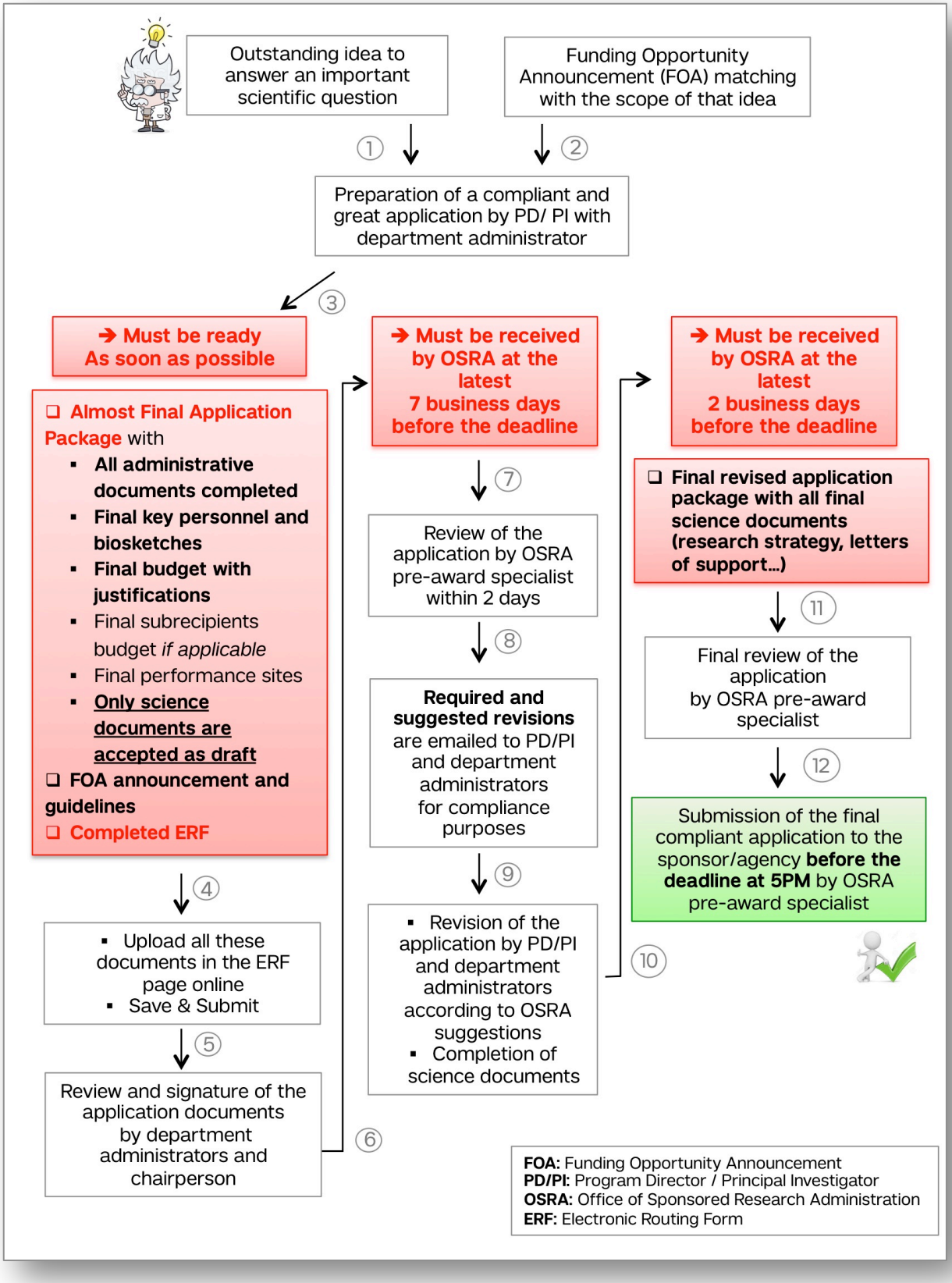
F32 Fellowship Application to the NRSA Guide 101

Weill Cornell Medicine

Disclaimer:

The Office for Education and Training in Research Administration (OETRA) at Weill Cornell Medicine has generated this guide. This document is updated as of ***November 18th, 2015****. The users of that document are* ***responsible*** *for verifying that at the time of their application, the Funding Opportunity Announcement (FOA) strictly follows these guidelines. Each FOA always has its own specific requirements and the NIH may change or modify application guidelines and regulations after November 18th, 2015.*

I. Grant Application Process and Time Line at Weill Cornell Medicine



II. Preparation of a Compliant F32 Fellowship Application at the NRSA

1- Before You Start an F32 Application at the NRSA

A- Important Considerations for F32 Applications

- ☐ **F32** is an **Individual Postdoctoral Fellowship** from the NIH Ruth L. Kirschstein National Research Service Award (**NRSA**).
- ☐ Trainees Sponsorship is a **Training Award for career development** **not a Research Award for research needs.**

- ☐ **F32** support promising applicants during their mentored postdoctoral training under the guidance of outstanding faculty sponsors.
- ☐ The applicant must show evidence of **high academic performance** in the sciences and **commitment** to a career as an independent researcher.
- ☐ The program of research and training that are proposed should **enhance the individual's potential to develop into a productive, independent researcher.**

- ☐ F32 fellowship applicants need to be supported by:
  - **One or multiple mentors**: they are called **sponsor(s)** throughout the application.
  - **Referees**: they have to provide reference letters through an independent system of submission.

- ☐ The **major considerations** for review of the application are:
  - **Candidate's potential for a productive career.**
  - **Relevance of training priorities.**
  - **Characteristics of the sponsor(s) and of the environment.**
  - **Availability of funds for research.**

- ☐ All fellows are required to pursue their research training **full-time**. Part-time training will be considered upon written request with supporting documents.

- ☐ The NIH encourages applications from individuals sufficiently **early** in their postdoctoral training period.

- ☐ **Dates of submission each year:**
  - ☐ April 8th: Cycle 1
  - ☐ August 8th: Cycle 2
  - ☐ December 8th: Cycle 3

B- Applicants' Eligibility

- ☐ **Doctoral Degree:** For an F32 postdoctoral fellowship to be activated, the applicant must have received PhD, MD, DO, DC, DDS, DVM, OD, DPM, ScD, EngD, DrPH, DNSc, ND, PharmD, DSW, PsyD or equivalent doctoral degree from an accredited domestic or foreign institution.

- ☐ **Citizenship Status:** Applicants must be US Citizen, non-citizen national of US or permanent resident of the US at the time the fellowship starts.

- ☐ Applicants can only receive up to 3 years of aggregate Kirschstein-NRSA support at the post doctorate level. That includes any combination of support from institutional training grant and individual fellowship award. If an applicant was on a T32 grant for one year, then that applicant could only request 2 years of support by a F32 fellowship.

- ☐ Applicants must be registered in **eRA Commons with the "PD/PI role"**. To set up an applicant's eRA Commons account with the PD/PI role, contact OSRA at grantsandcontracts@med.cornell.edu.

- ☐ Applicants cannot hold an employee position with the Federal Government at the time the fellowship starts.

- ☐ Applicants cannot have **2 NRSA fellowship applications pending for review at the same time.**

- ☐ **Multiple PD/PI** status is not authorized.

C- About the SF 424(R&R) form

- ☐ The SF 424(R&R) is the Standard Form 424 (Research & Related). This is the grant application package to the NIH that needs to be filled in.

- ☐ The Program announcement for F32 Fellowship applications is located at http://grants.nih.gov/grants/guide/pa-files/PA-14-149.html
  READ IN DETAILS!

☐ How To Get the SF 424 (R&R) Form relevant to your F32 application?

- ☐ Online, on the PA for the F32 fellowship page http://grants.nih.gov/grants/guide/pa-files/PA-14-149.html, there is a section "**Required Application Instructions**" where it is explained that there are several options to submit the application to the agency through Grants.gov.

- **1-** You can use the ASSIST system to prepare, submit and track your application online. You can download an application package from Grants.gov.
- **2-** You can complete the forms offline, submit the completed forms to Grants.gov and track your application in eRA Commons.
- **3-** Or, you can use other institutional system-to-system solutions to prepare and submit your application to Grants.gov and track your application in eRA Commons.
- You can then choose below between two active buttons:
  - " Apply Online Using Assist"
  - "Apply Using Downloadable Forms"

☐ When you select "**Apply Using Downloadable Forms**", a new page opens up with the title "Important Note for All Applicants". At the bottom of that page, click on " **Proceed to Grants.gov to Download Application**".

☐ A new page opens up with the title "View Grant Opportunity" under the icon "Application Package". At the bottom of this page, there is a table with columns presenting the following titles:
CFDA / Competition ID / Competition Title / Open Date / Close Date / Actions.
In the "Action" column, click on " **Select Application Package to Download**" (Bottom right).

☐ You will be asked to give your email address and to submit.

☐ A new page opens up with the title "View Grant Opportunity" under the Icon "Application Package". You should then:

1. **Download Application Instruction**: Click and get the instructions.
2. **Download Application Package**: Click and get the FORM-C of the SF424(R&R) specific to your FOA: Usually the title of that document is" oppNAME OF THE FOA-cidFORMS-C.pdf":

☐ When you open up the specific SF424(R&R) Form C related to your F32 fellowship application, which is your **application package to the NIH**, multiple fields are already populated.

- **Opportunity title**
- **Offering Agency**
- **Opportunity Number**
- **Competition ID**
- **Opportunity Open Date**
- **Opportunity Close Date**
- **Agency Contact**

☐ This SF424(R&R) Form C that has just been downloaded is SPECIFIC to your F32 and cannot be used to apply to another FOA!

