Expert Feedback on NIH/AHRQ Rigor and Transparency Guidelines

Tufts CTSI Overview

- Tufts Clinical and Translational Science Institute (Tufts CTSI) was established in 2008 with a Clinical and Translational Science Award (CTSA)
  - Part of a consortium of more than 60 national CTSAs
  - ***Research services*** institutes "working together to speed the translation of research discovery into improved patient care."
  - Funded by the NIH

NIH National Center for Advancing Translational Sciences

Tufts CTSI's Mission & Purpose

Established in 2008 to translate research into better health

- Stimulate and expedite innovative clinical and translational research, with the goal of improving the public's health
- *Entire spectrum* of clinical and translational research is critical to meeting the promise and the public's needs of biomedical science

39 Tufts CTSI Partners

13 Tufts Schools & Centers
Cummings School of Veterinary Medicine
Fletcher School of Law & Diplomacy
Friedman School of Nutrition Science & Policy
Graduate School of Arts & Sciences
Institute for Clinical Research & Health Policy Studies at Tufts Medical Center
Jean Mayer USDA Human Nutrition Research Center on Aging
Sackler School of Graduate Biomedical Sciences
School of Dental Medicine
School of Engineering
School of Medicine
Tisch College of Citizenship & Public Service
Tufts Center for the Study of Drug Development
Tufts Innovation Institute

3 Academic Partners
Brandeis University
Northeastern University
RAND Corporation

7 Tufts-Affiliated Hospitals
Baystate Medical Center
Lahey Clinic
Maine Medical Center
New England Baptist Hospital
Newton-Wellesley Hospital
St. Elizabeth's Medical Center
Tufts Medical Center

6 Industry/Non-Profit Partners
Blue Cross Blue Shield of Massachusetts
Eli Lilly and Company
Institute for Systems Biology and P4 Medicine Institute
Minuteman Health Network
Pfizer, Inc.
Tufts Health Plan

10 Community-Based Partners
Action for Boston Community Development (ABCD)
Asian Community Development Corporation
Asian Task Force Against Domestic Violence
Asian Women for Health
Boston Chinatown Neighborhood Center
Center for Information and Study on Clinical Research Participation
Greater Boston Chinese Golden Age Center
Health Resources in Action
Museum of Science, Boston
New England Quality Care Alliance

How Can CTSI Help?

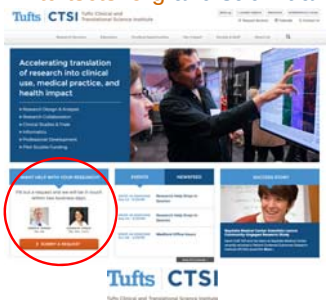
- Connections with other researchers, industry, the community, and policy-makers across the Tufts CTSI network and national CTSA consortium via our **Navigators & Research Collaboration team**.
- Consultations on **comparative effectiveness**, **one health**, **research process improvement** and **stakeholder and community engagement** projects and grants, as well as **regulatory issues** and other areas of translation.
- Study design and data analysis (pre- and post-award) through the **Biostatistics, Epidemiology, and Research Design (BERD) Center**, including drop-in sessions.

How Can CTSI Help?

- 24/7 clinical trial support through our **Clinical and Translational Research Center (CTRC)**.
- Informatics tools for electronic data capture (**REDCap**), resource sharing, and collaboration.
- Training & professional development including MS and PhD degrees, certificate programs, seminars & workshops, and **paid career development awards and fellowships**.
- Funding through one-year interdisciplinary **pilot studies grants** that support the initial stages of research.

How to Request Tufts CTSI Services

- Visit www.tuftsctsi.org and submit a request



Summary of the NIH/AHRQ Rigor and Transparency Guidelines

Amy Gantt, MA
Director, Office of Research Development
Tufts University
amy.gantt@tufts.edu

This session will provide:

- Summary of changes to proposal content for the National Institutes of Health (NIH) and Agency for Healthcare Research and Quality (AHRQ)

Resources Describing Changes

- Summary of all changes, with links for additional information
  http://grants.nih.gov/reproducibility/index.htm
- FAQs for each element of Rigor & Reproducibility
  http://grants.nih.gov/reproducibility/faqs.htm
- Dr. Mike Lauer's blog. Several entries describe NIH's expectations
  http://nexus.od.nih.gov/all/category/blog/
- Reviewer guidance on Rigor and Transparency
  http://grants.nih.gov/grants/peer/guidelines_general/Reviewer_Guidance_on_Rigor_and_Transparency.pdf

Summary of Rigor & Transparency Requirements

ELEMENT	SECTION OF APPLICATION	DEFINITION	OVERALL SCORE?
Scientific Premise	Significance	The general strengths & weaknesses of the prior research as crucial to support the application	Yes
Scientific Rigor	Approach	Application of the scientific method to ensure robust & unbiased study design, methods, analysis, interpretation & reporting of results	Yes
Consideration of Relevant Biological Variables	Approach	Sex as a biological variable, as well as other variables, will be factored into research designs, analyses, &reporting in vertebrate animal & human studies	Yes
Authentication of Key Resources	Attachment	Transparently reporting on what has been done to authenticate key resources that vary over time	No

