

CTSA Competitive Renewal Tips and Tools

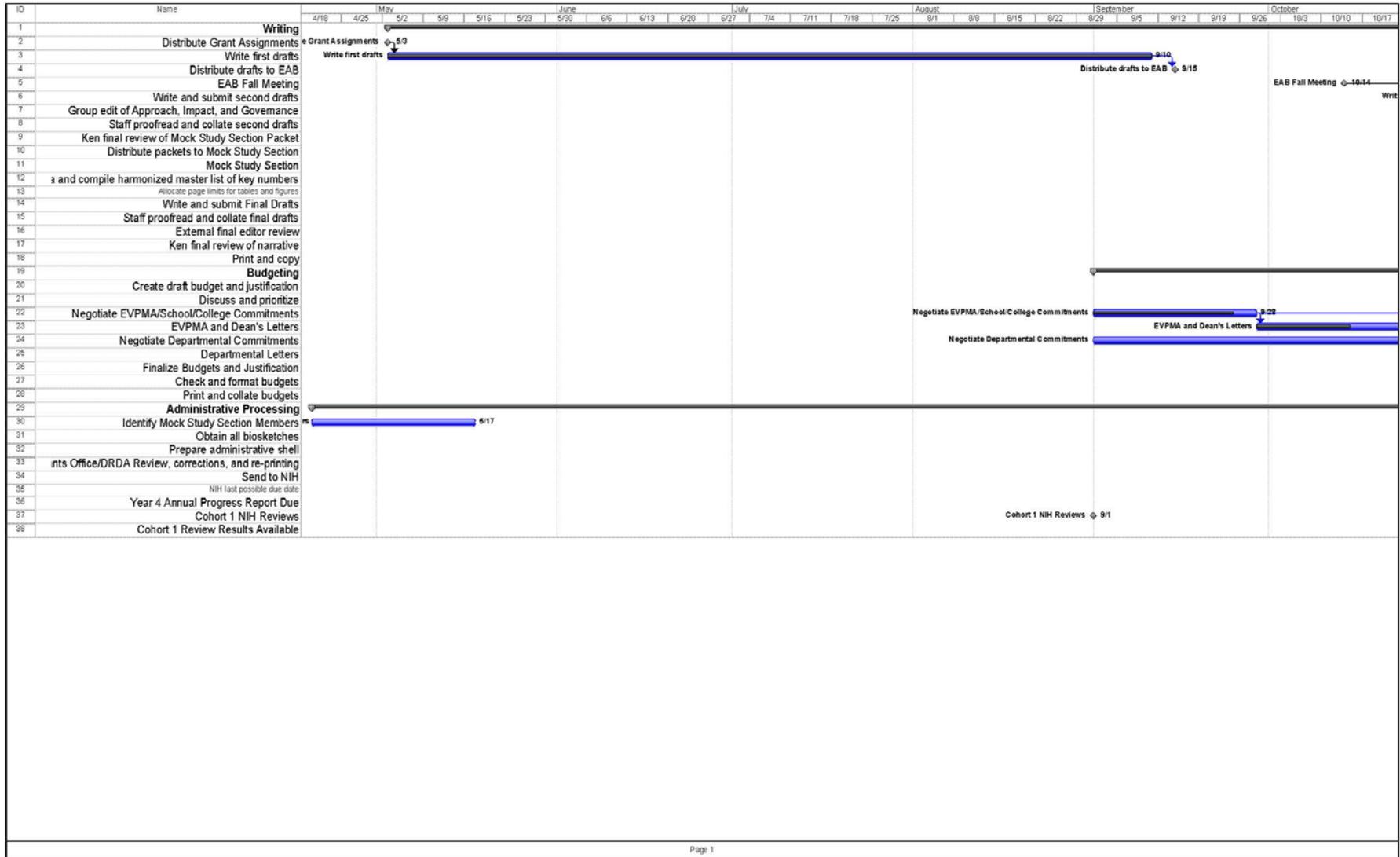
Thank you to the many contributors listed at the end of this document

