

Planning for NIH and AHRQ Grant Application Changes



Tufts CTSI Overview

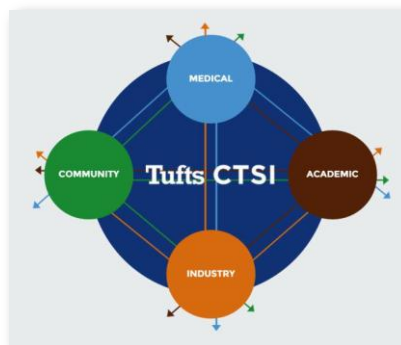
- Tufts Clinical and Translational Science Institute (Tufts CTSI) was established in 2008 with a Clinical and Translational Science Award (CTSA)
 - Part of a consortium of more than 60 national CTSAAs
 - **Research services** institutes "working together to speed the translation of research discovery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



Tufts CTSI's Mission & Purpose



- Our mission is to *stimulate and promote innovative clinical and translational research*, with the goal of improving the public's health
- We serve this objective by *facilitating, improving, and supporting others' research*, and through education and training
- A **research services** institute



39 Tufts CTSI Partners

12 Tufts Schools & Centers

Cummings School of Veterinary Medicine
 Fletcher School of Law & Diplomacy
 Friedman School of Nutrition Science & Policy
 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 Arts & 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

3 Academic Partners

Brandeis University
 Northeastern University
 RAND Corporation

10 Tufts-Affiliated Hospitals

Baystate Medical Center
 Carney Hospital
 Lahey Hospital & Medical Center
 Maine Medical Center
 MetroWest Medical Center
 New England Baptist Hospital
 New England Sinai Hospital & Rehabilitation Center
 Newton-Wellesley Hospital
 St. Elizabeth's Medical Center
 Tufts Medical Center

5 Industry/Non-Profit Partners

Blue Cross Blue Shield of Massachusetts
 Institute for Systems Biology and P4 Medicine Institute
 Minuteman Health Network
 Pfizer, Inc.
 Tufts Health Plan

9 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
 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.



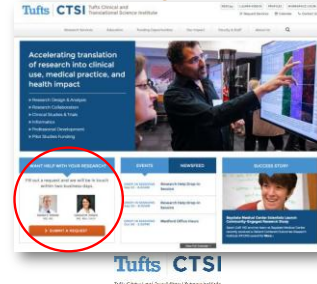
How Can CTSI Help?

- 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. Submit



How to Request Tufts CTSI Services

- Visit www.tuftsctsi.org and submit a request



Planning for NIH and AHRQ Grant Application Changes

December 8, 2015

- **Zoya Davis-Hamilton, EdD, CRA**
Sr. Associate Director, Research Administration, Tufts University
zoya.hamilton@tufts.edu
- **Amy Gantt, MA**
Director Office of Research Development, Tufts University
amy.gantt@tufts.edu
- **Kathleen Benoit, CRA**
Senior Research Administrator, Tufts University
kathleen.benoit@tufts.edu
- **Debbie Slater, MHA**
Director Research Administration, Medical and Surgical Specialties, Tufts Medical Center; dslater@tuftsmedicalcenter.org

This session will provide:

- List of changes to proposal content, policies, instructions and forms of the National Institutes of Health (NIH) and Agency for Healthcare Research and Quality (AHRQ)
- Implementation dates
- Details on each area of change
- References to NIH notices describing each change

Future session

- Another seminar is planned on NIH rigor and transparency
- Will focus on feedback from NIH reviewers

Announcements of Changes

- **NOT-OD-16-004** –summary of all upcoming changes to NIH/AHRQ policies, instructions and forms for 2016 grant applications
- Details on each change available in separate notices numbered NOT-OD-16-005 through **012**
- **NOT-OD-16-017** - Summary of changes of the revised NIH Grants Policy Statement
- NIH grants policy and guidance page: <http://grants.nih.gov/grants/policy/>

Areas of Changes

- Rigor and transparency ([NOT-OD-16-011](#) & [NOT-OD-012](#))
- Vertebrate animals ([NOT-OD-16-006](#))
- Definition of child ([NOT-OD-16-010](#)) & updates to Inclusion Forms
- Data safety monitoring / Clinical Trials ([NOT-OD-16-004](#))
- Research training ([NOT-OD-16-004](#) & [NOT-OD-16-007](#))
- Peer review assignment request ([NOT-OD-16-008](#))
- Font requirements ([NOT-OD-16-009](#))
- Biosketch clarifications ([NOT-OD-16-004](#))
- Postaward changes ([NOT-OD-16-005](#))
- Changes to the NIH Grants Policy Statement ([NOT-OD-16-077](#))

