Fulfillment of Research Advocacy Functions in the CTSA Final May 2010

Instructions

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

If multiple processes (e.g. Compliance office, Support office, HRPP office) address the RSA Functions *within one institution,* please collaborate on collecting the information in order to submit a single survey for that institution.

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 the Research Subject Advocacy (RSA) functions are administered and implemented 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 the RSA functions 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.

Section I: Basic Information

1. Please select your institution or the institution that you partner with for the CTSA:

Your institution (if different than above)

2. Year of CTSA award:

- ◯ 2006
- ◯ 2007
- ◯ 2008
- ◯ 2009

3. Person completing the form:

Title:

Name:

Email:

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4. The answers on this survey apply to:

- ◯ The entire CTSA Center (for centers with central organization and uniform practices across partnering institutions)
- ◯ A specific institution within the CTSA, e.g. hospital, school, or partner with a distinct set of practices (please specify below)

In all questions below indicating "CTSA/institution", please answer according to your selection in #4 above.

5. Which Core of the CTSA provides primary financial support for RSA functions described in this survey?

- ◯ Regulatory Knowledge and Support
- ◯ Administrative Core
- ◯ Research Ethics and Design
- ◯ PCIR
- ◯ Community Engagement
- ◯ Other CTSA-funded core
- ◯ Non-CTSA funded core/department

Section I: Basic Information (continued)

6. Which Non-CTSA funded core/department provides primary financial support for RSA functions described in this survey?

- ◯ Institutional Review Board
- ◯ Office of Human Subject Protections
- ◯ Hospital/University Compliance Office
- ◯ Hospital/University QA.QC Office
- ◯ Hospital/University Regulatory Affairs Office
- ◯ Other (please specify)

Section I: Basic Information (continued)

7. Has the institution completed AAHRPP accreditation?

- ◯ Yes
- ◯ No
- ◯ Actively in process

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Section II: RSA Advocacy Functions

The questions in the subsequent sections refer to the CTSA Research Advocacy Functions endorsed as Best Practices by the CCSC in April 2008, and listed here. They are provided here for your reference while completing the survey

Best Practice #1: The RSA functions should have a reporting pathway to institutional officials of appropriate authority and free of conflict of interest.

Best Practice #2: The RSA functions should be complementary to and integrative with existing entities at the institution to promote and facilitate safe and ethical conduct of human research.

Best Practice #3: The RSA functions should have, or have direct access to, an authority that can temporarily suspend a research activity based on ethical and safety concerns so that problems can be explored or resolved through proper procedures. This capacity enables preliminary intervention in problems that might not necessarily invoke an IRB suspension.

Best Practice #4: The RSA functions should be a resource to the research community and to participants, have a voice in policy regarding research ethics, participants' rights and research safety, and play a role in the human subject protection and responsible conduct of research educational programs of the institution.

Section III: Institutional organization

Part I: Examples of institutional organization

Further below, the survey contains questions about the organization of your CTSA in fulfilling the RSA functions. Please read these general descriptions of organizational approaches, and consider the organization and scope of the RSA activities and functions at your CTSA/ institution as preparation for the later questions. These descriptions are provided only to help to frame the questions and are **not** intended to be recommendations or models at this time.

Examples of Organizational Approaches:

The Research Subject Advocacy functions are fulfilled by:

I – A designated Research Subject Advocate (RSA) with reporting authority to a high institutional official (and not the IRB Chair); the RSA has close interactions with the IRB and other research institute education and compliance departments, with a scope that's limited to the CTSA.

II – A designated RSA, as in #I, with expanded scope of responsibilities to include all research at the institution (including non-CTSA research).

III – A designated senior research administrator organizes and integrates the activities of one or more designees who execute the activities related to Research Subject Advocacy functions; for example, a Research Integrity Officer manages an RSA (person) who oversees subjects protections and implements compliance enforcement and education activities within the scope of investigators/protocols utilizing CTSA resources.

IV – As in #III, with expanded scope to integrate multiple institutions, centers, and/or entities.

V – The functions of Research Subject Advocacy are fulfilled under the structure defined by the requirements for AAHRPP accreditation and creation of the HRPP, without defining a separate RSA or RSA program.

