Understanding NIH Awards – Best Practices
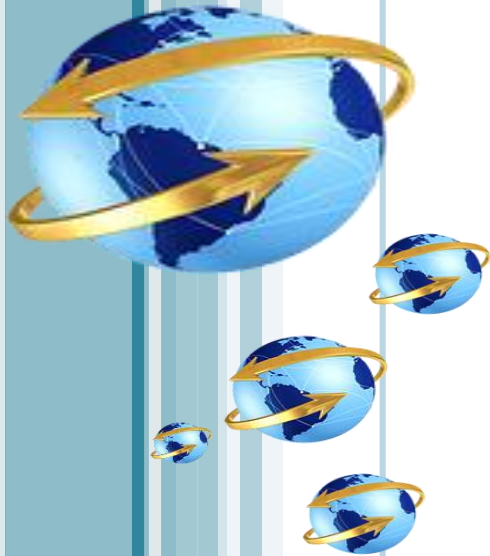
AGENDA FOR TODAY

- Pre submission factors for consideration
- Walk through the timeframe from post submission through award review
  - Notices prior to receiving the award
  - What does it all mean?
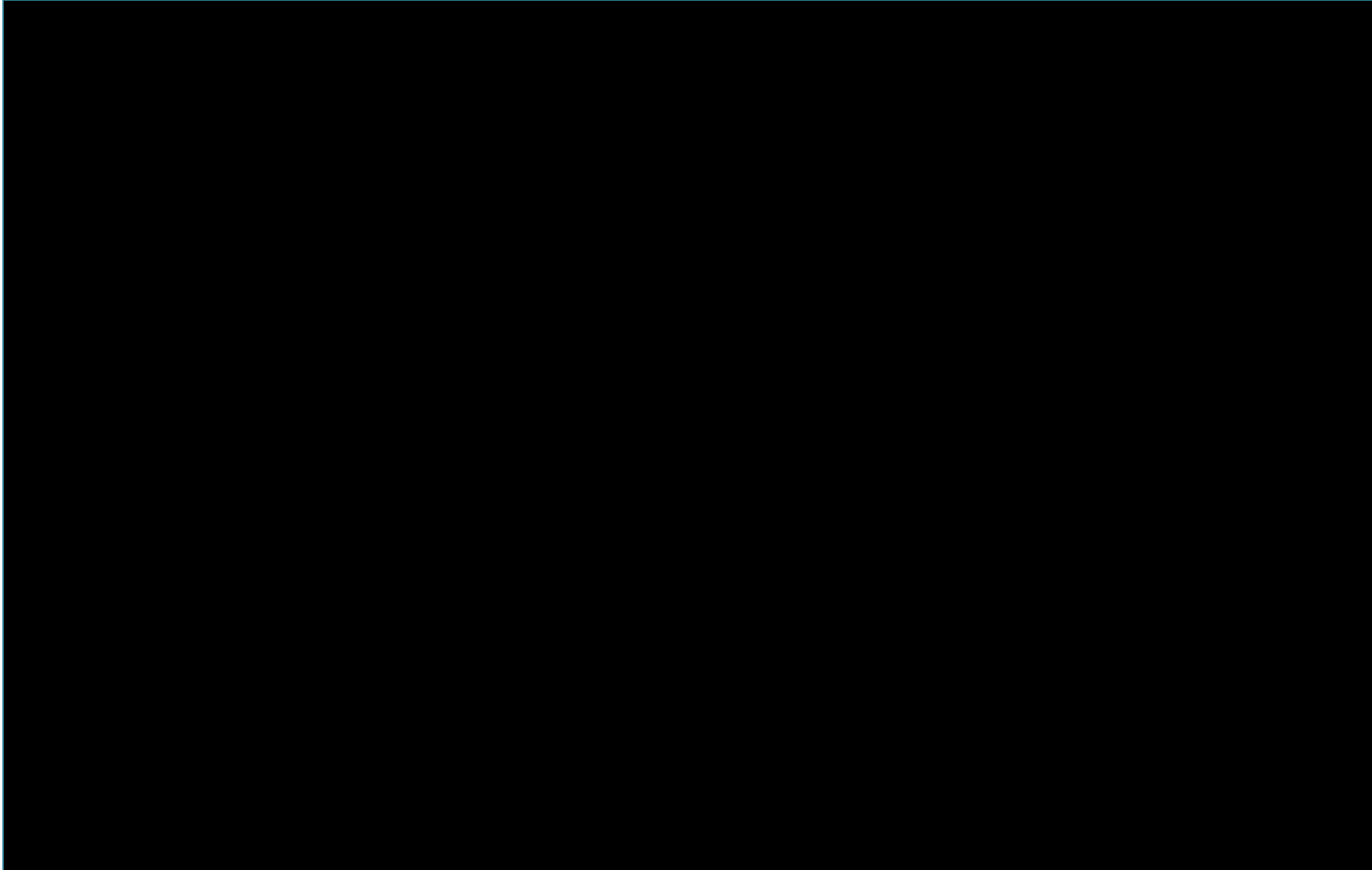 - Compliance and management of the award

PRE SUBMISSION FACTORS

- New submission procedures effective
  May 25, 2016
- Debarment and Suspension
- DUN and Bradstreet Registration
- SAM.gov
- Maximum F&A Rate (indirect costs)

Applying made easy!

CHECKLIST FOR R01 APPLICATIONS

- ❑ **Significant Changes to NIH Application Guide for Applications Due on or after May 25, 2016**

- ❑ **How to apply – application guide - http://grants.nih.gov/grants/how-to-apply-application-guide.htm**

- ❑ Total costs (direct and indirect) are limited to $499,999 annually over a 5-year period
- ❑ Format Attachments:
  - ❑ Font: Arial, Helvetica, Palatino Linotype or Georgia; size 11 points or larger
  - ❑ At least one-half inch margins (top, bottom, left, and right) for all pages.
  - ❑ Do not include headers or footers in your attachments.

- ❑ **Required Attachments**
  - ❑ Project Summary/Abstract (30 lines of text)
  - ❑ Project Narrative (2-3 sentences)
  - ❑ Bibliography and References Cited
  - ❑ Facilities and Resources
  - ❑ Equipment
  - ❑ Other Attachments
  - ❑ Biosketch for senior/key personnel *(5 pages per bio)*
  - ❑ Introduction *(for resubmission or revision applications only)*
  - ❑ Specific Aims *(1 Page)*
  - ❑ Research Strategy *(12 pages)*
  - ❑ Progress Report Publication List *(Renewal applications only)*
  - ❑ Budget Justification
  - ❑ Subcontractor Budget Justification *(if applicable)*

- ❑

CHECKLIST CONTINUED

- ❑ If yes to human subjects:
  - ❑ Protection of Human Subjects
  - ❑ Data Safety Monitoring Plan (*if applicable*) **(NEW-Attachment required)**
  - ❑ Inclusion of Women and Minorities
  - ❑ Inclusion of Children
  - ❑ Inclusion Enrollment Report **(NEW)**

- ❑ If yes to vertebrate animals:
  - ❑ Vertebrate Animals **(NEW)**

- ❑ Other Documents (*if applicable*):
  - ❑ Select Agents Research
  - ❑ Multiple PD/PI Leadership Plan
  - ❑ Consortium/Contractual Arrangements
  - ❑ Letters of Support
  - ❑ Resource Sharing Plan
  - ❑ Authentication of Key Biological and/or Chemical Resources **(NEW)**
  - ❑ Assignment Request Form (*optional*) **(NEW)**
- ❑ Appendix
- ❑ Cover Letter