Implementation Dates

- **Phase 1:**
 - applications with due dates on or after January 25, 2016
 - Existing forms (FORMS-C) – updated November 25, 2015
 - updated application guides
 - fellowship applications are incorporated into the general application guide and no longer maintained as a separate document
- **Phase 2:**
 - applications with due dates on or after May 25, 2016
 - introduction of new forms (FORMS-D)
 - new application guides will be issued by March 25, 2016
- **Revised NIH Grants Policy Statement** applies to awards with budget periods beginning on or after October 1, 2015.

Proposal Content Changes: Rigor and Transparency

- **Amy Gantt, MA**
Director, Office of Research Development
Office of the Vice Provost for Research
Tufts University

Rigor and Transparency

- Objective – to enhance reproducibility of research findings
- **Research Strategy:** updates to **Significance** (consideration of the strengths and weaknesses of published research or preliminary data) & **Approach** (achieving robust & unbiased results, factoring in biological variables such as sex)
- New attachment **Authentication of Key Biological and/or Chemical Resources** (cell lines, specialty chemicals, antibodies, and other biologics). Attachment uploaded in Other Attachments section of R&R Other Project Information form
- Will not impact institutional training and individual fellowship applications until Phase II (New “Plan for the Instruction in Methods for Enhancing Reproducibility” attachment will be added to the PHS 398 Research Training Program Plan)

Rigor & Transparency – Scored Review Criteria

Reviewers will be asked to consider the following additional review questions:

- Is there a strong scientific premise for the project?
- Have the investigators presented strategies to ensure a robust and unbiased approach?
- Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?
- Reviewers will comment on the brief plans proposed for identifying and ensuring the validity of key biological and/or chemical resources.

Rigor & Transparency – Scientific Premise

Is there a strong scientific premise for the project?

- All sections of your proposal should answer the question: *Why should NIH give you money to complete this research?*
 - Institute/Center Mission
 - Reviewer enthusiasm
 - Impact on public health

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 – 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

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 (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)

Rigor & Transparency – Key Biological and/or Chemical Resources

Included in this plan are those key biologic or chemical resources *necessary for your work* that

- May differ from laboratory to laboratory or over time
- May have qualities and/or qualifications that could influence the research data

Rigor & Transparency – Key Biological and/or Chemical Resources

Do not circumvent page limits!

- This document may only focus on your plans to authenticate or validate your resources
- Any other methods should be included in research strategy – violation may mean that your proposal will be rejected!

Rigor & Transparency – Key Biological and/or Chemical Resources

Structure of the Document

- Briefly describe the methods you plan to use to authenticate your key resources
- As consensus guidelines emerge for different types of key resources, state which guidelines you plan to follow
- Investigators may supply one description they will use for a number of resources in the same category (e.g., one method for authenticating several different cell lines)
- Actual data demonstrating that authenticated resources are available are not needed

(from FAQs found at
<http://grants.nih.gov/reproducibility/faqs.htm#11438>)

Rigor & Transparency – Key Biological and/or Chemical Resources

Other FAQs:

- If a key resource is under development, the authentication plans should be a part of your research strategy and NOT a part of this document
- If you are collecting cells to culture as a part of your research project, those methods – including authentication – should be described in the research strategy
- An external evaluator to authenticate key resources is not required, though in certain cases that may be the best approach

(from FAQs found at
<http://grants.nih.gov/reproducibility/faqs.htm#11438>)

Questions?

- **Question and Answer Session Moderator**
Debbie Slater, MHA
Director Research Administration
Medical and Surgical Specialties
Tufts Medical Center

Proposal Content Changes: Policies, Instructions and Forms

- **Zoya Davis-Hamilton, EdD, CRA**
Sr. Associate Director, Research Administration
Office of the Vice Provost for Research
Tufts University
- **Kathleen Benoit, CRA**
Senior Research Administrator
Office of the Vice Provost for Research
Tufts University

Vertebrate Animals Section (VAS)

Objective – to remove redundancy with Institutional Animal Care and Use Committee review. *Does not apply to AHRQ*

- A description of veterinary care is no longer required
- Justification for the number of animals has been eliminated
- A description of the method of euthanasia is required only if the method is not consistent with American Veterinary Medical Association (AVMA) guidelines