Rigor & Transparency
Scientific Premise

Scientific Premise should be addressed in the Significance section

- **Significance = Background + Justification**
  - Review of relevant literature that makes an argument for why your work is needed
  - Tie to I/C mission (or RFA description)
  - *Do not "kitchen sink" this section!* It should be a focused, coherent and – above all – an engaging justification of your work

Rigor & Transparency
Scientific Premise

Evaluate the Scientific Literature

- **Discuss the strengths, weaknesses and limitations of the studies presented in the scientific literature related to your proposed research**
- ***This provides the foundation for the justification of your work***
  - If you are not required to provide preliminary data (e.g., R21), this assessment of the literature is critical

Rigor & Transparency
Rigorous & Unbiased Approach

Have the investigators presented strategies to ensure a robust and unbiased approach?

- **The Approach is the most important section of your proposal for scoring purposes**
  - Spend most of the space in the research strategy describing and justifying your approach

Rigor & Transparency
Rigorous & Unbiased Approach

Scientific Rigor should be discussed in the Approach section

- **Describe your approach clearly and completely!**
  - Justify your methods, using preliminary data, the scientific literature, or other credible sources
  - "We will use the methods devised by Jones, et al. (2015)" is not sufficient
  - Remember that reviewers will not necessarily be experts – write for those outside your (sub) field

Rigor & Transparency
Rigorous & Unbiased Approach

- **Expected Outcomes**
  - Demonstrate that your research will have an impact on your field (and on public health) regardless of whether your hypotheses are accepted or rejected
- **Statistical Analyses**
  - Beware of perceived "p-hacking"
  - If possible and appropriate, add a biomedical statistician to your proposal to ensure that all analyses are unbiased
  - You can receive assistance through the CTSI on study design and analysis!

Rigor & Transparency
Rigorous & Unbiased Approach

Innovation vs. Scientific Rigor

- Identify and manage the risk associated with innovative research
  - Consider the scientific premise
  - Identify the factors that are unknown
  - Incorporate strategies to reduce bias and ensure the methods are designed to generate robust results appropriate for the stage of research
- Regardless of stage of research, results should be reproducible and provide a foundation for future studies

Rigor & Transparency
Relevant Biological Variables

Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

- **In the Approach section, include a subheading for human subjects or vertebrate animals**
  - In this section, describe the population you will be using, and why you chose this particular population
  - Ask yourself why you have chosen particular inclusion/exclusion criteria (human subjects) or animal model and explain to the reviewers why your choices are necessary
  - Discuss with the Program Officer if vertebrate animal research must focus only on one sex or other biological variable (e.g., race, age, etc.) unless the reason is obvious

Rigor & Transparency

Key Biological and/or Chemical Resources

Reviewers will comment on the brief plans proposed for identifying and ensuring the validity of key biological and/or chemical resources.

- **This plan is a separate attachment**
  - Included are cell lines, specialty chemicals, antibodies, and other biologics (among others)
  - NOT included are standard laboratory reagents that are not expected to vary (e.g., buffers and other common biologicals and reagents)
- **Focus *only* on plans to authenticate or validate resources – *do not use this section to circumvent page limits!***
- **For more information, please see FAQs:** http://grants.nih.gov/reproducibility/faqs.htm#11438

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Thank you!

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NIH Study Section Chair Perspective and Advice

John Castellot, PhD

NIH Study Section Chair

Navigator

Tufts Clinical and Translational Science Institute (CTSI)

Professor of Integrative Physiology & Pathobiology

Tufts University School of Medicine

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Resources Describing Changes

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Additional Resource

or, Why We Need Rigor

or, Sometimes the Truth Makes Us Wince

https://www.youtube.com/watch?v=0Rnq1NpHdmw&sns=em

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Rigor & Transparency
Scientific Premise

Scientific Premise should be addressed in the Significance section

- Significance = Background + Justification
  - Review of relevant literature that makes an argument for why your work is needed
  - Tie to I/C mission (or RFA description)
  - *Do not "kitchen sink" this section!* It should be a focused, coherent and – above all – an engaging justification of your work

Think of the Scientific Premise as the *scientific foundation* for the proposed work, including both published literature and your preliminary data; it is *not* the hypothesis

Grantsmanship: Make it easy for the reviewers to see you've followed the new rules . . . Instead of having a section entitled *Rationale*, call it *Scientific Premise*

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Rigor & Transparency
Rigorous & Unbiased Approach

Have the investigators presented strategies to ensure a robust and unbiased approach?