Part II: Describing the institutional organization

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Please answer the questions below regarding your CTSA, and your institution, as you selected in #5. The questions regard the organization, authority, responsibility, scope and implementation of the RSA functions at your CTSA and your institution, moving from the highest level of responsibility to the level of direct implementation.

AUTHORITY

8. What are the institutional roles of the <u>one person</u> or entity with overall responsibility for the fulfillment of the RSA functions at the highest level at the CTSA?

- [ ] Dean
- [ ] Human Research Protection Program Chair
- [ ] IRB Chair
- [ ] VP for Research
- [ ] VP for Research Operation
- [ ] Provost
- [ ] CTSA PI
- [ ] Clinical Research Center Director
- [ ] Other (please indicate)

9. Under the institutional authority for Research Subject Advocacy named above, RSA functions are fulfilled within which research entities?

- ◯ All CTSA-associated institutions/entities, but only CTSA specific research/elements/functions
- ◯ All CTSA-associated entities, both CTSA and non-CTSA functions/departments
- ◯ Only this institution/entity (not entire CTSA) , CTSA functions/departments only
- ◯ Only this institution/entity (not entire CTSA), both CTSA and non-CTSA functions/departments

10. At the CTSA/institution, is there human research conducted that is not under the overall authority of the individual with highest responsibility regarding the RSA functions?

- ◯ No
- ◯ Yes (please describe briefly)

RESPONSIBILITY

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11. In executing the Research Subject Advocacy Functions, does the CTSA/institution have a designated program or office responsible for organizing and integrating fulfillment of these functions? (e.g. RSA Office, Office of Research Integrity, Clinical Research Office, etc.)

- ◯ Multiple entities; no primary responsibility
- ◯ No middle level organizing/integrating entity
- ◯ Yes, one designated office/program organizes execution

12. What is/are the institutional role(s) of that entity or person responsible for the organizing and integrating the execution of the functions?

- ☐ Research Subject Advocate
- ☐ HRPP Chair
- ☐ IRB Chair
- ☐ Clinical Research Office
- ☐ IRB Administrator
- ☐ Regulatory Knowledge and Support Core Director
- ☐ Other (please specify)

13. Is this the same person with the highest overall responsiblity for RSA functions?

- ◯ Yes
- ◯ No

14. Does the institution have a person who is designated as the "Research Subject Advocate"?

- ◯ Yes
- ◯ No

15. To whom does the Research Subject Advocate report?

- ◯ To the person of the highest responsibility at the CTSA
- ◯ To the office that organizes the fulfillment of RSA functions
- ◯ No RSA
- ◯ Other (please provide title)

SCOPE

16. Is there CTSA-funded human research conducted at your center, for which the person of highest authority does not organize/implement Research Subject Advocacy functions?

- ◯ Yes
- ◯ No

17. Is there additional human subjects research, NOT funded by the CTSA, for which the person of highest authority provides RSA functions?

- ◯ Yes
- ◯ No

ACTIVITIES

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18. Are there activities performed as part of the Research Subject Advocacy Functions that are collaborative, complementary and/or integrated with related services provided by other CTSA or institutional entities? (Choose all that apply)

- [ ] No collaborative/complementary activities
- [ ] Human subjects protection/GCP training for investigators
- [ ] Human subjects protection/GCP training for coordinators
- [ ] Human subjects protection/GCP for other research staff/students
- [ ] IRB liaison
- [ ] Protocol development/navigation
- [ ] DSMP development
- [ ] Safety review of protocol design
- [ ] Safety review of protocol conduct
- [ ] Research ethics education
- [ ] Research ethics consultation
- [ ] Auditing/monitoring
- [ ] AE reporting
- [ ] Informed Consent oversight
- [ ] Subjects rights/advocacy
- [ ] Compliance
- [ ] Policy development/harmonization
- [ ] Clinical Research Management – process mapping/improvement
- [ ] Research on Research Ethics
- [ ] Research on Clinical Research Management
- [ ] Research on education/compliance
- [ ] Other (please specify)

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19. Are there functions/activities the RSA/program provides that are not provided by other human protection entities at the center? (Choose all that apply)