- ❑ Subcontractors (*if applicable*):
  - ❑ Performance Site
  - ❑ Key Personnel Profile
  - ❑ Biosketch for senior/key personnel (*5 pages per bio*)
  - ❑ Facilities and Resources
  - ❑ Equipment
  - ❑ Detailed Budget
  - ❑ Budget Justification

SUBMISSION NOTICES

- Errors and Warnings
- eRA Commons Failures
- Warnings ONLY
- Submission Receipt
- Validation
- Tracking Number Assignment
- Retrieval Receipt
- Referral

Application Errors and Warnings

GRANT ████████████████████ ACTION REQUIRED TO COMPLETE
SUBMISSION - Application Errors and Warnings
1 message

era-notify-test@mail.nih.gov <era-notify-test@mail.nih.gov>   Tue, Apr 19, 2016 at 3:10 PM
Reply-To: eranotifications@mail.nih.gov
To: infoed.help@foundation.sdsu.edu, awards@foundation.sdsu.edu

ACTION REQUIRED TO COMPLETE SUBMISSION OF NIH GRANT APPLICATION:

NIH has received the electronic grant application Grants.gov Tracking # GRANT ████████ / PI ████████,
████████. Our systems have identified errors and warnings associated with your application and have placed the
list of errors and warnings in eRA Commons. Your application will not move forward for further processing and
funding consideration at NIH unless you address all identified errors and the authorized organization
representative submits your changed/corrected application to Grants.gov before the submission deadline.

You must correct all of the listed errors. Warnings will not prevent your application from completing the
electronic submission process, but serve as reminders to verify that your application complies with specific
requirements in the funding opportunity announcement and application guide. Changed/corrected applications to
address errors or warnings must be submitted by the submission deadline. Changed/corrected applications
submitted after the submission deadline will be subject to the NIH Late Policy and may not be accepted.

Applicants should refer to the funding opportunity announcement and the application guide for detailed guidance
on correcting application content. In addition, the Applying Electronically website (http://grants.nih.gov/grants/
ElectronicReceipt/index.htm) contains additional resources that may assist you.

View detailed steps for PI to track submission status.
View detailed steps for AOR/SO to track submission status.
View detailed steps for submitting a changed/corrected application.

If you still require support after taking full advantage of these resources, please contact the eRA Service Desk.

Some notices will advise to review
the errors, but don't provide details.

eRA COMMONS FAILURE

GRANT ██████████████████████ **ACTION REQUIRED TO COMPLETE SUBMISSION - Missing or Invalid eRA Commons Username**

1 message

---

era-notify-test@mail.nih.gov <era-notify-test@mail.nih.gov>
Reply-To: eranotifications@mail.nih.gov
To: infoed.help@foundation.sdsu.edu, awards@foundation.sdsu.edu

Wed, Apr 20, 2016 at 9:34 AM

ACTION REQUIRED TO COMPLETE SUBMISSION OF NIH GRANT APPLICATION:

NIH has received the electronic grant application Grants.gov Tracking # GRANT██████ / PI ████████████. **NIH was unable to process your application because it was missing critical information required by NIH.** NIH requires that the PD/PI's correct eRA Commons User ID be entered in the 'Credential' field for the PD/PI on the R&R Senior/Key Person Profile (Expanded) component of the application.

Because the Credential field was not completed accurately, your application was considered incomplete; therefore the eRA Commons could not fully check the application against the instructions in the application guide and the funding opportunity announcement. You may receive new error and/or warning messages once you submit a changed/corrected application to Grants.gov.

All changed/corrected applications to address this Credential error and any subsequently identified errors or warnings must be made by the submission deadline for your application to be considered on-time. Changed/corrected applications submitted after the submission deadline will be subject to the NIH Late Policy and may not be accepted.

Applicants should refer to the funding opportunity announcement and the applica████ on correcting application content. In addition, the Applying Electronically website ElectronicReceipt/index.htm) contains additional resources that may assist you.

Some notices provide information regarding the error(s) that are preventing a successful submission.

View detailed steps for submitting a changed/corrected application.

If you still require support after taking full advantage of these resources, please contact the eRA Service Desk.

CHECK ASSEMBLED: WARNINGS ONLY

GRANT▮▮▮▮▮▮▮▮▮▮▮▮▮▮ **Check Assembled Application in eRA Commons - Warnings Only**
1 message

era-notify-test@mail.nih.gov <era-notify-test@mail.nih.gov>   Wed, Apr 20, 2016 at 12:10 PM
Reply-To: eranotifications@mail.nih.gov
To: infoed.help@foundation.sdsu.edu, awards@foundation.sdsu.edu

NIH has received the electronic grant application Grants.gov Tracking # GRANT▮▮▮▮ / PI ▮▮▮▮▮▮ and has placed the assembled application in the eRA Commons for your review. Our systems have identified warnings associated with your application. These warnings will not prevent your application from completing the electronic submission process, but are reminders to verify that your application complies with specific requirements in the funding opportunity announcement and application guide.

Any submission to correct these warnings must be done before the submission deadline (5PM local time of the due date).

By the submission deadline, the application must be error free in order to move forward for consideration. Submissions made after the deadline will overwrite the previous submission; these are subject to the late policy and are rarely accepted.

You have a viewing window of two business days (i.e., Monday - Friday, excluding federal holidays) to **check the assembled application before it automatically moves forward to NIH staff for further processing and consideration.** Once the application has moved forward, no additional changes to the application will be accepted through Grants.gov or eRA Commons.

Within the viewing window, signing officials have the authority to reject an application to stop it from completing the submission process. After an application is rejected, a changed/corrected application can be submitted to address warnings or other issues if it is still before the submission deadline. Changed/corrected applications submitted after the submission deadline will be subject to the NIH Late Policy and may not be accepted.

It is your responsibility to view the entire assembled application in eRA Commons and notify the eRA Service Desk within the viewing window (and before the application deadline) if the assembled application does not correctly reflect the information submitted to Grants.gov (e.g., submitted information is missing in image, graph/chart appears upside-down). The eRA Service Desk will provide guidance on appropriate corrective actions.

View detailed steps for PI to track submission status.
View detailed steps for AOR/SO to track submission status.
View detailed steps for AOR/SO to reject an application.
View detailed steps for submitting a changed/corrected application.

If you still require support after taking full advantage of these resources, please contact the eRA Service Desk.

SUBMISSION RECEIPT

GRANT ████████ **Grants.gov Submission Receipt**
1 message

DoNotReply@grants.gov <DoNotReply@grants.gov>   Thu, Apr 7, 2016 at 8:42 AM
To: awards@foundation.sdsu.edu

Your application has been received by Grants.gov, and is currently being validated.
Your submission was received at Apr 07, 2016 11:42:36 AM EDT

Validation may take up to 2 business days. To check the status of your application please click here
http://www.grants.gov/applicants/track-my-application.html?tracking_num=GRANT████

Type: GRANT

Grants.gov Tracking Number: GRANT████

We will notify you via email when your application has been validated by Grants.gov and is being prepared for Grantor agency retrieval.
        DUNS Number: 0733713460000

        AOR name: S2S#San Diego State Research Foundation SN#B5D6....0DEE Exp.Dt 11/22/2018

        Application Name: Stemness and Differentiation Potential Are Defined by Metabolism in Cardiac Progenitor Cells

        Opportunity Number: PA-14-149

        Opportunity Name: Ruth L. Kirschstein National Research Service Award (NRSA) Individual Postdoctoral Fellowship (Parent F32)

        https://apply07.grants.gov/apply/login.faces?cleanSession=1&userType=applicant

Thank you.
Grants.gov
If you have questions please contact the Grants.gov Contact Center:
support@grants.gov
1-800-518-4726
24 hours a day, 7 days a week. Closed on federal holidays.

