Supplemental Digital Appendix 1 for Kost RG et al. Accrual and recruitment practices at Clinical and Translational Science Award (CTSA) institutions: A call for expectations, expertise, and evaluation. *Academic Medicine.*

Instructions and Definitions

Recruitment and Retention Practices Survey - CTSA

The purpose of the survey is to identify potential best practices, and successful models of recruitment and retention in the consortium, and to contribute data on the current state of recruitment and retention activities in the consortium.

Please refer to the definitions and points below in deciding whether to submit a single or multiple surveys from your CTSA.

Definitions:
"CTSA" – Named recipient of the CTSA award, e.g. "Rockefeller University" includes all institutions/activities funded through the CTSA award;

"Institution" – any entity named and/or funded as a collaborating partner in the CTSA grant proposal and award, e.g. XXX Hospital, YYY Clinical Network.

Instructions:
Complete a single survey: If multiple processes apply to Recruitment and Retention related activities at the CTSA, for instance there are research team-dependent activites, core services, and mixed methods of both local and central recruitment/retention practices, *within one institution,* please collaborate on collecting the information in order to submit a single survey that best captures the situation.

Complete a single survey: If Recruitment and Retention related activities are conducted across one or more institutions within the CTSA under a single overarching authority, then the completion of a single survey may accurately represent the practices at the CTSA.

Complete multiple surveys: If Recruitment and Retention related activities are administered differently among the numerous distinct institutions making up a single CTSA, then the Regulatory Knowledge and Support representative is asked to identify the person best able to answer the survey at each of the participating institutions, and to facilitate the completion and submission of the survey for each institution.

Please do not distribute multiple surveys to investigators or research teams at this time. We are currently seeking a high level assessment of practices. We will provide a separate link for collection of more granular (investigator level) data if desired.

Section I: Basic Information

1. Please select the CTSA with which your institution is identified or partners:

The name of your specific institution (if different than above)

2. Year of CTSA award:

- 2006
- 2007
- 2008
- 2009

3. Person completing the form:

Name:

Title:

Email:

4. The Definitions below will help the Taskforce understand how to interpret your answers in this survey:

Definitions:
"CTSA" – Named recipient of the CTSA award, e.g. "Rockefeller University", includes all institutions/activities funded through the CTSA award;

"Institution" – any entity named and/or funded as a collaborating partner in the CTSA grant proposal and award, e.g. XXX Hospital, YYY Clinical Network.

With regard to the definitions above, please indicate whether the answers on this survey apply to:

- ◯ The CTSA (including affiliated institutions)
- ◯ A specific institution within the CTSA, e.g. hospital, business school, partner (please specify below)

5. Within your CTSA/Institution, are there very succesful or valuable recruitment or retention practices conducted that are that your center will share?

- ◯ Yes, successful Recruitment practices
- ◯ Yes, successful Retention practices
- ◯ Yes, both Recruitment and Retention practices
- ◯ No practices to share

6. To which activity would your CTSA/institution attach higher priority to gain new/best practices?

- ◯ Recruitment
- ◯ Retention
- ◯ Both Recruitment and Retention

Section II: Recruitment

Definitions:

"Non-sponsored" protocols are studies for which the main decision-making authority is not held by an outside

sponsor and is usually held by the Principal Investigator.

"Sponsored" protocols are studies for which the main decision-making authority lies with industry/pharmaceutical, or other outside collaborators and not with the Principal Investigator

7. What are the top 3 methods by which Recruitment is conducted for protocols at the CTSA? (Select up to 3 for each category of study)

	Sponsored studies	Non-sponsored studies	Studies at a decidated center (e.g. vaccine or cancer center)
By individual research teams, (PI and coordinator/nurses)	☐	☐	☐
By a central recruitment office/team at the center	☐	☐	☐
Mixed model: by individual teams, and by central resources	☐	☐	☐
By a subcontract to an outside recruiting agency	☐	☐	☐
Referral by a primary caregiver	☐	☐	☐
Self referral via websites and advertisements	☐	☐	☐
Referral through a volunteer registry	☐	☐	☐
Don't know	☐	☐	☐

8. How are Recruitment Timeline Targets chosen for <u>non-Sponsored Protocols</u>?

◯ The investigator conducts a feasibility assessment using existing datasets to determine the recruitment timetable.

◯ The IRB <u>requires</u> feasibility assessments be conducted using existing datasets for recruitment of comparable studies, in determining timelines for recruitment and strategies to meet them.

◯ The investigator selects the recruitment target date without specifying a basis.

◯ Don’t know.