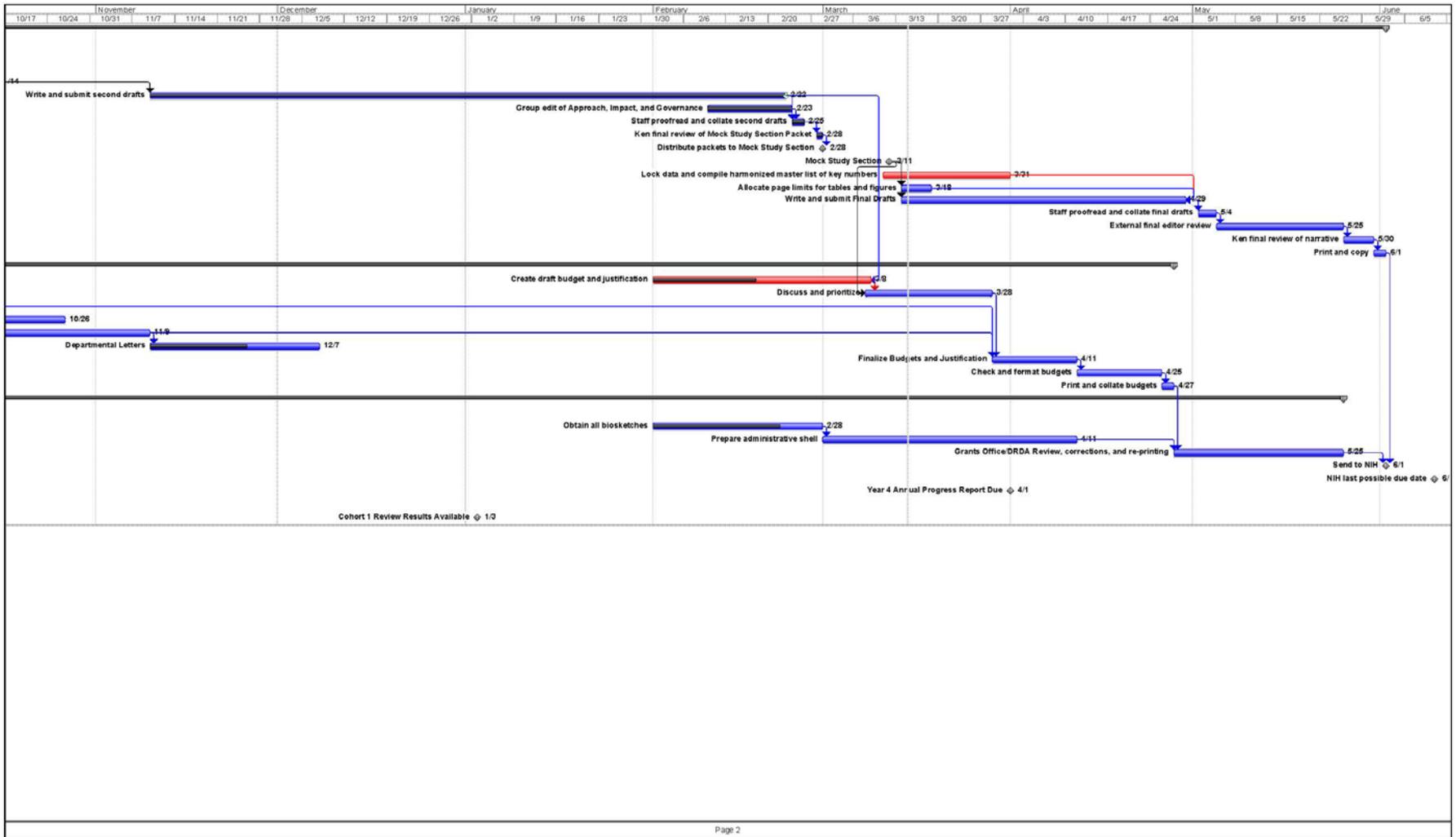
1. Start as early as possible (1 year in advance is not too early). Give everyone lots of advance notice about what the timeline will be. Make sure it is padded to absorb unpredictable delays. An example of a timeline that can be used as a communication tool is included.
2. **Start with substance – work with faculty to begin the process by actually determining your priorities and re-aligning your activities, rather than just diving in to writing. Engage stakeholders broadly to benefit from collaborative ideas. Consider doing this up to 2 years before your renewal.**
3. **Prepare your data. Get staff started early on ensuring that any and all tracking/activity data for the past 4 years is clean and complete – the writers will be returning again and again to ask for numbers, so prepare early.**
4. Next nail down your budget (at least the ‘bottom line’ amount going to each core). This includes your institutional commitments.
5. Work with faculty to develop a template for the narratives – an example of a template is included. Getting their input helps ensure your faculty buy in to the template so they will not deviate from it. A very detailed template avoids re-work down the line.
6. Create a style sheet that people can use to ensure that things are named and abbreviated consistently. An example of a style sheet is included.
7. There should be one person who is the primary project manager, monitoring and adjusting the timeline. This is time-consuming, so be sure the person has the needed time to actually take this on: it can’t be #50 on their ‘renewal to-do’ list – it should be #1. Communicate the status of the timeline on a very regular basis. Consider a visual system (red, yellow, green) to show which tasks are falling behind and may need extra attention.
8. Learn as much as you can about what the review process will be (call your program officer). It will influence how you structure the grant.
9. Now you are ready to write! Consider doling out writing assignments in small increments, ie. Specific aims are due first (then reviewed and discussed). Now everyone must write a paragraph about impact and turn in by the deadline, etc. This will alert you early on if someone is not delivering or simply does not write grants very well. If you find such an individual, do not be afraid to make a change or assign that person helpers.
10. Communicate and re-communicate the RFA requirements and review criteria for each section. As sections are reviewed and edited by multiple people over many months, and people struggle to fit in all the innovative ideas they come up with, you may find that some required content has gotten cut without anyone really noticing. Be watchful of the budget and justification to ensure that they ‘keep up’ with new ideas that appear during the writing process. A sample ‘checklist’ that can be used to review sections for completeness is included.