PLEASE NOTE: This email is for notification purposes only. Please do not reply to this email for any purpose.

VALIDATION RECEIPT

GRANT████ **Grants.gov Submission Validation Receipt for Application**
1 message

DoNotReply@grants.gov <DoNotReply@grants.gov>   Thu, Apr 7, 2016 at 8:42 AM
To: awards@foundation.sdsu.edu

Your application has been received and validated by Grants.gov and is being prepared for Grantor agency retrieval.

DUNS Number: 0733713460000

AOR name: S2S#San Diego State Research Foundation SN#B5D6....0DEE Exp.Dt 11/22/2018

Application Name: ████████████████████████████████████

Opportunity Number: PA-14-149

Opportunity Name: Ruth L. Kirschstein National Research Service Award (NRSA) Individual Postdoctoral Fellowship (Parent F32)

https://apply07.grants.gov/apply/login.faces?cleanSession=1&userType=applicant

You will be notified via email when your application has been retrieved by Grantor agency.

Thank you.
Grants.gov
If you have questions please contact the Grants.gov Contact Center:
support@grants.gov
1-800-518-4726
24 hours a day, 7 days a week. Closed on federal holidays.

PLEASE NOTE: This email is for notification purposes only. Please do not reply to this email for any purpose.

TRACKING NUMBER ASSIGNED

GRANT ▮▮▮▮ **Grants.gov Agency Tracking Number Assignment for Application**

1 message

DoNotReply@grants.gov <DoNotReply@grants.gov>   Thu, Apr 7, 2016 at 8:46 AM
To: awards@foundation.sdsu.edu

Grantor agency has assigned the following Agency Tracking Number to your application: ▮▮▮▮.

You will need the Agency Tracking Number when corresponding with the Grantor agency about your application.

Use the Grants.gov Tracking Number at Grants.gov to check your application's status and to review your Agency Tracking Number.
Type: GRANT
    Grants.gov Tracking Number: GRANT ▮▮▮▮
    DUNS Number: 0733713460000
    AOR name: S2S#San Diego State Research Foundation SN#B5D6....0DEE Exp.Dt 11/22/2018
    Application Name: ▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮
Cells
    Opportunity Number: PA-14-149
    Opportunity Name: Ruth L. Kirschstein National Research Service Award (NRSA) Individual Postdoctoral Fellowship (Parent F32)
    https://apply07.grants.gov/apply/login.faces?cleanSession=1&userType=applicant

Thank you.
Grants.gov
If you have questions please contact the Grants.gov Contact Center:
support@grants.gov
1-800-518-4726
24 hours a day, 7 days a week. Closed on federal holidays.

PLEASE NOTE: This email is for notification purposes only. Please do not reply to this email for any purpose.

RETRIEVAL RECEIPT

GRANT████████ **Grants.gov Grantor Agency Retrieval Receipt for Application**
1 message

DoNotReply@grants.gov <DoNotReply@grants.gov>   Thu, Apr 7, 2016 at 8:34 AM
To: awards@foundation.sdsu.edu

Your application has been retrieved by the Grantor agency.

Type: GRANT

Grants.gov Tracking Number: GRANT████████

DUNS Number: 0733713460000

AOR name: S2S#San Diego State Research Foundation SN#B5D6....0DEE Exp.Dt 11/22/2018

Application Name: ████████████████████████████████

Opportunity Number: PA-14-149

Opportunity Name: Ruth L. Kirschstein National Research Service Award (NRSA) Individual Postdoctoral Fellowship (Parent F32)

https://apply07.grants.gov/apply/login.faces?cleanSession=1&userType=applicant

We will notify you via email when your Grantor agency has assigned an Agency Tracking Number to your application.

Thank you.
Grants.gov
If you have questions please contact the Grants.gov Contact Center:
support@grants.gov
1-800-518-4726
24 hours a day, 7 days a week. Closed on federal holidays.

PLEASE NOTE: This email is for notification purposes only. Please do not reply to this email for any purpose.

NOTIFICATION: ADVANCE TO REFERRAL

Auto verified electronic application AN # ███████ **; PI:** ███████████
Title: ██
████ **; Grants.gov Tracking #: GRANT1** ███████████
1 message

era-notify@mail.nih.gov <era-notify@mail.nih.gov>   Tue, Apr 12, 2016 at 9:05 PM
Reply-To: commons@od.nih.gov
To: awards@foundation.sdsu.edu

eRA has received grant application titled: ███████████████████████████████████
████ ; at least 2 business days have passed since application image was assembled and made available to you
for viewing. The grant application has now advanced to the next step - Referral.

You can view and track the status of this grant application via the 'Status' module in eRA Commons (log into
eRA Commons and select the 'Status' tab on the top blue menu bar).

If you have any questions about this email, please contact the eRA Help Desk via the web at
http://era.nih.gov/help/, by phone 1-866-504-9552 (tty: 301-451-5939) or commons@od.nih.gov .

NOTICES: POST SUBMISSION

- Administrative – e.g. Institution Transfer
- Just in Time

ORGANIZATIONAL TRANSFERS

information regarding your NIH application

1 message

era-notify@mail.nih.gov <era-notify@mail.nih.gov>   Mon, Mar 21, 2016 at 10:45 AM
Reply-To: ███@mail.nih.gov
To: ███████████, awards@foundation.sdsu.edu
Cc: ███@mail.nih.gov

March 21, 2016

Dr. ████████████
San Diego State University
████████████████████████
San Diego, CA 92120-1832

Dear Dr. ████████:

Your application (1R21DC████████) entitled "████████████████████
████" has been received at the Division of Receipt and Referral at the Center for Scientific Review.

We have determined that your application is a resubmission of (1R21DC████████) and that there has been a change in applicant organization from (UNIVERSITY OF ███████████████████████) to (SAN DIEGO STATE UNIVERSITY). Before we can process your application, we will need a letter from the signing official at your former organization/institution which confirms their willingness to relinquish the ability to submit this application.

This letter may be attached as a pdf file to an email sent to ██@mail.nih.gov. If you have any questions, please contact me or this office at the number provided below.

Best Regards,

████████████

Assistant Director

Division of Receipt and Referral

NIH/Center for Scientific Review

Tel: 301-435-████

Email: ██@mail.nih.gov

Project Directors changing institutions in the midst of a re-submission process, must have a relinquishment letter from their previous organization that allows the new institution to take ownership of the application.

REQUEST FOR JUST-IN-TIME INFORMATION

1 message

era-notify@mail.nih.gov <era-notify@mail.nih.gov>   Tue, Mar 15, 2016 at 7:20 PM
Reply-To: eraNotifications@mail.nih.gov
To: ██████████████.sdsu.edu
Cc: awards@foundation.sdsu.edu

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

Principal Investigator: ████████████

Application ██████████████ entitled ████████████████████████████ has completed the first phase of peer review.

This is NOT a Notice of Grant Award, nor should it be construed as an indicator of possible award. This notification requests Just-In-Time information.

Please follow the instructions contained on the following website: http://grants1.nih.gov/grants/peer/jit.pdf. The requested information must be submitted using the Just-In-Time submission feature of the NIH commons found in the Commons Status section. For information on the Commons, see: https://public.era.nih.gov:443/commons/

If you have questions about this request, contact your assigned Grants Management Specialist or Program Official. Contact information for these individuals can be found in the Commons Status system.