☐ BASIC ORGANIZATION OF THE SF424(R&R) FORM

- ☐ **A list of mandatory sections** (page 1), these sections are already included in the SF424(R&R) PDF document after the section "Instructions". Each section needs to be filled in and attachments uploaded.
- ☐ **A list of optional sections** (page 1) that **must be selected appropriately depending on the project characteristics. As a result,** each selected section opens up in the application package. Each section needs to be filled in and attachments uploaded.
- ☐ An "**Instructions**" section provides additional guidelines for compliance (page 1).
- ☐ A series of sections to be filled in and attachments uploaded.
- ☐ Be careful, **NOT ONLY the yellow boxes outlined in red must be filled in!**

- ☐ Follow the specific requirements of the F32 application, specially the Section IV "Application and Submission Information".

- ☐ Carefully follow the instructions in the SF424(R&R) Application Guide available at http://grants.nih.gov/grants/funding/424/index.htm#inst

- ☐ If the SF424(R&R) application guidelines and F32 instructions conflict: the instructions of the **F32 instructions always supersedes.**

- ☐ The SF424(R&R) form requires a Grants.gov-compatible version of Adobe Reader software. The compatibility can be checked at http://www.grants.gov/web/grants/applicants/adobe-software-compatibility.html.

D- Relevant Resources

- ☐ **General NIH F Kiosk for Fellowships:** https://researchtraining.nih.gov/programs/fellowships
- ☐ **F32 Parent Announcement PA-14-149:** http://grants.nih.gov/grants/guide/pa-files/PA-14-149.html
- ☐ **General NIH Grants Policy Statement for Fellowships:** http://grants.nih.gov/grants/policy/nihgps/HTML5/section_11/11.2_individual_fellowships.htm#
- ☐ **General SF 424 Guide for General Applications:** http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf
- ☐ **SF 424 guide for Fellowships:** http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_Fellowship_VerC.pdf
- ☐ **Frequent Asked Questions by Post Doctorates:** http://www.nigms.nih.gov/training/indivpostdoc/pages/PostdocFellowsFAQ.aspx#20
- ☐ **US Department of Health and Human Services Public Health Service (DHHS-PHS), Supplemental Grant Application Instructions http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf**

E- Formatting Rules for PDF attachments

- ☐ Specific requirements may apply to your application- ALWAYS CHECK YOUR FOA GUIDELINES!
- ☐ Prepare ALL PDF documents to be attached to the application using **black font color**, **size 11 points or larger with** the following recommended fonts: **Arial, Helvetica, Palatino Linotype, or Georgia.** For applications submitted for due dates on or after May 25, 2016 the fonts Garamond, Times New Roman and Verdana can also be used.
- ☐ For **figures, graphs, diagrams, charts, tables and figure legends:** Colors can be used in figures and a smaller type size than 11 points can be used but all text must be in a **black** font color, clear, legible, and follow the font typeface requirement.
- ☐ PDF converters usually reduce font sizes, so it is important that each final PDF document, the font is **at least 11 points** and that the type density is **no more than 15 (characters + spaces) per linear inch** and **no more than six lines per vertical inch**.
- ☐ The final PDF document should have at least **one-half inch margins** (top, bottom, left, and right) for all pages.
- ☐ Do **NOT** include any information in the margins, header or footer, **not even page numbers**.
- ☐ The final size of the PDF must be 8.5 inch x 11 inch.
- ☐ For PDF documents' titles:
  - **USE ONLY A-Z, a-z, 1-9,- and _ .**
  - **DO NOT USE** ampersand **&, parenthesis, comma, more than 1 space between 2 characters, or more than 50 characters.**
- ☐ Use only a one-column format.
- ☐ Disable security with password prior to uploading a PDF to the SF424(R&R). *If you are not the owner of the password-protected file*, print a copy, scan it and upload the scanned file to the SF424(R&R). **PDFs with security features result in submission errors.**
- ☐ ***Tip with electronic signatures:*** if you have any issues with electronic signature, print out the document, sign it and then scan it to get a PDF.
- ☐ Page limitations information for each attachment is available at http://grants.nih.gov/grants/forms_page_limits.htm.

F- eRA Commons

- ☐ The eRA Commons is an online interface where signing officials, principal investigators, trainees and post-docs at institutions/organizations can access and share administrative information relating to research grants.

- ☐ Signing Officials and Principal Investigators from applicant organizations do need an eRA Commons account.

- ☐ The PD/PI(s) (Program Director/Principal Investigator) of the application **must** be registered in eRA Commons **prior to submission to the NIH** at https://era.nih.gov/reg_accounts/register_commons.cfm
- ☐ The **eRA Commons** account stays with each PD/PI throughout her/his career. The same account can be affiliated with multiple institutions.
- ☐ **PD/PIs are responsible for keeping their eRA Commons account profile UPDATED and ACCURATE.**
- ☐ All the other key personnel on an application don't have to be registered in eRA commons and to provide their eRA commons ID.

- ☐ When a research administrator needs to have an eRA Commons account set up with the PD/PI role, please contact an OSRA pre-award specialist at grantsandcontracts@med.cornell.edu for support, or email the OSRA pre-award specialist assigned to your department. The updated list of OSRA Departmental Assignments is available at http://osra.weill.cornell.edu/about_us/dept_assign_gco.html.

2- GUIDE FOR THE SF424(R&R) FORM SECTION

NON SCIENCE SECTION DUE 7 BUSINESS DAYS BEFORE THE DEAD LINE

A- Parts to be completed by the Department Administrator

☐ For **all legal information related to WCMC** (**Box 5-6-7-13-14-19**), refer to the parent R01 form available at http://osra.weill.cornell.edu/forms/Grants_Gov_Adobe_Forms_C_WCMC_Template.pdf.

☐ **PLEASE PAY ATTENTION:**

- ☐ Use the last updated Adobe package available on WCMC website. As of July 2015, Grants_gov_Adobe _Forms_C_WCMC_Template is the most current. (This form is **only** to get the appropriate **LEGAL INFORMATION**).
- ☐ Carefully enter the exact same information as stated.
- ☐ Check that there is no additional space after entering any information, as it will result in error.
- ☐ Check that set of numbers in phone numbers are separated with a dash.
- ☐ The organization name is **"Joan & Sanford I Weill Medical College of Cornell University"**.
- ☐ The **DUNS** (Data Universal Numbering System) for WCMC is **0602175020000.**
- ☐ The **EIN (**Employer Identification Number) for WCMC is **13-1623978.**
- ☐ The WCMC email for the Institution Applicant Information is grantsandcontracts@med.cornell.edu
- ☐ The congressional district of applicant is for WCMC: **NY-012.**

☐ The Title of Applicant's Project cannot exceed **200 characters**, including spaces between words and punctuation (**Box 11**).

☐ Make sure that the start and end dates match the dates selected in the budget (**Box 12**). Verify the earliest start date per cycle of submission at http://grants.nih.gov/grants/funding/submissionschedule.htm.

☐ **Estimated Project Funding (Box 15): Do last, after the budget is complete!**

- ☐ Total Federal Funds Requested (Box 15a): enter the total funds requested according to the student's budget once it is completed.

Student's Budget

It can cover stipend at NIH scale, tuition & fees, and standard institutional allowance for the duration of the award.

Stipend: NRSA stipend levels are available at https://www.nhlbi.nih.gov/research/funding/general/nrsa-fund-guide

- ***Tuition & fees*** can be requested by postdoctorates. That can include the costs associated with the specific courses in support of the research training experience and identified in the "Activities planned under this award". At the time of the award, the amount for tuition and fees provided by the NRSA will be 60% of the amount requested up to a cap of $4,500. This formula is for award calculation purposes, but at the time of the application, request the full amount.

  Institutional allowance for post doctorates is of $7,850.00 for FY 2015 according to http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-048.html. Costs for health insurance and for administering fellowships are part of Institutional allowance. A fellow's health insurance is allowable **ONLY** if applied consistently to all individuals in a similar training, regardless of the source of support.

  The final stipend and institutional allowance will be determined at the time of the award.
  NIH does not reimburse indirect costs for fellowships.
  The total budget amount = (Stipend amount /year + Institutional allowance/year + Tuition& Fees/year) x numbers of years requested

- ☐ Total Non-Federal Funds for the project (Box 15b): should be $0.
- ☐ Total Federal & Non-federal funds (Box 15c): should be the same $ amount as in Box 15a.
- ☐ The Estimated Program Income (Box 15d): $0.

☐ **Box 16**: Is the application subject to review by state executive order 12372 process? **Check "NO":** the program is not covered by E.O 12372."

B- Parts to Be Completed by the Applicant Fellow

☐ **Box 17** must be checked **" I agree"** and that **engages the PI's responsibility in case of false, fictitious or fraudulent statements or claims regarding criminal, civil or administrative penalties.**

☐ **The Cover Letter** is **REQUIRED** and **must contain the list of referees** that the applicant will have reference letters submitted.

About the referees and the letters of references:

- ☐ **At least 3 letters of reference** should be submitted for the application but **no more than 5**.
- ☐ **Only the individuals who can make the most meaningful comments about the qualifications of the research career of the applicant should be used.**
- ☐ **The sponsor(s) of the application cannot be counted as reference(s).**
- ☐ The applicant should select **at least one referee** who is **not in her/his current department**.
- ☐ **If not submitting a reference from the dissertation advisor or chief of service, provide an explanation.**

- ☐ **For the referees**, provide their **names, degrees, department affiliations and institution of affiliation.**
- ☐ **Make sure, the selected referees will provide their reference letter in time, no later than the application receipt due date.**
- ☐ **The reference letters** should be **submitted directly by the referees** and not as part of the electronic application through Grants.gov on the eRA Commons website at https://public.era.nih.gov/commons/public/reference/submitReferenceLetter.do?mode=new
- ☐ Instructions for referees are available in the Individual Fellowship Application Guide SF414(R&R) at http://grants.nih.gov/grants/funding/424/index.htm, in the section 5.4, Part B, "Instructions for Referees".