- [ ] No unique activities
- [ ] Human subjects protection/GCP training for investigators
- [ ] Human subjects protection/GCP training for coordinators
- [ ] Human subjects protection/GCP for other research staff/students
- [ ] IRB liaison
- [ ] Protocol development/navigation
- [ ] DSMP development
- [ ] Safety review of protocol design
- [ ] Safety review of protocol conduct
- [ ] Research ethics education
- [ ] Research ethics consultation
- [ ] Auditing/monitoring
- [ ] AE reporting
- [ ] Informed Consent oversight
- [ ] Subjects rights/advocacy
- [ ] Compliance
- [ ] Policy development/harmonization
- [ ] Clinical Research Management – process mapping/improvement
- [ ] Research on Research Ethics
- [ ] Research on Clinical Research Management
- [ ] Research on Education/compliance
- [ ] Other (please specify)

20. Are there activities performed as part of the Research Subject Advocacy Functions that are redundant or duplicate services provided by other CTSA or institutional entities?

- [ ] No redundant activities
- [ ] Human subjects protection/GCP training for investigators
- [ ] Human subjects protection/GCP training for coordinators
- [ ] Human subjects protection/GCP for other research staff/students
- [ ] IRB liaison
- [ ] Protocol development/navigation
- [ ] DSMP development
- [ ] Safety review of protocol design
- [ ] Safety review of protocol conduct
- [ ] Research ethics education
- [ ] Research ethics consultation
- [ ] Auditing/monitoring
- [ ] AE reporting
- [ ] Informed Consent oversight
- [ ] Subjects rights/advocacy
- [ ] Compliance
- [ ] Policy development/harmonization
- [ ] Clinical Research Management – process mapping/improvement
- [ ] Research on Research Ethics
- [ ] Research on Clinical Research Management
- [ ] Research on Education/compliance
- [ ] Other (please specify)

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21. To what functional committee(s) has the person/persons charged with execution of the RSA function been formally appointed?

	Voting Member	Non-voting Member
IRB	◯	◯
Scientific steering committee	◯	◯
SOP committee	◯	◯
Safety committee	◯	◯
Research and Development Committee	◯	◯
QA/QC Committee	◯	◯
HRPP Committee	◯	◯
Biosafety Committee	◯	◯
COI Review Board	◯	◯
Council for translational research – institutional	◯	◯
Governance committee for CTSA	◯	◯
Medical Ethics/research ethics	◯	◯

Other or None (please specify)

22. Are there established processes for integration of the RSA functional entity into problem solving with with the human subject protection program?

- ☐ No established process
- ☐ Standing meetings
- ☐ Ad hoc meetings
- ☐ Written SOPs
- ☐ Shared reporting structure
- ☐ Formal consultation
- ☐ Other (please specify)

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23. Are there established processes for integration and problem solving <u>across key function groups within your CTSA</u>?

- [ ] No established process
- [ ] Standing meetings
- [ ] Ad hoc meetings
- [ ] Written SOPs
- [ ] Shared reporting structure
- [ ] Formal consultation
- [ ] Other (please specify)

Evaluation/Metrics

24. Is there a program or activity that provides exceptional value, importance or innovation in the fulfillment of the RSA functions? (e.g. Orientation of Scholars or trainees by introductory seminar, formal apprenticeship to experienced coordinator)

25. How is the quality and value of this important activity assessed?

Additional Comments

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

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Thank you for completing Part I of this two-part survey.

Please complete Part II, which can be found at:
http://www.surveymonkey.com/s/L7PZH7P

Your participation supports evidence-based recommendations.

RSA Activity Table Final May 2010

1. Activity Table, instructions

Below you are asked to indicate which office (function) fulfills various activities at your CTSA-funded institution, and whether the activity is tracked and/or evaluated. Some of these activities may fulfill CTSA Research Subject Advocacy Best Practice functions. Other activities may be complementary to RSA or Regulatory Knowledge functions.

The choices listed below represent functions and do not need to match the exact title of your institution's department to be selected. Please seek the necessary input from colleagues to provide meaningful answers regarding practices at your CTSA.