JIT Submission Confirmation

Just in Time Submitted for Grant Application: F32HL███████ to the NIH

1 message

era-notify@mail.nih.gov <era-notify@mail.nih.gov>   Wed, Mar 30, 2016 at 1:26 PM
Reply-To: commons@od.nih.gov
To: awards@foundation.sdsu.edu, jjin@mail.sdsu.edu

A Just in Time Submission was submitted by Signing Official: Gulizia, Rick to the NIH for grant application:
F32HL███████1 associated with Principal Investigator ██████████ using the NIH Commons.

The Just In Time information submitted to NIH is available for review in the Grant Detail section of the Commons
Status module. To access this information, go to Status, retrieve the grant application and click on the
Application Id link available in the result set.
If you have any questions about this email, please contact Rick Gulizia at awards@foundation.sdsu.edu, who
initiated this action.

For any further questions about this email, call the eRA Service Desk at 1-866-504-9552 or refer to
http://grants.nih.gov/support for additional methods of contact. Please access Commons at
http://public.era.nih.gov/commons/.
For more information please visit http://era.nih.gov/

RENEWALS: COMPLIANCE

Noncompeting Continuation for Grant # :U1QHP███ - Change Requested by HRSA

1 message

███████████ @hrsa.gov>   Tue, Mar 22, 2016 at 2:09 PM
To: ████████ <awards@foundation.sdsu.edu>, ███████████████████

A Change Request for Noncompeting Continuation has been requested by HRSA. Following are the details:

Grant Number :U1QHP███
Grantee Name: SAN DIEGO STATE UNIVERSITY FOUNDATION

Tracking Number: ██████
Budget Period: 07/01/2015 - 06/30/2016

Submitted on: 03/22/2016

Following Comments were added by the HRSA Reviewer for your information:

Thanks for your revised NCC report. However, it is still incomplete in Attachment 1. Please revise and resubmit by noon on 3/23:

1) Complete information in the remainder of the project period (3/14/2016-6/30/2016) by organizing each objective in detail and; 2) Complete information in the upcoming year of the project period (7/1/2016-6/30/2017) by organizing each objective in detail.

Thanks,

████████████████

This deliverable can be accessed in the EHBs by clicking the following link:
https://grants.hrsa.gov/████████████████████████
███████████████████████

This Request will also be available in EHBs from the "Noncompeting Continuations" under Submissions sections of the Grant Hand Book. If you have any questions, please contact your project officer (PO).

For any questions regarding online submission, please contact the call center at 877-Go4-HRSA/877-464-4772/301-998-7373 or Email at CallCenter@HRSA.GOV.

NOTE: This is a system generated message. Please do not respond to this message.

> Revisions must be completed or follow on funding will be delayed

WORKING TO GET IT RIGHT!

From: era-notify@mail.nih.gov [mailto:era-notify@mail.nih.gov]
Sent: Monday, February 15, 2016 12:37 PM
To: ▌▌▌▌▌@sdsu.edu
Cc: awards@foundation.sdsu.edu; awards@foundation.sdsu.edu; ▌▌▌▌▌@nih.gov; G
MeRANotifications@mail.nih.gov; ▌▌▌▌▌@nih.gov; ▌▌▌▌▌@mail.sdsu.edu
Subject: eRA Commons: RPPR for Grant ▌▌▌▌▌ Submitted to NIH with a Non-
Compliance warning

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

Dear Grantee,

The progress report for the above-reference award includes citation(s) that are out of
compliance with the NIH Public Access Policy. Compliance with the NIH Public Access Policy
is a legal requirement and a term and condition of all NIH awards. This award will be
delayed until all publications arising from it are in compliance with the policy.
The Authorized Organization Representative (AOR) or PD/PI with delegated Progress Report
Submit Authority must provide verification that all publications are in compliance with
the NIH Public Access Policy, to the Grants Management Specialist (GMS). The Public Access
compliance verification may be submitted either using the new Progress Report Additional
Material (PRAM) link on the eRA Commons Status page or via email.

Subsequent funding WILL NOT be issue until ALL issues are resolved.

Instructions for SO/AOR verification:
- Verify that the PD/PI has used My NCBI to enter publications and/or update
  compliance status.
- Include a My NCBI PDF report demonstrating all the formerly non-compliant
  public access citations are now compliant. To process your award, every
  citation in the report should be either complete, in process or exempt N/A).
  Please see http://publicaccess.nih.gov/citation_methods.htm for more
  information about acceptable compliance statuses for public access papers.
  We have more information about My NCBI
  athttp://publicaccess.nih.gov/communications.htm.
- If unable to provide verification, provide a justification for why the specific
  publication(s) cannot be brought into compliance.

NIH awardees are responsible for ensuring that evidence of compliance is included in all NIH
applications, proposals and reports. If you have questions about the Policy, please check
the NIH Public Access Website or send an email to PublicAccess@nih.gov.
For any further questions about this email, call the eRA Help Desk at 1-866-504-9552 or
refer to http://grants.nih.gov/support for additional methods of contact. Please access
Commons at http://public.era.nih.gov/commons/.
For more information please visit http://era.nih.gov/

NIH may provide specific instructions for complying with requirements.

From: ███████████████████████████ @foundation.sdsu.edu]
Sent: Monday, February 29, 2016 3:47 PM
To: █████████ (NIH/NIGMS) [E] ██████████ @nih.gov>
Cc: ████████████████ @mail.sdsu.edu>; ████████████████████ @sdsu.edu>;
████████████████████ @mail.sdsu.edu>
Subject: Fwd: FW: eRA Commons: RPPR for Grant ████████████ Submitted to NIH
with a Non-Compliance warning

Dear ████████
I have been working with ████████ and the project team to correct our non-compliant
citation. We would like to know if there is a way we can remove the below citation from our
report as we are unable to correct the citation?

██
██ . Molecular ██
████████████████████████████████ . 2015 Feb;28(1)██
PubMed PMID: ██████████ ; NIHMSID: ████████ .

If you can advise we'd greatly appreciate it.

Thank you,

████████████
████████████
SDSU Research Foundation
5250 Campanile Drive
San Diego, CA 92182-1931
████████████████
████████████████
████ @foundation.sdsu.edu

It may be necessary for the
institution's sponsored programs
staff to intervene and work with
the sponsor in order to become
complaint.

On Mon, Feb 29, 2016 at 1:53 PM, ███████████ (NIH/NIGMS) [E]
███████████ @nih.gov> wrote:

Good Afternoon ███████,

I am sorry to hear that you are having trouble correcting the non-compliant publication. What is the specific problem and have you reached out directly to the Public Access Support Center (PASC) with your questions? The Public Access Support Center will make the final determination on compliance for this publication. You can contact them for assistance by replying directly to the email highlighting the non-compliant publication issue.

As for removing the publication, Recipients are required to report all papers that meet the criteria of the NIH public access policy in the publication section of their Type 5. Failing to report applicable papers instead of bringing the paper into compliance is not consistent with the terms and conditions of the grant award.

Let me know if you need more information or if you have trouble receiving a response from PASC.

Kindest Regards,

███████████
Grants Management Specialist (E)
National Institute of General Medical Sciences
███████████
Bethesda, MD 20892-6200
███████████ @nih.gov
███████████

Like our organizations, different areas within the NIH work to resolve outstanding issues with grantee organizations.

On Mon, Feb 29, 2016 at 1:54 PM, ███████████ @foundation.sdsu.edu> wrote:

Thank you ███████, we will work with PASC.

Thank you,
███████████
███████████
███████████

DOUBLE CHECK

From: ███████████████████████ @foundation.sdsu.edu]
Sent: Wednesday, March 09, 2016 2:44 PM
To: ████████ (NIH/NIGMS) [E] ████████████ @nih.gov>
Cc: █████████████████ @mail.sdsu.edu>; ██████████████ @sdsu.edu>; ████████████████ @mail.sdsu.edu>; ████████████████ NIH/NIGMS) [E] ████████████████ @nih.gov>
Subject: Re: FW: eRA Commons: RPPR for Grant 5R25 ████████ Submitted to NIH with a Non-Compliance warning

Dear █████
We are still working to correct this publication. I was wondering if you'd be able to advise if there is anything that might hold up our award, with a start date of 4/1/16.

