The Components—> 50 pages!!, > 6 months

Breaking Down the Elements by Time Needed

Developed with your GFA

- Science
- Budget
- Human v cell
- Support
- Resource
### Components R01 (et. Al) Overview

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**How can CTSI help YOU??**

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### Science Pieces

- **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)**

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*Children's National*
Science Pieces Details

- **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

Human Pieces

- **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

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

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

- 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!

Human Pieces Details

- 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
Non-Human Pieces

- **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)

Budget Details

- **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
Support Pieces

- **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**

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Resource Pieces

- **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**

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- **Basic elements of an R01**
- **Key personnel / Biosketch**
  - Personal Statement
  - Publications
  - Research support
- **Letters of support**
- **Resource Sharing Plan**
- **LOS by CTSI, and Plan examples**

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- **Templates for Facilities and Resources, including PCI/CTSI**
Yellow brick road to an excellent grant....
...CTSI can help!

Prerequisites:
- Publication in field
- Preliminary data
- Probability of success

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](mailto:bcwalker@childrensnational.org)

• Visit [www.ctsicn.org](http://www.ctsicn.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

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
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

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
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

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.
Thank you!