9. How is Recruitment conducted for <u>Cancer Center Protocols</u>? (check all that apply)

☐ By individual research teams, (PI and coordinator/nurses)

☐ By a central recruitment entity at the center

☐ Mixed model: by team and with central resources

☐ By a subcontract to an outside recruiting agency

☐ Through primary care giver referral

☐ Self referral via clinicaltrial.gov, internet listings and advertisements

☐ Through a volunteer registry and self referral (e.g. ResearchMatch)

☐ Don't know

☐ No Cancer Center

10. How is Recruitment conducted for Sponsored Protocols? (check all that apply)

- [ ] By individual research teams, (PI and coordinator/nurses)
- [ ] By a central recruitment entity at the center
- [ ] Mixed model: by team and with central resources
- [ ] By a subcontract to an outside recruiting agency
- [ ] Through primary care giver referral
- [ ] Self referral via clinicaltrial.gov, internet listings and advertisements
- [ ] Through a volunteer registry and self referral (e.g. ResearchMatch)
- [ ] Don't know

11. How are Recruitment Target Dates chosen for Sponsored Protocols?

- ( ) The IRB requires feasibility assessments be conducted using existing datasets for recruitment of comparable studies, in determining timelines for recruitment and strategies to meet them.
- ( ) The investigator selects the recruitment target date.
- ( ) The Sponsor selects the recruitment target date.
- ( ) Don’t know.

12. Is there a mechanism in place to track/referee whether multiple approved studies at one center are competing for the same patient population?

- ( ) Yes
- ( ) No
- ( ) Don’t know

If 'Yes', please explain.

13. If recruitment services are provided to investigators from a center or central service, what is the financial model? (Check all that apply)

- [ ] Charge back to departments/investigators for recruitment for Investigator-Initiated studies
- [ ] Charge back to Sponsors for recruitment for sponsored studies
- [ ] Free/core service for Investigator-Initiated studies
- [ ] Free/core service for all type research protocols
- [ ] Cost-sharing model
- [ ] Outsourced recruitment by study-specific contract
- [ ] No recruitment resources provided to investigators

Additional details of interest:

14. What do you believe are the three most important elements of successful study Recruitment at your CTSA? (Select 3)

- [ ] Feasibililty of recruitment assessment performed before starting recruitment
- [ ] Referral of participants by their personal physicians
- [ ] Through referral/collaboration with private practioners
- [ ] Recruitment of prior volunteers through coordinators
- [ ] Recruitment of willing volunteers from a participant registry
- [ ] Adequate budget
- [ ] Quality of advertising
- [ ] Quality of recruitment plan overall
- [ ] Quality of recruitment services from support center
- [ ] Nature/quality of first interaction (telephone pre-screen, scheduling, etc)
- [ ] Quality of Informed Consent discussion with coordinator
- [ ] Quality of Informed Consent discussion with investigator
- [ ] Relationship established with coordinator
- [ ] Relationship established with investigator
- [ ] The nature of the studies (e.g. trials offering novel treatments)
- [ ] Financial compensation for participants
- [ ] Other (please specify)

15. If you have a recruitment practice that you would like to share with the consortium, please describe it here. If you have a means to evaluate its success, please include details.

16. Please name up to three (3) additional activities that you think would enhance Recruitment at your center if they could be provided.

- [ ] Feasibility of recruitment assessment performed before starting recruitment
- [ ] Referral of participants from personal physicians
- [ ] Recruitment of prior volunteers through coordinators
- [ ] Recruitment of willing volunteers from a participant registry
- [ ] Adequate budget
- [ ] Quality of advertising
- [ ] Quality of recruitment plan overall
- [ ] Quality of recruitment services from support center
- [ ] Nature/quality of first interaction (telephone pre-screen, scheduling, etc)
- [ ] Quality of Informed Consent discussion with coordinator
- [ ] Quality of Informed Consent discussion with investigator
- [ ] Relationship established with coordinator
- [ ] Relationship established with investigator
- [ ] The nature of the studies (e.g. trials offering novel treatments)
- [ ] Financial compensation for participants
- [ ] Other (please specify)

17. What additional aspects of Recruitment models, practices, metrics, etc. would you be interested in learning more about?

18. At your center, is there an IRB approved mechanism to identify and individually contact previous research participants to inform them about new opportunities to participate in research for which they might be eligible (other than care giver referral)?

- [ ] Yes, there is a protocol in place to obtain consent for future contact
- [ ] Yes, there is a mechanism to send newsletter/email to prior participants as continuous update of available research
- [ ] No, only previous PIs may contact prior research participants
- [ ] No, there is no mechanism to contact previous research participants
- [ ] Do not know
- [ ] Other (please specify)

19. At your center, how much time typically elapses between the date of final IRB approval of an <u>non-Sponsored protocol</u>, and the date of enrollment of the first subject?