Thank you,

████████████
████████████
████████

Follow up to ensure that there aren't any other outstanding issues.

ONE MORE ITEM...

Hi ▮▮▮▮▮▮ ,

I worked up the grants management review for this award and noted that section G10a in the RPPR (Anticipated Unobligated Balance) was left blank. To avoid a delay, please provide the estimated amount of unobligated funds.

If the end of year balance is expected to be greater than 25% of the current year's total approved budget, provide an explanation for the remaining unobligated balance. If you are requesting to carry forward more than 25% of authorized funds, provide a general description of how you intend to spend the funds.

Please note all information must be submitted through an official authorized to sign for the applicant organization. The Program Officer may request additional information following the completion of the programmatic review.

If you have any questions please contact me at the information below.

Thank you and have a nice weekend.

▮▮▮▮▮▮▮▮
Grants Management Specialist (E)
National Institute of General Medical Sciences
▮▮▮▮▮▮▮▮
Bethesda, MD 20892-6200
▮▮▮▮▮▮▮▮@nih.gov
▮▮▮▮▮▮▮▮

All items must be in compliance - failure to complete will result in a delay until all reporting aspects are met.

From: [████████████r@foundation.sdsu.edu]
Sent: Friday, March 18, 2016 1:09 PM
To: [████████ (NIH/NIGMS) [E] ████████@nih.gov>
Cc: [████████████@mail.sdsu.edu>; ████████████@sdsu.edu>; ████████████@mail.sdsu.edu>; ████████████ (NIH/NIGMS) [E] ████████@nih.gov>; ████████████@foundation.sdsu.edu>

Subject: Re: FW: eRA Commons: RPPR for Grant 5R25████████Submitted to NIH with a Non-Compliance warning

Dear █████████,
Please find our justification below, I'm working on preparing a signed letter from our Authorized Official today, but didn't want to delay the process any farther. Additionally, can you clarify if the below justification is sufficient. <mark>I was not sure if you need an estimated dollar amount.</mark>

If you have any questions or require additional information please let me know. Do you know when we can anticipate the notice of award?

The SDSU ████ Program anticipates only having 1-2% more than the normally allocated 25% for carryover for the 2015-2016 grant year. This 1-2% of unspent funds is a result of a handful of programmatic items: a larger than expected number of ████ students performed summer research offsite and were funded by other institutions for that period, yielding an unanticipatedly large amount of unspent student support funds. Additionally, this year travel expenses were lower than expected, as a majority of our students obtained travel awards for conferences such as ████████████ that are keystone research events for our program. We anticipate using the remaining carry-over, as we will be working with a full roster of 25 students soon, based on the number of students graduating, the number of applicants we have received, and program interviews conducted thus far.

Thank you,
████████████
████████████
████████████

If uncertain, ask!

Ensure that the information provided is considered complete for the item requiring clarification and submission.

ADDITIONAL INFORMATION NEEDED!

On Fri, Mar 18, 2016 at 10:25 AM, ██████████ (NIH/NIGMS) [E]
██████████ @nih.gov> wrote:

Hi ██████

Thank you for your response. The justification is sufficient but please provide an estimated dollar amount for the unobligated balance. For institutional concurrence, we do not require a formal letter, an email from an Authorized Official confirming your response (and providing $ figure) will suffice. We will not be able to issue the new NoA until the non-compliant publication(s) has been brought into compliance. Please let me know the status of the non-compliant publication.

Thank you and have a nice weekend.

██████████

Confirmation related to the provided justification

However, still an outstanding issue that will prevent follow on funding from being issued, until resolved.

REQUIREMENTS MET

From: ██████████████████████ @foundation.sdsu.edu]
Sent: Tuesday, March 22, 2016 3:50 PM
To: █████████ (NIH/NIGMS) [E] ████████████ @nih.gov>
Cc: ██████████████████ @mail.sdsu.edu>; ██████████████████████ @sdsu.edu>;
████████████████████ @mail.sdsu.edu>; ████████████████ (NIH/NIGMS)
[E] ████████████████ @nih.gov>; ██████████
████████ @foundation.sdsu.edu>; ████████████████ t@foundation.sdsu.edu>;
████████████████ @foundation.sdsu.edu>
Subject: Re: FW: eRA Commons: RPPR for Grant 5R25████████████ Submitted to NIH
with a Non-Compliance warning

Dear ████████,
Please find attached a signed response to the amount of unobligated balance anticipated for
this year. Additionally, the NIH non-compliant report still states that the submission is
under review.

I hope that we have satisfied all NIH requests in order to release the notice of award. If
there are any additional items pending please advise.

Thank you,

████████████
██████████████
████████████

SUCCESS!...AWARD REVIEW

Understanding Terms and Conditions

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Must acknowledge support and list award number with disclaimer.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of General Medical Sciences of the National Institutes of Health under Award Number R25██████. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Provide advanced notice prior to issuing press releases.

Conflict of Interest requirements

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

SECTION 1 – AWARD DATA

SECTION I – AWARD DATA – 4R25 █████████

Award Financial Figures - may require approval to modify budget categories.

Award Calculation (U.S. Dollars)

Salaries and Wages	$350,178
Fringe Benefits	$71,305
Personnel Costs (Subtotal)	$421,483
Consultant Services	$10,100
Materials & Supplies	$26,500
Travel	$20,250
Other	$5,400

If cost share or matching was required, it would be shown in this area.

AKA: Indirect / Overhead

Federal Direct Costs	$483,733
Federal F&A Costs	$38,702
Approved Budget	$522,435
Total Amount of Federal Funds Obligated (Federal Share)	$522,435
TOTAL FEDERAL AWARD AMOUNT	$522,435

AMOUNT OF THIS ACTION (FEDERAL SHARE) $522,435

Current Year

Provides funding information for all years. (Last year of the project.)

SUMMARY TOTALS FOR ALL YEARS

YR	THIS AWARD	CUMULATIVE TOTALS
17	$522,435	$522,435

Fiscal Information:

CFDA Name:	Biomedical Research and Research Training	
CFDA Number:	93.859	
EIN:	1956	
Document Number:	RGM ████	
PMS Account Type:	P (Subaccount)	
Fiscal Year:	2016	

Employer Identification Number

Catalog of Federal Domestic Assistance Name/Number - must be included in subagreements

IC	CAN	2016
GM	8472194	$522,435

SECTION II – PAYMENT/HOTLINE INFORMATION – 4R25

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 4R25

Proposal is now part of the award.