11. Have a backup for every activity, including writing. The backup needs to know how things are progressing and where things are stored. Crosstraining and communication takes time but pays off.
12. Pull the team (both faculty and staff) together regularly to review progress on the whole grant, not just pieces. Make sure your team includes financial experts.
13. Many CTSA's do mock review panels or hire external reviewers (EABs can play this role, as well). Have your faculty identify external experts they'd like as reviewers and try to recruit those people. Your faculty will usually will nominate someone they respect. When it is time to send their draft section to their chosen reviewer, you may find it is much more polished than it would be if they were just turning it in to the PI!
14. The closer you get toward the deadline, the smaller your circle of editors. As you approach the deadline, only one to three people should be 'authorized' to make any changes to the official document. This helps ensure consistency and avoids re-work (otherwise you will find one editor changes it all to read X, then the next just changes it back to read Y, and so on). You can still get lots of help by having people edit and mark up paper copies, but the decisions about what changes get into the master copy need to be made by a very small team.
15. If there is an office that has to review and approve your document before it's submitted, consider meeting face-to-face with them to look at an early draft so that concerns can be resolved ahead of time.
16. Streamline your annual report, since it will be due during the busiest writing time.
17. Try to find a graphic artist/illustrator that will work with you. Consider working with a professional science writer/editor.
18. Check the RFA frequently for changes.
19. Help everyone on staff be invested – anyone can proofread, check page numbers, etc. Ask for help when you need it, and people will pitch in.
20. Take good care of yourself and your team. Bring in food, celebrate milestones, thank people publicly. Schedule in a break now and then. Plan a lovely vacation for the week after the deadline!

Thank you to contributors: Lorri Schieri, Maureen Goode, Leslie McHale, Stacey Scirocco, Susan Autry, Laura Meiners, Maija Williams, Tom Fogg, Ana Austin and Andrew West

Sample Overall Timeline (Contributed by University of Michigan)





Sample Section Template (contributed by University of Michigan)

CTSA Section Template Sample – TITLE GOES HERE

1. Aims

Introductory paragraph. Note that throughout we are using half-inch margins, Arial 11-pt font, and single spacing. We have fully justified paragraphs with a left indent to start the paragraph. We use a blank line in between major sections. A blank line between paragraphs is not required. If you have any concerns about improving the size or placement of figures, please contact Ana so that a staff member can assist you if you would like.

The following specific aims are designed to meet national CTSA Strategic Goals [list strategic goals]:

In the renewal period, we will:

Aim 1. Entire text of the aim is written in bold font.

Strategies/approaches: (1) Strategies and approaches are not bolded; (2) numbers are used to order the strategies; (3) etc.

Aim 2. Entire text of the aim is written in bold font.

Strategies/approaches: (1) etc.

In Summary,...A summary paragraph contains your primary impact statement and clearly shows reviewers how clinical and translational research will be transformed once your aims are achieved.

Figure 1: Summary of Core Impact

2006 Baseline	CTSA Impact as of 2011	Planned CTSA Impact as of 2017

2. Significance

“Italicized vignette or quote would be included here.”

A brief paragraph here should address the following review criteria: “Will the proposed CTSA significantly improve the overall quality of clinical and translational science at the applicant institution? Are the overall program vision and strategy adequate to satisfy the intent of this initiative to facilitate and sustain a home for clinical and translational science that incorporates a wide range of clinical disciplines, specialties, and subspecialties? Will the proposed CTSA have potential to make a significant contribution to a national consortium of CTSA’s?”

3. Innovation

A **brief** paragraph here should address the following review criteria: “Does the CTSA program propose innovative approaches to integrate clinical, basic, and other relevant disciplines (eg. Public health, bioinformatics). Does the program develop or employ novel concepts, approaches, methodologies, tools, or technologies that will improve the discipline? Is the program likely to develop novel approaches to promote the efficiency of clinical and translational research?”