☐ **The cover letter could also contain** the following information but this is **not a requirement**:

- ☐ Application Title.
- ☐ Funding Opportunity Title: "Ruth L. Kirschstein National Research Service Award (NRSA) Individual Postdoctoral Fellowship (Parent F32)".
- ☐ Request to assign the application to a specific institute and scientific study section.
- ☐ Disciplines involved if multidisciplinary.

☐ *No page limitations for the cover letter.*

3- GUIDE FOR THE PHS FELLOWSHIP SUPPLEMENTAL FORM SECTION

A- Section A > Application Type

☐ **VARIOUS TYPES OF APPLICATIONS**

☐ **New Application** = Type 1 = Refers to an application not previously proposed, or one that has not received prior funding. This is a request for financial assistance for a project that is not currently receiving NIH support and must compete for support. A new application is being submitted for the first time.

☐ **Renewal** = Type 2 = A request for additional funding for a period subsequent to that provided by a current award. A renewal application competes with all other applications and must be fully developed as though the applicant is applying for the first time. *Very rare for fellowships.*

☐ **Revision** = Type 3 = A request for an increase in support in a current budget period for expansion of the project's approved scope or research protocol. The request may specify budgetary changes required for the remainder of the project period as well as for the current budget period. A revision application must have the same title as the currently funded grant. A Type 3 prefix also refers to a request/award for a non-competing administrative supplement. *Very rare for fellowships.*

☐ **Resubmission**. An unfunded application that the applicant has modified following initial review and resubmitted for new consideration. Before a resubmission application can be submitted, the PD/PI must have received the summary statement from the previous review. **A resubmission application may be submitted for any of the three preceding types of applications.**

☐ **Non-Competing Continuation Progress Report** =Type 5 = A non-competing progress report is required to continue support of a PHS (Public Health Service) grant for the second or subsequent budget period within an approved competitive segment. A Research Performance Progress Report is used.

B- Section B > Research Training Plan

❖ It is **strongly recommended** that fellowship applicants and sponsors speak with a PHS (Public Health Service) program official (PO) for Institute or Center (IC) specific guidance before preparing their application. A list of contacts can be found at http://grants.nih.gov/grants/guide/contacts/parent_F32.html. **Applicants should send their biosketch and the specific aims of the research proposal to discuss the application and the best strategies to follow.**

❖ **The Research Training Plan should be developed in collaboration with the sponsor(s) and written by the fellow applicant.**

☐ Introduction to Application (Box 1)

- ☐ Only for resubmission application.
- ☐ Includes responses to previously raised issues and summary of substantial additions, deletions and changes made to the previous application.
- ☐ *Limit to 1 page.*

☐ Specific Aims (Box 2)

- ☐ **The MOST IMPORTANT part of the application: Polish it!**
- ☐ State concisely the goals of the proposed research.
- ☐ Detail for each goal, specific objectives organized around testing a hypothesis and solving a specific problem.
- ☐ Summarize the expected outcome(s) including impact in the field.
- ☐ *Limit to 1 page.*
- ☐ *Science document due 2 business days before the deadline to OSRA.*

☐ Research Strategy (Box 3)

- ☐ The applicant **must describe** a well-defined research project (typically hypothesis-driven) that is well-suited to her/his stage of career development.
- ☐ The applicant **should describe** the **background** leading to the proposed research, the **significance** of the research (importance of the problem and how the proposed project will improve scientific knowledge), the **proposed approach** (design and methods) for achieving the stated specific aims stated, the rationale for the proposed approach, potential pitfalls, and expected/alternative outcomes of the proposed studies.
- ☐ It may be beneficial to include **pertinent preliminary data** to demonstrate feasibility.
- ☐ There is no section "Innovation", unless specified in the FOA but the applicant may want to infuse a **sense of novelty throughout the research strategy**.
- ☐ *Limit to 6 pages.*
- ☐ *Science document due 2 business days before the deadline to OSRA.*

☐ **Progress report Publication List**: **(Box 4)** Only for **renewal applications,** which are very **rare**.

☐ Human Subjects

➢ **If human subjects are included in the research project, the 3 following documents must be uploaded:**

☐ 1- The **Protection of Human Subjects** document (**Box 8**). Several descriptions and justifications must be detailed in that document. For a complete and detailed list, refer to the section **4.1** "Protection of Human Subjects" of the US DHHS- PHS Supplemental Grant Application Instructions available at http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf

☐ *Science documents due 2 business days before the deadline to OSRA.*

☐ 2- The **Inclusion of Women and Minorities** document (**Box 9**): Four points must be addressed at the minimum:

- ***1-*** *Planned distribution of subjects by sex/gender, race and ethnicity for each proposed study and a completed table of the Planned Enrollment Report.*
- ***2****-Description of the subject selection criteria and rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design.*
- ***3****- Compelling rationale for proposed sample specifically addressing exclusion of any sex/gender, racial or ethnic group of the population under study.*
- ***4****- Description of the proposed outreach programs for recruiting sex/gender, racial and ethnic group members as subjects.*
- For more details please refer to the section 4.2 "Inclusion of Women and Minorities"" of the US DHHS- PHS Supplemental Grant Application Instructions available at http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf
- If not applicable to the study, only state "not applicable" after a heading entitled "Inclusion of Women and Minorities".

☐ *Science documents due 2 business days before the deadline to OSRA.*

☐ 3- The **Inclusion of Children** document (**Box 10**): A child is defined in the NIH guidelines as an individual under the age of 21 years old. For grant applications due on or after 01-25-16, children are defined as individuals under 18 years old instead.

- Provide a description of the plans to include children, with the age ranges to be included and the rationale for selecting that specific range, and if children are excluded, a justification for the exclusion.
- A description of the expertise of the investigative team for working with the children included in the study should be addressed.
- Additional Protections for Children Involved as subjects in Research apply (45 CFR part 46 subpart D).
- For more details please refer to the section 4.4 "Inclusion of Children" of the US DHHS- PHS Supplemental Grant Application Instructions available at http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf
- If not applicable to the study, only state "not applicable" after a heading entitled "Inclusion of Children".

☐ *Science documents due 2 business days before the deadline to OSRA.*

☐ Other Research Training Plan Sections

- **Only if** the research project includes **Vertebrate Animals**

The Vertebrate Animals document must cover the following **five topics** (Box 12):

- ☐ Provide a detailed **description of the proposed use of the animals** in the work outlined in the "Research Strategy" section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
- ☐ **Justify** the use of animal, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
- ☐ Provide information on the **veterinary care** of the animals involved.
- ☐ Describe the **procedures** for ensuring that **discomfort, distress, pain, and injury** will be limited to that which is unavoidable in the conduct of scientifically sound research.
- ☐ Describe the **use of analgesic, anesthetic, and tranquilizing drugs** and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury. It must be stated whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia.

☐ *Science document due 2 Business days before the deadline to OSRA*

- **Only if a Select Agent** (i.e. **hazardous biological agents and/or toxins)** is included in the project

The Select Agent Research document **must** cover the following **three topics** (Box 13):

- ☐ **Identify** the select agent(s).
- ☐ Provide the **registration status** of any legal entity where the research with the select agent will be performed.
- ☐ Detail the **safety** and **monitoring procedures** that will be performed.

☐ *Science Document due 2 Business days before the deadline to OSRA*

- **Resource Sharing Plan (Box 14)**

It adds value to the application to demonstrate how the research resources developed will be made available to the scientific community (Box 14). This document is **highly recommended** to be included when the development of model organisms is anticipated and large-scale human and non-human genome data are expected to be generated.

☐ *Science document due 2 business days before the deadline to OSRA*

- **Respective Contributions (Box 15)**

Describe the **collaborative process between the applicant and the sponsor(s)/ co-sponsor(s) in the development, review and editing of the research training plan**. Discuss the respective roles in accomplishing the proposed research. *Limit to 1 page.*

☐ *Science document due 2 business days before the deadline to OSRA*

➢ Selection of Sponsor and Institution (Box 16)

Explain the **rationale for the selection of the sponsor(s) and institution**. When postdoctoral fellowship applicants request training at either their doctorate institution or at the institution where they have been trained for more than one year, they must explain why further training would be **valuable** at this institution. *Limit to 1 page.*

- ☐ *Science document due 2 business days before the deadline to OSRA*

➢ Responsible Conduct of Research (Box 17)

All applications **MUST** include a plan to fulfill **NIH requirements for Instruction in the Responsible Conduct of Research (RCR).**

- ☐ The plan must address the five, required instructional components outlined in the NIH policy:
    1. *Format:* the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with **only on-line instruction is *not acceptable***).
    2. *Subject Matter:* the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics.
    3. *Faculty Participation:* the role of the mentor(s) and other faculty involvement in the instruction.
    4. *Duration of Instruction:* the total number of contact hours of instruction.
    5. Frequency *of Instruction:* instruction must occur ***during each career stage*** and ***at least once every four years***.
- ☐ Applicants should document any prior instruction during the applicant's current career stage, including the inclusive dates instruction was last completed or when you plan to take a refresher if more than 4 years have lapsed since you last took the course.
- ☐ Refer to NOT-OD-10-019 for more details on RCR requirements at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html
- ☐ Applications lacking a plan for Instruction in the Responsible Conduct of Research **will not be reviewed.**

- ☐ WCMC offers an RCR course. Contact the RCR course Co-Director, Helene Brazier-Mitouart PhD, Research Administration Department at heb2020@med.cornell.edu for more information.
- ☐ *Limit to 1 page.*
- ☐ *Science document due 2 business days before the deadline to OSRA*

C- Section C > Additional Information

- Human Embryonic Stem Cells -

- The **Human Embryonic Stem Cells** is checked YES or NO (Box 5).