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

Uniform Guidance for HHS awards

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

WEEDING…

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

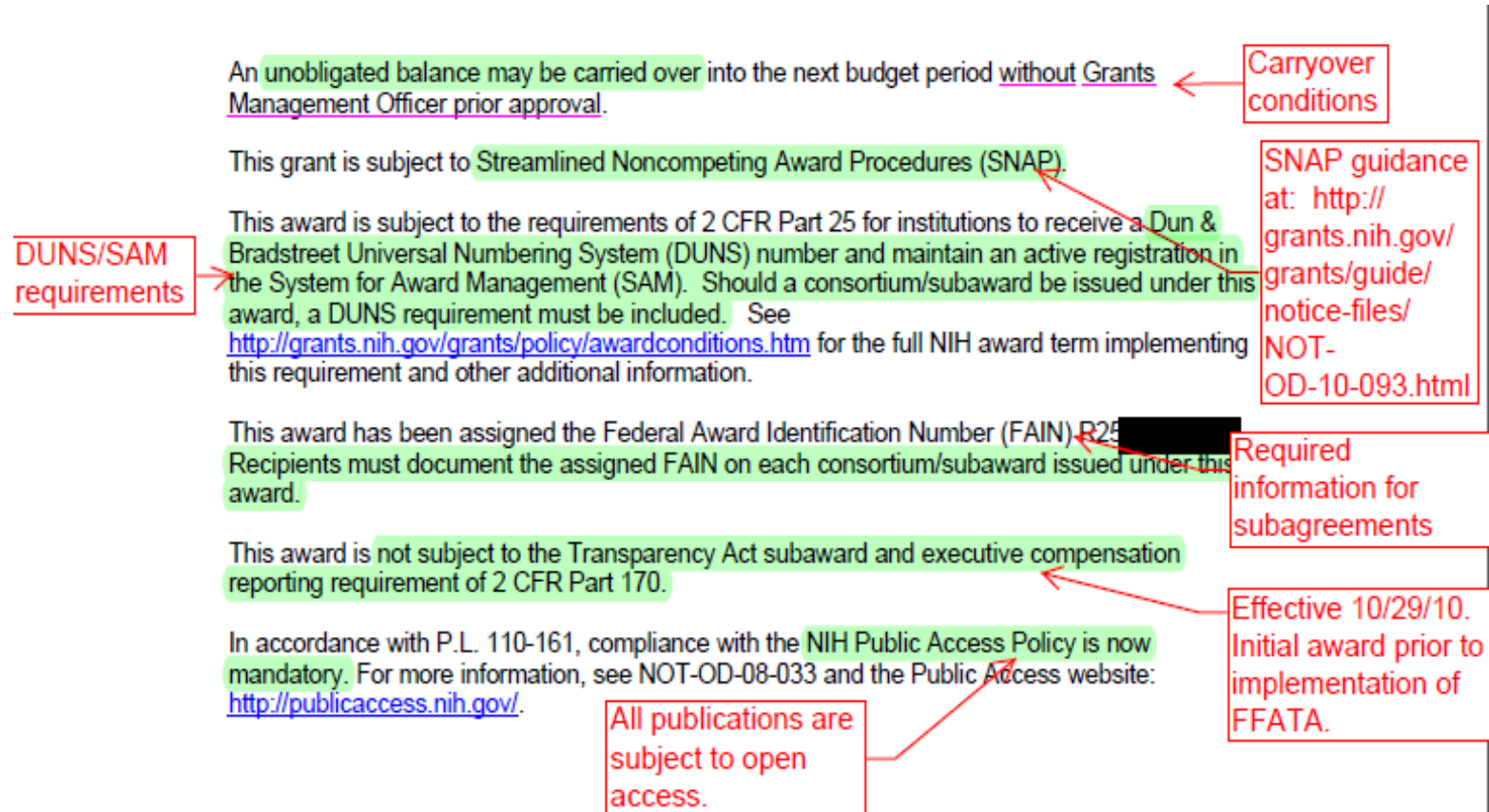**Download upon receipt of award - keep in award file.**

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

For your auditors…

Internal to NIH: Payment Management Systems

This award was issued as a non-competing continuation with a change in document number. This change was made solely to accommodate the HHS mandate to transition award payments to Payment Management System (PMS) subaccounts. Expenses for the project period should be treated as if this were a non-competing continuation award (e.g. Type 5). A Subaccount Transitional Federal Financial Report (FFR) is required for the previous budget periods to complete the transition. Recipients must use the SF-425 as they would for an interim or annual FFR and enter "Subaccount Transitional FFR" in box 12. This report covers grant funds in the pooled account and is used by NIH to end the grant's association with the pooled PMS payment account and transition award payments to the PMS subaccount established for the grant, including transferring any carryover funds and unliquidated obligations remaining in the pooled account. It is due within 90 days of the end of the calendar quarter in which the last budget period prior to this NoA ended. For more information, please refer to Notice NOT-OD-15-105

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R25 █████. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

This award is not subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Annotations:

- Carryover conditions
- SNAP guidance at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-093.html
- DUNS/SAM requirements
- Required information for subagreements
- Effective 10/29/10. Initial award prior to implementation of FFATA.
- All publications are subject to open access.

FINANCIAL REPORTING

Closeout guidance - due within 120 days after end

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the expiration date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for

additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

Ensure that reporting is exact!

CLOSEOUT GUIDANCE

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, R13, R25, S10.

Negative reports are required.

Unless an application for competitive renewal is submitted, a final progress report must also be submitted within 120 days of the expiration date. Instructions for preparing a Final Progress Report are at: http://grants.nih.gov/grants/funding/finalprogressreport.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the final progress report. Institute/Centers may accept the progress report contained in competitive renewal (type 2) in lieu of a separate final progress report. Contact the awarding IC for IC-specific policy regarding acceptance of a progress report contained in a competitive renewal application in lieu of a separate final progress report.

Guidance on programmatic reporting.

NIH strongly encourages electronic submission of the final progress report and the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

NIH Commons expedites

Email: The final progress report and final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Alternative submission options

Hard copy: Paper submissions of the final progress report and the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

ADDITIONAL GUIDANCE & TERMS

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final Progress Report is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Final year competive segment reporting for transfer projects.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made

SAM.gov reporting requirements for US funds - AKA: Debarment and Suspension and other activities. Includes all award entities.

publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income: Additional Costs

Two types of program income: additional and deduct.

"Special" Terms and Conditions

SECTION IV – GM Special Terms and Conditions – 4R25 ▮▮▮

1. This award is issued in accordance with the NIH fiscal policies described in NIH Guide Notice NOT-OD-16-046.

2. **Initiative for Maximizing Student Development:** This grant should be administered in accordance with the guidelines described in the INITIATIVE FOR MAXIMIZING STUDENT DIVERSITY (IMSD) Program Announcement (PAR-09-104) available at: http://grants.nih.gov/grants/guide/pa-files/PAR-09-104.html. These guidelines are in addition to the standard terms and conditions referenced in Section III of this Notice of Award. For additional information on this program, including training materials and answers to frequently asked questions, please visit the NIGMS Division of Training, Workforce Development, and Diversity (TWD) website: http://www.nigms.nih.gov/Training/Pages/default.aspx

3. In keeping with NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html), as this grant has multiple Principal Investigators (PIs), although the signatures of the PIs are not required on prior approval requests submitted to the agency, the grantee institution must secure and retain the signatures of all of the PIs within their own internal processes.

4. **RESTRICTION:** This award provides funding to support the following number of participants:

Undergraduate: 25 ← Document student status at the time of appointment

The grantee may not appoint more than the approved number of participants unless prior approval is first obtained from NIGMS.

5. **Student Appointments:** Electronic Statement of Appointment forms (Form PHS 2271) must be submitted for all student participants through the xTrain system. A Termination Notice is not required at the end of a student participant's appointment; however, if the actual period of support is different from what was originally proposed, the appointment must be amended to reflect the actual period of support. Additional information on xTrain, as well as training and reference materials can be found on the xTrain website: http://era.nih.gov/era_training/xtrain.cfm

Part of NIH Commons

6. None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable.

Current salary cap levels can be found at the following URL: http://grants.nih.gov/grants/policy/salcap_summary.htm

Can pay salaries above the cap, but salary above the cap CANNOT be from NIH funding.

Download and retain all policy guidance for the life of the project and the retention period.