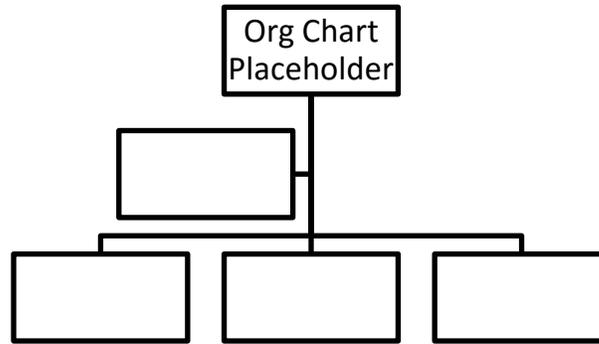
4. Accomplishments/Progress Report

4.1 Sub-sections within the progress report: If applicable, sub-sections here would be numbered as shown.

5. Approach

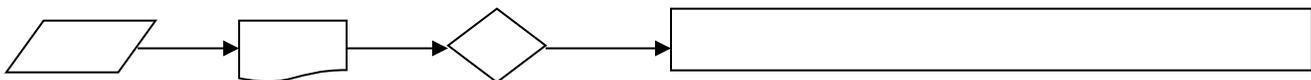
5.1 Overview and Structure:

Figure 2: Core Organizational Chart: [NOTE Org Charts will be standardized after drafts are submitted.]



A brief narrative overview of components of the program goes here

Figure 3: How users access services day-to-day [NOTE flow charts being created by evaluation core]



5.2 Investigators: A description of selected team members and their qualifications

5.3 Aim 1 Restate the aim here

Strategy 1: etc., etc., etc.

Strategy 2: etc., etc., etc.

5.X Integration with other cores: A brief description of how you integrate with other cores goes here.

6. Evaluation

The Evaluation Plan for this Core is more fully described in the overall Evaluation Plan for MICHHR, as required in the RFA. A Logic Model specific to this core is appended in the overall Evaluation Plan as well. However, major metrics and data sources for each aim are summarized here.

Aim	Metric of Success	Practical Data Source
Aim 1 briefly restated	Top 2-3 metrics	A note on where the data for each metric is coming from
Aim 2 briefly restated	Top 2-3 metrics	A note on where the data for each metric is coming from

7. Milestones and Implementation

The Milestones and Implementation Plan for this Core is more fully described in the overall milestones and implementation plan, but major milestones are summarized below.

Aim	Year 6	Year 7	Year 8	Year 9	Year 10
Aim 1 briefly restated	Concrete milestones in appropriate boxes				

Sample Style Sheet (contributed by University of Michigan)

benefitted (not benefited)

bi-directional (not bidirectional)

Biorepository and BioLibrary – capitalize if referring to ours

bullet points – Bullets should be flush left, with the text starting .25” in from the bullet.

capitalization – generally down-style, with exceptions where it makes sense

Michigan – use only to refer to the state of Michigan. Use UM or University of Michigan to refer to the university.

numbers above nine should be written as numerals (unless at the beginning of a sentence) 1, 2... 9, ten

numbered lists: (1) text; (2) text; (3) text; and (4) text.

\$200,000 (not 200K)

\$2M (not \$2,000,000)

figures/charts – flat vs. 3D, black if possible, contrasting shades of gray in complex charts, no box around them, Arial font, legends to the right, no titles at top – include in caption below with Core acronym and figure title in 10pt bold, e.g. **BIC-Figure 1. Diagram of innovation pipeline...** group caption with figure in Word

figure/chart/table names should follow this style: **EMC-Table 5: Characteristics of Scholars Participating in the Programs**

vignettes/quotes should be 10 pt. Arial italic, in a shaded box. (Highlight the text, click the “borders and shading” button from the paragraph formatting box, select “outside borders,” then select “borders and shading” and add 10% shading.)

*“In 2010 I received a pilot grant from MICHR to help characterize a biomarker of ovarian reserve in a population of patients with SLE. These results were submitted as supplementary data for an RO1 application, which was fully funded to conduct a multi-center clinical trial that will include the UM, Duke, UNC, NYU, and WPAHS and is on schedule to enroll the first patient in April 2011. In addition, a manuscript describing these findings will be submitted to the Journal of Reproductive Medicine this month.”
Wendy Marder, MD – Department of Internal Medicine-Rheumatology*

Official names and abbreviations

Biomedical Informatics Core – BIC (not Bioinformatics Core)

Biostatistics, Epidemiology and Research Design Core – BERD (not BERDE or RDEBE)

Children’s Health Initiatives Core – CHI

Clinical Research Ethics Team

Clinical Research Resources and Facilities Core – CRRF

Community Engagement and Research Core – CERC

Education and Mentoring Core – EMC

Sample Section Completeness Checklist (Contributed by Albert Einstein College of Medicine)

Contributed by Maija Williams, Albert Einstein College of Medicine. Similar tables were prepared for each section of the application. Contact Ms. Williams if you are interested in other sections.