- **The Approach is the most important section of your proposal for scoring purposes**
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Grantsmanship: Make it easy for the reviewers and include a short paragraph at the end of each Aim entitled *Scientific Rigor* that emphasizes your:

- Hypothesis-neutral (ie, unbiased) approaches
- Careful attention to positive and negative controls
- Use of independent corroboration of key results

Rigor & Transparency
Rigorous & Unbiased Approach

- **Expected Outcomes**
  - Demonstrate that your research will have an impact on your field (and on public health) regardless of whether your hypotheses are accepted or rejected
- **Statistical Analyses**
  - Beware of perceived "p-hacking"

- If appropriate, add a biomedical statistician to your proposal to ensure that all analyses are unbiased
- Power analyses for animal use must now go in the Research Plan, not the Vertebrate Animals section
- You can receive assistance through the CTSI on study design and analysis—more on this from Norma Terrin, PhD

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Rigor & Transparency
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  - In this section, describe the population you will be using, and why you chose this particular population
  - Ask yourself why you have chosen particular inclusion/exclusion criteria (human subjects) or animal model and explain to the reviewers why your choices are necessary
  - Discuss with the Program Officer if vertebrate animal research must focus only on one sex or other biological variable (e.g., race, age, etc.) unless the reason is obvious

- **Age, race, ethnicity, culture, and socioeconomic status** are all potentially important biological variables
- **Grantsmanship:** Provide a short paragraph entitled *Sex and Other Biological Variables* in the Approach section. If there are no important biological variables, state this explicitly. If there are, either state that you include them in your proposed studies or provide a succinct justification for not including them (this is where talking with you PO is important)

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- **For more information, please see FAQs:** *http://grants.nih.gov/reproducibility/faqs.htm#11438*

- **Grantsmanship:** This item is ***not scorable***, so concentrate on the other score-driving R+T items first if you have a **July 5 deadline**!

Panel Discussion

Panelists

- **Pilar Alcaide, PhD, MS**
  Assistant Professor
  Integrative Physiology and Pathobiology
  Tufts University School of Medicine

- **Caroline Attardo Genco, PhD**
  Arthur E. Spiller, MD
  Professor and Chair,
  Integrative Physiology and Pathobiology
  Tufts University School of Medicine

Panelists

- **Iris Jaffe, MD, PhD**
  Associate Professor of Medicine
  Tufts University School of Medicine
  Associate Director, Molecular Cardiology Research Institute
  Tufts Medical Center
  Director, Vascular Biology Research Center
  Faculty, Cell, Molecular, and Developmental Biology Program

- **Daniel Jay, PhD**
  Professor
  Developmental, Molecular and Chemical Biology
  Tufts University School of Medicine

Department of Labor (DoL) Fair Labor Standards Act (FLSA) Overtime Rule and Research

Presenters

Marcia S. Izzi, MPH
Business Finance Manager
Tufts Clinical and Translational Science Institute (CTSI)

Carol Seidel, BS
Director, Administration and Finance
Institute for Clinical Research and Health Policy Studies (ICRHPS)
Tufts Medical Center

Department of Labor (DoL) Fair Labor Standards Act (FLSA) Overtime Rule and Research

Topic: On May 18th, DoL published its final rule on overtime pay protections under the FLSA raising the salary threshold for overtime pay to $47,476 effective December 1, 2016.

What is the FLSA? The FLSA establishes minimum wage, overtime pay requirements and other pay related issues for eligible employers.

Department of Labor (DoL) Fair Labor Standards Act (FLSA) Overtime Rule and Research

How does the new rule impact Research?

- Anyone working in a qualifying ***salaried*** position at an annual rate of less than $47,476 or $913/wk must earn overtime > 40 hours
- This includes post-docs and salaried research staff
- Current non-exempt or hourly employees are not impacted by the new rule

Department of Labor (DoL) Fair Labor Standards Act (FLSA) Overtime Rule and Research

How is NIH responding?

- NIH Director Collins has stated that NRSA grants and stipend levels will be adjusted and additional funds will be awarded.
- NIH recognizes that non-NRSA RPG's fund post-docs and salaried staff who are currently below the new minimum and additional funds for these programs have not been offered at this time, yet salary levels will need to be adjusted or overtime will have to be paid for hours worked over 40 in any given week as of 12/1/2016.

Department of Labor (DoL) Fair Labor Standards Act (FLSA) Overtime Rule and Research

How should researchers approach budgeting for grant applications?

- Researchers can consider budgeting post-docs and other salaried staff at the new minimum annual salary of $47,476.

What are other institutions doing about this?

- Institutions are relying on their Human Resource Departments for guidance. Questions should be directed to your Research and/or Department Administrator.

Department of Labor (DoL) Fair Labor Standards Act (FLSA) Overtime Rule and Research

Additional Information

NIH Director Announcement in Huffington Post
http://www.huffingtonpost.com/francis-s-collins-md-phd/fair-pay-for-postdocs-why_b_10011066.html

Helpful webinar from CUPA
http://www.cupahr.org/events/webinar-20160525.aspx

DoL Website/FAQ's
https://www.dol.gov/WHD/overtime/final2016/

Questions?

Thank you!

Expert Feedback on NIH Rigor and Transparency Guidelines