- If Yes, the NIH registration number for the Stem Cells must be indicated. If the cell line is not listed at the time of submission on http://stemcells.nih.gov/research/registry/ or on http://grants.nih.gov/stem_cells/registry/current.htm, check " Specific stem cell line cannot be referenced at this time".

- Fellowship Applicant -

☐ **Goals for fellowship training and career:** The fellowship applicant must:
- ☐ Describe her/his overall career goals.
- ☐ Explain how the proposed research project and activities **enhance** her/his development and enable her/him to become a **productive, independent research scientist.**
- ☐ Detail how the proposed research training plan will enhance her/his knowledge, technical and professional skills, and facilitate her/his transition to the next career stage.
- ☐ *Limit to 1 page.*
- ☐ *Science document due 2 business days before the deadline to OSRA*

☐ **Activities planned under this award**:
- ☐ Training activities planned under this award should be well integrated with the research project.
- ☐ Describe the skills and techniques that the applicant intends to learn through courses and the non-research activities related to professional development. Development of skills for grant writing, presentation, and lab management are strongly encouraged. Briefly explain how these activities relate to the proposed research training.
- ☐ The applicant should include her/his participation to conferences (no more than two per year).
- ☐ The applicant should provide a timeline for the proposed research training and related activities by year with an estimate of the percentage of time to be devoted to each activity.
- ☐ *Limit to 1 page.*
- ☐ *Science document due 2 business days before the deadline to OSRA*

☐ **Doctoral Dissertation and Other Research Experience:** The fellowship applicant should **summarize** her/his research experience in **chronological order**. Postdoctoral should include the areas studied and conclusions drawn, as well as areas of research part of their thesis and previous postdoctoral project if applicable.
- ☐ *Limit to 2 pages.*
- ☐ *Science document due 2 business days before the deadline to OSRA*

☐ **Citizenship**: Select the appropriate option.

D- Section D > Sponsor(s) and Co-Sponsor(s)

- ☐ This document **has to be provided by the Sponsor(s) and Co-Sponsor(s) to the applicant.**

- ☐ The heading of the document must be " **Section II- Sponsor and Co-Sponsor Information**". The F32 fellowship supports a program of mentored research training from **outstanding faculty sponsors**.
- ☐ The following sections should be covered:
  - ☐ Availability of sufficient research funds for the applicant.
  - ☐ Sponsor/Co-Sponsor's previous fellows/trainees.
  - ☐ Training Plan, environment and high quality research facilities that can train the applicant.
  - ☐ Number of fellows and trainees to be supervised.
  - ☐ Assessment of the applicant's qualifications and potential for a career as **a productive and independent researcher (Evaluation from the sponsor(s)).**
  - ☐ **Role of the sponsor(s)** in the integrated research and training plan.
  - ☐ *If a team of sponsors is proposed*, one individual must be identified as the primary sponsor who will coordinate the applicant's research and training program. A plan should describe the role of each sponsor and how they will communicate and coordinate their efforts to mentor the applicant effectively.
  - ☐ A contingency plan to describes how the applicant's research training will be supported **should there be a gap in the sponsor's funding during the proposed award period.**
  - ☐ *Limit to 6 pages.*
  - ☐ *Science document due 2 business days before the deadline to OSRA*

E- Section E > Budget

- ☐ All fellowship applicants should list here ONLY the estimated costs of tuition and fees. Postdoctorates applying to F32 **can then list in that section the costs associated with the courses planned to support the research training experience** and that are identified in the section "**Activities Planned Under this Award**". At the time of the award, the amount for tuition and fees provided by the NRSA will be 60% of the amount requested up to a cap of $4,500. This formula is for award calculation purposes, but at the time of the application, request the full amount.

  - ☐ **Reminder:** Applicants can only receive up to 3 years of aggregate Kirschstein-NRSA support at the post doctorate level. That includes any combination of support from institutional training grant and individual fellowship award. If an applicant was on a T32 grant for one year, then that applicant could only request 2 years of support by a F32 fellowship.
  - ☐ **Note :** The stipend level for the 1st year of support depends on the number of full years of relevant post doctorate experience.
  - ☐ *Non science document due 7 business days before the deadline to OSRA*

F- Section F > Appendix

- ☐ **A maximum of 10 PDF attachments** is allowed in the Appendix, but **don't assume they will be read!**
- ☐ **No more than 3** of the following items **can be submitted**:
  - ☐ Manuscripts and/or abstracts already **accepted but not published yet**.
  - ☐ Manuscripts and/or abstracts that are published but a free, online, publicly available journal link is not available.
  - ☐ Patents directly relevant to the project.

- ☐ **Must not be included**:
  - ☐ **Publications publicly available**
  - ☐ **Unpublished theses or abstracts/manuscripts submitted but not yet accepted**.

- ☐ *Science document due 2 business days before the deadline to OSRA*

4- GUIDE FOR THE RESEARCH AND RELATED SENIOR/KEY PERSON PROFILE (EXPANDED) SECTION

☐ *Non science section due 7 business days before the deadline to OSRA*

☐ **Project Director/ Principal Investigator**: This is the **fellow applicant**.

- ☐ The applicant's eRA commons ID must be entered in the box " Credential, e.g., agency login".
- ☐ The applicant's eRA commons ID should be associated with a PD/PI status. Contact Grants& Contracts Office at WCMC to update the profile of the applicant if necessary at grantsandcontracts@med.cornell.edu.

- ☐ The biographical sketch must follow the new NIH guidelines. Specifically for fellows, the **4 sections** to complete are:
  - **A. Personal Statement**
  - **B. Positions and Honors**
  - **C. Contributions to Science**
  - **D. Scholastic Performance**

- ☐ General NIH Guidelines:
  - No more than 5 "contribution to science" areas **and** no more than half a page each.
  - No more than 4 publications per "Contributions to Science" section, each publication must have its PMCID (PubMed Central reference Number) if published after April 7th, 2008.
  - It is **highly recommended** to provide the link for a government website for the **"Complete list of published work in my Bibliography"** at the end of the "Contribution to Science" Section, such as My Bibliography.
  - Graphics, figures and tables are **not allowed**.
  - Limit to 5 pages.

- ☐ You can refer to the document 1 in this guide for a NIH Biosketch sample or download it at http://grants.nih.gov/grants/funding/424/postdocfellowbiosketchsample.docx
- ☐ Do not include transcripts of the diplomas obtained.

☐ **Senior/Key Person**: this section is for the sponsor(s) of the fellow and other key personnel.

- ☐ ***Choice of the sponsor(s):***
  - The applicant must identify a sponsor(s) who will mentor and supervise her/his training and research experience.
  - The primary sponsor should be an outstanding faculty investigator in the area of the proposed research training and be committed **both** to the applicant's research training and to the direct supervision of her/his research.

- The sponsor, or a member of the team of sponsors, should have a successful track record of mentoring postdoctoral fellows.
- **Applicants are encouraged to identify more than one sponsor, i.e., a team of sponsors, if this is deemed advantageous for providing expert advice in all aspects of the research and training program.** In such cases, one individual must be identified as the **primary sponsor** who will coordinate the applicant's integrated research and training program.
- **Sponsors must have their** eRA commons ID associated with a "sponsor" status. Make sure all sponsors have their profile updated and contact grantsandcontracts@med.cornell.edu. If necessary.

☐ ***Biographical sketch*** must follow the new NIH guidelines. The 4 sections to complete are

- **A. Personal Statement**
- **B. Positions and Honors**
- **C. Contributions to Science**
- **D. Research Support**.

The general guidelines provided above for the PD/PI's biosketch apply as well. In addition:

- Within the "Research Support" section, no percent effort or direct costs amounts should be provided.
- If the investigator has no active or completed research support, indicate under the "Research Support" section heading "None to report".
- You can refer to the document 1 in that guide for a NIH Biosketch sample or download it at http://grants.nih.gov/grants/funding/424/postdocfellowbiosketchsample.docx

5- GUIDE FOR THE RESEARCH AND RELATED OTHER PROJECT INFORMATION SECTION

☐ If the research project involves **Human Subjects:** Check **Yes** (Box 1).
- ☐ Provide the answers related to Federal regulations.
- ☐ Always choose IRB review "Pending".
- ☐ **Human Subject Federal Wide Assurance Number for WCMC: 00000093** (until February 9, 2019).

☐ If the research project involves **Vertebrate Animals**: Check **Yes** (Box 2).
- ☐ Always choose IACUC review "Pending".
- ☐ **Animal Welfare Federal Wide Assurance Number: A3290-01** (until January 31, 2016).

