-6 weeks of the of the review meeting (and no later than 30 days before the NINDS Advisory Council meeting). Once you have your summary statement, you may wish to contact your assigned program director and/or the NINDS Training and Workforce Development Office for guidance on how to proceed. If you have additional questions, please feel free to contact me.
Just In Time Requests (NIH)

- Automated
- Personalized
- Large Program Grants
- Equipment Grants
Just In Time

- JIT allows applicants and signing officials to submit certain elements of a competing grant application at a later date in the application process – after the peer review and as the application is being considered for funding. This includes information on Institutional Review Board (IRB) approval of the use of human subjects approval, verification of IACUC's approval of the proposed use of live vertebrate animals, etc. The application must meet certain business criteria and have achieved a certain score to be considered. Applicants should only submit JIT information when it is requested by the grantor agency.

- Sponsored Programs officers should confirm with the PI that a JIT is appropriate to submit.
Automated Just In Time

From:  era-netty@mail.nih.gov
To:  
Cc:  
Subject:  REQUEST FOR JUST-IN-TIME INFORMATION
Date:  Friday, December 21, 2018 2:05:55 PM

*** This is an automated notification - Please do not reply to this message. ***

Principal Investigator: [Redacted]

Application [Redacted] entitled Upgrade to 9.4T Animal MRI Scanner: Midwest Regional Resource has completed the first phase of peer review.

REQUEST FOR JUST-IN-TIME INFORMATION

THIS IS NOT A NOTICE OF GRANT AWARD NOR SHOULD IT BE CONSTRUED AS AN INDICATOR OF POSSIBLE AWARD

This is a standard notice and request for information from all principal investigators with grant applications receiving an impact score of 30 or less (regardless of the IC’s payline) which reflects NIH’s current tightened paylines and new Impact Scoring system. This notice is a request for Just-In-Time Information. NIH Institutes and Centers (ICs) have varying pay lines and funding strategies that determine which grants will be funded.

If a decision is made to fund this application, the assigned IC will need the following information PRIOR to making an award.

- Current Other Support: Provide active and pending support information for all individuals designated in an application as senior/key personnel—those devoting measurable effort to a project. Other support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual’s research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes or gifts are not included. There is no form page for providing other support, although sample format pages are available at https://grants.nih.gov/grants/funding/phs398/othersupport.doc and https://grants.nih.gov/grants/funding/phs398/othersupport.pdf. Note that effort devoted to projects must be measured in person-months.
  - For all senior/key personnel, provide details on how you would adjust any budgetary, scientific, or effort overlap if this application is funded.
  - For Career Development Award applications, information on all active support for the candidate, sponsor(s), co-sponsor(s), and Senior/Key Personnel may be requested by the awarding component prior to award.
Personalized Just In Time

From: (NIH/NIA/ERP) [mailto]@nih.gov
Sent: Monday, December 17, 2018 1:36 PM
To: SPA <SPA@kumc.edu>

Subject: Swardlow; 1 R01 AGXXXXX-01A1

Dear Ms. Maloney,

Preparations are being made for the administrative review of application 1 R01 AGXXXXX-01A1 [PI: Dr. RS]. Please submit the following information through the eRA commons no later than December 31, 2018.

- Other Support (active and pending) for Key Personnel not to exceed 12 calendar months' effort. Please note that the total level of effort, including the effort proposed on this application, cannot exceed 12 calendar months.

- Certification of IRB Approval

- Human Subjects Education Requirement

Please note that this e-mail is a request for information only and not a commitment to fund the application.

Sincerely,
Just in Time and Other Support

• Provide active support for all key personnel. Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts do not need to be included.

• All current effort commitments of the PI will be considered in conjunction with the pending application. Be aware of any other pending applications that may be in consideration for funding, as well.

• [https://grants.nih.gov/grants/faq-other-support-foreign-components.htm](https://grants.nih.gov/grants/faq-other-support-foreign-components.htm) related to NOT-OD-19-114
DEPARTMENT OF DEFENSE

AWARD NEGOTIATIONS

• Initial Communication in an automated email from eBrap requesting Current, Pending and Previous Support for Key Personnel

• Secondary Communication from a Grants Management Specialist requesting project-specific information including but not limited to:
  • Respond to Budget questions and may include a request to revise the budget
  • Reps and Certs
  • DOD compliance; they have their own approvals for IACUC and IRB
  • Additional information on Current, Pending and Previous Support
  • Salary Verification

• The above process can take from one to nine months. This is not an award, but the negotiation stage, and is considered “pending” until the contract is received.
NSF BUDGET REVISION

• Current & Pending Support is required at time of proposal submission.