Definition of Child

- Children must be included in all human subjects' research supported by the NIH, unless there are scientific and ethical reasons not to include them (this did not change)
- Children are now defined as **individuals under 18 years old** instead of under 21 years old
- Aligning the NIH definition for the age of a child with the typical age of consent and the common perception of the age of adulthood

Does not apply to AHRQ

Inclusion Forms

- Inclusion Enrollment Report form will be added to FORMS-D application packages
- Will replace the Planned Enrollment Report and Cumulative Inclusion Enrollment Report forms in FORMS-C
- NIH will provide more details about these changes prior to release of the updated form

Research Training

- "Recruitment and Retention Plan to Enhance Diversity" – additional focus on recruitment
- "Human Subjects" and "Animal Subjects" - no longer necessary to provide a list of grants trainees work on and IRB/IACUC approvals. Instead, describe how the institution will ensure that trainees only participate in exempt research or research approved by the IRB/IACUC
- "Progress Report" - report on publications that arose from work conducted by the trainee is moved to JIT
- Data tables via new xTRACT system or download at: <http://grants.nih.gov/grants/funding/424/datatables.htm>; reducing the number of tables from 12 to 8, minimizing reporting of individual-level information, extending tracking of trainee outcomes from 10 to 15 years

Clinical Trials

- New “Data Safety Monitoring Plan” will be added to FORMS-D application packages
- Will apply to applications for clinical trials
- Reporting results of clinical trials on ClinicalTrials.gov is still required by FDAAA after the NIH award period of performance has ended

Genomic Data Sharing

- Applications that propose to generate genomic data require Genomic Data Sharing Plan
- Investigators may request permission to transfer controlled-access genomic and phenotypic data from NIH-designated data repositories to cloud systems for storage and analysis

Peer Review Assignment & Proposal Compliance

- New optional PHS Assignment Request Form in FORMS-D
- Will include:
 - NIH institute assignment preference
 - Study Section preference
 - List of potential reviewers in conflict, and why
 - List of scientific expertise needed to review the application
- NIH may withdraw any application during the receipt, referral, or review process for non-compliance

Font Flexibility

- For applications submitted for due dates on or after May 25, 2016
- Additional flexibility regarding the fonts will be allowed in PDF attachments
- Although NIH will continue to recommend specific fonts, some other fonts will be allowed (both serif and non-serif) as long as they comply with specific type density and line spacing guidelines
- See allowed fonts in [NOT-OD-16-009](#)

Biosketch Clarifications

- A URL for a publication list is optional and, if provided, must be to a government website (.gov) like My Bibliography
- Publications and research products can be cited in both the personal statement and the contributions to science sections
- Graphics, figures and tables are not allowed
- Tufts CTSI | LEARN
<http://ilearn.tuftsctsi.org/courses/courseCatalog.aspx>
Under NIH Biosketch

Post-Award Forms and Instructions

- RPPR (new training data tables, address rigor) – already in effect
- Statement of Appointment (new list of training codes, reporting of tuition/fees and travel eliminated, updated list of Specialty Boards) – effective 1/22/2016
- Editorial clarifications to several forms – effective 1/22/2016
- Updates to Inclusion Enrollment Report Forms are forthcoming

No Cost Extension (NCE)

- NIH prior approval is not required to reduce effort during NCE
- Reduces administrative burden

Does not apply to AHRQ

In Conclusion

- Changes are rolled out in two phases between now and May, 2016
- It is important to pay attention to specific funding announcement and read the instructions in effect at the time of application
- A session that focuses on the feedback from NIH reviewers will be offered to the research community.

Questions?

- **Question and Answer Session Moderator**
Debbie Slater
Director Research Administration
Medical and Surgical Specialties
Tufts Medical Center

Contact Information

- **Zoya Davis-Hamilton, EdD, CRA**
Sr. Associate Director, Research Administration
Tufts University
zoya.hamilton@tufts.edu
- **Amy Gantt, MA**
Director Office of Research Development
Tufts University
amy.gantt@tufts.edu
- **Kathleen Benoit, CRA**
Senior Research Administrator, Tufts University
kathleen.benoit@tufts.edu
- **Fred Frankhauser, JD, RPh**
Director, Grants and Contracts, Tufts Medical Center
frankhauser@tuftsmedicalcenter.org

Please contact your designated Research Administrator with questions.

Thank you!