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CTSA Consortium Demonstration and Evaluation of Scientific Review Committee (SRC) Processes

Pilot Study

INVITATION TO PARTICIPATE

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Important Dates

- **Invitation Release – September 28, 2015**
- **Invitation Submission – October 9, 2015**
- **Notification of Participating Sites – October 19, 2015**

Background

From September 2014 to February 2015, a CTSA Consortium Scientific Review Committee (SRC) Consensus Working Group, composed of a diverse group of experts and research stakeholders from nine Clinical and Translational Science Awards (CTSAs) and the National Institutes of Health (NIH) assembled a set of recommendations for the scientific review process of human participant research prior to review by institutional IRBs. The overall goal was to create SRC processes that would enhance the scientific quality and feasibility of clinical research (see Appendix A, *Consensus Report on the Scientific Review Committee Processes*). The Working Group came to consensus on scientific review practices considered to be practical and effective. The Group also identified best practices, needs, issues, and challenges for institutions that conduct clinical research, in order to create SRC processes that facilitate widespread adoption. Based on this assessment, the Working Group generated the following recommendations:

1. A ***consensus plan for SRC processes*** for a range of clinical studies, including internally funded investigator-initiated projects, as well as those with federal, industry, or other funding. The plan also includes the need for pre-SRC review by CTSAs for their pilot, T, and K awardee projects, and potentially for other new or inexperienced investigators.
2. A ***consensus plan for metrics for evaluation*** of SRC processes, including for use in a pilot implementation of these processes.
3. ***Recommendations for informatics technology (IT) infrastructure*** to support the pilot program.
4. A ***consensus plan for a pilot study of the implementation of SRC processes*** at 12 CTSA institutions.

Purpose

This **invitation to participate** seeks to engage 12 CTSAs and their institutions as participants in a pilot study project to **implement and evaluate the SRC processes** as recommended by the Working Group (see Appendix A, *Consensus Report on the Scientific Review Committee Processes*). This project hypothesizes that implementation of the recommended SRC program will have a positive effect on the scientific quality and feasibility of clinical studies without a meaningful change in the efficiency of the ethical review process.

By using a pre-post, implementation comparison approach, this pilot study is intended to identify barriers and facilitators to implementation, to discern the impact on the quality and feasibility of clinical protocols, and to assess the efficiency of the SRC review process. The results are intended to inform CTSA-wide recommendations for institution of scientific review.

Rationale

Currently, in a wide range of forms and functions at institutions, SRC processes seek to support excellence, safety, and ethical conduct of human participant research. Specifically, SRC processes respond to the mandate that to be ethical for human participation, a proposed project must have a valid study design and analytic plan. Given the breadth of the issues that must be adjudicated by Institutional Review Boards (IRBs) in approving a study, a separate SRC review prior to, but integral to, full IRB review is intended to ensure that a study meets an acceptable standard of scientific rigor and feasibility.

Among CTSA-associated institutions, scientific review of clinical research protocols varies. Some have established SRC processes to review the scientific validity and feasibility of research protocols that work in conjunction with their IRBs. Others require assessment of protocols by clinical departments prior to, or in parallel with, IRB submission, and/or a voluntary scientific review process. Not every research institution has policies requiring scientific review of scientific merit and feasibility. This pilot project seeks to address the nationwide need for CTSA Consortium scientific review standards to conduct human participant research by implementing, evaluating, and disseminating a SRC process designed to improve clinical protocol quality and feasibility prior to IRB review, without causing meaningful delays.

This pilot study seeks to incorporate real-world variation between institutions. From a clinical trial perspective, this is analogous to the difference between *efficacy* trials and *effectiveness* trials. An efficacy trial aims to assess treatment impact in a homogeneous group of subjects under controlled conditions, whereas an effectiveness trial tests a treatment under usual practice conditions and across the range of patients for whom it will ultimately be used. In order to assess the “usual practice” of the recommended SRC process in its real-world application, the pilot study will include a heterogeneous sample typical of an effectiveness trial (see Appendix B, *Study Approach*). This pilot program is not simply recommending a new approach based on an idealized model and resulting guidelines; we will evaluate actual impact in “usual practice” across a range of 12 CTSA sites.

Objective

To demonstrate that the recommended SRC process is feasible, practical, and sustainable when implemented across "real world" institutional variations. The intent is that, if demonstrated to be effective, the SRC process will be disseminated throughout the CTSA Consortium and potentially to other institutions in the US that conduct clinical research. The ultimate goal is to enhance the quality of clinical research by substantially improving scientific review standards and practices.

Participation

CTSAs and their home institutions are invited to respond to this invitation to participate. The ultimate selection of sites (estimated at 12) will be based on having a diverse group of CTSAs and institutional processes, in order to gain the most possible from this pilot study.

Tufts Clinical and Translational Science Institute (CTSI) will serve as the Coordinating Center for this study, and will provide study sites with:

1. Project management to assist study sites with project-related needs and data collection.
2. An IT application designed to serve sites as a project management tool for the SRC process and a data management tool for recording the evaluation metrics. Sites with an existing project management tool for the IRB and/or SRC process are not required to use the study-specific tool for project management, but will use it for study data collection.

