establish quality management systems to ensure data integrity and subject protection.

4186

Single IRB and the CTSI: Liaison Model for the IRB Reliance Process

Christine Sego Caldwell[1], Amy J. Trullinger[2], and Scott Denne[1]
[1]Indiana University School of Medicine; [2]Indiana CTSI, Indiana University School of Medicine

OBJECTIVES/GOALS: Navigating the NIH Single IRB Policy has been challenging for investigators, study teams, and Human Research Protection Programs (HRPP). In response, the Indiana Clinical and Translational Sciences Institute (CTSI) created an innovative Single IRB Project Manager role (sIRB PM), uniquely placed within the Indiana CTSI. METHODS/STUDY POPULATION: The Single IRB Project Manager role was created in 2018 by the Indiana CTSI in response to the NIH Single IRB Policy for Multi-Site Research. The role of the sIRB PM is to serve as a liaison between the Indiana University HRPP, lead site, coordinating center, and participating sites when Indiana University serves as the Single IRB. This model has proven useful to both the IRB and lead site, notably in the following ways:

- **At study start-up,** the sIRB PM can handle complicated communications among sites and the IRB at the same time the lead site is responsible for many other administrative tasks related to start-up. By absorbing the workload of IRB approval for multiple sites, the sIRB PM provides the lead site more capacity to handle other essential tasks.
- The sIRB PM **translates** new terminology and facilitates processes that are new for sites.

RESULTS/ANTICIPATED RESULTS: Early assessment of this program is predominantly positive. The sIRB PM currently supports 24 external sites. In an NIA-funded 13 site study, all sites were added within 9 months of initial IRB approval of the protocol. This role fills a gap that benefits:

- **IRB staff** by allowing them to fulfill their duties of **screening and review** while leaving some of the reliance organization to the sIRBPM.
- **Lead PI** by allowing them to **focus on conducting the research** instead of the many administrative tasks required for single IRB review.
- **Participating sites** by having a **liaison to enter their amendments and reportable events** into an otherwise closed IRB software system.
- **All parties** by having the **sIRB PM manage document organization, storage, and distribution study-wide**.

DISCUSSION/SIGNIFICANCE OF IMPACT: The CTSI sIRB PM role effectively shifts administrative work caused by the sIRB mandate by merging research coordinator experience with regulatory experience while building upon an existing strong relationship with the HRPP. Future focus is on process education, standardizing pricing structure, and ensuring sufficient budget support in grants.

4349

Survey of Regulatory Reforms to Address Comprehension of Clinical Trial Results

Matthieu Kirkland[1], Christian Reyes[1], Nancy Pire-Smerkanich[1], and Eunjoo Pacifici[1]
[1]University of Southern California

OBJECTIVES/GOALS: Clinical research is the backbone of the medical community. However, there are few regulations to ensure clinical trial participants can understand their results, leading to volunteers feeling unvalued and unlikely to enroll in trials[1]. This study examines the need of lay summaries METHODS/STUDY POPULATION: To understand the current landscape of clinical trial summaries, literature searches were conducted using the University of Southern California Library database with keywords Title contains "lay language" OR "lay summary" AND any field contains "Trial" OR "clinical", and Title contains "natural language processing" AND "clinical trial" OR "Summary". Studies were deemed relevant if they discussed lay language summaries for health care realms or using Natural Language Processing (NLP) to increase comprehension. Papers published by the Center for Information and Study on Clinical Research Participation (CISCRP) were reviewed and their Associate Director was interviewed. RESULTS/ANTICIPATED RESULTS: Of 67 total results, 14 were determined to be relevant. Ten of the relevant results examined lay language summaries and their regulation and 4 were NLP studies. The European Medicines Agency set regulations mandating clinical trial summaries. However, researchers have difficulty validating to an appropriate reading level[2]. Difficulty and potential bias halted a U.S. mandate of lay summaries[3]. The nonprofit CISCRP has partnered with industry to develop unbiased clinical trial summaries resulting in all volunteers feeling appreciated and 91% understanding clinical trial results post summary[1]. Similarly, NLP software for annotating Electronic Health Records increased comprehension for 77% of patients[4]. DISCUSSION/SIGNIFICANCE OF IMPACT: In the U.S., a lack of regulations mandating lay summaries may be related to concerns by regulatory agencies that summaries in plain language may introduce bias[3]. Future looks into integration of NLP systems to clinical trials may create unbiased summaries and allow for FDA regulation.

Team Science

4436

A Content Analysis of CTSA Websites: The Identification and Evaluation of CTSA Program Hub Website Content Standards for Knowledge Management of NCATS CTSA Program Goals and Initiatives

Barbara Ann Tafuto[1], Reynold Panettieri[1], James Scott Parrot[1], Shankar Srinivasan[1], Kristi Holmes, PhD[2], and Dagobert Soergel[3]
[1]Rutgers University; [2]Northwestern University; [3]University of Buffalo

