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TREATS: A Protocol Review and Improvement Tool Synchronizing Reviews, Reviewers and Developers
Alicia Turner, BS; Troy Apple, DVM, ChE; Scott Bury, PhD, CPIA
Vanderbilt University Medical Center

Problem Statement:
IACUC protocols are tasked with effectively capturing pertinent study information to ensure animal welfare and to meet regulatory compliance. In an academic institution, this responsibility is exacerbated by study complexity and program diversity. Protocol approval is challenged by differing views from scientific reviewers, veterinary reviewers, and compliance staff regarding the interpretation of common standards, the requirements for level of detail, and the categorization of procedures. Our institution identified drift between the various reviewers as the groups were evolving distinct approaches to protocol assessment. Multiple protocol guidance documents existed in multiple locations and ambiguity existed regarding the final authority for decisions. We propose that consolidating protocol guidance into a single resource will create multiple improvements. TREATS (Text Review & Evaluation of Amazing & Tedium Studies) will capture protocol review guidance including its context, source, and overall aim. Program leadership can further use this tool to clarify their instruction when divergence occurs. The primary goal of TREATS is to improve protocol review consistency and proficiency. The creation of TREATS will clarify responsibilities, identify meaningful conflicts, point toward constructive resolution, and provide uniform feedback to the developers of protocol management software. These improvements will translate into a better customer experience for authors, auditors, and inspectors during protocol creation, implementation, and post-approval monitoring.

Description of the research:
TREATS as a tool of protocol review and management provides a common and definitive document guidance resource. This resource addresses document organizational strategy, question interpretation, and section goals. The process conveys decisions recorded in various pertinent meeting minutes to a common, protected document available to all stakeholders. Content is presented in TREATS with a source and time stamp providing context and history. In the event of conflict, program leadership will provide a final interpretation and additional guidance. The document mirrors the protocol format for ease of navigation while “read only” status to users will eliminate corruption. Information security can be tailored to each institution and is easily updated. By using a common word processor (Microsoft Word), extensive training or equipment needs are alleviated. A single text document enables enhanced search functions avoiding indexing over multiple files or databases. The process is simple and flexible, and the document is readily stored either locally or in the cloud. Implementation is straightforward without changes or interference to existing practices. TREATS is maintained by a single contact point such that cost is primarily labor as tracked via time study. Impact assessment of
TREATS includes using existing measures such as evaluating protocol turnaround times. Additional assessments include stakeholder satisfaction surveys.

Additional Information:
As research programs change in size, scope or content, its management strategies must likewise adapt. Using existing tools with an emphasis on flexibility, ease of implementation, and a scrutiny to cost effectiveness is critical for ongoing success. Having a clear and simple resource of protocol review guidance reduces repeated topic assessment and informs the conversation when guidance does change. Protocol development and review mandates a collaborative environment. Communication tools bridging program groups, such as TREATS, can make this collective effort more manageable.