



CTSA Clinical & Translational
Science Awards Program

Research and Services Module W. H. Wilson Tang/Nora Singer



MODULE GOALS

- To expand **research participant** recruitment/engagement of special populations and **catalyze collaborations** across health systems and communities
- To outreach, cultivate, and assure quality **environments** (personnel, facilities, equipment) for early clinical translation and across disciplines
- To provide project development support, stewardship and oversight for **citywide collaborative projects**

PLANS TO ACHIEVE GOALS

Office of Research Engagement and Outreach

- **Community Forums** to connect and engage community partners across CTSC partners
- **Advisory Forums** for testing/feedback of surveys/tools or implementation science
- **Innovators Forums** to engage cross-disciplinary innovators, including dedicate space to test engineering equipment/computational applications for novel solutions

Collaborative Research Core

- **Innovations Catalyst Program** to streamline study start up, recruitment services and project management for timely support of GMP/GLP-based protocols (biannual RFA)
- **Surveys Development Core** for design and development of surveys/focus groups with qualitative/quantitative methodologies and citywide deployment (quarterly RFA)
- **Health Impact Studies** with focus on dissemination and regional health impact (biannual RFA)



OUTCOMES AND METRICS

Reach and Effectiveness

- # studies meeting enrollment milestones and diversity targets
- # participants enrolled in satellite sites/remotely

Adoption

- # GMP/GLP-based protocols (single/multi-site) supported
- # novel test protocols supported / participants enrolled

Implementation and Maintenance

- # surveys/tools developed / # panels supported
- # citywide studies meeting enrollment milestones and diversity targets and sustainable impact

BERD

From Jennifer Gassman, Curtis Tatsuoka, Doug Gunzler

1. Provide **consultations** for investigators regarding use of optimal study designs and statistical analysis plans, design and analysis of retrospective and prospective studies, population health studies, and preliminary/exploratory data analysis for support of proof of principle
2. Apply **novel study designs and statistical methods** through collaborative clinical translational research projects and disseminate innovations
3. Support **design, development, and analysis of survey projects** and qualitative/ quantitative analysis and psychometrics (i.e. factor analysis) techniques
4. **Statistical analysis support for Health Impact Studies** including analyses of regional health impact



RKS/Bioethics

From Phil Cola, Joan Booth

1. Leverage use cases to develop **regulatory tool kit and standardize policy/processes** across CTSC (tele-research, data/resource sharing)
2. Share best practices on **research management** in clinical (hospital based settings), university or non-clinical settings, and community settings (i.e. clinicaltrials.gov, regulatory affairs, fiscal management, ethical considerations)
3. Advise on **appropriate data sharing** for collaborating institutions (local/national)
4. Provide **consultations for bioethics challenges** surrounding translational science.



YEAR 5 PLANS TO FILL GAPS

Q4 2021

- Present goals to EAC/SC
- Define R&S module membership/roster and governance
- Schedule team meetings
- Define budget
- Identify institutional resources and content expert contacts/processes
- Outline prelim data supporting goals
- Define logistic/workflow of (RFA, applications, review, execution, and metrics)

Q1 2022

- List stakeholders and partners/supporters and get biosketches/letters
- Clarify/outline interactions with/requests from other modules
- Trial run of operations across institutions and solicit feedback/refinement of processes
- Capture prelim data supporting trial runs
- First draft of 6-pages completed for review

Q2 2022

- Trial run of refined workgroup processes and show feasibility/impact
- Identify/refine metrics to measure based on goals
- Confirm interactions within and across Elements across institutions
- Internal mock peer review
- Revise 6-pages with feedback
- Submit grant!