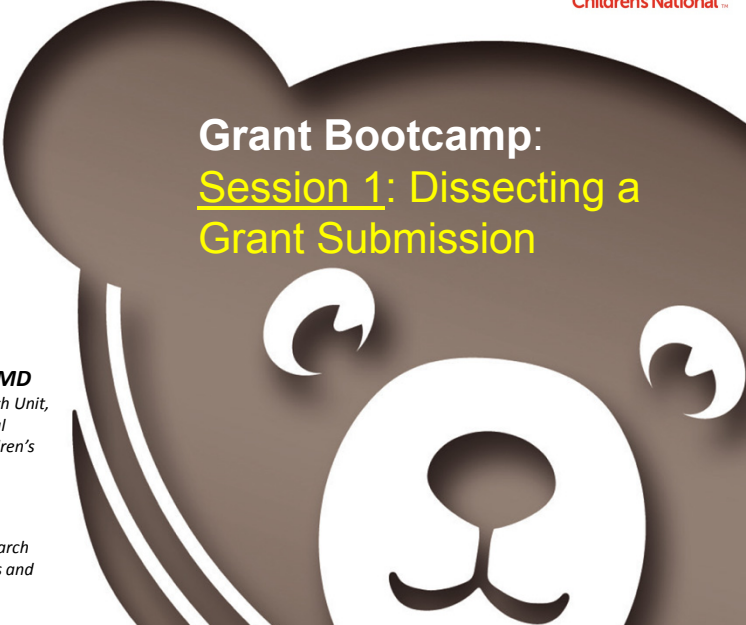


Grant Bootcamp: Session 1: Dissecting a Grant Submission

Kirsten Williams, MD
Director, Clinical Research Unit,
Clinical and Translational
Science Institute at Children's
National (CTSI-CN)

Stephanie Bair
Business Manager, Research
Finance, Office of Grants and
Contacts (OGC)

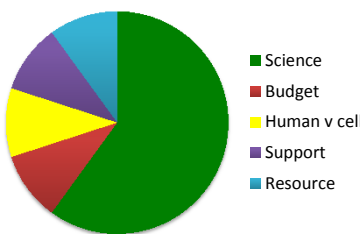



The Components → 50 pages!!, > 6 months

Breaking Down the
Elements by Time
Needed

Developed with your GFA

NIH	https://grants.nih.gov/grants/how-to-apply-application-guide/forms-sf424-research-forms-e.pdf
Section SF424	Items
Project/Performance Site Locations	All
Research & Related Other Project Information	1 through 6
	7 - Abstract, 30 lines or less
	8 - Narrative, 2-3 sentences
	9 - References
	10 - Facilities (Should include all sites)
	11 - Equipment (if applicable)
Senior/Key person profiles	12 - Other attachments (if applicable)
	Biosketches
	Demographic Data Project Role
Budget	Budget
Cover Page Supplement	Budget Justification
Checklist	All
PHS 398 Research Plan	1 Introduction (revisions or resubmissions only)
	2 Specific Aims, 1 page maximum
	3 Research Strategy, 12 page maximum
	4 Progress Report Publication List (renewals)
	5 Protection of Human Subjects (if applicable)
	6 Inclusion of Women and Minorities (required if "yes" to human subjects)
	7 Targeted/Planned Enrollment (required if "yes" to human subjects)
	8 Inclusion of Children (required if "yes" to human subjects)
	9 Vertebrate Animals (if applicable)
	10 Select Agent Research (if using biohazardous materials)
	11 Multiple PI Leadership plan (if applicable)
	12 Consortium/Contractual Arrangements (if you have subcontracts) pg. R-85
	13 Letters of Support (if applicable)
	14 Resource Sharing Plan (investigators seeking \$500k or more in one budget period) pg. R-86
	15 Authentication of Key Biological and/or Chemical Resources (if applicable) pg. R-87
	16 Human Subjects and Clinical Trials form (REQUIRED) pg. R-90
	17 Appendices (if applicable, limit 10) pg. R-88
Subcontractor Budgets (if applicable)	Budget Numbers
Assignment form	Budget Justifications
Cover Letter (if applicable)	Only needed if you have a preference for an awarding component or study section pg. R-143

Components Ro1 (et. Al) Overview

Science Pieces	Budget Pieces	Humans vs. Non-human	Support Pieces	Resource Pieces
<ul style="list-style-type: none"> • Specific Aims • Research Strategy • Narrative • Abstract • References • +/- intro for resubmission 	<ul style="list-style-type: none"> • Statement of work • Budget • Budget justification • *Outside Inst.* 	<ul style="list-style-type: none"> • Human subjects vs. Authentication of Key biological • Select agent animal • *ClinicalTrials.gov#* • Data Safety Monitoring • Dissemination • Inclusion... 	<ul style="list-style-type: none"> • Letters use of IND • Letters of CTSI • Cover page • Multi-PI plan • Resource sharing plan • Biosketches of Key 	<ul style="list-style-type: none"> • Equipment • Facilities/re sources

How can CTSI help YOU??