The choices in the drop down menus are:
Education Office
Research Subject Advocate
QA/QC/Compliance Office
IRB Staff
Human Research Protection Program Office
Not conducted
Other

The drop down menu choices for tracking methods are:
Paper
Electronic
Other
Not tracked

1. Please select your institution or the institution that you partner with for the CTSA:

Please specify institution (if different from above)

2. Please provide information about the person completing this survey:

Title:

Name:

Email:

2. Activities

Please indicate which offices/staff conduct these activities for human subject research:

RSA Activity Table Final May 2010

3. Human subject research training requirements and procedures

	For human research under the CTSA	For human research not on/under the CTSA	How is this activity tracked?
Orientation of investigators/staff to HSP requirements			
Maintenance of institutional SOPs for human subjects research			
Harmonization of policies for HSP across deparments			

Please describe any methods used to measure the value of these activites:

4. Verification of human subject training certification

	For human research under the CTSA	For human research not on/under the CTSA	How is this activity tracked?
Protocol-nonspecific Research Personnel (e.g. lab or data entry staff)			
Protocol-specific personnel			

Please describe methods used to measure the value of these activites:

RSA Activity Table Final May 2010

5. Protocol development

	For human research under the CTSA	For human research not on/under the CTSA	How is this activity tracked?
Study design support/service			
Recruitment of participants - guidance			
Informed Consent Document development			
Informed Consent Process oversight			
HIPAA			
DSMP design/development			

Please describe any methods used to measure the value of these activities:

6. Protocol Review

	For human research under the CTSA	For human research not on/under the CTSA	How is this activity tracked?
Design Review			
Recruitment Plan Review			
Informed Consent Process Review			
Informed Consent Document Review			
DSMP Review			

Please describe any methods used to measure the value of these activities:

RSA Activity Table Final May 2010

7. Protocol implementation

	For human research under the CTSA	For human research not on/under the CTSA	How is this activity tracked?
Verification of initial IRB approval			
Verification of program readiness			
DSMB monitoring			

Please describe any methods used to measure the value of these activities:

8. Protocol amendment/revision tracking

	For human research under the CTSA	For human research not on/under the CTSA	How is this activity tracked?
IRB approval obtained (verify)			
Re-consenting of participant (verify)			

Please describe any methods used to measure the value of these activities:

RSA Activity Table Final May 2010

9. Addressing Rights/Safety Concerns in real time

	For human research under the CTSA	For human research not on/under the CTSA	How is this activity tracked?
Real time compliance oversight			
Investigates Staff complaints about research conduct			
Investigates Participant complaints about research conduct			

Please describe any methods used to measure the value of these activities

10. Safety and Compliance Monitoring

	For human research under the CTSA	For human research not on/under the CTSA	How is this activity tracked?
Monitors AE tracking/reporting			
Monitors DSMP execution			
Conducts IND/IDE monitoring			
Monitors Deviation/violation reporting			

Please describe any methods used to measure the value of these activities:

RSA Activity Table Final May 2010

11. Audits

	For human research under the CTSA	For human research not on/under the CTSA	How is this activity tracked?
Conducts Not-for cause Audits			
Conducts For cause Audits			

Please describe any methods used to measure the value of these activities

RSA Activity Table Final May 2010

12. Education (check all that apply)

	Education Office	Research Subject Advocate	QA/Compliance Office	IRB Staff	Human Research Protection Program Office	Not conducted	Other
Provides mandated education in HSP	☐	☐	☐	☐	☐	☐	☐
Provides elective education in HSP	☐	☐	☐	☐	☐	☐	☐
Provides mandated education in GCP	☐	☐	☐	☐	☐	☐	☐
Provides elective education in GCP	☐	☐	☐	☐	☐	☐	☐
Provides training as part of audit response (CAP)	☐	☐	☐	☐	☐	☐	☐
Provides training in AE reporting	☐	☐	☐	☐	☐	☐	☐
Provides regulatory compliance updates	☐	☐	☐	☐	☐	☐	☐
Provides education in DSMP requirements	☐	☐	☐	☐	☐	☐	☐

Please describe methods used to measure the value of the activities:

Thank you for completing Part II of this 2-part survey.

If you have not completed Part I, please do so by going to:
surveymonkey.com/s/L7W5Q8Q.

If you have completed both parts, your participation is complete. Thank you.