- ( ) 1 - 2 weeks
- ( ) 2 - 4 weeks
- ( ) > 1 month
- ( ) 2 - 6 months
- ( ) > 6 months
- ( ) Do not know

20. At your center, how much time typically elapses between the date of final IRB approval of a <u>Sponsored protocol</u>, and the date of enrollment of the first subject?

- ( ) 1 - 2 weeks
- ( ) 2 - 4 weeks
- ( ) > 1 month
- ( ) 2 - 6 months
- ( ) > 6 months
- ( ) Do not know

Section III: Retention

21. Are specific activities/resources devoted to research subject Retention at the CTSA/Institution?

- [ ] Center-supported resources
- [ ] Research team/protocol-specific resources only
- [ ] Center and team-specific resources
- [ ] Only Sponsored studies have retention resources
- [ ] No activities/resources devoted to retention
- [ ] Do not know

Please describe any successful retention activities at your center for which you have data:

22. Have any tools been developed at your CTSA/Institution to help in predicting retention for participants, such as an inventory of potentially candidate protocol characteristics (duration, intensity, risk, etc) or participant characteristics (personality profile, very ill)?

- ( ) Yes
- ( ) No

Section III: Retention (continued)

23. Who conducts the retention prediction assessment?

- [ ] Research coordinator
- [ ] Investigator
- [ ] Research support office
- [ ] Recruitment office
- [ ] Business/utilization office
- [ ] Contracts office
- [ ] No retention assessments

24. The method for assessing retention potential is:

- ( ) An informal assessment
- ( ) Formalized into an SOP or work procedure
- ( ) Developed into a validated tool/instrument
- ( ) Research team-specific practice
- ( ) A center/institution-wide best practice

25. Will the center/institution share the method for predicting retention potential?

- ◯ No
- ◯ Yes

Please describe:

Section III: Retention (continued)

26. What are the three (3) most important elements of successful study participant Retention at your CTSA?

- ☐ Retention prediction assessment
- ☐ Referral of participants from personal physicians
- ☐ Participant's prior experience in research studies
- ☐ Involvement and buy-in from the referring physician
- ☐ Quality of the relationship established with the coordinator
- ☐ Quality of the relationship established with investigator
- ☐ Reminder calls/emails before return visits
- ☐ Participant appreciation efforts (gifts, gatherings, acknowledgements)
- ☐ The nature of the study itself (e.g. trials offering novel treatments)
- ☐ No-placebo protocols
- ☐ Comfort/convenience factors: distance of commute to research site, availability of parking, ease of finding research clinic, waiting time
- ☐ Financial compensation for participants
- ☐ Other (please specify)

27. If you have a retention practice that you would like to share with the consortium, please describe it here. If you have a means to evaluate its success, please include details.

28. Please name up to three additional activities that you think would enhance Retention at your center if they could be provided.

1

2

3

29. What additional aspects of Retention models, practices, metrics, etc. would you be interested in learning more about?

Section IV: Data Management

30. How are research participants registered and tracked at your Center? Select the highest level of registration that applies.

- ◯ In the general patient database – there is no tag to specifically identify or track research participants
- ◯ In the general patient database -- with a research-specific tag making it searchable to track research participants
- ◯ In a research registry that captures a subset of the overall Center, e.g. Cancer registry, CRC database.
- ◯ In an institution-wide database designated for capturing research participants
- ◯ In departmental databases (OB/GYN, Cardiology, Endocrinology, etc)
- ◯ In the PIs local database (hard drive, lab server, excel spreadsheet)
- ◯ On paper in protocol-specific paperwork
- ◯ Other (please specify)

31. Does anyone track whether <u>non-Sponsored</u> studies at your institution are meeting enrollment and accrual targets on schedule? (select the highest level of tracking at the institution)

- ◯ Only tracked by the PI/research team
- ◯ Accountable to the IRB at annual continuing review
- ◯ Tracked by IRB, RSA, Compliance office, Research Office or other administrative function more often than annually
- ◯ Don't know
- ◯ Other (please specify)

32. Does anyone track whether Sponsored protocols at your institution are meeting enrollment and accrual targets on schedule? (may select more than one answer)

- ◯ Only tracked by the PI/research team
- ◯ Accountable to the IRB at annual continuing review
- ◯ Tracked by IRB, RSA, Compliance office, Research Office or other administrative function on a regular basis
- ◯ Not tracked
- ◯ Don't know
- ◯ Tracked by the Sponsor
- ◯ Other (please specify)

Section V: Planning

33. Are there remedies offered by the CTSA/institution for studies that do not accrue within the projected timeline?

- ☐ Yes, additional financial resources are directed to the research to improve accrual.
- ☐ Yes, assistance in seeking additional outside financial resources
- ☐ Yes, recruitment assistance (personnel, T/E) is offered to improve accrual.
- ☐ Yes, consultation is offered on additional recruitment strategies
- ☐ No remedies.
- ☐ Other (please specify)

34. Are there penalties applied to Investigators for hosting studies that do not accrue within the projected timeline?

- ☐ Yes, funds are withheld pending accrual
- ☐ Yes, the ability to contract for additional sponsored protocols is curtailed for non-accrual repeat-offenders.
- ☐ Yes, the IRB increases scrutiny of sponsored studies for that investigator.
- ☐ No penalties.