Overall Impact: Prior Funding Period Progress Report		
Required Content	Yes	No
The impact that the CTSA has had on the quality and extent of clinical and translational science at the applicant institution.	<input type="checkbox"/>	<input type="checkbox"/>
Progress made toward the goals and milestones proposed for the previously funded grant application should be described, and the contribution of the institutional commitment to the integrated “home” for clinical and translational research tabulated.	<input type="checkbox"/>	<input type="checkbox"/>
The success with which the CTSA was integrated with pre-existing clinical and translational research at the institution.	<input type="checkbox"/>	<input type="checkbox"/>
The impact of the CTSA in the previous project period on health research communities outside the awarded institution, including local organizations, regional affiliations as well as national clinical and translational research communities, should be described.	<input type="checkbox"/>	<input type="checkbox"/>
List which of the five CTSA Consortium Strategic Goals staff has participated in and the impact that their contribution has had both locally and on the consortium.	<input type="checkbox"/>	<input type="checkbox"/>
Leadership in CTSA Key Function Committees should also be described in this section.	<input type="checkbox"/>	<input type="checkbox"/>

Start early and you can never be too organized. We tried to follow a calendar with firm deadlines but many of our leaders didn't really start working hard on this until the last six weeks. That's fine if you want to work non-stop night and day, weekends and holidays for six weeks solid but it's less than ideal. In the end we believe we delivered a good product but none of us want to go through that again anytime soon. I can't stress enough you must get senior leaders on board early to buy in to the urgency of the effort.

We developed a number of tools which proved useful:

Calendar Example:

	Time	Section	Activity	Primary Author	Status
Preparation Phase	Wednesday, June 30, 2010	-	Communication with External Advisory Committee (EAC) members, inviting reappointment and scheduling day to meet in early to mid-January 2011	Director of Communications and EAC	complete
	Monday, July 26, 2010	F.(1)	Meet with Tracking and Evaluation to discuss data required for impact section	Executive Council and Tracking and Evaluation	unable to complete
	Aug - Sep 2010	F(2) and F(4)	By examining documents such as Year 4 Statements of Work, Year 3 Progress Reports, CTSA Review Criteria, etc., PI will meet with Program leadership to discuss progress against specific aims and logic model - discuss what to keep, what to stop and what to start	PI and Program leadership	discussions took place but not as formally as described
	Friday, August 20, 2010	-	Provide summary of EAC comments to program directors as well as identification of recurring themes	Administrator	complete
	Tuesday, August 31, 2010	F(2)	Initial meeting between PI and institutional leaders to discuss broad goals of renewal	PI, select Co-Pis and administrator	complete
	Monday, September 20, 2010	F(4)	PI to have initial meetings with each program director to discuss initial outline of renewal	PI, program directors and administrator	complete
	Wednesday, September 22, 2010	D, F(2), & F(4)	Leadership Retreat - program directors present initial outline to ACTSI leaders for feedback and recommendations. Administrator will present updated calendar and responsibility list as well as approach to assembling the renewal proposal. PI will discuss budget guidance	Executive Council, Leadership Council, Administrative Home, Co-Program Directors, Key Staff and facilitator	complete

Responsibility List Example:

ACTSI Renewal Responsibility List					
as of: Thursday, September 22, 2011					
Section:	Primary Author	Other Contributors	Reviewers	Page Limitation:	Comments:
Letter of Intent					Done
Routing Update					Proposal is routing through divisions and departments. Young responding to their questions/concerns as they arise. SOM has done a preliminary review and has requested a collaborative split of several of our projects. Young working on this task now.
A. Face Page(s)	Sidnee Paschal Young		Andrew West	n/a	Young working
B. Description, Performance Sites, and Key Personnel	Sidnee Paschal Young		Andrew West		Complete
(1) Description	Andrew West		Jeff Sands and David Stephens		Complete
(2) Performance Sites	Sidnee Paschal Young				Complete
(3) Significant Key Personnel	Sidnee Paschal Young				Complete
(4) Other Significant Contributors	Sidnee Paschal Young	Rondereo Sidney, Maribel Baker, Robin Hudson, Kris Rogers & Elizabeth Thompson			Complete
C. Table of Contents	Andrew West				West and Thompson will compile at the end
D. Detailed Budget Page for Initial Budget Period and Entire Period of Support	Sidnee Paschal Young	Geneanne Trevillion (MSM), Maribel Baker (GT), Beverly Yandell (MSM) and Robin Hudson (KPG)	Dr. Stephens, SOM and OSP		Complete - double checking figures

Daily Update. This can be weekly or monthly in the lead up but during the last few weeks, you'll want to start providing daily updates either early every morning or late every evening.

