# The Added Value of Qualitative Research to CTSA Evaluations

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Figure 2. Clarification of RSAC Output Results

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RSAC User De-

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### INTRODUCTION

Researchers outside the social sciences often fail to incorporate qualitative data in their analyses. To better understand the process and outcomes of each core and program in the University of Illinois at Chicago (UIC) Center for Clinical and Translational Science (CCTS), we have incorporated a mixed-methods research design to our evaluation. This poster describes the added value of qualitative data collection and analysis methods as found in our evaluation.

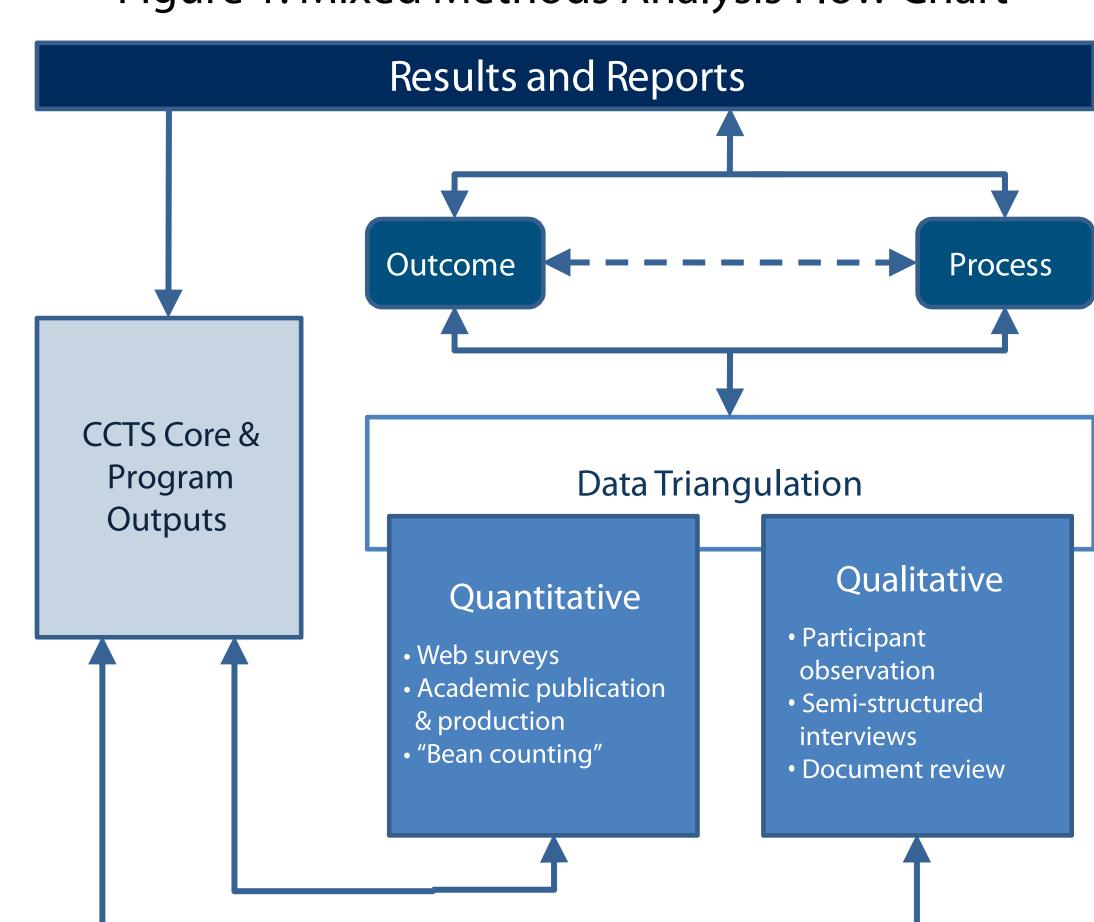
### METHODS

- 1) Theoretical framework. All data collection and analyses are based on specific aims linked to logic models for each CCTS core and program, including overarching specific aims for the entire center. The logic models guide the entire evaluation process and interpretation of findings.
- 2) Samples. Core group leaders, staff, service participants, stakeholders, and controls.
- 3) Mixed Methods Approach
- a) Goal. Triangulation of data can help improve the validity of research findings by using methods that have different strengths and weaknesses. The triangulation, or comparison of findings about similar evaluation questions, looks for consistency in the findings, in order to strengthen the findings. However, when results are inconsistent, triangulation can suggest additional areas for exploring the data.
- b) **Qualitative** 
  - Goal. To address process and implementation evaluation as CCTS cores produce intended outcomes.
- ii) Data collection. Participant observation, semi-structured interviews, document review (e.g., minutes, announcements, CTSA proposal, revised specific aims, program documents)
- iii) Analysis. Development of case studies for each core and program describing progress towards accomplishing specific aims, staffing, changes in plans and logic models, strengths, challenges, and lessons learned.

#### c) Quantitative

- Goal. To provide short- and long-term feedback on core and program outputs to CCTS leadership.
- ii) Data collection. Web surveys, academic publication and production, "bean counting" (e.g., service hours, funding allocation, event attendees, Web usage)
- iii) Analysis. Development of dashboard indicators by use of descriptive and graphical summaries as well as time series analyses of trend data.
- d) Mixed Methods Analysis. Using data from all sources for each specific aim to interpret the results of both qualitative and quantitative data (see Figure 1).

Figure 1. Mixed Methods Analysis Flow Chart



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### RATIONALE FOR INCLUDING QUALITATIVE DATA

- 1) Clarification of Findings. These methods can clarify each other's results. This is particularly important when results do not make sense, are contradictory, or do not appear to be producing intended program outcomes.
- a) Example: Qualitative interviews begin to clarify conflict in quantitative Regulatory Support and Advocacy Core (RSAC) results (see Figure 2).
- Findings from the Office of the Vice Chancellor for Research about the IRB indicates that using the RSAC takes longer to IRB protocol approval (see Figure 3).
- ii) However, qualitative interviews of those who have used the RSAC show they are satisfied (see Table 1). It is an example of reporting qualitative findings in a quantitative way. Responses were similar across gender and RSAC service provider.