OTHER REQUIREMENTS

7. OTHER PROGRAM REQUIREMENTS: The policies as stated in the NIH Grants Policy Statement (for research grants) and the Program Announcement referenced above must be followed. Key elements include, but are not limited to:

Allowable/Unallowable Costs: The Program Announcement referenced above includes detailed information on appropriate charges, limitations on personnel effort and compensation, and specific items of cost that are unallowable.

Rebudgeting: Funds for the direct support of student participants provided in this award (i.e. salaries, fringe benefits, tuition/fees, and student travel) are restricted and may not be rebudgeted without the prior written approval of NIGMS. However, any unused student participant funds carried forward into the next budget period are unrestricted and may be rebudgeted within the limitations set for in the NIH Grants Policy Statement, the Program Announcement referenced above, and the terms and conditions of this Notice of Award.

Student Qualifications: It is the responsibility of the grantee institution to monitor the qualifications of students prior to their participation in the program. A student participant must be a citizen, a non-citizen national, or have been lawfully admitted for permanent residence. A non-citizen national is a person who, although not a citizen of the United States, owes permanent allegiance to the U.S. They are generally persons born in lands that are not States, but are under U.S. sovereignty, jurisdiction, or administration (e.g. American Samoa). An individual lawfully admitted for permanent residence must possess a Permanent Resident Card (I-551) prior to appointment on the grant. Individuals on temporary visas are not eligible for support.

Participant Monitoring: Grantees must have a system in place for monitoring student progress including their retention, transfer, and successful completion of their degree(s), if applicable.

Human Subjects/Vertebrate Animals Research: It is understood that no trainee will be permitted to work on any project involving live vertebrate animals or human subjects that has not been approved by the IACUC and/or IRB, as appropriate. If any trainee undertakes a project that includes human subject research studies, these must conform to the NIH policies on the inclusion of women, minorities, and children in study populations.

Unobligated Balances: As indicated in Section III of this Notice of Award, an unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval; however, NIGMS staff reserves the right to make budgetary reductions to award commitments in cases where recipients have accrued excessively large unobligated balances.

CONTACT INFORMATION

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: ███████████
Email: ███████████ @nih.gov

Program Official: ███████████
Email: ███████████ @nih.gov Phone: 301-███████ Fax: 301-███████

Awarded Budget

Direct Costs

Budget	Year 17
Salaries and Wages	$350,178
Fringe Benefits	$71,305
Personnel Costs (Subtotal)	$421,483
Consultant Services	$10,100
Materials & Supplies	$26,500
Travel	$20,250
Other	$5,400
TOTAL FEDERAL DC	$483,733
TOTAL FEDERAL F&A	$38,702
TOTAL COST	$522,435

F&A Details

Facilities and Administrative Costs	Year 17
F&A Cost Rate 1	8%
F&A Cost Base 1	$483,773
F&A Costs 1	$38,702

NOA – No Cost Extension

Notice of Award

EXPLORATORY/DEVELOPMENT GRANT
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 04/06/2016

NATIONAL INSTITUTE OF MENTAL HEALTH

Effective Date of the revision, unless otherwise noted

Grant Number: 5R21MH_____ REVISED
FAIN: R21MH_____

Revision to an existing award

Principal Investigator(s):
_____, PHD

Project Title: Mental Health _____

Jennie Amison
Director, Division of Research Affairs
SAN DIEGO STATE UNIVERSITY FOUNDATION
Graduate and Research Affairs
5500 Campanile Dr.
San Diego, CA 92182

Award e-mailed to: awards@foundation.sdsu.edu

Period Of Performance:
Budget Period: 04/01/2015 – 03/31/2017
Project Period: 04/01/2014 – 03/31/2017

Double check dates against original award

Dear Business Official:

REVISIONS TO TERMS AND CONDITIONS

TOTAL FEDERAL AWARD AMOUNT $265,956

AMOUNT OF THIS ACTION (FEDERAL SHARE) $0

Denotes an administrative change.

SECTION IV – MH Special Terms and Conditions – 5R21MH██████ REVISED

REVISION #1

NO-COST EXTENSION:
This revised award provides a first no-cost extension through 3/31/17 in accordance with the recipient's request dated 3/30/16. The project period end date has been adjusted accordingly. In extending the final budget period, the

recipient agrees to update all required certifications, including human subjects and animal welfare, in accordance with applicable regulations and policy.

All terms and conditions of prior award remain in effect.

Ensure all compliance continues to be approved throughout the project period.

COMMON OTHER AWARD ACTIONS

- Freedom of Information Request
- Inclusion of Data
- Data and Safety Monitoring Plan
- Financial Conflict of Interest
- Research Program Progress Reports
- Progress Report Additional Materials
- Final Progress Report
- Closeout Guidance

FREEDOM OF INFORMATION ACT (FOIA) REQUESTS

The National Cancer Institute has received a Freedom of Information request of Grant# 2U54CA██████████. Attached is a copy of a pre-disclosure notice with your most recent address I have on record; as well as a copy of the Freedom of Information request, and the DHHS Federal guidelines in which we follow when releasing grant information.

Per NIH Policy Statement (abbreviated):
The Freedom of Information Act, 5 U.S.C. 552, and implementing HHS regulations (45 CFR 5) require NIH to release certain grant documents and records requested by members of the public, regardless of the intended use of the information. ...
NIH generally will release the following types of records pursuant to a FOIA request:
Funded applications and funded progress reports, including award data.
Final reports that have been transmitted to the grantee organization of any audit, survey, review, or evaluation of grantee performance.
NIH generally will withhold the following types of records or information in response to a FOIA request:
Pending grant applications...
Financial information pertaining to project personnel...
Information pertaining to an individual...
Predecisional opinions in interagency or intraagency memorandums or letters expressed by Federal government officers, employees, or consultants
Evaluative portions of site visit reports and peer review summary statements, including impact scores
Trade secrets and commercial, financial, and otherwise intrinsically valuable items of information that are obtained from a person or organization and are privileged or confidential
Information which, if released, would adversely affect the competitive position of the person or organization
Patent or other valuable commercial rights of the person or organization.

INCLUSION OF DATA

era-notify@mail.nih.gov <era-notify@mail.nih.gov>   Tue, Mar 22, 2016 at 2:39 PM
Reply-To: eraNotifications@mail.nih.gov
To: awards@foundation.sdsu.edu

PI routed Inclusion Data for:

- 4R37HD███████ - T█████████████████████
- Inclusion Data Record (IDR) # - ███████████
- Study Title - ████████████   Retain with programmatic reporting.

If you have any questions about this email, please contact ████████████ at
████████ @sdsu.edu, who initiated this action.

If you incur any problem while using the eRA Commons, please contact the eRA Help Desk at 1-866-504-9552 or commons@od.nih.gov.

DATA AND SAFETY MONITORING PLAN

Dear Colleague:

This is a reminder that if your IRB has determined that this NHBLI funded grant poses greater than minimal risk to human subjects, you must address your compliance with the IRB approved Data and Safety Monitoring Plan (DSMP) in your upcoming annual progre ss report.

The NHLBI updated its Data and Safety Monitoring Policy in October 2011. This policy, accessible via NHLBI's website at http://www.nhlbi.nih.gov/funding/policies/dsmpolicy.htm, require s that Principal Investigators of all clinical trials or clinical research that poses greater than minimal risk to address the following in their annual progress reports:

Requirements for reporting.

1. Adherence to the DSM plan.
2. A summary of any DSM issues that have occurred during the previous year.
3. Any changes in the human subjects research or to the DSM plan that affect risk. Modifications to the human subjects research or DSM plan should be submitted to the NHLBI GMO or CO prior to implementation of the change in study practice.
4. New and continuing IRB approvals.