	Proposal is routing through divisions and departments. Young responding to their questions/concerns as they arise. SOM has done a preliminary review and has requested a collaborative split of several of our projects. Young working on this task now.
Routing Update	
A. Face Page(s)	Young working
B. Description, Performance Sites, and Key Personnel	
(1) Description	Complete
(2) Performance Sites	Complete
(3) Significant Key Personnel	Complete
	Complete
C. Table of Contents	West and Thompson will compile at the end
D. Detailed Budget Page for Initial Budget Period and Entire Period of Support	Complete - double checking figures
E. Biographical Sketches and Research Support	Complete
F. Institutional Clinical and Translational Science Award Program	
(1) Overall Impact: Prior Funding Period	6/10 Sent to Stephens by Janet last night for final review
(2) Approach	6/10 Final review
(3) Governance	6/10 Final review
(4) Biomedical Informatics Program (BIP)	6/10 check formatting before converting to PDF

Your CTSA Specific Directions – some of the instructions allow interpretation. You’ll want to establish rules for everyone to follow. This will make editing easier towards the end.

Category	Topic	Question	Answer/Direction
Budget	Budget Assumptions	What budget expectations should program directors assume? Flat?	NCRR issued a letter telling us to assume flat funding based on year 5 of the initial funding period. Institutional funding is being pursued with vigor - it wouldn't hurt to assist with any lobbying efforts. Please discuss with senior leadership.
Content	Address the RFA		Make sure your component section addresses the component section specific items (if applicable) in Section IV. Application and Submission Information
Content	Coordination with other ACTSI programs, CTSA institutions, and non-CTSA institutions.		Be sure to discuss and share what you plan to include in your section about collaboration with another ACTSI program - each section must be able to stand on its own and coordinate with other sections. Will come up with a table to be used by each component section describing interactions with other ACTSI programs, other CTSA institutions, and other non-CTSA institutions.
Content	renewal must match web-site		Be sure what is written in component section does not contradict what is on web-site, APR, brochures or any other publicly available materials - reviewers will check anything that seems outlandish.
Content	Review Criteria		Make sure the component section addresses Section V. Application Review Information
Content	uniformity of format		Each component section will be standardized to the extent allowable. Although each will have some differences depending on the RFA. Expect further direction on our format later.
Content	Wow!		Make sure to end with a Wow! Specific Aim. At the same time, be sure to capture the reviewer's attention as early as possible in the component section. You have to get them excited and thirsty for more. For the most part, ending with a science Wow! Is a good idea unless Dr. Stephens has told you otherwise.)For instance, CIN may end with a CERP Wow!)
Instructions	Appendices	Are appendices allowed?	No, appendices are not allowed. However, we are allowed a section titled, "19. Other Tables, graphs, figures, Drawings and Charts - Other Tables, Graphs, Figures, Drawings and Charts (12 each , 60 pages total). The organization and content of these tables are left to the applicant; however summary and graphical displays are encouraged. They may be sited in the text so as best to facilitate review." If you need to use any of this space, please include at the end of your section under the heading, "Other Tables, Graphs, figures, Drawings and Charts. Keep in mind that you may not be able to include everything you want considering space limitation.

Key Contact List

By all means, establish a single key contact person for each program or institution and make it known to that person and to everyone else that they are the single person responsible for deliverables from their program or institution.

Program	Contact Person	e-mail address	phone number
CIN	Debora Clem	dclem@emory.edu	404-712-1993
RETC	Cheryl Sroka	csroka@emory.edu	404-727-5096
CERP	Katherine Erwin	kerwin@msm.edu	404-756-5278
ERKS	Carlton Dampier	cdampie@emory.edu	404-778-2561
TTR	Deb Smith	dasmit3@emory.edu	404-727-9717
PiCoTraCS	Rob Taylor	rntaylo@emory.edu	404-727-9106
BERD	Bob Lyles	rlyles@emory.edu	404-727-1310
BIP	Tahsin Kurc	tkurc@emory.edu	404-727-3339
CTRPP	Carlton Dampier	cdampie@emory.edu	404-778-2561
Tracking & Evaluation	Leo Andres	landre2@emory.edu	404-712-0064
Governance	Andrew West	awest2@emory.edu	404-727-9296
Institution	Responsible Person	e-mail address	phone number
Emory	Andrew West	awest2@emory.edu	404-727-9296
Morehouse School of Medicine	Rondereo Sidney	rsidney@msm.edu	404-752-1664
Georgia Tech	Maribel Baker	maribel.baker@bme.gatech.edu	404-385-0247
Children's Healthcare of Atlanta	Kris Rogers	Kristine.Rogers@choa.org	404-785-7503
Kaiser Permanente Georgia	Bob Davis	Robert.L.Davis@kp.org	404-365-4106

Bold letters indicate confirmation of Key Contact.

Key contact will be given access to eRooms and will be the designated person for a program or institution from which the renewal preparation team will turn to for assistance.

