



CCSG 101

Teresa Christiansen

John Gricoski

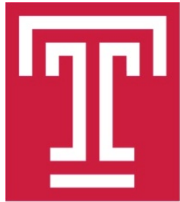
Dr. Robert Houlihan

Robert Mitchell

Lowell Smith



A Cancer Center Designated by the National Cancer Institute



FOX CHASE CANCER CENTER

TEMPLE HEALTH



Characteristics	Description
Organizational Type	Comprehensive, Free-Standing Temple University Health System
Research Conducted	Basic/Clinical/Population Science
Number of Members	166: 119 Primary + 47 Collaborating
Annualized Funding Base	>\$50 Million Total Costs
# of New Analytic Cases	>3,000
# of Clinical Trials	190 Interventional (166 Treatment)
Types of Trials Available	All

Guidelines: Timelines / Internal Review

- CCSG Due Dates: January 25, May 25, September 25
- Suggestions:
 - Minimum 1 Year to prepare a CCSG Renewal application
 - Time-line needs to be well communicated and endorsed
 - Allow adequate timing for critiques and re-writes
 - You may wish to stagger dates for cores, Programs, etc.
 - Develop time-line with external & internal reviewers
 - Select internal reviewers with requisite expertise
 - Hold session to bring the internal review team up to speed on new guidelines and review criteria
 - Program Leaders to independently read other Program reports
 - Cross reference data that appears in multiple sections



The University of Kansas Cancer Center

Characteristics	Description
Organizational Type	Matrix
Research Conducted	Basic/Clinical/Population Science
Number of Members	Total: 183 (133 Full, 50 Associate)
Annualized Funding Base	\$62.7 million (CY2016)
# of New Analytic Cases	3,000- 4,000
# of Clinical Trials	Open to accrual :422
Types of Trials Available	All



Membership

CCSG Guidelines

- Membership criteria defined by Center. **Must** follow your definition.
- Individuals selected for scientific excellence and ability to work together
- Most will have peer-reviewed funding
- A few may contribute in other ways



University of Kansas Membership

- Annual membership meeting – programs leaders and associate directors
 - Program assignments
 - Full or Associate status
- All members are reviewed and new members are assigned to program
 - Funding
 - Publications
 - Clinical Trials
 - Cancer Center leadership roles
- Program leaders must justify why members are in their program





Characteristics	Description
Organizational Type	Free-standing
Research Conducted	Basic/Clinical/Population Science
Number of Members	151
Annualized Funding Base	>\$50 Million
# of New Analytic Cases	>5000
# of Clinical Trials	443 Interventional: 183 Open to accrual, 238 Open to Follow Up
Types of Trials Available	All

Guidelines: Catchment Area

- Definition and Requirements
 - CCSG objective to support “Activities that engage the populations within the catchment area in the conducted research and other Center activities”
 - Includes addressing incidence and mortality among minority and underserved populations
 - Important criteria for Comprehensiveness and mostly consolidated within new Community Outreach and Engagement section
 - Catchment area defined by the Center
 - Population based, typically by county or state
 - Must include area surrounding cancer center area
 - Contiguous
 - Easily defensible at site visit

- IT Implications: Data Intense
 - Population demographics cut by gender, race, ethnicity, age and county/state
 - Incidence and mortality data sources (e.g., State Registry, SEER, ACS)
 - Additional data mining to determine what is unique to catchment area (e.g., an underserved population, high incidence rate in a particular cancer)
 - Multi-year data to show trends or confirm no trends
 - Determine research issues relevant to catchment area (two-way analysis)
 - Excel for analysis, but will likely need a graphic or dashboard to present results
 - Multiple data sources make developing a single system challenging

Our Center Approach

Topic	Approach
Timelines & Internal Review	Excel based assignment grid with review schedule, due dates, status
Membership & Program Alignment	In-house system developed to track Members. Data linked to programs, grants and publications for reporting
Catchment Area	Collect population data (demographics, incidence/mortality); patient demographics including accrual; compare to research strengths; epidemiologists to validate data
Document Version Control	Specific file naming convention, formal redlining, single hand-offs (requires time), archive all versions, single point-person to coordinate
EAB Utilization	Post materials online ahead of meetings; ask advisors for redlined drafts of grant sections; disseminate comments quickly to all areas
Educating Leaders	Meetings, email, presentations; drafts of narratives and data tables and narratives provided (transparency as process moves along)
Data Tables	DT1 in Excel; DT2 through in-house grant system with excel clean-up; DT3 custom dashboard pulls from registry and OnCore; DT4 see below
Clinical Trials	Custom dashboard developed; supplemented with expert utilizing Excel, not yet directly linked to membership/program data, so scrubbing required
Publications	Tracking through validated Pubmed query; data feeds custom reports and dashboards by program and Member; same team tracks open access compliance
Site Visit Preparation	Versioning of presentations similar to narrative; at least 3 full dress rehearsals; many more smaller group reviews; seek broad feedback (transparency)