Eligibility

For consideration to participate, a CTSA and its institution should meet the following criteria:

1. Documented organizational agreement to participate (i.e., letters of support from the IRB Chair and Institutional Official),
2. The ability to collect the required evaluation metrics (see Application Guidelines and Appendix B, *Study Approach*),
3. Willingness from the CTSA PI to participate, provide coordination of the project, and identify a staff person who will be responsible for collecting and submitting study metrics.

Timeline

This pilot study is expected to be a 19-month project:

Pre-Study, Baseline: 10/2015-4/2016
Implementation, Intervention: 5/2016-4/2017.

Invitation Guidelines

Provide information (form provided) that includes the following:

1. Brief statement of interest (include confirmation of eligibility based on criteria above);

2. Name of institution and brief description of CTSA;

3. To ensure recruitment of CTSAs with a range of characteristics, indicators of the volume of protocols:
    a. Number of CTSA pilot awards, T awards (if applicable), and K awards funded in FY 2014 or the last 12 months,
    b. Number of active clinical protocols at your institution in 2014 or the last 12 months,
    c. Number of hospitals/sites involved with human subject research,
    d. Number of IRB reviews at your institution in 2014 or the last 12 months,
    e. Number of operating CTRCs or GCRCs at your institution,
    f. If possible, number of clinical study protocols reviewed by your institutional IRB in 2014 or the last 12 months,
    g. If possible, number of clinical study protocols reviewed by your institutional SRC in 2014 or the last 12 months (if applicable).

4. Brief description of current scientific review process. As part of this description, please include a characterization of your organization as falling into one of three categories:
    a. No scientific review process other than IRB review,
    b. Voluntary scientific review at the departmental or unit level,
    c. Formal scientific review in addition to IRB review, including but not limited to a SRC.

    Note: If your organization's scientific review process does not fit within one of these three categories, please provide a brief description of how you would characterize it.

    For organizations with some type of SRC process, the applicable Standard Operating Procedures can be sent in lieu of writing a description.

5. Letter(s) of Support from the IRB Chair and/or Institutional Official Should be sent to Aaron Kirby (akirby@tuftsmedicalcenter.org) by Friday, October 9, 2015. If you anticipate a delay in obtaining a letter of support, please notify Aaron Kirby prior to Friday, October 9, 2015.

Willingness to participate includes:

1. After the initial baseline pre-intervention phase, following the SRC processes or provide explanations for any variations in process due to institutional needs. Please see *Consensus Report on the Scientific Review Processes,* Appendix A.
2. Collecting pilot study metrics. Participation in the pilot study will entail collecting the evaluation metrics prospectively during baseline and intervention phases (see Appendix B, *Study Approach*). In addition, within the first two weeks of the pre-study phase, participating CTSAs will submit retrospective preliminary data including, but not necessarily limited to, the following data points:
    a. Number of clinical trial protocols reviewed by IRB in 2014 or the last 12 months
    b. Number of clinical trial protocols reviewed by SRC in 2014 or the last 12 months (if applicable)
    c. Number of days for IRB and SRC review. *Use the 2014 calendar year (or the last 12 months) to calculate the mean, standard deviation, median, minimum, maximum, 25th and 75th percentiles, for:*
        i. Number of days from clinical study submission for ethical review (including scientific review, if applicable) until approval. If scientific review is separate from IRB review, then a categorization of the number of days into two components: IRB review and scientific review. Please indicate whether scientific review is conducted by SRC, or another process.
        ii. Number of days that clinical protocols are with PI for revisions during the IRB process

iii. Number of days that clinical study protocols are with PI for revisions during the scientific review process, if applicable

3. Collecting and submitting data to the pilot study's electronic data capture system in an ongoing manner for the duration of the study
4. Being available for one site visit from Tufts CTSI Project Manager.
5. Participating in a pre-study protocol training webinar and monthly phone calls with Tufts CTSI project manager
6. Participating in one semi-structured key informant telephone interviews by the Site Principal Investigator during the pre-study or baseline phases of the project. (Additional key informant interviews may be requested during the implementation period.)

Invitation Review Process:

The SRC Coordinating Center will review each application. Pilot sites will be chosen based on:

1) Eligibility
2) Fulfilment of the requirements described in the Application Guidelines
3) Distribution of sites that represent a diversity of settings and approaches

Questions

Please direct all questions to:

Aaron Kirby, MSc Manager
Project Administration
Tufts Clinical and Translational Science Institute (CTSI)
Telephone: 617-636-5619
Fax: 617-636-7757
Email: akirby@tuftsmedicalcenter.org

Submission

Submit completed applications electronically to: http://www.tuftsctsi.org/src-processes-pilot-study-invitation-to-participate/

Appendices

Please see separate documents

- Appendix A: Consensus Report on the Scientific Review Committee Processes
- Appendix B: Study Approach (as approved by NCATS)