Submitting Your Application and RCR

Christy Taylor, CRA
Training Manager, Research Services

Learning Objectives

- Discuss the application process at UTMB
- Understand the background of current regulations and practices in Responsible Conduct of Research (RCR)
- Identify required components of RCR
What is the Office of Sponsored Programs (OSP)?

• A Resource
• Works with externally funded research projects submitted by UTMB and its employees
• Reviews proposals for compliance with guidelines and regulations
• All proposal must be submitted through OSP for appropriate signatures
• Submits the proposal to the sponsor on behalf of PIs
• Negotiates and accepts awards on behalf of UTMB

OSP PreAward

• Creating/ Affiliating an eRA Commons account
• Assistance with budget development
• Understanding grant guidelines
• Review and forward any recommendations and/or corrections
• The Signing Official submits/signs the proposal
Preparing to Submit a Proposal

- Locate the funding announcement (PA, RFA, RFP) from the sponsor
- Notify your PreAward analyst of your intent to submit
- Complete your required COI training
- Obtain guidelines, application, and forms from the sponsor
  - Email funding announcement and sponsor guidelines to your PreAward analyst

  Erica Huff, CRA, Manager  Cathy Sainz, CRA
  Beth Schilling  Tricia Smith
  Kristi Speights, CRA

NIH Standard Due Dates for F and K Series

<table>
<thead>
<tr>
<th>Activity Codes</th>
<th>Program Description</th>
<th>Cycle 1 Due Date</th>
<th>Cycle II Due Date</th>
<th>Cycle II Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>K series</td>
<td>Research Career Development</td>
<td>Feb 12</td>
<td>Jun 12</td>
<td>Oct 12</td>
</tr>
<tr>
<td>New</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>K series</td>
<td>Research Career Development</td>
<td>Mar 12</td>
<td>Jul 12</td>
<td>Nov 12</td>
</tr>
<tr>
<td>Renewal,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>resubmission,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>revision</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F Series Fellowship</td>
<td>Individual National Research Service Awards (Standard)</td>
<td>Apr 8</td>
<td>Aug 8</td>
<td>Dec 8</td>
</tr>
<tr>
<td>New, renewal,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>resubmission</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F31 Diversity</td>
<td>Individual Predoctoral Fellowships (F31) to Promote</td>
<td>Apr 13</td>
<td>Aug 13</td>
<td>Dec 13</td>
</tr>
<tr>
<td>Fellowships</td>
<td>Diversity in Health-Related Research</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New, renewal,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>resubmission</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

http://grants.nih.gov/grants/funding/submissionschedule.htm
Documentation Needed to Submit a Proposal

- Proposal Routing Form signed by PI and approved by department chair
- Program announcement and guidelines
- Detailed budget and justification
- Entire grant application package and forms, including training plan for RCR
- Cost sharing form (if applicable)
- Forms and templates are available online http://research.utmb.edu/AskForFunding/Forms.shtm

Tips for a Successful Grant Submission

- Start early!
- Read and re-read the sponsor guidelines
- Discuss your project with your mentor
- Allow sufficient time for your proposal to be reviewed by OSP (at least 5 days)
- Set your timeline to accommodate a submission at least 48 hours prior to the deadline
- Application has to be error free by 5 p.m. on day of deadline
Responsible Conduct of Research
The Basics

Applies to all NIH
• Institutional Research Training Grants
• Individual Fellowship Awards
• Career Development Awards (Individual and Institutional)
• Research Education Grants
• Dissertation Research Grants
• Other grant program with a training component - mentioned in the Funding Opportunity Announcement

Starting Point: RCR Components

Subject Matter
• Research Misconduct
• Protection of Human Subjects
• Welfare of Laboratory Animals
• Conflict of Interest (Personal, Professional, Financial)
• Data Management
• Mentor & Mentee Responsibilities and Relationships
• Collaborative Research
• Authorship and Publication
• Peer Review
• Roles of Science in Society
Format

- Face-to-Face instruction required
- Combination of didactic (lecture) and small group discussion (i.e., case studies)
- Faculty participation in research training
- Online courses as adjuncts to supplemental classroom RCR instruction
- Online not adequate as only source of instruction

Duration of Instruction

- Substantive contact hours – minimum of 8 contact hours
- One-time exposure inadequate and lacking sufficient depth
- Series of programs or seminars
  - Learning over longer periods
  - Linking individual programs to broader picture
  - Allowing time to apply classroom learning
Frequency

- Must be administered at least once during each career stage of all participants
- At least once every 4 years
- Required for K12/ KL2
- Senior fellows/ career development recipients (F33, K02, K05, K24) may fulfill requirement by teaching or leading discussions

Documentation

- A list of faculty sponsors, mentors, instructors, and discussion leaders must be provided
- Must provide details for the RCR related training at multiple stages
  - New (Type 1) - include information about your plan for RCR
  - Renewal (Type 2) – (if applicable) describe what RCR instruction took place during past project period
  - Continuations (Type 5) – description of instruction in RCR as required in the PHS 2590

http://research.utmb.edu/AskForFunding/RCR.shtm
Documentation Sample

Sample Scholar, MD
Instruction in the Responsible Conduct of Research

NIH Award begin date, 2009 – NIH Award end date, 2012

Activity Title: Scientific Writing for Clinical Research
Course Director: Cecilia Bethel, PhD
Schedule: Session 1 (September 10), Session 2 (September 17), Session 3 (September 24)
Prerequisites: None
Course Description:
1. Introduction to Scientific Writing
2. Literature Review
3. Data Analysis
4. Manuscripts
5. References
6. The End Notes

Tuition/Ticket Fee
1. Conference Fee:
2. Program Fee:
3. Admissions:
4. Housing:
5. Travel Allowances:
6. Prevailing Wage:

Available at UTMB

<table>
<thead>
<tr>
<th>Course Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEHU 6101 Ethics of Scientific Research</td>
<td>General Lab Safety &amp; Good Laboratory Practice (GLP)</td>
</tr>
<tr>
<td>Regulation and Ethics in Clinical Research</td>
<td>Good Laboratory Practice (GLP) Basic Training</td>
</tr>
<tr>
<td>Scientific Writing</td>
<td>Writing Effective SOPs</td>
</tr>
<tr>
<td>Conflict of Interest</td>
<td>Implementing Good Documentation Practices</td>
</tr>
<tr>
<td>Research Projects Management 101</td>
<td>CITI Human Subjects Training</td>
</tr>
<tr>
<td>Navigating the IRB and Investigator Responsibilities</td>
<td>AALAS Learning Library</td>
</tr>
<tr>
<td>Advanced Training on the Protection of Human Research Participant</td>
<td>Clinical Research: Tools and Techniques</td>
</tr>
<tr>
<td>UTMB Guidelines for Authorship</td>
<td>Introduction to Competitive Grant Writing</td>
</tr>
<tr>
<td>Animal Research Topics &amp; IACUC Protocols</td>
<td>Scientific Writing &amp; Grant Proposal Preparation</td>
</tr>
</tbody>
</table>

utmb Health Office of Sponsored Programs
Questions