DR. T’S CORNER

NIH achieves milestone to accelerate multisite clinical studies

Developing new treatments for diseases often requires large numbers of clinical research participants enrolled in the same study at numerous geographical sites. These multisite clinical trials are well-positioned to discover whether a promising therapeutic is safe and effective, and may provide medical professionals with the information needed for treating their patients. However, the initiation of such studies may be delayed because each site typically relies on its own Institutional Review Boards (IRBs) to provide ethics reviews of the risks and benefits of the proposed research.

The National Institutes of Health (NIH) is leading policy and programmatic initiatives to streamline this overly cumbersome process. NIH’s National Center for Advancing Translational Sciences (NCATS) announced that all Clinical and Translational Science Awards (CTSA) Program sites have signed on to the NCATS Streamlined, Multisite, Accelerated Resources for Trials (SMART) IRB authorization agreement. This agreement — which now includes a total of more than 150 top medical research institutions — will enable all participating study sites to rely on the ethics review of one IRB for each study, making it possible to initiate multisite studies within weeks instead of months. For patients waiting to enroll in a study, this could make a life-saving difference.

The SMART IRB authorization agreement serves as a model to help investigators adhere to the NIH’s policy on single IRB use for multisite studies. This policy was designed to improve IRB efficiencies while ensuring the protection of research participants so that research can proceed expeditiously. The authorization agreement effort was led by Harvard Catalyst, University of Wisconsin-Madison Institute for Clinical and Translational Research, and Dartmouth Synergy. Through these institutions, a team of NCATS-supported SMART IRB ambassadors facilitated and provided critical guidance and support to assist institutions in joining and implementing the SMART IRB authorization agreement. “This milestone is a giant step toward a nationwide model for greater efficiency in IRB review, which is critical to getting more treatments to more patients more quickly,” said NCATS Director Christopher P. Austin, M.D. “It was made possible by the teamwork of hundreds of experts across the country who worked together to achieve what was thought to be impossible even a few years ago.”

A NOTE FROM JORI LESZCZYNSKI

I am happy to announce that the University has purchased NTM eSirius 3G as the new IACUC Protocol and Animal Facility Management Software system to replace Topaz Elements. The decision to move to this new system is an effort to improve the process for PIs, research staff, as well as those working behind the scenes in OLAR, IACUC and EHS.

At this point we are still in the very early stages of the process, as we have just finalized the contract. Over the next several weeks, the team implementing the new system will be meeting with NTM to develop timelines for transitioning to eSirius. We will communicate with you what those timelines are, including hosting several town hall meetings to keep you updated and train individuals on the new system. Our goal is to move as quickly as possible without sacrificing quality.
I would like to thank Chancellor Elliman, Dean Reilly, Vice Chancellor Traystman, and Vice Chancellor Carrothers for their support of this change. New computer software systems require a significant investment, so this change would not be possible without the resources that they have allocated to this project. I would also like to thank the members of the committee charged with choosing a new system, as well as countless others that attended the company presentations and worked with the demos to provide feedback. Your work was invaluable in helping us come to this decision.

Thank you all in advance for your patience as we transition to the new system. Please let me know if you have any questions.

RESEARCH CORNER

Kevin S. Masters, PhD

Health psychology and behavioral medicine focus on the interactions between psychological variables, behavior, and health. It is widely recognized that: 1) chronic diseases are a substantial health burden to individuals and to the health care system and, 2) these diseases are significantly influenced by psychological and behavioral factors. In some cases these diseases can be prevented and in others their course can be modified with appropriate behavioral health intervention. Two primary pathways through which these effects occur are: 1) psychophysiological reactions to stress; and 2) behavioral/lifestyle practices that influence health. We study both of these pathways primarily through focus on what might be called “higher order constructs.” In the Cardiovascular Health and Life Meaning (CaLM) Lab, our focus is on the possible role of life meaning. Several studies demonstrate a positive relationship between life meaning and a number of beneficial health outcomes, including cardiovascular health and decreased mortality. Nevertheless, much remains unknown. Though lifestyle practices can improve health profiles, the vast majority of individuals fail to enact these behaviors over the long-term. Our research has demonstrated that individuals who are more aware, on a daily basis, of what is meaningful in their lives are also more likely to remain physically active. But can we intervene to improve both quality of life and health behavior? To investigate this question we have piloted a mobile phone app (Colorado Meaningful Activity Project; COMAP) designed to bring awareness, at opportune times, to individually established links between meaningful life engagement and physical activity. To address the psychophysiological pathway, we are currently launching a lab based study to investigate the role of meaning in dampening harmful patterns of cardiovascular reactivity to and recovery from psychological stressors. Finally, we are beginning work investigating the possible influence of life meaning on medical decision making among individuals with heart failure, hypothesizing that those with higher experienced life meaning may be more likely to make decisions in accord with their values and health goals. Please visit our web page at: https://calmlab.wordpress.com/research/.

NEED TO FIND A REPLICATION PARTNER OR A COLLABORATOR?

StudySwap can help.

 Newly launched in March, it already has hundreds of twitter followers looking for the latest post. Originally inspired by a RetractionWatch post, the creators hope “that the use of open and transparent exchange agreements, which are essentially publicly posted collaboration contracts, will be effective in ensuring that collaborations via StudySwap are positive and productive experiences for all involved.” “…collaborators will need to come to agreements on open data policies, have a system in place for full ethics approval at all institutions involved, and decide if they will follow other open science procedures such as pre-registration...We strongly believe in the potential of multi-site collaborations and we hope that StudySwap is a tool to help facilitate them.” See full article at: http://retractionwatch.com/2017/04/19/need-find-replication-partner-collaborator-theres-online-platform/ )