The responsibility for human subjects protections for projects performed under grants issued by the NIH resides with the institutions and investigators. The NHLBI, as the funding sponsor, is responsible for ensuring that appropriate plans and reporting mechanisms are in place and implemented. We appreciate the assistance of investigators and their business offices in complying with this policy.

Roles of the grantee and the sponsor.

Sincerely yours,

FINANCIAL CONFLICT OF INTEREST

A New Financial Conflict of Interest (FCOI) ID # ███ report has been successfully received through the eRA Commons for the above referenced grant. The information provided will be evaluated by professional and scientific staff to determine whether an Institutions actions are sufficient to manage the identified FCOI. The agency will follow-up when additional information is needed to complete the review and/or address specific questions, if necessary. If additional information is required, the status of the FCOI record will change to a Work in Progress (WIP), which will allow the Institution to submit the additional information.

Please remember that for any FCOI previously reported by the Institution, the Institution shall provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists.

Additional information on the FCOI reporting Requirements can be found in Section "H. Reporting Requirements" of the Frequently Asked Question document posted on the Office of Extramural Research - Financial Conflict of Interest webpage found at here.

* Note - FCOI ID will be FCOI Family ID for 2011 reg. FCOIs

Please access the eRA Commons at http://public.era.nih.gov/commons/

Document the compliance section of the award file with notification.

ANNUAL FCOI NOTICE

A New Financial Conflict of Interest (FCOI) ID # ▮▮▮ report has been successfully received through the eRA Commons for the above referenced grant. The information provided will be evaluated by professional and scientific staff to determine whether an Institutions actions are sufficient to manage the identified FCOI. The agency will follow-up when additional information is needed to complete the review and/or address specific questions, if necessary. If additional information is required, the status of the FCOI record will change to a Work in Progress (WIP), which will allow the Institution to submit the additional information.

Please remember that for any FCOI previously reported by the Institution, the Institution shall provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists.

Additional information on the FCOI reporting Requirements can be found in Section "H. Reporting Requirements" of the Frequently Asked Question document posted on the Office of Extramural Research - Financial Conflict of Interest webpage found at here.

* Note - FCOI ID will be FCOI Family ID for 2011 reg. FCOIs

Please access the eRA Commons at http://public.era.nih.gov/commons/

Document the compliance section of the award file with notification.

RESEARCH PROGRAM PROGRESS REPORTS

era-notify@mail.nih.gov <era-notify@mail.nih.gov>   Fri, Apr 1, 2016 at 2:34 PM
Reply-To: commons@od.nih.gov
To: ▇▇▇▇@mail.sdsu.edu, awards@foundation.sdsu.edu
Cc: rcsd@foundation.sdsu.edu

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

Gulizia, Rick has submitted RPPR for Grant R25AG▇▇▇▇-04 associated with Program Director/Principal
Investigator ▇▇▇▇▇▇ and may now be viewed in the eRA Commons by going to Status, executing
a query for the grant and selecting link associated with the Grant Number.

For any further questions about this email, call the eRA Service Desk at 1-866-504-9552 or refer to
http://grants.nih.gov/support for additional methods of contact. Please access Commons at
http://public.era.nih.gov/commons/.
For more information please visit http://era.nih.gov/

Research Program Progress Reports must be
submitted and approved prior to follow on
funding being awarded.

ADDITIONAL MATERIALS REQUIRED

era-notify@mail.nih.gov <era-notify@mail.nih.gov>   Fri, Mar 18, 2016 at 11:00 AM
Reply-To: commons@od.nih.gov
To: awards@foundation.sdsu.edu, ███████@mail.sdsu.edu

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

███████ has completed processing PRAM for Grant 5R01NR█████-03 and has forwarded it to you. Please review the PRAM in the NIH eRA Commons system and take the appropriate action for its eventual submission to the NIH. Please use the link provided below to access the eRA Commons login screen.

If you have any questions about this email, please contact ███████ at ███████@MAIL.SDSU.EDU, who initiated this action.

For any further questions about this email, call the eRA Service Desk at 1-866-504-9552 or refer to http://grants.nih.gov/support for additional methods of contact. Please access Commons at http://public.era.nih.gov/commons/.
For more information please visit http://era.nih.gov/

PRAM = Progress Report Additional Materials. Action must be taken (review), before the progress report will be accepted.

FINAL PROGRESS REPORTS

era-notify@mail.nih.gov <era-notify@mail.nih.gov>   Tue, Apr 5, 2016 at 12:42 PM
Reply-To: eraNotifications@mail.nih.gov
To: ▮▮▮▮▮▮ @mail.sdsu.edu
Cc: HLeRANotifications@mail.nih.gov, awards@foundation.sdsu.edu

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

The Final Progress Report has been submitted   ←——— Document the file
                                                             with notification.
to the NIH for Grant 1 R56 HL1▮▮▮▮-01A1

in the eRA Commons by .

You may access this documentation in eRA Commons by going to Status, executing a query for the grant and
selecting link associated with the Grant Number.

For any further questions about this email, call the eRA Help Desk at 1-866-504-9552 or refer to
http://grants.nih.gov/support for additional methods of contact. Please access Commons at
http://public.era.nih.gov/commons/.
For more information please visit http://era.nih.gov/

CHECKLIST FOR COMPLETION

Dear Signing Official:

The above referenced grant ended on 03/31/2016. As reflected in the terms and conditions attached to the final Notice of Award, NIH grant closeout policy requires the submission of three final reports no later than 120 calendar days after termination of the grant.

The following documents must be submitted no later than 07/29/2016.

X Final Federal Financial Report (Final FFR) - The grantee organization business office is responsible for the completion and submission of this document. NIH requires submission of the final FFR via the eRA Commons at https://commons.era.nih.gov/commons. The final FFR must indicate the exact balance of unobligated funds and may not reflect unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and FFR cash transaction data in the Payment Management System (PMS). It is the recipient's responsibility to reconcile reports submitted to PMS and to the NIH awarding IC. NIH will reject the Final expenditure FFR if the Federal share of expenditures reported on it do not match the net cash disbursements reported in the last PMS quarterly cash disbursement report.

X Final Progress Report (FPR) - A FPR is required. There is no standard form or template for this report; however, all final progress reports submitted electronically must be submitted as Adobe Portable Document Format (PDF) files. Specific details regarding Final Progress Report requirements are located in Section 8.6.2 of the NIH Grants Policy Statement at http://grants.nih.gov/grants/policy/#gps.htm

> No specific format, but must use Adobe PDF.

X Final Invention Statement (HHS 568) - The Final Invention Statement form is located at http://grants.nih.gov/grants/forms.htm

> Negative report must be filed.

All final Federal Financial Report expenditure data, if applicable, must be submitted through the eRA Commons at https://commons.era.nih.gov/commons. All non-financial closeout documents (the Final Progress Report and the Final Invention Statement, if applicable) may be submitted through the eRA Commons or at the address below.

> Two submission options for non-financial reporting.

Thank you for your attention in fulfilling your organization's grant closeout requirements. Should you have any questions, please contact me at the address below.

READ AND REVIEW

http://grants.nih.gov/policy/nihgps/index.htm

OIG Hotline Information

OIG Hotline Information:

- The HHS Inspector General maintains a toll-free hotline for receiving information concerning fraud, waste or abuse under grants and cooperative agreements. Such reports are kept confidential and callers may decline to give their names if the choose to remain anonymous:

Office of Inspector General

Department of Health and Human Services

Attn: HOTLINE

PO Box 23489

Washington, DC 20026

Telephone Number: 1-800-447-8477 (1-800-HHS-TIPS)

E-mail: HHSTips@oig.hhs.gov

Web Address: http://oig.hhs.gov/fraud/hotline/