☐ **Project Summary/Abstract** (Box 7): Summary of the proposed project for **dissemination to the public**. The applicant should describe concisely the research training plan. That abstract should also contain **a statement of objectives** and **methods** of the research project. **No confidential information** should be included as that summary falls under the Public Access Policy. *Limit to 30 lines.*
- ☐ *Science document due 2 business days before the deadline to OSRA*

☐ **Project Narrative** (Box 8): Describe the **relevance of the research to public health**. *Limit to 2 or 3 sentences.*
- ☐ *Science document due 2 business days before the deadline to OSRA*

☐ **Bibliography & References Cited** (Box 9): Include all the references cited in the Research Strategy. Include **PMCID** for each reference of articles published after April 7th, 2008. **Be relevant, pertinent and concise with the references**. *No page limitations.*
- ☐ *Science document due 2 business days before the deadline to OSRA*

☐ **Facilities & Other Resources** (Box 10): Description of the facilities available to the candidate (Laboratory, Animal Facilities, Computers, Office, Clinical and Other) and the resources applicable to the proposed work. Indicate their capacities, relative proximity and availability to the project in order to demonstrate how the scientific environment in which the research will be done, contributes to the feasibility of the projects and probability of success. *No page limitations.*
- ☐ *Non science document due 7 business days before the deadline to OSRA*

☐ **Equipment** (Box 11): List major items of equipment already available for the project and if appropriate identify location and pertinent capabilities. *No page limitations.*
- ☐ *Non science document due 7 business days before the deadline to OSRA*

☐ **Other Attachments** (Box 12):

☐ **Letters of support from collaborators and dissertation advisor (not required):**
- These letters are from **people who do not provide a letter of reference.**
- Relevant information of the applicant's planned research training and future goals can be detailed here.
- *No page limitations.*
- *Non science document due 7 business days before the deadline to OSRA*

☐ **It used to be required to provide an "Additional Educational Information" document (**description of the resources available to the applicant). THIS IS NO LONGER REQUIRED (NOT-OD-14-137).

6- GUIDE FOR THE PROJECT PERFORMANCE SITE LOCATIONS SECTION

- **Do not select** the box "I am submitting an application as an individual and not on behalf of a company, state, local or tribe government, academia, or type of organization". The NIH only accepts applications from registered organizations!
- Indicate the information on the primary site and any additional site where the work will be performed.
- All site locations include a 9 digit DUNS (Data Universal Numbering System). The **DUNS** for WCMC is **0602175020000.**
- For Congressional District Foreign site Locations, DUNS is "000000000".
- A 9 digit zip code xxxxx-xxxx is included. Use the USPS tool if necessary: https://tools.usps.com/go/ZipLookupAction!input.action

7- GUIDE FOR THE PLANNED ENROLLMENT REPORT AND PHS 398 CUMULATIVE INCLUSION ENROLLMENT REPORT

☐ Applies only when conducting clinical research with human subjects.
☐ For these sections to appear within the SF424(R&R), the applicant needs to select on page 1, in the optional part " Planned Enrollment Report" and "PHS 3898 Cumulative Enrollment Report".

8- Check these Common Errors Before Submission of the SF 424(R&R) to OSRA Pre-Award

- ☐ General guidelines from the sponsor have not been followed.
- ☐ Incorrect or missing administrative information (e.g. DUNS #, email address, eRA Commons ID).
- ☐ Attachments are not in the PDF format.
- ☐ Required PDF attachment(s) is/are missing.
- ☐ PDF attachments exceed page limitation specified in the FOA and SF424(R&R) application guide.
- ☐ PDF attachments are larger than 8.5 x 11 inch (typically seen in letters of support or appendix).
- ☐ PDF attachments' names include ampersand, comma, more than one space or more than 50 characters.

9-After Completing SF 424(R&R)

- ➢ Run the "Check Package for Errors" feature on the SF424(R&R) located next to the "Save" icon on the first page of the SF424(R&R) form.

- ➢ Appropriately address the errors within the SF424(R&R) document if any detected.

III. PREPARATION OF THE ELECTRONIC ROUTING FORM (ERF)

A- First Time Preparing an ERF?

- ☐ Begin by contacting an OSRA pre-award specialist at grantsandcontracts@med.cornell.edu
  - To be added and approved to access the ERF system at: *https://erf.med.cornell.edu/routing/RARFClient/routingClient.html*.
  - To have your account appropriately set up for you to prepare an ERF on behalf of one of your PIs.

- ☐ Make sure that every PI working on an ERF for the first time, complete first the **online course "Research Compliance Training"** accessible at: http://weill.cornell.edu/research_compliance/training/.
  This is required for faculty and post-doctorates.

B- Grant Application Title

- ☐ Use the same exact title as in the grant proposal application.

C- PI Contact

- ☐ PI Name.
- ☐ PI Department/ Division: if you are proxy for multiple PIs, select the corresponding department for the PI.
- ☐ PI Phone: if the pre-populated information is incorrect, you cannot change it. Please make a comment in the top right corner of the ERF page.
- ☐ PI Email.
- ☐ Administrative Contact Name, Phone, Email.
- ☐ If an ERF with multiple investigators is set up, additional PI(s) need to be added in the Section " Weill Cornell Key Personnel" by clicking on "Add Key Personnel". The "Contact PI" for the application should be the main PI initiating the routing form.

D- Project Summary

- ☐ Application Deadline: If non-applicable, insert the start date of the budget period or the date of the ERF submission.
- ☐ Proposed Start/End Date of the project.
- ☐ **Proposal Type**: Select from the drop down menu: New, Continuation, Renewal, Revision, Resubmission (See definitions on page 8 of this guide).

- **Activity Type**: Select from the drop down menu: Grants, Industry Sponsored Research Agreement, Clinical Trial Agreement, Clinical Trial Grant, Registry Service Agreement.

  - **Grant:** A type of financial assistance awarded by one party, often a government department, corporation or foundation to a recipient, often a nonprofit entity, educational institution, business or an individual, for the conduct of research or other program as specified in an approved proposal. A grant is used whenever the awarding office anticipates no substantial programmatic involvement with the recipient during the performance of the activities.

  - **Industry Sponsored Research Agreement**: An industry Sponsored Research Agreement (SRA) is a contract between Weill Cornell Medicine and a industry sponsor for the purposes of funding and conducting research at Weill Cornell Medicine. An industry Sponsored Research Agreement is a legal contract that governs the scope of work, deliverables, funding and intellectual property terms and conditions of basic and applied research and product development at Weill Cornell Medicine sponsored by the industry entity.

  - **Clinical Trial Agreement (CTA):** A CTA is an agreement governing the terms and obligations of all parties during the conduct of a clinical trial. A CTA must be fully executed prior to study activation. Weill Cornell Medicine, New York Presbyterian Hospital and the sponsor are all parties to a CTA.

  - **Clinical Trial Grant:** This is a type of grant dedicated to clinical trials. In a clinical trial, participants receive specific interventions according to the research plan or protocol created by the investigators. These interventions may be medical products, such as drugs or devices; procedures; or changes to participants' behavior, such as diet. The NIH has such grants dedicated to clinical trials such as R34.

  - **Registry Service Agreement:** A Registry Agreement is a contract governing clinical situations, clinical studies or clinical trials in which patients are required to provide informed consent to have their health information recorded in a registry database.

- **Agency Name**: Select from the drop down menu. If the agency name is missing, contact the OSRA pre-award specialist assigned to your department to add the agency name to the list.
- **Agency Grant / Contract Number**: If none, type "N/A".
- **FOA number**: If none, type "N/A".

- Subaward **to**: Add the name and the institution of the subrecipient if applicable.
- Subaward **from**: Add the name and the primary institution if applicable.
- The questions related to Subaward are **not applicable for F32 fellowships.**

E- Budget Details

- ☐ Direct costs for year 1 (or for any year of a grant the ERF applies to).
- ☐ Total Direct Costs
- ☐ **Indirect Cost Rate: does not apply to F32 fellowships application**

F- Weill Cornell Key Personnel

- ☐ **Senior/Key Personnel:** The PD/PI and other individuals who ***contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant.*** Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if their involvement meets this definition. Consultants and those with a post-doctoral role also may be considered senior/key personnel if they meet this definition. ***Senior/key personnel must devote measurable effort to the project whether or not salaries or compensation are requested***. "Zero percent" effort or "as needed" are not acceptable levels of involvement for those designated as Senior/Key Personnel (NIH definition).

- ☐ **Committed Effort**: *For competitive applications*, list 0%. *For non-competitive applications*, list the effort that is committed to the project for the upcoming year.

- ☐ **Proposed Effort:**
  - ☐ For an ERF on year 1 of a grant: the proposed effort should match the effort indicated in the budget's application.
  - ☐ For an ERF associated to any year 1+ of a grant: the proposed effort should match the effort that was committed to the project as per the application.
  - ☐ For non-competing renewals: a reduction of 25% or more in the percent effort requires an NIH prior approval. Contact the Program Officer at the NIH responsible for the FOA.

- ☐ Any reportable **financial conflicts**? (This section **MUST** be completed by each key personnel and cannot be done by a proxy).

  - ☐ **If NO**, the investigator or key personnel does not have a financial interest related to the research.

    - ☐ **If the PI works at Weill Cornell Medicine**
      - Check "No" in the ERF.
      - *What used to be necessary, but is no longer required:*

      - Also check "No" in the "Conflicts Memo for ERF" accessible at: http://researchintegrity.weill.cornell.edu/forms_and_policies/forms/Conflicts_Memo_for_ERF.pdf
      - Then upload that completed Conflicts Memo into the ERF "Miscellaneous Documents" (lower left corner) on the ERF page.

- ☐ **If the PI is external to Weill Cornell Medicine** (in case of a subcontract), the following form must be filled in and uploaded into the ERF "Miscellaneous Documents" (lower left corner): http://researchintegrity.weill.cornell.edu/pdf/conflicts/No_Financial_Interest_to_Disclose.pdf

☐ **If YES**, the investigator or key personnel does have a financial interest related to the research.