Make sure you come up with an acronym list early on so editing will be easier. You don't want to be using multiple acronyms (GT, Ga Tech, GA Tech, etc.). It will irritate reviewers.

Example of an acronym list:

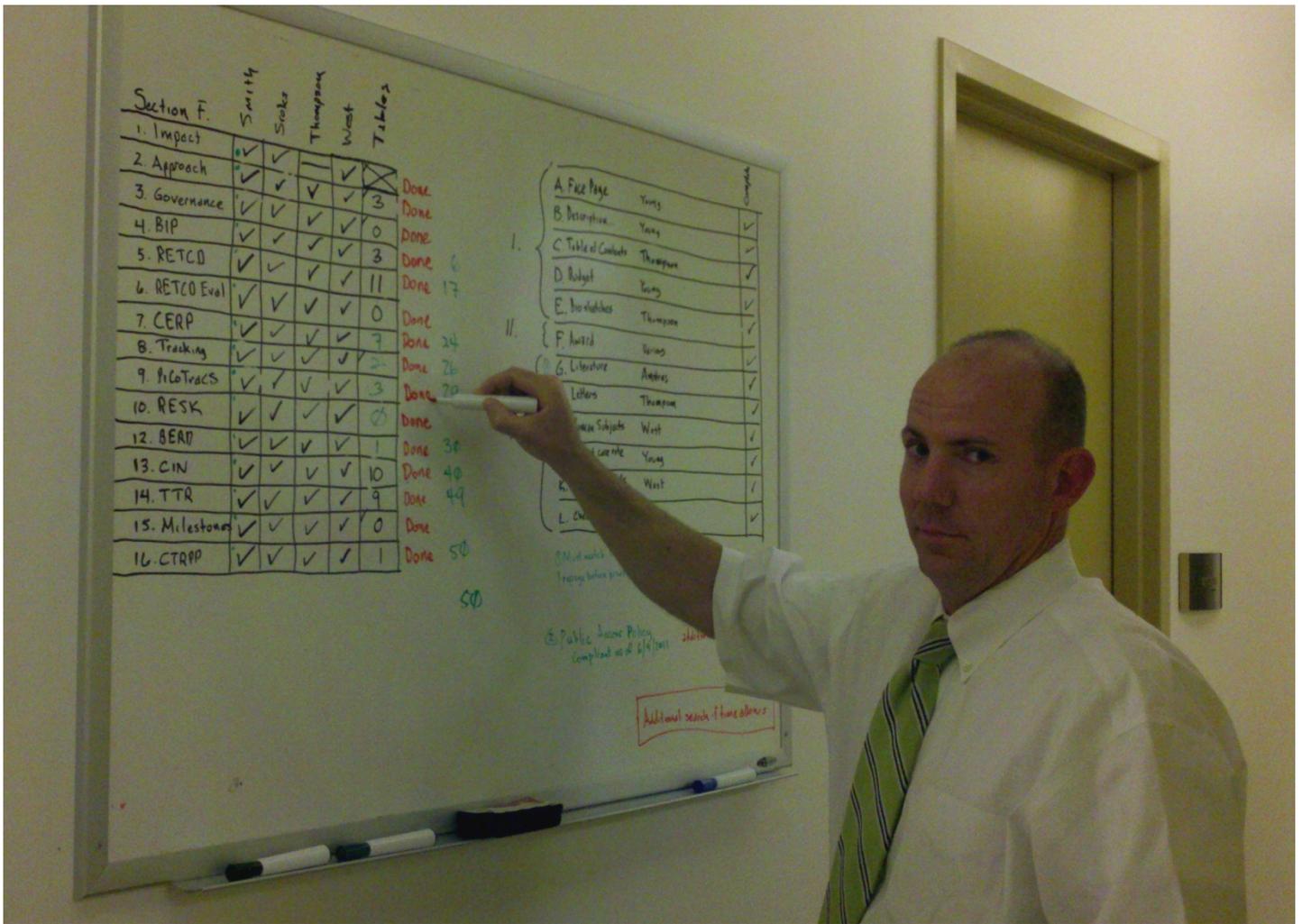
Acronym or Abbreviation	Defined
ACTSI	Atlanta Clinical & Translational Science Institute
ARC-NEx	Atlanta Research Consortium for Nutrition and Exercise
ARTy	ACTSI Recruitment System
ATC	Advanced Technology Consortium
BCC	Biostatistics Consulting Center
BERD	Biostatistics, Epidemiology & Research Design
BGIN	Biostatistics in Genetics, Immunology, and Neuroimaging Training Program
BIG	Bioinformatics Interest Group
BimCore	The Biomolecular Computing Resource
BIP	Biomedical Informatics Program
SDBDMC	Study Design, Biostatistics, and Data Management Core
CAB	Community Advisory Board
caBIGÒ	cancer Biomedical Informatics Grid
CBO	Community Based Organization
CBOC	Community Based Outpatient Clinics
CBPR	Community Based Participatory Research
CBRN	Community Based Research Networks
CCI	Center for Comprehensive Informatics
CDC	Centers for Disease Control and Prevention
CDE	Common Data Element
CDISC	Clinical Data Interchange Standards Consortium
CDW	Clinical Data Warehouse
CER	Comparative Effectiveness Research
CERCI	Comparative Effectiveness Research Core Integrator
CERP	Community Engagement and Research Program
CFAR	Center for AIDS Research
CHC	Community Health Clinic
CHC	Community Health Center
CHD	Center for Health Discovery
CHEDA	Center for High Throughput Experimentation, Design and Analysis
Children's	Children's Healthcare of Atlanta - DO NOT USE CHOA!
CHW	Community Health Worker
CIN	Clinical Interaction Network
CIS	Clinical Interaction Site
CPN	Community Physician's Network
CR Assist	Clinical Research Assist
CRC	Clinical Research Center
CRM	Clinical Research Management