- iii) Themes from the qualitative analysis around satisfaction of RSAC services are reported below.
  - (1) Satisfaction with RSAC services:
  - (a) "Excellent! Careful, diligent work in assuring that IRB forms were filled out in great detail, facilitating the implementation of our research."
  - (b) Very responsive. Quickness of completion was important.
  - (2) Dissatisfaction with RSAC services: The investigator was experienced in IRB submission and felt that RSAC could not add to his protocol. He expected that usual IRB barriers would be eliminated by RSAC.
  - (3) RSAC services were somewhat helpful: "It was somewhat helpful for me to sort out the IRB process, but I ended up not moving forward on the project."
- iv) Next steps: We will collect additional data to assist in making the best interpretation of the findings. Are there differences in research and IRB experience, background training (MD vs. PhD), type of submission (initial, continuing, amendment, etc.) and other characteristics of RSAC and non-RSAC participants?
- 2) Informing the development of other research methods in the study: Qualitative data can be used to develop constructs, survey items and otherwise improve the quality of quantitative data collection methods. Findings from the quantitative methods can suggest methods of inquiry for the qualitative methods.
- a) **Example:** Qualitative assessment of a conference offered suggestions for survey development.
  - Participant assessment of a CCTS-related conference noted there was a lot of variation in the quality and difficulty level of the presentations, suggesting inclusion of questions for each speaker.
  - ii) The draft survey had an item about time management at the conference. Participant observation noted time was managed well, so there would likely not be much variation here and may be a possible question to drop.
- 3) Increasing the range of inquiry by using methods appropriate to the research question: For example in process evaluation, questions about attrition rates, numbers of attendees and sessions offered are better answered with quantitative methods. Details about why people dropped out are more likely to be informative when the dropouts are interviewed with qualitative semi-structured interviews. However, all of this data together describes a richer picture of program process and implementation.
- a) Example: The RSAC director and staff noticed a drop in the number of service requests over a few months (see Figures 4 and 5). One of their main concerns was that they had begun charging for services; they worried that researchers would not pay for them. We conducted semi-structured interviews with RSAC users to address this issue (see Table 2).
  - Themes from the qualitative analysis around planning to use RSAC services are reported below.
    - (1) None of the respondents knew about the charge system yet.
  - (2) None of the respondents had returned because they did not have another IRB protocol to submit.
  - (3) Yes, even if there was a charge.
    - (a) It makes sense to use RSAC because it would cost less than hiring a regulatory person for their staff.
    - (b) Might reserve for more complex studies or new types of protocols.
  - (4) Concerns with charges
    - (a) The burden will fall on the IRB because fewer people will use RSAC, so applications will not be prepared as well and they will take more time to review.
    - (b) "Free is better, but if there's a fee, there needs to be some leeway depending on whether the PI is funded or not funded. If they can't pay, there should be a way for waiving or lowering the cost."
    - (c) "I've never seen this in the NIH budget. Will they cover this charge?