- ☐ **If the PI works at Weill Cornell Medicine**,
  - Check "Yes" in the ERF.
  - The conflicted researcher needs to log into the online COI (Conflicts of interest) system to fill out an annual survey and then create an SSR (Study Specific Report) for the project at https://conflicts.med.cornell.edu/COI.
  - The conflicts management office will review the SSR and follow up with the researcher and any related administrative offices as necessary.
  - *The following used to be necessary, but this is no longer a requirement:*
  - Check "Yes" in the Conflicts Memo for ERF" accessible at: http://researchintegrity.weill.cornell.edu/forms_and_policies/forms/Conflicts_Memo_for_ERF.pdf

- ☐ **If the PI is external to Weill Cornell Medicine** (in case of a subcontract)
  - Fill the following form and uploaded into the ERF "Miscellaneous Documents" (lower left corner): http://researchintegrity.weill.cornell.edu/pdf/conflicts/Financial_Interest_to_Disclose.pdf

☐ **Independently of your answer**, it is mandatory that you complete the Conflicts of Interest survey available at the Weill Research Gateway WRG at https://wrg.weill.cornell.edu/

G- Questionnaire

☐ Will you be using the Clinical and Translational Science Center (CTSC)?

☐ Will this project include any work at Weill Cornell Medicine -Qatar and/or involve Weill Cornell Medicine -Qatar personnel?

☐ Will this project require the sharing or export of materials, information, and/or technology outside the United States and/or with foreign nationals (including foreign nationals working in the lab) within the United States?

- ☐ **If YES**, Complete and upload in Additional Documents, the Export Controls Checklist. Form accessible at: http://osra.weill.cornell.edu/forms/ExportControlsChecklist.pdf.
- ☐ For assistance on Export Controls, contact Danielle Gaibor, Senior Manager Business Process Solutions at Weill Cornell Medicine at dag3004@med.cornell.edu.

- ☐ Will institutional/departmental funds be used to support a portion of this project? (i.e. cost sharing?)
  - ☐ **If YES**, Complete and upload in Additional Documents the institution/department funding form accessible at: http://osra.weill.cornell.edu/forms/Cost_Sharing_Form.pdf.

- ☐ Does this require purchase of a network-connected device other than a desktop computer or printer (e.g. server, computational cluster, network-attached laboratory device)?

- ☐ Is it likely that intellectual property will evolve or will change from the scope of work?
  - ☐ *The following used to be required but it does not apply any longer:* If Yes, complete and upload the Scope of work (SOW) form accessible at: http://osra.weill.cornell.edu/forms/Scope_of_Work_Form.pdf.

- ☐ Does your study involve human subjects?
  - ☐ **If YES and this is a new grant submission**: Indicate ***pending*** and action must be initiated by the PI with the IRB office for IRB approval (IRB: Institutional Review Board). For information and assistance with the IRB approval process, contact Rosemary Kraemer, Director of the IRB & Research Integrity at Weill Cornell Medicine at rtkraeme@med.cornell.edu.

  - ☐ **If YES and this is not a new grant submission:** Enter protocol numbers and approval dates obtained with the IRB office at Weill Cornell Medicine.

- ☐ Does your study involve laboratory animals?
  - ☐ **If YES:** Indicate ***pending*** and action must be initiated with IACUC for approval (IACUC: Institutional Animal Care and Use Committee). For information and assistance with the Animal Protocol and IACUC approval process, contact Jennifer Akl, Coordinator of the Institutional Animal Care & Use Committee at Weill Cornell Medicine at jea2012@med.cornell.edu.

- ☐ **Does your research involve work in a research or clinical laboratory?** (*That question will only appear if the ERF PI's profile is not updated or if the PI is not registered in the ERF data base)*

  - ☐ **If the research involves work in a research or clinical laboratory,** upload the Combined Research Safety Checklist (RSC) and Institutional Biosafety Committee (IBC) Laboratory Registration available at http://researchintegrity.weill.cornell.edu/forms_and_policies/forms/research_safety.pdf

    - ☐ Complete the first page to determine if other sections need to be filled in:

    - **For Professor, Associate Professor or Assistant Professor with the status of PI:** If the laboratory is not yet registered to the Institutional Biosafety Committee, **and** if the research is conducted in Weill Cornell owned or leased research facilities (such as New York Presbyterian Hospital, New York Blood

Center or the Hospital for Special Surgery), the rest of the document must be completed.

- **The Environmental Health and Safety (EHS) research safety checklist**. EHS can be contacted at ehs@med.cornell.edu on the following topics:
  - Chemical safety
  - Biological safety
  - Radiation safety
  - Personal protective equipment
  - Laboratory safety
  - Equipment and physical hazard safety
  - Fire and emergency response
  - Hazardous material shipment
  - Waste management

- **The Institutional Biosafety Committee (IBC) laboratory Registration form**. IBC can be contacted at ibc@med.cornell.edu on the following topics (non exhaustive list):
  - Recombinant DNA, synthetic nucleic acids
  - Genetically modified cells or organisms
  - Viral vectors
  - Bacteria, fungi, parasites
  - Select agent or toxins

- **For Research Associates, Instructors, Post doctorates and Students:** it is required to complete the **RSC and IBC Laboratory Registration short Form** accessible at http://researchintegrity.weill.cornell.edu/institutional_biosafety_committee/ibc_forms.html

☐ **If the research involves work in a research or clinical laboratory *AND* the clinical work involves Weill Cornell Medicine-Qatar PIs**, the PI must complete the Qatar Research Risk Assessment Checklist form available at https://redgate.qatarweill.cornell.edu/sites/ehs/Pages/,DanaInfo=redbench.qatarweill.cornell.edu,SSL+Home.aspx

H- Summary of the Documents to upload in the Additional Documents Section

Only the applicable documents should be uploaded:

- ☐ Export Controls Checklist.
- ☐ RSC and IBC forms.
- ☐ Grant Application Package (Details in the next section)

That Section is in the lower left corner of the ERF screen page.

I- Check these Common Errors in the ERF

- ☐ Incorrect agency selected.
- ☐ Incorrect activity type selected.
- ☐ Missing key personnel.
- ☐ IBC forms missing.

IV. GRANT APPLICATION SUBMISSION TO OSRA PRE-AWARD FOR REVIEW

1. ERF AND GRANT APPLICATION PACKAGE SUBMISSION TO OSRA PRE-AWARD

☐ Once the ERF is complete, the **draft of the grant application package must be uploaded to the ERF page in the Miscellaneous Documents,** section "Additional Documents" (lower left corner).

- ☐ The **grant draft application package** contains the documents requested by the sponsor and OSRA pre-award:
  - ☐ FOA announcement and guidelines.
  - ☐ **Grant application package:** Final documents **except science documents that can be draft.**
  - ☐ **All following information must be final**
    - **Final key personnel and final biosketches.**
    - **Final budget with justifications** for Weill Cornell Medicine
- ☐ In case some documents are too heavy to be uploaded on the ERF webpage, please **email all documents of the draft grant application package to your OSRA pre-award specialist** at grantsandcontracts@med.cornell.edu.

☐ Once the draft application package is uploaded to the ERF page, the PI can click on **"Save"** and **"Submit for Review"** (icons on the top left corner). A proxy cannot validate that final submission step.

☐ Once submitted for review, the ERF along with the draft application package will need to be **approved first by the department administrators** before being **reviewed by the OSRA pre-award specialist**.

☐ **OSRA pre-award specialist must received the ERF along with the draft application package at least 7 business days before the sponsor application deadline.**

☐ **Important Notes:**

- ☐ Each person logged in the ERF system **must log out** (and not just close the window) in order to allow other administrators to be able to log in.
- ☐ When the ERF is delayed for signature by **all administrators**, it is advised to print the ERF which allows to track which department administrator or chairperson has yet to approve the ERF.

2. ERF AND GRANT APPLICATION PACKAGE REVIEW BY OSRA PRE-AWARD

☐ Within 2 days after receipt, the OSRA pre-award specialist thoroughly reviews the ERF and the draft application package submitted by the PI.
☐ Detailed comments and notes are emailed back to the PI and department administrator with advised and/or required modifications.
☐ The PI and the department administrator should address OSRA pre-award specialist's comments for compliance of the grant application package as soon as possible.

☐ **2 business days before the agency deadline**, the PI should submit the final reviewed application by email to the OSRA pre-award specialist, which contains:

☐ The non-science documents from the grant application package appropriately revised according to the OSRA pre-award specialist' comments.
☐ All of the final science related documents such as:

- Specific aims.
- Research strategy.
- Resource Sharing Plan.
- Responsible Conduct of Research.
- Goals for fellowship training and career
- Activities Planned under this Award
- PLEASE REFER to the Chapter

☐ Upon receipt of that final package, OSRA pre-award specialist performs a final review to make sure that the grant application in its entirety is compliant with agency's criteria.

☐ **Delay in internal submission to OSRA pre-award:** If the grant application package is **received late** i.e. less than 7 business days before the deadline **and/or** the final grant package is received less than 2 business days before the deadline, please reach out to your OSRA pre-award specialist to inform her/him about the delay, and be aware that only a **cursory review** of the application may be able to be performed as a result of the delay.

V. Grant Application Submission to the Agency by OSRA Pre-Award

- Before submitting the SF424 (R&R) form application, the OSRA pre-award specialist selects the icon "Check Package for Errors" on the SF424 (R&R) form.

- Once the application is properly completed, the " Save and Submit " icon at the top of the SF424(R&R) form becomes active and can be selected by the OSRA pre-award specialist: the final compliant application is submitted in "Grants.gov" on the investigator's behalf under the authority of the AOR (Authorized Organization Representative) of WEILL CORNELL MEDICINE. More information is available at http://osra.weill.cornell.edu/pre_award/institutional_information.html.