Cancer Center Support Grant 101



**University of Maryland Marlene and Stewart
Greenebaum Comprehensive Cancer Center**

**CCAF Annual Meeting
April 30 – May 2, 2017**



A Cancer Center Designated by the
National Cancer Institute



University of Maryland Marlene & Stewart Greenebaum Comprehensive Cancer Center

Characteristics	Description
Organizational Type	Matrix
Research Conducted	Basic/Clinical/Population Science
Number of Members	248 members (115 Full, 133 Associate)
Annualized Funding Base	\$61.7M
# of New Analytic Cases	3,400
# of Clinical Trials	218 Clinical Trials; 159 interventional
Types of Trials Available	All



A Cancer Center Designated by the
National Cancer Institute



Utilizing the External Advisory Board

- EAB composition & mission in PAR-17-095
- Discuss EAB recommendations in Planning & Evaluation section
 - Provide reports at site visit
- Read past EAB reports
- Compare your application, achievements & what you're writing about to their recommendations.

Utilizing the External Advisory Board

- Use EAB as mock Site Visit team
- *No Spin Zone*, full disclosure
- Sounding board for new initiatives
 - Formal & informal source of information & advice
- Influence on institutional leadership
 - Tell them what to write about



Characteristics	Description
Organizational Type	Matrix
Research Conducted	Basic/Clinical/Population Science
Number of Members	144
Annualized Funding Base	\$30 - 50 Million
# of New Analytic Cases	1,000 – 2,000
# of Clinical Trials	313 Open to accrual, 229 Open to Follow Up
Types of Trials Available	All

■ Definition and Requirements

- The role of peer review is to assess the extent to which the center has promoted or is likely to promote excellence in research that may lead to a reduction in the incidence, morbidity, and mortality attributable to cancer to persons within their catchment area and beyond.
- Reviewers also evaluate how well the center’s leadership, organization, and processes for development and evaluation facilitate scientific productivity, strengthen the institution’s research capabilities, and enable its investigators to take advantage of scientific opportunities beyond what would have likely occurred at the institution without the CCSG.¹
- PAR 17-095: “Site Visit” found once (Organizational Capabilities)
- “Information Letter” providing guidance for Site Visit Agenda, On-site Logistics, and requested Action Items issued to Center ~2 weeks after submission date.
 - Action Items due back to NCI within 3 weeks.

¹Source: “Peer Review Processes Relevant to the CCSG.” URL: <https://cancercenters.cancer.gov/GrantsFunding/CCSGPeerRev>
Date Accessed 4/25/2017.

Guidance for the Site Visit Agenda and On-Site Logistics

- Site Visit begins at 8:00 AM and completed by 2:00 PM
- Director's Overview
 - Broad overview of the Cancer Center
 - Six Essential Characteristics
 - Major changes in Organization/Leadership Since Last Review, or Submission
 - Major scientific achievements
 - 25-30 minutes, 15-20 minutes for Q/A
- Administration
 - Clarify outstanding issues
 - Budget review
- Program(s)
 - Most critical area for peer evaluation
 - Quality of science and the “value-added”
 - Presentation time for each Program should not exceed 10 minutes with equal time for questions