3

Science Pieces

14+ pages (14)



- **Specific Aims** – 1 page to sell your case– 3 aims for > 2 years of funding (intro to problem, brief recap of prelim data, sp. Aims of this grant, 1 sentence of how it will change the world)
- **Research Strategy** –12 pages (ref excluded):
 - Significance
 - Innovation
 - Approach: prelim data, research plan, expected results/pitfalls
- **Narrative (few lines)**
- **Abstract (paragraph)**
- **References (linked to Res. Strategy)**



Grants Enhancement Program (GEP)



4

Science Pieces Details

+1 page (15)



- **Rests on the statistical soundness:**

- Analysis of prior data (statistical significance of work)
- If clinical trial, power (how many people does it take?)
- Comparison of groups (human or non): method of comparison, expected difference, and thresholds of significance
- Approach: prelim data, research plan, expected results/pitfalls



**Biostatistics
Epidemiology &
Research
Design (BERD)**



5

Human Pieces

+20 pages (35)



- *R01 With Clinical Trial vs. UG3/UH3*

- **NEW Human Subject Section**

- Trial components (endpoints, eligibility)
- Conditions/focus
- Timing of trial initiation
- Enrollment table by gender/ethnicity
- Summary/study design
- ClinicalTrials.gov #
- + Data Safety Monitoring Plan
- + sIRB, Study Team
- + Inclusion/Protection/Recruitment/retention



**GEP, CT.gov #,
and sIRB**



6

Human Pieces

+20 pages (35)



• Clinical Trial Components:

- Biobank?
- Neuropsych/patient reported outcome needs?
- Bionutrition needs?
- Phlebotomy?
- Investigational infusions?
- Biosampling during procedures?
- Nursing care?
- Protocol development/ Protocol Builder



PCI's Clinical Research Unit (CRU)

Participant and
Clinical Interactions
(PCI) can provide all!



7

Human Pieces Details

pages (35)



- Obtain Clinicaltrials.gov # - 10 days
- **sIRB = single IRB Required (> 2018)**
 - Single IRB oversight
 - CNMC can support 1-2 trials
 - Access to 3 additional sIRB via CTSI's Trial Innovation Network (TIN)
 - Grant language
- Some grants require IRB approval
 - Scientific Review
- Separate detailed stat section



CT.gov#, sIRB,
Scientific Review
Committee, & BERD



8

Non-Human Pieces

+1-2 pages (37)



- **Authentication of key biological or other chemical resources**

- “All key resources... will be authenticated to enhance reproducibility”
- List all strains, describe phenotype, delineate source
- List all cell lines, all biologics
- Includes references



Grants
Enhancement
Program (provides
templates)



9

Budget Details

+5-10 pages (45)



- **Start early > 8 weeks out**
- Develop template for:
 - Individuals/salary support
 - Laboratory items (CBC or flow cytometry antibodies)
 - Biobank? Clinical Research Unit?
- If sub (**outside** institution, identify: site PI, budget and grant contacts and their timelines!)
- **For clinical elements:**
 - PCI-CRU services – Camilla Colvin
 - **Non PCI-CRU – contact your GFA**

Budget Development
for PCI/Clinical
Research Unit Services



10

Support Pieces

+13 pages (58)



- **Letters of Support (LOS):**
 - can provide for CTSI
 - Colleagues/key collaborators
 - Use if IND
- **Biosketches – key personnel**
 - New format
 - Time to get all the ones needed
- **Cover page– choosing your Institute**
- **Multi-PI Plan– coordination, division of labor, conflict resolution**
- **Resource Sharing Plan**

Basic elements of an R01

Key personnel / Biosketch

Personal Statement
 Positions and Honors
 Publications (limited to 15)
 Relevant to the application
 Other publications important to the field
 Research support – any overlaps

