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

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

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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.

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Survey of Regulatory Reforms to Address Comprehension of Clinical Trial Results

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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

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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

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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

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