CTSI Coordinator Connect

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In this issue:

Innovations in Informed Consent

For years, the informed consent process has been relatively uniform: a thorough and engaging dialogue between participants and research teams has been anchored around a written informed consent document. The document itself bears the burden of explaining every element of informed consent required by federal law, and as crucial as these elements are to a participant's informed choice to take part in a study, this can lead to many pages of legalese that are difficult for people to understand and interpret.

New innovations in informed consent aim to supplement the process with enhancements that help simplify complicated ideas and increase participant engagement and understanding. Visual accompaniments to informed consent are one helpful tool for breaking down the formal language of the consent document into more easily understood content. Here at the University of Pittsburgh, Dr. Charles Jonassaint and research coordinator Jordan Driscoll recorded an informed consent video for the CALM SCD study, which investigates links between pain and stress in patients with sickle cell disease. The video explains the study in lay terms and familiarizes patients with the research staff they will eventually encounter in person.

Another example of enhancing informed consent with visuals comes from All of Us Pennsylvania, the local arm of the national All of Us precision medicine study. A simple video explains in a concise and friendly way both the purpose of the research and what it involved for participants. All of Us also uses a phone app to obtain informed consent and collect surveys. It uses periodic quizzes to assess understanding and guides participants to re-review any parts of the consent that do not appear to be clearly understood. Participants are then able to complete online surveys prior to their clinic visit, where research staff are available to review consent and answer any lingering questions.

In fact, phone apps are increasingly common in research, thanks in part to commercial providers like Apple Research Kit and Research Stack (for Androids), which have developed apps that allow for online completion of consent, survey completion, and data tracking. These environments are able to host videos and produce graphics that help participants better understand study procedures and manage their own participation.

Sage Bionetworks, a non-profit company that develops collaborative practices and technology to support the integration of data science into biomedical research, recently published a free guide for developing informed consent, particularly in the online/app environment which has a host of useful information for researchers.

Research Resources: Protocol and Biosketch Development Tools

National Institutes of Health (NIH) Clinical e-Protocol Writing Tool

In an effort to assist researchers in developing clinical protocols, the NIH, in conjunction with the Food and Drug Administration, developed an interactive, online e-Protocol Writing Tool. This tool was originally designed to guide investigators in the creation of protocols for clinical trials that are being conducted under a Food and Drug Administration (FDA) Investigational New Drug (IND) or Investigational Device Exemption (IDE) application. It has recently been expanded for use in other types of studies.

The tool provides step-by-step electronic entry of important protocol elements like study design, objectives and endpoints, statistical considerations, and description of study interventions and procedures. It requests completion of all elements that define a rigorous, scientifically sound protocol. Features of the tool allow for email notifications to study team members when completed sections are ready for review, and export functions allow the completed document to be exported for external reviews.

The Clinical e-Protocol Writing Tool has been in existence for several years, and added a recent enhancement via the integration of a new Behavioral and Social Sciences Research Template, which expands the types of studies that can use the tool to guide protocol development. The expansion was a response to the 2014 revised definition of clinical trials, which broadened the term so that it now covers some behavioral and social science studies that had not previously met the requirements that define an investigation as a clinical trial.

Science Experts Network Curriculum Vitae (SciENcv)

SciENcv is an electronic system that helps researchers efficiently compile personal data required for federally funded grant applications. It allows users to quickly create, share and maintain NIH biosketches, which summarize investigator credentials and are required for all NIH sponsored grant submissions. This free profile service is part of My NCBI, an NIH supported service.

Three options exist for creating new profiles: new biosketches can be created from scratch using a template that prompts for the required information, data can be exported from era COMMONS (an online interface where all investigators with federal funding share personal and grant data with sponsors) , or an existing biosketch can be duplicated and then edited. The first option is valuable for researchers who have not created a biosketch before and may not be familiar with the required fields and conventions of standard biosketch format. SciENcv is free and any researcher may register. Find out more at the SciENcv website.

Funding Opportunities

Wiley Prize in Biomedical Sciences

The Wiley Foundation presents a yearly $50,000 prize to scientists who demonstrate outstanding leadership and innovation in the biomedical sciences. The Foundation is particularly interested in pure or applied life science research that challenges accepted thinking and applies novel approaches to further understanding of biological systems and processes. Nominations will be accepted through Monday, September 30, 2019. More here.

Clinic and Laboratory Integration Program (CLIP)

The Cancer Research Institute provides funding to speed the translation of laboratory discoveries to cancer treatments that can be tested in clinical trials. CLIP grants offer support to scientists who are investigating questions relevant to the development of immunotherapies and optimizing immunotherapy for cancer patients. More here.

Interpersonal Processes in Alzheimer's Disease and Related Dementias: Clinical Interactions and Care Partnerships

The National Institute on Aging is sponsoring research that examines the relationships between Alzheimer's patients, their caregivers, and healthcare professionals, and the implications of these relationships on outcomes for patient care. Funding is intended to fill the need for developing family-centered approaches that benefit from the involvement and insight of caregivers. Basic and translational research is sought in two high priority areas: 1) effective communications and relationships among patients, and 2) associations between close relationship processes and health in caregiving relationships. More here.

Refinement and Testing of Interventions to Sustain ADHD Treatment Effects Across Settings and Developmental Transitions

The National Institute of Mental Health is providing pilot funding for research that examines preliminary effectiveness of modified or augmented interventions which promote enhanced, long term improvement of ADHD symptoms. Proposed studies should address both effectiveness of interventions as well as increased understanding of the interventions' mechanisms of action. More here.

