Regulatory Knowledge and Support: Standardization of Scientific Review Committees Across Clinical Translational Science Programs

Philip A. Cola, PhD

A major goal of creating Clinical Translational Science Award (CTSA) Programs across the United States was to provide standard infrastructure for the effective and efficient conduct of clinical research across Academic Medical Centers (AMCs). This represented opportunities for novel process approaches. It was a way for the National Institutes of Health (NIH) to assist institutions and investigators alike in the transformation of the clinical research enterprise in order to meet the demands of contemporary society[1]. It is within this context that awardee institutions created regulatory knowledge and support components within their CTSA infrastructure. These components have been charged with finding ways to reduce investigator regulatory burden as well as finding novel approaches that lend themselves to standardization across other AMCs and CTSA programs[2].

An important area within the regulatory knowledge and support components is the protection of human subjects in research through ethical principles for human subject research[3]. The intent of these protections have always been that independent review committees should review research to ensure respect for participant rights while minimizing risks in relation to anticipated benefits[4]. In order to accomplish this Institutional Review Boards (IRBS) must have mechanisms to consider a study's scientific quality and operational feasibility in order to ensure that protocols can be completed while achieving goals and objectives to answer study question(s) and ensure that the fewest number of participants are exposed to risk. Additionally, study question(s) must be deemed worthwhile to answer[5].

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[1] Zerhouni, E. A. (2005). Translational and clinical science-time for a new vision. *New England Journal of Medicine*, *353*(15), 1621.

[2] Strasser, J. E., Cola, P. A., & Rosenblum, D. (2013). Evaluating various areas of process improvement in an effort to improve clinical research: discussions from the 2012 Clinical Translational Science Award (CTSA) Clinical Research Management workshop. *Clinical and Translational Science*, *6*(4), 317-320.

[3] U.S. Department of Health and Human Services. The Belmont Report 1979. Retrieved May 11, 2020. https://www.hhs.gov/ohrp/regulations- and-policy/belmont-report/index.html

[4] U.S. Department of Health and Human Services. Federal Policy for the Protection of Human Subjects (Common Rule, 45 CFR 46) 2018. Retrieved May 11, 2020. https://www.ecfr.gov/cgi-bin/retrieveECFR?%20gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=%20pt45.1.46&r=PART&ty=HTML

[5] Institute of Medicine. Responsible Research: A Systems Approach to Protecting Research Participants. Washington, DC: The National Academies Press. 2003.

Recently, 12 CTSA programs collaborated to study scientific quality and feasibility reviews, as part of the ethics review process, and the results of their research were published in *Clinical Translational Science* earlier this year[6]. This work emanated out of the CTSA Scientific Review Committee (SRC) Consensus Group where standardization of the SRC process was deemed critical to support investigators and institutions in their overall translational science missions. Overall, the goal of this study hypothesized that implementing the Consensus Group recommendations would improve the scientific quality of biomedical research protocols without a meaningful change in overall duration of ethics review.

The study assessed SRC feasibility and standardization at CTSA-affiliated AMCs using a mixed method approach. Initially 10 AMCs were assessed pre/post intervention. Intervention was an attempt to implement SRC recommendations at each participating site. Pre-intervention, four AMCs did not have SRC processes and six had SRC processes that were in need of re-alignment based on working group consensus recommendations. These data were collected via qualitative interviews.

It was found that broad-based communication, senior-level organizational support, external motivations (i.e., grant funding, prestige, etc.), and committed SRC reviewers by discipline all facilitated successful implementation of SRC recommendations. However, limited resources including staffing, operational variability by organizations with local mandates, limited SRC decision authority, and lack of anticipated benefits of SRC review were recurring barriers of successful implementation of SRC recommendations.

Additionally, this study looked at research protocol quality, which did not significantly change between pre and post-implementation of SRC recommendations. However, SRC and IRB administrators suggested improved quality post-implementation. IRB turnaround time was not impacted in 40% of the protocols reviewed based on SRC recommendations, but for 60% of the protocols in the study sample, review time increased, at least in part due to SRC recommendations, if the protocol review time exceeded 3 weeks.

Study conclusions included recommendations for further design of locally effective SRCs, increased attempts are needed to build buy-in either through improved communication or senior-level organizational mandates. Additionally, there was a renewed call for the sharing of best practices, improved workflow between SRC and IRB reviews, and a call for additional planning time for implementation of SRC review recommendations. Therefore, the CTSA SRC Consensus Group recommendations appear actionable and feasible. However, more

[6] Selker, H. P., Welch, L. C., Patchen-Fowler, E., Breeze, J. L., Terrin, N., Parajulee, A., LeClair, A., Naeim, A., Marnocha, R., Novak, J.M., Caldwell, C. S., Cola, P.A., Croker, J.A., Cifu, D.X., Williams, K.M., Snyder, D.C., & Kitterman, D. (2019). Scientific Review Committees as part of institutional review of human participant research: Initial implementation at institutions with Clinical and Translational Science Awards. *Journal of Clinical and Translational Science*, *4*(2), 115-124.

work on standardization of processes and consideration of local institutional variables are needed for continued implementation of SRC recommendations on a broader national level.

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