• PI, Co-PI or OAU may revise the budget of a submitted proposal at the request of the NSF Program Office and forward to AOR for approval.
  o PI requests show up in FastLane under Forwarded/Submitted Revised Budgets.
  o PI initiates the revised budget request in response to Program Office feedback about the project proposal.
  o If the budget is reduced by more than 10%, a Budget Impact Statement must be included. If the reduction is less than 10%, it is optional.
  o AOR must sign and submit the revised budget to NSF.
  o If an NSF Program Officer has not asked you to submit a revised budget but you need to correct a submitted budget, use the Proposal File Update module to correct the submitted budget.
NSF PROPOSAL FILE UPDATE

- PI, Co-PI or OAU may update a proposal file after submission in accordance with PAPPG Chapter III.C and forward to AOR for approval.

  - An update request must contain a justification that addresses:
    1) why the change or file replacement is being requested and
    2) Any differences between the original and proposed update.

  - A request is accepted automatically if submitted prior to:
    - the deadline date (if applicable)
    - AND
    - initiation of external peer review.

  - A request after the these timeframes requires acceptance by the cognizant NSF Program Officer.

  - Requests show up under Proposals/Supplements/File Updates/Withdrawals in FastLane.
Non-Standard Terms and Conditions

AMERICAN CANCER SOCIETY:

7. TOBACCO-INDUSTRY FUNDING POLICY
Scientific investigators or health professionals who are funded by the tobacco industry for any project, or whose named mentors in the case of mentored grants are funded by the tobacco industry for any project, may not apply and will not be eligible for American Cancer Society research and training grants. Scientific investigators, health professionals, or named mentors who accept funding from the tobacco industry for any project during the tenure of an American Cancer Society research or training grant must inform the Society of such funding, whereupon the American Cancer Society grant will immediately be terminated. Tobacco industry funding includes: funds from a company that is engaged in, or has affiliates engaged in the manufacture of tobacco produced for human use; funds in the name of a tobacco brand, whether or not the brand name is used solely for tobacco goods; funds from a body set up by the tobacco industry or by one or more companies engaged in the manufacture of tobacco goods.
June 20, 2018
Revised August 17, 2018

[Redacted]

University of Kansas Medical Center Research Institute, Inc.
3901 Rainbow Boulevard
Kansas City, KS 66160

[Redacted]

Award Period: July 1, 2018 to June 30, 2019
Award Amount: [Redacted]
Awardee Institution: University of Kansas Medical Center Research Institute, Inc.
Award Number: [Redacted]
Program Number: [Redacted]
Center Number: [Redacted]

Dear Dr. [Redacted]

We are pleased to inform you that the Cystic Fibrosis Foundation (CFF) has approved funding for your CF Center in the amount of [Redacted] for the award period July 1, 2018 to June 30, 2019. This award is contingent upon the availability of funds and is subject to the Terms and Conditions Governing CF Center Accreditation and CF Center Awards from the Cystic Fibrosis Foundation, dated July 1, 2018. Please note, these updated 2018 terms and conditions must be forwarded to the Authorized Institutional Official at your organization for review and approval prior to signing the Official Assurances on page 3 of this award letter. CFF requires that you and the Authorized Institutional Official sign the Official Assurances page of this letter, and email a PDF copy to the CFF Grants and Contracts Office at grants@cff.org.

This award will be paid to the above named Awardee Institution in two equal payments, in arrears, scheduled for late November 2018 and late February 2019. Please note, however, CFF will not release payments for this award until the deliverables noted in the table below are received, approved by CFF, and on file with the CFF Grants and Contracts Office.
COMPLIANCE

• In research, compliance involves adherence to a system of policies and regulations that prescribe standards for the use of federal grant money, and impose penalties or sanctions for any misbehaviors or non-compliance.
COMPLIANCE CONSIDERATIONS

• Responsible Conduct of Research (RCR)
• Financial Conflict of Interest (FCOI)
• Institutional Review Boards (IRB), Single IRB (sIRB)
• Institutional Animal Care and Use Committee (IACUC)
WHO IS RESPONSIBLE?