# Table 2. Whether User Will Use RSAC Services Again, by Study Role & Gender (n = 13) Table 1. Satisfaction with RSAC Services, by Study Role & Gender (n = 13) Date source: Qualitative semi-structured interviews with RSAC service users. Date source: Qualitative semi-structured interviews with RSAC service users.

- (5) Not sure if they would return
- (a) "Maybe, maybe not. I can't predict the future. They already helped me. It's not because they are not good, but I learned it. Maybe if I had a new type of protocol."
- (6) Next steps: Interviewing potential referrers and users about potential use of RSAC to see if a new barrier is present.
- 4) Details the steps needed for replication of a program: Describing the program processes that may contribute to program success or failures, so others can benefit by avoiding these program failures, is essential to improving complex programs and informing policy development. It may also be important in documenting intermediate steps, important when key CTSA outcomes (e.g., publications as a result of CTSA involvement) are very long-term.
- a) Example: The Community Engagement Research Core (CERC) did not change its specific aims but changed its goals and implementation plans dramatically. This would not have been noticed with our survey methods. However, one of the evaluation team was in the role of participant observer at monthly CERC leadership meetings. She was able to describe these changes and their actual implementation process.
- 5) Using both types of methods can address gaps in data: One type of method can provide more timely data about current activities, while another can provide long-term outcome data (such as intellectual products).
- a) CCTS Example Anticipated Gaps in Data:
  - Publication data will be delayed at least 2-3 years after use of CCTS service. Semi-structured interviews with CCTS users has identified examples of intermediate outcomes and planned publications.
  - A pilot grant allowed one recipient to take an overwhelming amount of data and have it analyzed in the Design and Analysis Core (DAC).
  - ii) The director of DAC developed a new method for analyzing this type of data, which allowed the researcher to empirically support a new method for researching Alzheimer's disease.
  - iii) The recipient indicated that she had two minor papers developed already and that the DAC director would likely publish the method he developed.

## LESSONS LEARNED

- 1) Increased time and resources are needed. The planning and implementation of mixed methods studies are much more complex than studies with one method.
- 2) Mixed-methods studies require researchers who value the integration of qualitative and quantitative data. At least one researcher on the team needs skills and training in mixed methods.
- 3) Additional research is more labor intensive. A large evaluation, like evaluating a CTSA, takes much more coordination.