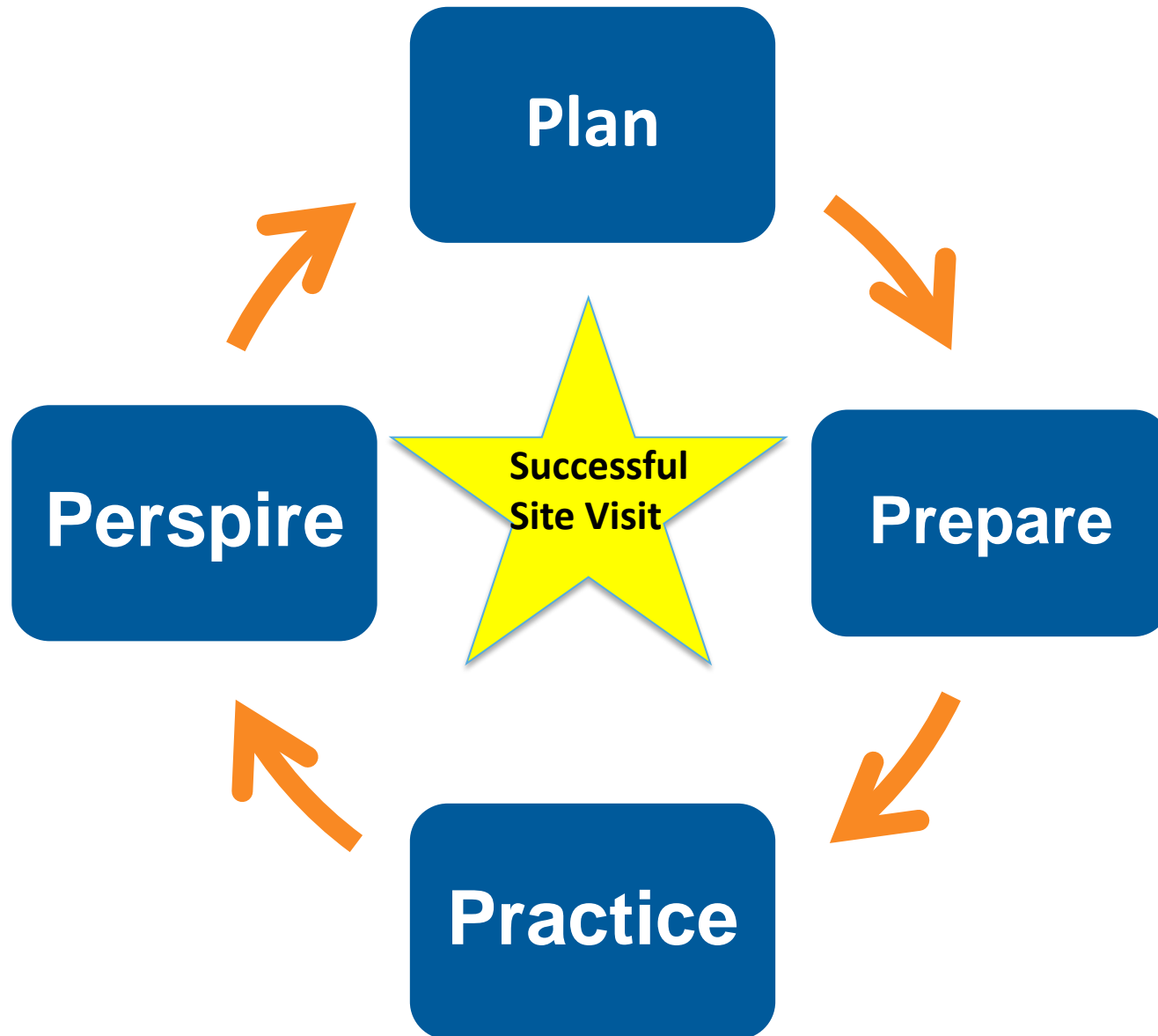
- All other sections equal time must be scheduled for Q/A (maximum 10 minutes)
 - CPDM
 - PRMS
 - Inclusion of Women, Minorities, and Children in Clinical Research
 - Up to a 10 minute Q/A session should be scheduled for any component included in the CCSG application not having a presentation
- Tour of Facilities
 - 30-minute session for tours and posters followed by a 5 minute Q/A session
- Executive Sessions (Typically, two scheduled)
 - First session may include lunch with team meeting privately for one hour
 - Final session for 15 minutes after all presentations are completed
- Review materials to be available
 - DSMP
 - Data Table 2 (as of 60 days prior to review)
 - Pending grants and contracts
 - Data Table 4 (as of 60 days prior to review)
 - Center member biosketches
 - Institutional protocols
 - Strategic Plan
 - Minutes/agendas of external/internal advisory committees
 - Community engagement activities

Topic	Approach
Agenda	Initial agenda developed and sent to SRO. Several revisions occurred via internal discussions with new presentations added and times revised. Remained in contact with SRO and final agenda accepted after Mock Site-Visit.
Room Selection	Several rooms identified, few met requirements. Two needed to be reserved for the site visit location and a back-up. Once suitable room identified, it was booked regularly for practices.
Practices	Central schedule maintained by Administration with Presenters being kept up-to-date regularly. Presenters received professional coaching to aid in delivery. Practices were conducted individually and in groups with audience engagement to refine delivery.

Topic	Approach
Presentations	<p>Templates distributed with instructions. Presenters met with Director to review slides; revised after practices; again after Mock Site Visit. Final slide deck locked down and all slides reviewed a final time.</p>
Food	<p>Potential vendors identified, one selected for Mock Site Visit. Opted to go with a known vendor for Site Visit.</p>
Notebooks for Review	<p>Managed by Administration, areas tapped to provide data, reviewed by multiple staff, printed and tabbed in-house.</p>
Reviewer Notebooks	<p>Managed by Administration; contracted out for printing, proof reviewed and go-ahead to print was given once satisfied. Random sampling conducted on delivered product.</p>
Room Set-Up	<p>Room reserved afternoon before visits. Volunteer staff arranged room to diagramed specs. Contracted AV services.</p>

Topic	Approach
Posters	Developed Poster templates and distributed them to Core Directors. Met with Directors several times during design phase. Final versions sent to printer for production and Reviewer Notebook inserts.
Staff Assignments	Engaged entire Administrative staff to participate. Each assigned specific responsibilities. 38 staff participated throughout the day.
After Visit Party	Relax, unwind, and maybe take the next day off.