- After verification by "Grants.gov", the application is assigned a **tracking number**: GRANTXXXXXXXX.

- The application proceeds through the eRA commons system for additional verification.

A- When no error and no warning are detected in the eRA system

The application is officially submitted to the NIH and the status of the application is updated in the eRA commons to "Submitted".

1. A confirmation email is sent to the PI and to the OSRA pre-award specialist, which can take several minutes to several hours to receive depending upon the number of applications in queue for submission.
2. A grant application compiled image is available on eRA Commons and **MUST** be checked by the PI for any error as soon as possible.
3. If any error is detected and the PI wants to address it, then the application **CAN** be rejected within 2 business days (a justification must be provided in eRA), revised and resubmitted by an OSRA pre-award specialist following the same steps described below.

B- When an error is detected in the eRA system

The PI MUST revise the application to address the error(s).

1. Once revised, the application can be submitted by the OSRA pre-award specialist with the status "Changed" and not "New Application" (Box 1 of the SF424 form). The Grants.gov tracking number from the initial application needs to be included in Box 4c.

2. Upon resubmission, the application will be verified in Grants.gov and in eRA Commons. The final application to the NIH must be compliant and error-free before 5PM on the deadline day.

C- When a warning is detected in the eRA system

It is at the discretion of the PI to address this warning or to process the application as is.

1. The PI can address the warning and the OSRA pre-award specialist will submit the revised application as "Changed" and not as "New Application" (Box 1 of the SF424 form). The Grants.gov tracking number from the initial application needs to be included in Box 4c.
2. Upon resubmission, verification of the application will occur in Grants.gov and in eRA Commons. The final application to the NIH must be compliant and error-free before 5PM on the deadline day.

D- If an application does not obtain the status "no error" before 5PM on the deadline day

The re-submission of the reviewed application will be processed **the next business day** by the OSRA pre-award specialist.

E- NIH policy on late applications

The policy is stated in the SF424 (R&R) and PHS 398 application instructions that can be found at http://grants.nih.gov/grants/forms.htm

- ☐ Permission for a late submission is not granted in advance.
- ☐ In rare cases, late applications will be accepted only when accompanied by a **cover letter** that details compelling reasons for the delay.
- ☐ While the reasons for late submission are sometimes personal in nature, specific information about the timing and cause of the delay should be provided so an informed, objective decision can be made. **Only the explanatory letter is needed; no other documentation is expected**. This letter is available only to NIH staff who have a need to know (such as those with referral or review responsibilities); it is not available to reviewers or other staff.
- ☐ See more at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-035.html

➢ As a general rule, the **earlier** an application is submitted before the deadline, the **more time** can be allocated to fix any detected errors or warning, the **more chance** the application has to be submitted in compliance with the requirements from Grant.gov, eRA and the PI.

VI. ACRONYMS

AOR: Authorized Organization Representative
COI: Conflicts of Interest
CTSC: Clinical and Translational Science Center
DC: Direct Costs
DHHS: Department of Health and Human Services
DUNS: Data Universal Numbering System
EIN: Employer Identification Number
e.g.: example gratia (latin phrase for "for example")
EHS: Environmental Health and Safety
ERF: Electronic Routing Form
eRA: Electronic Research Administration
FAQ: Frequently Asked Questions
F&A: Facilities and Administrative
FOA: Funding Opportunity Announcement
FY: Fiscal Year
IACUC: Institutional Animal Care and Use Committee
IBC: Institutional Biosafety Committee
IDC: Indirect Costs
IRB: Institutional Review Board
i.e.: id est (latin phrase for " which means" or "that is")
ID: Identification
N/A: Non-applicable
NIH: National Institutes of Health
NRSA: The Ruth L. Kirschstein National Research Service Awards
OSRA: Office of Sponsored Research Administration
PDF: Portable Document Format
PD/PI: Program Director/Principal Investigator
PI: Principal Investigator
PHS: Public Health Service
PMCID: PubMed Central reference Number
RSC: Research Safety Checklist
RFA: Request For Application
SF424(R&R): Standard Form 424 (Research & Related)
SOI: Statement Of Intent
SOP: Standard Operating Procedure
SOW: Scope of work
SSR: Study Specific Report
WCM: Weill Cornell Medicine
WCMC: Weill Cornell Medical College

VII. SUPPORTING DOCUMENTS

1- GUIDE FOR BIOGRAPHICAL SKETCH FOR FELLOW NIH FORMAT

APPLICANT BIOGRAPHICAL SKETCH—Instructions

(see below for Actual Postdoctoral Sample)

Use only for individual predoctoral and postdoctoral fellowships, dissertation research grants (R36), and Research Supplements to Promote Diversity in Health-Related Research (Admin Suppl). DO NOT EXCEED FIVE PAGES.

NAME OF APPLICANT:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING *(Most applicants will begin with baccalaureate or other initial professional education, such as nursing. Include postdoctoral training and residency training if applicable. High school students should list their current institution and associated information. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	START DATE MM/YYYY	END DATE *(or expected end date)* MM/YYYY	FIELD OF STUDY

NOTE: The Biographical Sketch may not exceed five pages. Follow the formats and instructions below.

A. Personal Statement

Briefly describe why you are well-suited to receive the award for which you are applying. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer-reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.

- ***R36 Applicants (PD/PI) Only:***
  In addition to the information outlined above, include a description of your career goals and intended career trajectory, as well as your interest in the specific areas of research designated in the FOA.

- ***Diversity Supplement Candidates Only:***
  In addition to the information outlined above, include a description of your general scientific achievements and/or interests, as well as your specific research objectives and career goals. Indicate any source(s) of current funding.

B. Positions and Honors

List in chronological order all non-degree training, including postdoctoral research training, all employment after college, and any military service. High school students and undergraduates may include any previous positions. Clinicians should include information on internship, residency and specialty board certification (actual and anticipated with dates) in addition to other information requested. This information is used in the reviewing the application and in determining the stipend level for Postdoctoral Fellowships. State the Activity/Occupation and include start/end dates, field, name of institution/company, and the name of your supervisor/employer. If

you are not currently located at the applicant organization, include your projected position at the applicant organization as well.

ACTIVITY/ OCCUPATION	START DATE MM/YYYY	END DATE MM/YYYY	FIELD	INSTITUTION/ COMPANY	SUPERVISOR/ EMPLOYER

Academic and Professional Honors

List any academic and professional honors that would reflect upon your potential for a research career and qualifications. Include all scholarships, traineeships, fellowships, and development awards. Indicate sources of awards, dates, and grant or award numbers. List current memberships in professional societies, if applicable.

C. Contributions to Science (for predoctoral students and more advanced candidates only; high school students, undergraduates, and postbaccalaureates should skip this section)

Considering your level of experience, briefly describe your most significant contributions to science. While all applicants may describe up to five contributions, graduate students and postdoctorates are encouraged to consider highlighting two or three they consider most significant. These may include research papers, abstracts, book chapters, reviews, as well as non-publication research products, such as materials, methods, models, or protocols. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the relevance of the finding(s) to science, technology, or public health; and your specific role in the described work. For each contribution, you may reference up to four peer-reviewed publications or other non-publication research products (can list audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. Please also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine. Manuscripts listed as “pending publication” or “in preparation” should be included and identified. Indicate if you previously used another name that is reflected in any of the citations.

D. Scholastic Performance

Predoctoral applicants: Using the chart provided, list by institution and year all undergraduate and graduate courses with grades. In addition, in the space following the chart, explain any marking system if other than 1-100, A, B, C, D, F, or 0-4.0 if applicable. Show levels required for a passing grade.

Postdoctoral applicants: Using the chart provided, list by institution and year all undergraduate courses and graduate scientific and/or professional courses germane to the training sought under this award with grades. In the space following the chart, explain any marking system if other than 1-100, A, B, C, D, F, or 0-4.0 if applicable. Show levels required for a passing grade.

YEAR	SCIENCE COURSE TITLE	GRADE	YEAR	OTHER COURSE TITLE	GRADE

2- Biographical Sketch Sample for Postdoctoral Fellows NIH Format

APPLICANT BIOGRAPHICAL SKETCH SAMPLE—POSTDOCTORAL FELLOWS

(Note this Sample is for a Postdoctoral Fellowship Applicant only and does not include information specific to R36 or Diversity Supplements. For a Predoctoral Fellowship Sample, See: http://grants.nih.gov/grants/funding/424/predocfellowshipbiosample.docx)

Use only for individual predoctoral and postdoctoral fellowships, dissertation research grants (R36), and Research Supplements to Promote Diversity in Health-Related Research (Admin Suppl). DO NOT EXCEED FIVE PAGES.