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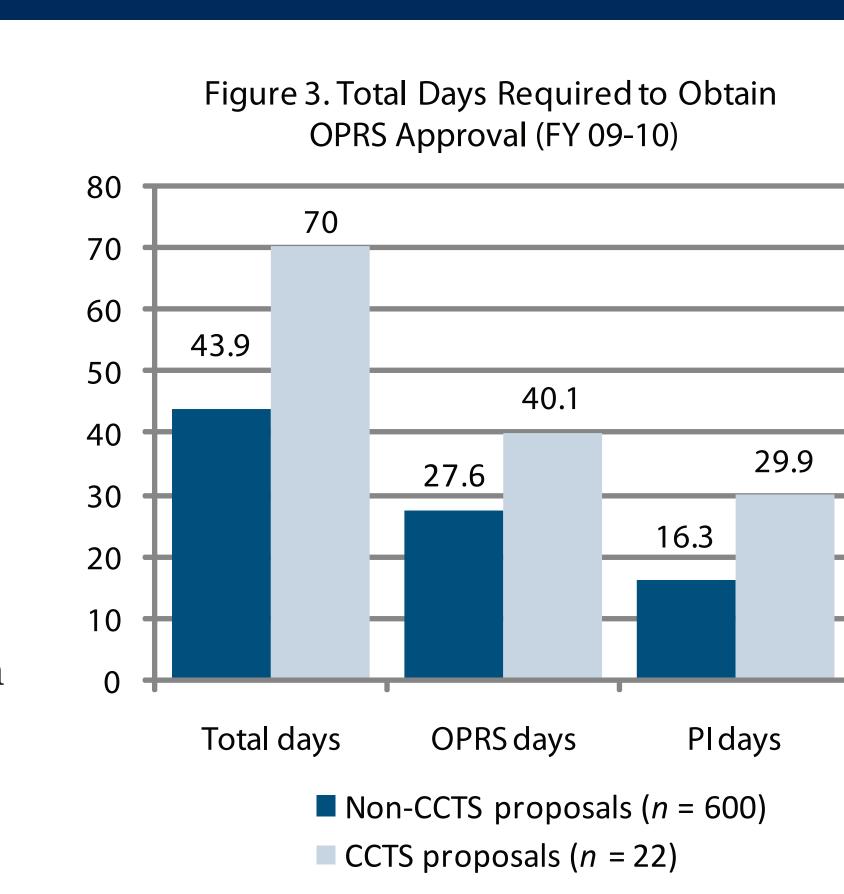


Figure 4. RSAC Service Requests by Month (AY 09-10)

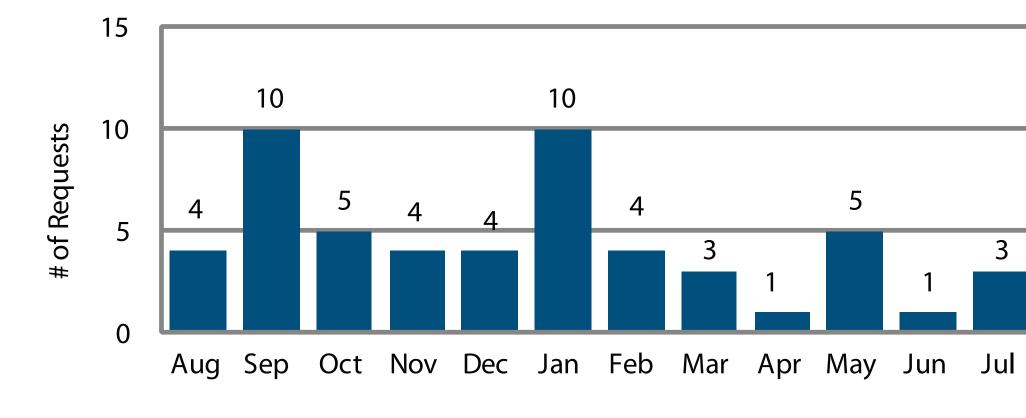


Figure 5. RSAC Service Hours by Month (AY 09-10)