Our Center Approach



Educating About Key Data in the Application

- Suggestions:



“Assume nothing” – You (the administrator) have a broad perspective of the application, but do all stakeholders?

- Make sure that Program Leaders, Shared Resource Directors, etc. are aware of:
 - Membership – who is in their Program, what value do they add, what are they working on, what grants do they have
 - Funding – how much, what types, be able to defend cancer relevance of particular funding if asked
 - Synergies – how important Cores are to Programs, and how Programs are important to one another (collaborations, etc.)
- Methods of Communication:
 - Group meetings, one-on-one, shared drive, updates of centralized data, emails, key data fact cards

Fox Chase Cancer Center

Topic	Approach
Timelines & Internal Review	18 month timeline utilizing an Excel based assignment grid with review schedule, due dates, status. Multi-level review process with the Cancer Center Director & Senior Research Leadership reviewing final grant application (both hardcopy & electronic versions) prior to submission.
Membership & Program Alignment	Formal application process for Cancer Center membership. Application reviewed by Program Leaders for cancer relevance and program alignment ; Recommendations made to a Cancer Center Membership Committee .
Catchment Area	Collect population data (demographics, incidence/mortality); patient demographics including accrual; compare to research strengths; FCCC catchment comprises 15 counties in PA & NJ, 7.2M population; Cancer burden exceeds the national avg. by 17% in this area.
Document Version Control	Shared Drive utilization with only with only appropriate personnel access; Specific file naming convention, formal redlining, archive all versions, single point-person to coordinate. Cancer Center Admin. has ultimate “ lockdown ” of shared drive.
EAB Utilization	2 EAB meetings prior to application submission. Initial for feedback on the direction & final meeting is an application review (approx. 3 months prior to submission). We will also utilize consultants for specific components of concern.
Educating Leaders	Meetings, email, presentations; drafts of narratives and data tables provided. Reviewing membership with each program leader.
Data Tables	DT1 in Excel; DT2 through InfoEd grant system with scrubbing/clean-up involved; DT3 custom dashboard pulls from registry and OnCore; DT4 see below.
Clinical Trials	Custom dashboard developed in-house; supplemented with expert utilizing Excel, not yet directly linked to membership/program data, so scrubbing required.
Publications	Tracking through validated Pubmed query; data feeds custom reports and dashboards by

Data Management

CCSG Guidelines

- Center chooses the reporting period
- Data Table Guides
- Publications
 - Transdisciplinary collaboration and coordination
 - Research program contributions
 - Development funds accomplishments
- Developmental Funds return on investment
- Must provide updated information at site visit (<60 days)



University of Kansas Data Management

- Reports on a calendar year basis
- Member information is stored in homegrown database
 - Funding
 - Publications
 - Clinical Trials
 - Pilot Awards
- Data is reviewed by program leaders quarterly
- Program leaders make decision on cancer relevance



Guidelines: Publications

- Definition and Requirements
 - Critical metric sprinkled throughout the entire application, especially in:
 - Director’s Overview
 - Programs
 - Developmental Funds
 - Required statistics:
 - Intra-programmatic
 - Inter-programmatic
 - Inter-institutional
 - Inter-Consortium (if applicable)
 - Publications resulting from pilot funding (Developmental Funds)
- IT Implications:
 - Must implement an ongoing process
 - Greatest challenge – accurately linking author names to your Members
 - Adapt dynamically to changes in membership or program alignment
 - Analysis tools to evaluate impact of changes
 - Ensure all are cancer related
 - Determine criteria for determining the “selected list”
 - Define “top tier” and “widely cited” definitions and apply consistently
 - Anticipate tracking by other topics (e.g., by aim, developing programs, specific cancers)
 - Tracking PMID and PMCID and ensure Open Access requirements are met

CCSG 101

Version Control

- 1,375 double-sided, single spaced pages
- Provide template to all authors
 - Section Headings
 - Page Limits
 - Standardize format, font
- Name a single point-of-contact
 - Controls receipt and storage of drafts
 - Air traffic controller



CCSG 101

Version Control

- File sharing system
 - Establish sharing and access permission
- Establish a naming convention
 - ProgramAcronym_author initials_date
 - mm_dd_yyyy
- Use *Track Changes*
- Save everything
 - Each version
 - Until?





CCSG 101

Teresa Christiansen

John Gricoski

Dr. Robert Houlihan

Robert Mitchell

Lowell Smith