Letters of support Resource Sharing Plan Summary

Limited to 30 lines
 Public health relevance

• Narrative 3 sentences

**LOS by CTSI,
 and Plan
 examples**

11



Resource Pieces

+5 pages (63)

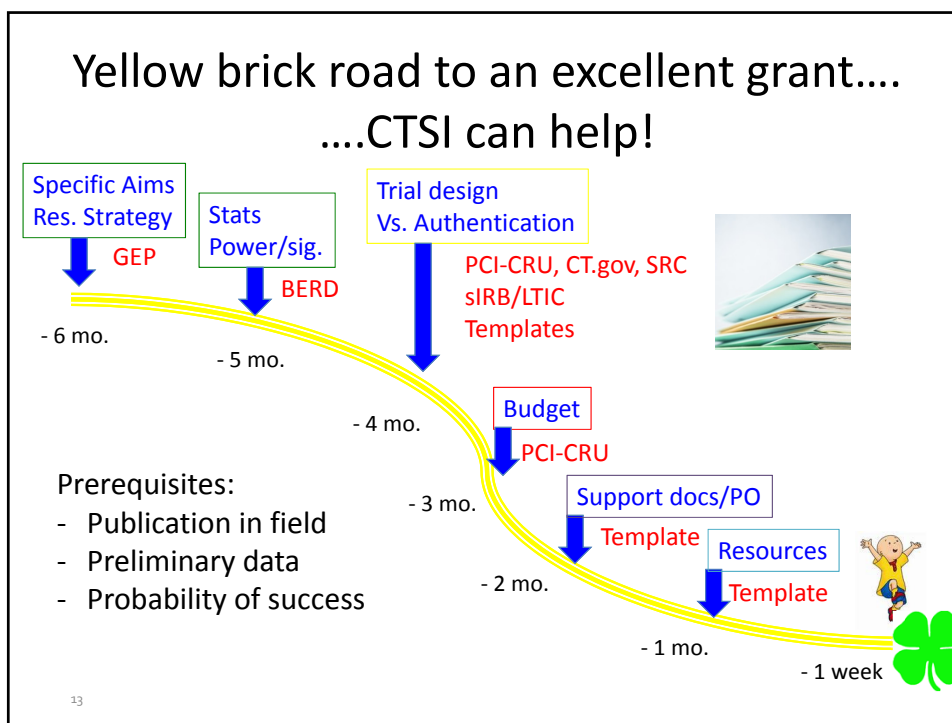


- Equipment
- Facilities/resources-
 - Children's CTSI resources
 - Positive aspect of PCI/CTSI support
 - Specialize for particular grant protocol (e.g. imaging study needs to address radiology support)
- Connect with Program Officers
 - Ensure scope fits in new guidelines

**Templates for
 Facilities and
 Resources,
 including
 PCI/CTSI**

12





Clinical and Translational Science Institute at Children's National (CTSI-CN)

To learn how the CTSI-CN can help you:

- **Contact:**

Bendu C. Walker, CTSI-CN

Administrative Director

Phone: 202-476-275

Email: bcwalker@childrensnational.org

- Visit www.ctsinc.org to learn more about our resources and services.



Work with Grants Office to complete budget and application

- Every investigator is assigned a Grants & Finance Administrator (GFA) from the business office.
 - Assists with all aspects of application
 - Assists with management of award if funded

15



Work with Grants Office to complete budget and application

- Kickoff meeting/call with GFA
 - Review Funding Opportunity Announcement (FOA), ask for clarifications if needed
 - ID collaborators
 - Responsibility matrix: assign responsibilities and set timelines

16



Work with Grants Office to complete budget and application

- The grants office has already taken care of setting up profiles, registering with the federal government, having a signing official, etc.!
- Based on the information provided in the meeting, the GFA will draft the budget
 - Consultants should provide their quotes
 - Subcontractors should provide their own budgets

17



Work with Grants Office to complete budget and application

- The PI should provide information and documents in final PDF form to the GFA as they are complete
- The GFA will set up a proposal shell in Children's submission system (Bear Grants) and complete and upload information and documents

18



Work with Grants Office to complete budget and application

- The PI/Candidate must turn in all items on or before the 7th business day prior to the day we must get it out of the office:
 - If we are prime, then it is calculated from the sponsor's deadline
 - If we are a subcontractor, then it is calculated from the date the prime needs it from us
 - This is often several weeks before the sponsor's due date

19



Sponsor Review

The waiting begins!

Often for federal applications, it can take months for the results of the review to be known and commonly it may take close to a year until an award is received.

20



Thank you!