Other (please specify)

35. Do contracts for Sponsored protcols at your instituion/CTSA generally specify funding for the time, effort, and other costs of participant recruitment?

- ◯ No funds
- ◯ Yes, funds for participant compensation only
- ◯ Yes, funds for advertising only
- ◯ Yes, some funds, but generally underfunded
- ◯ Yes, funds for advertising, time and effort, and participant compensation; funds are adequate overall
- ◯ Other (please specify)

36. Is there an institutional process to evaluate the feasibility of successfully enrolling a study <u>before the IRB approves a study</u>?

- ◯ No
- ◯ Yes (please describe)

37. Is there an institutional process to evaluate the feasibility of successfully enrolling a <u>study before the center administration approves a contract</u> for a sponsored study, including adequate recruitment resources?

- ◯ No
- ◯ Yes (please describe)

38. Does the protocol review process require that the PI always indicate a target date by which time enrollment will be complete?

- ◯ Yes, for Sponsored studies only
- ◯ Yes, for Investigator-initiated studies only
- ◯ Yes, for all studies
- ◯ No
- ◯ Don't know

39. In the last 3 years, how many Sponsored studies did not attain the stated enrollment target within 6 months of the target date?

- ◯ <5% of sponsored studies
- ◯ 5-10% of sponsored studies
- ◯ 11-25% of sponsored studies
- ◯ More than 25% of sponsored studies
- ◯ No tracking of this information
- ◯ Other (please specify)

40. What is the source of the data above regarding under-accrued Sponsored studies?

- ☐ IRB administrative records
- ☐ Scientific/utilization review committee records
- ☐ Business/financial office records
- ☐ CTSA administrative records
- ☐ Legal office records
- ☐ Contracts Office administrative records
- ☐ Personal knowledge/best guess
- ☐ Other (please specify)

41. If a Sponsored study underperforms regarding accrual, is there a written policy or standard practice for closing that study?

- [ ] Finance/contracts routinely recommends closure of study
- [ ] Sponsors close the study
- [ ] Utilization review committee closes the study
- [ ] No policy or practice
- [ ] Don't know
- [ ] Other (please specify)

42. In the past 3 years, how many Sponsored studies have been closed for non-accrual at your center?

- ( ) <5% of sponsored studies
- ( ) 5-10% of sponsored studies
- ( ) 11-25% of sponsored studies
- ( ) More than 25% of sponsored studies
- ( ) No tracking of this information
- ( ) Other (please specify)

43. What is the source of the data provided regarding closure of Sponsored studies for under-accrual?

- ☐ IRB administrative records
- ☐ Scientific/utilization review committee records
- ☐ Business/financial office records
- ☐ CTSA administrative records
- ☐ Legal office records
- ☐ Contracts Office administrative records
- ☐ Personal knowledge/best guess
- ☐ Other (please specify)

44. In the last 3 years, how many non-Sponsored studies did not attain the stated enrollment target within 6 months of the target date?

- ○ <5% of Investigator-initiated
- ○ 5-10% of Investigator-initiated
- ○ 11-25% of Investigator-initiated
- ○ More than 25% of Investigator-initiated
- ○ No tracking of this information
- ○ Other (please specify)

45. What is the source of the data above regarding under-accrued non-Sponsored studies?

- ☐ IRB administrative records
- ☐ Scientific/utilization review committee records
- ☐ Business/financial office records
- ☐ CTSA administrative records
- ☐ Legal office records
- ☐ Contracts Office administrative records
- ☐ Personal knowledge/best guess
- ☐ Other (please specify)

46. If a non-Sponsored study underperforms regarding accrual, is there a policy or standard procedure for closing that study?

- ☐ IRB routinely recommends closure or closes study
- ☐ Finance/contracts routinely recommends closure of study
- ☐ Utilization review committee closes the study
- ☐ No policy or practice
- ☐ Don't know
- ☐ Other (please specify)

47. In the past 3 years, how many non-Sponsored studies have been closed for non-accrual at your center?

- ○ <5% of Investigator-initiated studies
- ○ 5-10% of Investigator-initiated studies
- ○ 11-25% of Investigator-initiated studies
- ○ More than 25% of Investigator-initiated studies
- ○ No tracking of this information
- ○ Other (please specify)

Additional Comments

48. Please provide any additional comments related to the survey questions and survey topic.