NAME OF APPLICANT: Leilani Robertson-Chang

eRA COMMONS USER NAME (credential, e.g., agency login): RobertsonL

POSITION TITLE: Postdoctoral Researcher

EDUCATION/TRAINING *(Most applicants will begin with baccalaureate or other initial professional education, such as nursing. Include postdoctoral training and residency training if applicable. High school students should list their current institution and associated information. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	START DATE MM/YYYY	END DATE *(or expected end date)* MM/YYYY	FIELD OF STUDY
Swarthmore College	B.S	08/1995	05/1999	Engineering
UC San Diego	Ph.D.	08/2001	09/2007	Molecular Biology
Michigan State University (postdoc)	n/a	09/2007	Present	Bioinformatics/Immunology

A. Personal Statement

My long term research interests involve the development of a comprehensive understanding of key developmental pathways and how alterations in gene expression contribute to human disease. My academic training and research experience have provided me with an excellent background in multiple biological disciplines including molecular biology, microbiology, biochemistry, and genetics. As an undergraduate, I was able to conduct research with Dr. Xavier Factor on the mechanisms of action of a new class of antibiotics. As a predoctoral student with Dr. Tanti Auguri, my research focused on the regulation of transcription in yeast, and I gained expertise in the isolation and biochemical characterization of transcription complexes. I developed a novel protocol for the purification for components of large transcription complexes. I was first author of the initial description of the Most Novel Complex. A subsequent first author publication challenged a key paradigm of transcription elongation and was a featured article in a major journal. During my undergraduate and graduate careers, I received several academic and teaching awards. For my postdoctoral training, I will continue to build on my previous training in transcriptional controls by moving into a mammalian system that will allow me to address additional questions regarding the regulation of differentiation and development. My sponsor Dr. I.M. Creative is an internationally recognized leader in the transcription/chromatin field and has an extensive record for training postdoctoral fellows. The proposed research will provide me with new conceptual and technical training in developmental biology and whole genome analysis. In addition, the proposed training plan outlines a set of career development activities and workshops – e.g. grant writing, public speaking, lab management, and mentoring students – designed to enhance my ability to be an independent investigator. My choice of sponsor, research project, and training will give me a solid foundation to reach my goal of studying developmental diseases in man. During my second postdoctoral year in Dr. Creative's lab my father had a severe stroke that eventually ended his life. I was out of the lab for six months dealing with my father's incapacitating illness and end-of-life issues. This hiatus in training reduced my scientific productivity.

a. Robertson-Chang L and Auguri, T. 2004. A tandem affinity purification tag approach allows for isolation of interacting proteins in *Saccharomyces cerevisiae*. Proc Natl Acad Sci U S A. 98, 151-160.

b. Robertson-Chang L, Schneider K, Chen M, Auguri T. 2006. Rapid Isolation and Characterization of the Most Novel Transcription Complex in *Saccharomyces cerevisiae* and its role in transcription elongation. Cell. 128, 770-9.

c. Robertson-Chang L, Schneider K, Chen M, Auguri T. Rapid Isolation and Characterization of the Most Novel Transcription Complex in Saccharomyces cerevisiae and its role in transcription elongation. Oral presentation, 2006 CSHL Meeting on Mechanisms of Eukaryotic Transcription. Cold Spring Harbor, NY, August 2006.

B. Positions and Honors

Positions and Employment

ACTIVITY/ OCCUPATION	START DATE MM/YYYY	END DATE MM/YYYY	FIELD	INSTITUTION/ COMPANY	SUPERVISOR/ EMPLOYER
Engineer	08/1999	06/2001	Structural engineering	The IBeam Group	Sandip Mehta
Postdoc	10/2007	12/2007	Molecular biology	UC San Diego	G. Chadwick Murray
Postdoc	01/2008	present	Bioinformatics/ Immunology	Michigan State University	I.M. Creative

Other Experiences and Professional Memberships

1997- Sigma Xi

2000- Association for Women in Science

2002- National Society for Bioinformatics and Biotechnology

Academic and Professional Honors

1995-1997 Daughters of Hawaii Scholarship

1995-1999 National Merit Scholarship

1999 Paula F. Laufenberg award for best senior project in the Department of Engineering, Swarthmore College

1999 B.S. awarded with high honors, Swarthmore College

2001 STAR award for public service in engineering, The IBeam Group

2002-2005 Ford Foundation Predoctoral Fellowship for Minorities

C. Contributions to Science

1. Early Career: My early career contributions were focused on applying my knowledge of structural engineering to improving the design and integrity of tensile structures. More specifically, I worked with a team of engineers at the IBeam Group to develop concrete with a higher tensile strength that could be utilized in large structures such as suspension bridges. My particular role in the project was to identify candidate polymers, determine the ultimate tensile strength of these polymers, and make recommendations as to which polymer would afford concrete the most structural integrity under various stresses.

a. Robertson-Chang, L. and Janessa, A.J. 1998. Redesigning the Golden Gate bridge. Abstract for poster presentation, National Undergraduate Symposium on Science and Engineering, Baltimore, MD.

b. Lorentson, C., Robertson-Chang, L., Sauer, N., and Mehta, S. 2000. Use of high-tensile concrete in cantilevered structures. J. Applied Engineering 63, 413-424.

2. Graduate Career: My graduate research contributions focused on transcriptional gene regulation in *Saccharomyces cerevisiae.* Results from my research were highly relevant as they provided new details into the workings of complex biological systems, and allowed for further extrapolations into the development of certain diseases and their progression. I originally developed a novel protocol for the purification for components of large protein complexes. A subsequent publication, in which I isolated and characterized a long sought after transcription complex, challenged a key paradigm of transcription elongation and was a featured article in a major journal.

a. Robertson-Chang L and Auguri, T. 2004. A tandem affinity purification tag approach allows for isolation of interacting proteins in *Saccharomyces cerevisiae*. Proc Natl Acad Sci U S A. 98, 151-60.

b. Robertson-Chang L and Auguri, T. A tandem affinity purification tag approach allows for isolation of interacting proteins in *Saccharomyces cerevisiae*. Abstract for poster presentation, 2004 Yeast Genetics and Molecular Biology Meeting, Seattle, Washington, September 2004.

c. Robertson-Chang L, Schneider K, Chen M, Auguri T. 2006. Rapid Isolation and Characterization of the Most Novel Transcription Complex in *Saccharomyces cerevisiae* and its role in transcription elongation. Cell. 128, 770-9.

d. Robertson-Chang L, Schneider K, Chen M, Auguri T. Rapid Isolation and Characterization of the Most Novel Transcription Complex in Saccharomyces cerevisiae and its role in transcription elongation. Oral presentation, 2006 CSHL Meeting on Mechanisms of Eukaryotic Transcription. Cold Spring Harbor, NY, August 2006.

3. Postdoctoral Career: As a postdoctoral fellow, my research has provided a compelling link between mutations arising in stress response proteins and the development of various autoimmune diseases in humans. Previous studies have shown dysregulation in the innate immune response lead to autoimmune diseases in humans. A few Rtc homologues have now been identified in humans and appear to play a role in the regulation of genes in the innate immune response. My research is focused on the transcriptional regulator Rtc from *Drosophila melanogastor*. I have shown that specific mutations affecting Rtc lead to disruptions in downstream gene regulation involved in the innate immune response.

a. Robertson-Chang, L. and Murray, G.C. 2006. Stress, flies, and videotape: the Drosophila stress response. Ann. Rev. Physiol. 346, 223-245.

b. Robertson-Chang, L., Yager, L.N., and Murray, G.C. 2007. Rtc is an essential component of the Drosophila innate immune response. Genetics 145, 884-891.

c. Yao, M., Dionne, C.-F., Robertson-Chang, L., and Murray, G.C. 2007. Up-regulation of Drosophila innate immunity genes in response to stress. Science 304, 1754-1756.

d. Robertson-Chang, L., Cescaloo, Q., and Murray, G.C. 2008. Structural analysis of Drosophila Rtc. In preparation.

Complete List of Published Work in MyBibliography:

http://www.ncbi.nlm.nih.gov/sites/myncbi/collections/public/1tay8xsxteXIw5R2StTcjhq5X/?sort=date&direction=ascending

D. Scholastic Performance

YEAR	SCIENCE COURSE TITLE	GRADE
	SWARTHMORE COLLEGE	
1996	Introduction to Molecular Biology	A
1996	Introductory Chemistry I	B
1996	Physics for Engineers	A
1997	Introductory Chemistry II	C
1997	Organic Chemistry I	A
1998	Organic Chemistry II	A
1998	Biochemistry	A
1999	Cell Biology	A
	UC SAN DIEGO	
2001	Seminar in Genetics	P
2002	Statistics for the Life Sciences	P
2003	Ethics in Biological Research	CRE
2004	Seminar in Physiology & Behavior	P

YEAR	OTHER COURSE TITLE	GRADE
	SWARTHMORE COLLEGE	
1995	Introduction to Engineering	A
1995	Calculus I	A
1996	Calculus II	B
1996	Structures and Design	A
1996	Linear Algebra	B
1997	Structural Materials	B
1997	Structural Materials Laboratory	A
1997	Numerical Computation & Graphics Tools	A
1997	Engineering Graphics and Computer-Assisted Design	A
1997	Principles of Structural Design I	B
1997	Statistics, Probability, and Reliability	A
1998	Principles of Structural Design II	A
1999	Senior Project	A

Except for the scientific ethics course, UC San Diego graduate courses are graded P (pass) or F (fail). Passing is C plus or better. The scientific ethics course is graded CRE (credit) or NC (no credit). Students must attend at least seven of the eight presentation/discussion sessions for credit.

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* **OSRA SOPs** (Standard Operating Procedures) related to this guide are the following:

- ☐ Submitting a Competitive Grant Application for OSRA Review at http://osra.weill.cornell.edu/forms/Grants-Submission-to-OSRA.pdf

- ☐ Electronic Routing Form Review and Approval at http://osra.weill.cornell.edu/forms/ERF+reivew+SOP.pdf

* **For more support:**

- ☐ Contact your OSRA pre-award specialist assigned to your department. The updated list of OSRA Departmental Assignments is available at http://osra.weill.cornell.edu/about_us/dept_assign_gco.html or call 646-962-8290.

- ☐ Contact Helene Brazier-Mitouart, Education Manager, Office for Education and Training in Research Administration, Weill Cornell Medicine: email at heb2020@med.cornell.edu or call 646-962-6204.