CTSI Updates

CTSI Expands Integrating Special Populations Core (ISP)

CTSI's Integrating Special Populations Core has expanded to include a new liaison for persons with disabilities. The ISP was developed to help engage underrepresented populations in research, including pregnant women, newborns, children, older adults, persons with disabilities, African Americans and other ethnic minorities, people living in rural areas and the LGBTQ communities.

The Core employs a group of liaisons with experience engaging these populations; the liaisons are supported by a "Mind Bank" of faculty with expertise in research across the lifespan and with underrepresented communities. One mission of the Core is to advise researchers on all aspects of research involving these populations.

The Core provides advice from the conceptual to the practical. Its members help with big picture issues like identifying research gaps and opportunities, as well advising researchers regarding strategies for locating and engaging target groups and best practices for recruitment. The Core strives to foster relationships between underrepresented populations and the research community.

The Core recently hired RaNaja Kennedy to act as the liaison for persons with disabilities. She spoke about the importance of her role ensuring that people with physical, cognitive, and mental health issues are included equally in research: "It's 2019, and everything should be intersected. No one should be left out." Personal experience with affected family members inspired her involvement with this work.

Kennedy looks forward to forging partnerships with local hospitals, schools, and other institutions, as well as making community connections. She sees herself as "the bridge between researchers, clinicians, patients, and community members." More on ISP here.

Regulatory Updates

House Bill Seeks to Expand Access to Genetic Counselors

For certain research, genetic counselors play an important role. When studies involve return of results to participants regarding conditions with a genetic component, they are key in helping people interpret results and understand implications and treatment options. Precision medicine, which seeks to improve healthcare by developing prevention and treatment strategies based on individual differences in genes, environment, and lifestyle factors, is increasingly at the forefront of research. Though not all studies involve return of results directly to participants, as precision medicine studies become increasingly common, the role of genetic counselors in research will grow in importance.

Given this, a recently introduced bill in Congress is of interest to the research community. H.R. 3235, the "access to Genetic Counselor Services Act of 2019," would allow the Centers for Medicare and Medicaid Services (CMS) to recognize and reimburse genetic counselors as service providers. If passed, this legislation should improve access to genetic counselors for Medicare and Medicaid recipients, as they will be able to be directly connected with a genetic counselor through their physician, rather than referred to a second physician who works with a genetic counselor, which is the current lengthy process.

If H.R. 3235 passes, it may impact genetic research by increasing access to genetic counseling for Medicare and Medicaid recipients. This is particularly relevant for studies that propose to return of results, as many do, especially when the results are actionable (meaning the participant may be able to take steps to ameliorate risk).

The provision may also result in savings in public dollars, as the proposed rate of reimbursement for genetic counselors is 85% of what is currently paid to physicians. The bill was sponsored by Representatives Dave Loebsack (D-IA) and Mike Kelly (R-PA), who worked with the National Society of Genetic Counselors to develop the bill.

More about H.R. 3235 here.

Dear CTSI

Hello Readers! This space is reserved for your questions. If you have a research question you would like to see answered in print, please send it to cliftons@pitt.edu and look for answers in our next edition.

Dear CTSI,
What is the difference between coercion and undue influence?

Answer: Coercion and undue influence both represent forms of pressure that impede a potential participants' ability to truly, willingly consent to research procedures.

Coercion occurs when a person is threatened with harm in retaliation for non-participation; an example would be the overt or implied threat that refusal would result in losing access to healthcare, which may be of particular concern if the investigator is also the participant's personal physician.

Undue influence occurs when the reward or compensation for participation is excessive to the degree that it might entice a potential participant into making a decision that is actually not in his or her best interest. This is of particular concern with at-risk populations like the homeless and people in lower socio-economic income brackets, who may be more vulnerable to financial enticement. Undue influence can take more subtle forms; as when employees or students are asked to take part in research conducted by employers or professors; there may be unspoken social pressures in these situations which detract from the voluntary nature of consent.

Federal regulations require investigators to minimize the possibility of undue influence or coercion; beyond the rules, it is also generally understood that this is a major ethical obligation for the research community. Avoiding these practices ensures that participation is truly voluntary and the principles of the Belmont Report: beneficence, respect for persons, and justice are respected.

Upcoming Events

Identifying Issues in the Responsible Conduct of Research
Presented by the University of Pittsburgh Clinical and Translational Science Institute
Wednesday, September 4, 2019 12 p.m.– 1:00 p.m.
More information: https://ctsievents.pitt.edu/Applicants/Create?eventGuid=0a281a4b-0363-404b-87e0-1237b9e1e3fc

Privacy & Health Related Research in a Data Driven World (Webcast)
Presented by the Office of Human Research Protections
Thursday, September 19, 2019 8:15 a.m.- 4:15 p.m.
More information: https://www.hhs.gov/ohrp/education-and-outreach/exploratory-workshop/2019-workshop/index.html

ClinicalTrials.gov: Background, Requirements, and Process
Presented by The University of Pittsburgh Research Conduct and Compliance Office
Wednesday, September 25, 2019 12 p.m. - 1:00 p.m., RCCO Learning Resource Center, 3500 Fifth Avenue Room 305
More information: http://rcco.pitt.edu/event/clinicaltrialsgov-background-requirements-process-92519

TBA: The Pittsburgh chapter of the Association of Clinical Research Professionals (ACRP) will be holding a professional development event in September, topic TBD. Check the ACRP website for updates.

Questions for us? We'd love to hear from you:
https://ctsi.pitt.edu/contact-us/

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