- Everyone; this is a shared responsibility due to the complicated nature of compliance.
- The most risky activity has its own oversight office.
- Report it; that is why the oversight office exists.
<table>
<thead>
<tr>
<th>Notification Timing</th>
<th>Tissue/STEM Cell/Biosafety/Radiation</th>
<th>Email address</th>
</tr>
</thead>
<tbody>
<tr>
<td>At Submission</td>
<td>Human Tissue or Body Fluids Type&lt;br&gt;• Fetal&lt;br&gt;• Embryo</td>
<td><a href="mailto:stemcell@kumc.edu">stemcell@kumc.edu</a></td>
</tr>
<tr>
<td></td>
<td>What type of Stem Cells?&lt;br&gt;• Human Embryonic&lt;br&gt;• Human Fetal Stem Cells&lt;br&gt;SCNT/stem cells derived from SCNT embryos and other non-reproductive IVF embryos (eg parthenogenesis)</td>
<td><a href="mailto:stemcell@kumc.edu">stemcell@kumc.edu</a></td>
</tr>
<tr>
<td></td>
<td>Will the project include Select Agents (Yes)</td>
<td><a href="mailto:ehs@kumc.edu">ehs@kumc.edu</a> and <a href="mailto:jbc@kumc.edu">jbc@kumc.edu</a></td>
</tr>
<tr>
<td>At JIT/NOA</td>
<td>What type of Stem Cells?&lt;br&gt;• Induced Pluripotent Stem Cells</td>
<td><a href="mailto:stemcell@kumc.edu">stemcell@kumc.edu</a></td>
</tr>
<tr>
<td></td>
<td>Will the project include recombinant DNA? (yes)</td>
<td><a href="mailto:jbc@kumc.edu">jbc@kumc.edu</a></td>
</tr>
<tr>
<td></td>
<td>Will the project include radioisotopes or radiation producing equipment? (Yes)</td>
<td><a href="mailto:rsr@kumc.edu">rsr@kumc.edu</a></td>
</tr>
<tr>
<td></td>
<td>Will the project include biohazards or hazardous materials? (Yes)</td>
<td><a href="mailto:ehs@kumc.edu">ehs@kumc.edu</a></td>
</tr>
<tr>
<td></td>
<td>Human and Animal Research&lt;br&gt;(not including any of the above)</td>
<td></td>
</tr>
<tr>
<td>At JIT/NOA</td>
<td>Will the project include Human Subjects? (Yes)</td>
<td><a href="mailto:humansubjects@kumc.edu">humansubjects@kumc.edu</a></td>
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<td>At JIT/NOA</td>
<td>Will the project include vertebrate animals?</td>
<td><a href="mailto:jacuc@kumc.edu">jacuc@kumc.edu</a></td>
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<tr>
<td></td>
<td>Conflict of Interest</td>
<td></td>
</tr>
<tr>
<td>At JIT/NOA Or</td>
<td>All PHS Compliant Awards&lt;br&gt;For “investigators”&lt;br&gt;• Research cert&lt;br&gt;• fCOI training</td>
<td><a href="mailto:coi@kumc.edu">coi@kumc.edu</a></td>
</tr>
<tr>
<td>Submission</td>
<td>Foundations and other Federal agencies (eg, NSF, DOD, EPA) may have different timing and specifications for COI review.</td>
<td><a href="mailto:coi@kumc.edu">coi@kumc.edu</a></td>
</tr>
</tbody>
</table>
Responsible Conduct of Research (RCR) Training

- Includes topics such as:
  - Research Integrity
  - Conflict of Interest (personal, professional, financial)
  - Data management
  - Responsible authorship and publication (plagiarism)
  - Peer review
  - Mentorship and training
  - Misconduct in research
Responsible Conduct of Research (RCR) Training

All faculty and staff engaged in research (for this purpose defined as all investigators and other research personnel, regardless of title or position, who are involved in the design, conduct or reporting of research, regardless of funding) is required to complete RCR training.

Practice at KUMC:

- Complete designated RCR modules in CITI once every four years
- Attend or view two live seminars or conferences on RCR every four years.
Financial Conflict of Interest

- Investigator - the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research.

- Investigator’s Institutional Responsibilities - professional obligations on behalf of the Institution, which may include: activities such as research, teaching, research consultation, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

- Practice at KUMC: Annual Cert, Project Specific Cert, FCOI Training prior to release of funding (checked at proposal submission and initiated if not competed or outdated).
IRB and sIRB

- The IRB reviews protocols and grant applications for research that involves human subjects for subject safety and congruency.
- Proposal may be submitted and documented as “Pending”. The approval will be requested at Just-in-Time.
- sIRB at submission: Pre Award (at KUMC) verifies with KUMC IRB the rate to be used when KUMC acts as IRB of record. Indirects can only be applied to secondary activities.
- New Awards must receive IRB review even if similar work has already received IRB approval
  - PI can request a modification to an already approved protocol to have the new award and users listed
  - Department administrators may be relied on to review the NOA to be aware of any award restrictions, etc., and assist in facilitating paperwork.
IACUC and CONGRUENCY

- Congruency: Protocol and grant review assures that the number and type of animals listed in the protocol are appropriate and congruent and that all personnel have completed the required training for the care and use of laboratory animals.
- Oversees the animal facilities and monitors all activities to assure that animals are treated humanely, given proper care, and ensure that the facilities are in compliance with all laws, regulations and policies.
- Approval may be listed as “Pending” on an application.
- New awards must receive review and approval even if similar work has already received IACUC approval
  - PI can request a modification to an already approved protocol to have the new award and users listed.
  - Department administrators may be relied on to review the NOA to be aware of any award restrictions, etc., and assist in facilitating paperwork.
DEEMED EXPORTS

• Release of technology or source code subject to the EAR to a foreign national in the United States is “deemed” to be an export to the home country of the foreign national under the EAR (EAR§734.2(b)(2)). Although the ITAR doesn't use the words "deemed export", disclosing or transferring technical data subject to the ITAR to any non-US person is considered to be an export "whether in the United States or abroad" (ITAR §120.17(a)(5)).