OBJECTIVES/GOALS: Introduction: Between 2014 and 2019 the National Institute of Health (NIH) through the National Center for the Advancement of Translational Science (NCATS) has awarded

https://doi.org/10.1017/cts.2020.351 Published online by Cambridge University Press

about $2.7 billion to U.S. Academic Medical Centers to build a national network of clinical and translational science program hubs that serve to meet their key goals and initiatives. Today there are about 60 Clinical and Translational Science Award (CTSA) program hubs. Each CTSA program hub has a corresponding website highlighting its clinical and translational science centered programs and activities. These websites are a critical communication gateway to promote NCATS goals and initiatives. Objective: The objective of this research is to evaluate the NIH funded Clinical and Translational Science Award (CTSA) program hub websites for NCATS goals and initiative content alignment, navigability, and interactivity. METHODS/STUDY POPULATION: Methods: Each CTSA program hub website was systematically evaluated for information or tools that align with the five NCATS / CTSA Goals and eight CTSA nationally identified program initiatives. Each NCATS goal and CTSA initiative was subsequently ranked by information diversity level (text, tool, interactivity) and navigation level (click distance from the home page). RESULTS/ANTICIPATED RESULTS: Results: Four of the five NCATS goals are thoroughly and consistently represented among the CTSA Consortium with workforce development, patient and community engagement, and quality and efficiency of research being the top three. Informatics is thoroughly and consistently represented, but not always clearly identified on the home page. The most underrepresented goal is integration of special and underserved populations which was identified on only 60% of CTSA program hub websites. The most common focus of the eight CTSA program initiatives is the Trial Innovation Network in CTSA program hub websites. The Smart IRB comes in a distant second. The remaining six initiatives are severely underrepresented. DISCUSSION/SIGNIFICANCE OF IMPACT: Discussion: The identification of these gaps among the CTSA program hubs presents an understanding of content management and website functionality among the consortium from 3 principal approaches. First it creates an understanding of CTSA program hub content alignment with its funding source goals and initiatives. Such an understanding presents an opportunity to promote ways to create a better aligned consortium with improved collaboration pathways by the funding source through program hub website content standards. Second, it creates an opportunity for program hubs to understand and respond to the messaging their websites are presenting as it relates to the funding source. Third, it provides an opportunity to identify specific program initiatives and goals the CTSA institutions independently chose to highlight which can open a dialog to the better understanding the value of the program initiatives as they relate to the needs of CTSA program hubs. Ultimately, CTSA websites through content alignment should lead to an improved user experience.

4045

A TL1 Team Approach to Identify Factors Affecting Rural Tobacco Users' Participation in Research and Quitting Tobacco Use*

Neo Gebru[1], Rachel Elisabeth Damiani[1], Janice Krieger, and Robert F Leeman[1]
[1]University of Florida Clinical and Translational Science Institute

OBJECTIVES/GOALS: Guided by the health belief model and social identity theory, we aim to identify socio-cultural and psychological factors that influence rural tobacco users a) participation in research and b) quitting tobacco use. We also explore how citizen scientists are perceived as disseminators of messages. METHODS/STUDY POPULATION: In Phase I of this multi-stage project, we are conducting in-depth interviews with approximately 30 tobacco users. Interviews are on-going, and have been conducted with 16 participants thus far from four rural counties in Florida. The interview consists of semi-structured questions and multiple validated questionnaires. Specifically, we ask a series of questions about participants' barriers to participating in research, tobacco use history, and internet use and message preferences. Additionally, we include questionnaires on participants' substance use, nicotine dependence, motivation to quit, and willingness to participate in research studies. RESULTS/ANTICIPATED RESULTS: Initial findings suggest that rural tobacco users have an overall positive perception of research, and many choose to participate in research for altruistic reasons (i.e. they want to help others). Further, participants noted described feeling stigmatized due to their tobacco use. Although most began smoking to fit in with their community, many now feel on the outs. Participants also reported logistical barriers to participating in research, including lack of transportation. DISCUSSION/SIGNIFICANCE OF IMPACT: Findings can inform the development of recruitment materials to resonate with rural adults, including by emphasizing the collective potential to help by participating. This interdisciplinary highlights areas for collaboration to enhance the reach of health education and public health messages.

4037

Assessing Leadership Skills in Translational Science Training: The Rockefeller University Leadership Survey

Roger Vaughan[1], Michelle Romanick[1], Donna Brassil[1], Rhonda G Kost, MD[1], Sarah Schlesinger, MD[1], and Barry S. Coller, MD[1]
[1]Rockefeller University

OBJECTIVES/GOALS: There is universal recognition of the importance of team science and team leadership. We have developed a semi-quantitative translational science specific team leadership competency assessment tool and have begun implementation studies to assess the impact of personalized feedback on the team science leadership skills of KL2 Clinical Scholars. METHODS/STUDY POPULATION: To create the instrument, we employed a modified Delphi approach by conducting a thorough literature review on Leadership to concretize the relevant constructs, then used these extracted constructs as a springboard for the Rockefeller Team Science Educators (TSE's) to discuss and refine the leadership domain areas, collectively create domain-specific survey items. Further discussion helped refined the number, grouping, and wording. Scholars also contributed feedback in item development. We piloted the Leadership Survey by having all of the Rockefeller TSEs rate Clinical Scholars, and having each Scholar rate themselves. Each item was answered using a six-point Likert scale where a low score indicated poor expression and a high score represented excellent expression of the specific leadership attribute. RESULTS/ANTICIPATED RESULTS: Incorporation into a REDCap data base made consenting and rating process by TSE's and the Scholars straightforward. The a priori domains (Foundational Leadership Competencies, Professionalism, Team Building and Team Sustainability, Appropriate Resource Use and Study Execution,

https://doi.org/10.1017/cts.2020.351 Published online by Cambridge University Press