Whether you have one person proofreading the entire document or multiple people doing it, it's good to have a checklist of things to look for when you are doing your final proofreading. Here's an example of a checklist:

Category	Topic	Question	Response	Responsibility
Content	Specific Aims	Do your Specific Aims match up to what is written in Approach, Tracking and Evaluation and other applicable section?		Smith
Instructions	Bibliography	<p>Let's go with NEJM. If you are using EndNote or RefManager to set up the references you can set the journal style and all refs will be formatted properly.</p> <p>Examples below:</p> <ol style="list-style-type: none"> 1. Morehouse SI, Tung RS. Statistical evidence for early extinction of reptiles due to the K/T event. Journal of Paleontology 1993;17:198-209. (journal) 2. Billoski TV. Introduction to Paleontology. 6th ed. New York: Institutional Press; 1992. (book) 3. Schwartz MT, Billoski TV. Greenhouse hypothesis: effect on dinosaur extinction. In: Jones BT, Lovecraft NV, eds. Extinction. New York: Barnes and Ellis; 1990:175-89. (chapter) 		
Instructions	Citations	Are all citations legitimate? Did they actually cite the ACTSI? And are they are listed in PubMedCentral ESPECIALLY if they are Spotlights?		Smith
Instructions	Font	Is Arial font size 11 used throughout the section?		Thompson
Instructions	Form Page	Is the correct 6/2009 PHS continuation form page used?		Thompson
Instructions	Header	Does the header read as one tab followed by "Stephens, David S." including the period after the "S."		Thompson
Instructions	Use of URLs	Did you check to make sure no URLs are listed?		Thompson
Style	"Executive" or "Leadership" committees at the program level	Did the program be sure not to refer to any of their committees as "Executive" or "Leadership."		Thompson
Style	color	Did you use color in your section and if yes, are you confident it will conform with the following NCRR guidance: Hard copies of the applications are received by the NIH Center for Scientific Review (CSR) and are then scanned to generate a pdf in black and white, which is what is provided to the reviewers. If colors are used in figures, graphics, or tables, the scanned black and white image has a smeared appearance. Our recommendation is not to use color unless it is absolutely essential. After your submission of the application to CSR, the NCRR Office of Review can accept color pdfs of the pages containing color figures and make them available to reviewers, but please note that the reviewers would have to make an extra effort to view these pages.		Smith
Style	commas and semi-colons	Were you careful to use semicolons to separate units of a series when one or more of the units contain commas? Example: This conference has people who have come from Boise, Idaho; Los Angeles, California; and Nashville, Tennessee. Were you careful to use		Thompson

Also, I can't stress this enough. It is very important to hire a professional grant writer. I know that may sound excessive especially for smaller CTSA's like ours but good grant writers are worth their weight in gold. It's worth spending \$5,000 or \$10,000 to put together a good proposal when you are seeking \$20M to \$100M in Federal funding. A professional grant writer is critical.

Dry Erase Board



We had a dry erase board on the wall in the middle of the hallway between our offices. We used this board during the last six weeks to keep track of progress. This is a photo of me writing “Done” next to the last component of Section F.



Final prep takes a day. You have to generate 6 or 8 copies of a document which will probably be over 1,000 pages. Ours was 1,166 pages. We even had our copier technician come in a few days before we started printing everything to make sure our main printer was all lubed up and ready to go.

Again, you can never be too organized and you can't start too early. We had a snow storm which shut Atlanta down for close to a week (we're not used to that much snow and ice down here – whatever) and forced us to cancel an important meeting of our External Advisory Council. That valuable feedback was delayed until later in the process – not sure if that was a good thing or not. The trick is to have your EAC review your proposal early enough to make a difference but not too early. If they look at a very preliminary draft, it will be a waste of their time.