• Deemed exports are a concern of colleges and universities as it involves the exposure of foreign nationals, such as students, visiting professors, consultants, etc., to potentially sensitive academic research.

• The faculty member, not the university, is held liable for EAR or ITAR violations.
F&A (Indirect) COST CONSIDERATIONS

Modular applications are submitted with full F&A for graduate student tuition in the event the student leaves/graduates to a non-student position prior to award. At JIT, NIH will request verification of F&A rates and what exclusions should be applied.
SPECIAL SITUATIONS

- Departing faculty
- Incoming/outgoing faculty prior to award
- Change in consortia prior to award
- Submitted to incorrect FOA
- Budget revisions
- Missing Proposal Sections
CHANGE IN CONSORTIA

A change in consortia will sometimes occur after proposal submission when a collaborating investigator transfers to a new institution:

- Updated information for the new subcontract will typically be submitted at NIH Just-In-Time. Ideally, this should happen as soon as possible prior to award.
- The GMS will request an updated budget and budget justification for the new subcontract institution. Additional biosketches may also be needed if new Key Personnel are added from the new site.
- Total budget should align with the amount submitted for the initial subcontract.
- Updated and signed Subrecipient Commitment Form should be obtained from the new institution.
INCORRECT FOA

Sometimes an FOA will expire and a PI would like to rush to submit to the expiring FOA.

- Keep in mind that the original due date of the application will drive which FOA is used. Example: If the FOA expires January 8, 2019 and the PI is submitting an application for the February 5, 2019 deadline, the newly issued FOA must be used, even if you submit prior to February 5th.
INCORRECT FOA cont’d

There are also instances when a PI identifies an opportunity but the specific NIH I/C the PI requests the application to go to does not participate.

- It is ideal if this is caught prior to submission during review of the proposal. However, if it’s not caught in review and submitted as is, NIH will either withdraw the application or give the opportunity to switch FOAs.
- If NIH withdraws the application, the PI may be able to contact the PO of the specific I/C to see if they have an FOA that will fit. This could prevent the application from being withdrawn, but is case-by-case depending on the PO of that specific I/C.
REVISED BUDGETS

• Only revise a budget when specifically requested to do so by the sponsor. Do not revise a budget based on reviewer comments.

• Revised budgets must be reviewed by the Sponsored Programs Administration (SPA) office prior to submission.

• In most cases, the sponsor will require a revised budget to be submitted through the “business office” which means the SPA office.
MISSING PROPOSAL SECTIONS

• What do you do? What can you do?
• Certain missing information may be requested at JIT (Authentication Plan, Dissemination Plan…)
• Private Sponsors can be more lenient
• If an NIH application is submitted prior to the 5pm deadline and it’s noticed that a section is missing, you can resubmit a changed/corrected application with a cover letter after 5pm; however, it’s possible that the application will not make it past DRR/CSR. These situations are reviewed on a case-by-case basis.
PRE-AWARD SPENDING

• Most federal agencies, including NIH & NSF, allow for 90 days pre-award spending without prior agency approval.
• Grantees may incur allowable pre-award costs within the 90-day period immediately preceding the start date of the grant providing:
  • the approval of pre-award spending is made and documented in accordance with the grantee's procedures; and
  • the advanced funding is necessary for the effective and economical conduct of the project.
• Universities have different policies about what level of documentation and internal approvals may be required.
• In the case of a renewal award, costs incurred under the previous award number cannot be transferred to the new grant.
PRE-AWARD SPENDING cont’d

- Pre-award expenditures are made at the grantee's risk. Grantee authority to approve pre-award costs does not impose an obligation on the sponsor:
  - in the absence of appropriations;
  - if an award is not subsequently made; or
  - if an award is made for a lesser amount than the grantee anticipated.

- Requests for pre-award costs for periods exceeding 90 days require agency approval.

- Additional information on pre-award costs is available in 2 CFR §§ 200.308(d)(1) & (d)(4).

- Requests for pre-award spending on industry contracts that are not yet fully executed involve the highest risk and are therefore not allowed at many institutions.
Questions?

Deborah Maloney, Executive Director, Center for Veterans Research and Education, USA
Deborah.Maloney@cvre.org

Katie Knight, Grant Manager, University of Kansas Medical Center, USA
kknight3@kumc.edu