NEW VERSION OF TCPS2 RELEASED

In December 2014 the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC) released a revision of the 2nd Edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans or TCPS2 (2014) which replaces TCPS2 (2010) as the official human research ethics policy of the Agencies.

Changes include increased emphasis on the participant’s decision-making capacity, more detailed guidance around alterations to consent requirements, clinical trial registration, trial reporting and data access, clarified REB review requirements, and the full integration of CIHR’s Guidelines for Human Pluripotent Stem Cell Research.

TRANSPARENCY IN RESEARCH

In recent years, there has been increased emphasis on the transparency in clinical trials, making the results of trials open, accessible, and accountable. The main means of increasing transparency have been:

1. Mandatory registration of interventional clinical trials in a publicly accessible database and,
2. Required reporting of trial results.

To support increased clarity and compliance are changes in legislation and guidance.

Canada, legislation includes the clinical trial registration initiative and the Food and Drugs Act, recently amended by Bill C-17, Protecting Canadians from Unsafe Drugs Act (Vanessa’s Law). Among other measures, Bill C-17 addresses transparency, mandating the public disclosure of information by sponsors concerning clinical trials, such as mandatory registration and the disclosure of summary results, which will be set out in regulations.

The recently revised TCPS2 (2014) also includes amendments related to clinical trial registration and the reporting of results, clarifying and strengthening the requirements in these areas. Funding from the Tri-agencies (CIHR, SSHRC, and NSERC) is now contingent on satisfying the below criteria. The agencies have also released an open access policy on publications requiring grant recipients to ensure that any peer-reviewed journal publications arising from Agency-supported research are freely accessible within 12 months of publication through online repositories or journals.

TCPS2 (2014) recommendations (from Articles 11.3 and 11.8):
- All clinical trials shall be registered before recruitment of the first trial participant in a publicly accessible registry that is acceptable to the World Health Organization (WHO) or the International Committee of Medical Journal Editors (ICMJE)
- New information must be submitted to the publicly accessible trial registry along with reports of findings once the trial is completed.

Other international groups like the World Health Organization and AllTrials campaign have released similar recommendations to increase the transparency of clinical trials.

For more information on best practices for clinical data sharing, please see the Institute of Medicine’s (IOM) report: “Sharing Clinical Trial Data, Maximizing Benefits, Minimizing Risk” and accompanying infographic.
Clinical Research in Alberta

Alberta is host to numerous clinical trials in a wide range of fields including oncology, psychology, metabolic disorders and more. Stay on top of the latest research in the province by viewing recently opened clinical trials. If you have a clinical trial that will be opening for recruitment in the upcoming months, let us know and we will include it on our website.

Health Canada (HC) and FDA News

Keeping you informed of changes in regulations - * Are open for comments

Vanessa’s Law (HC): The passage of Vanessa’s Law (The Protecting Canadians from Unsafe Drugs Act) was announced by Health Canada in November. Vanessa’s Law introduces important safety improvements and transparency measures to the Food and Drugs Act, strengthening the regulation of therapeutic products, improving adverse event reporting, and allowing Health Canada to act quickly when a serious health risk is identified.

Risks in Bioequivalence Study Protocols- Draft Guidance (FDA): “How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD” was released in December 2014. This draft guidance aims to facilitate a prospective abbreviated new drug application (ANDA) applicant in accessing the reference listed drug (RLD) to perform testing for bioequivalence to support the application.

*Clinical Trial Imaging Endpoint Process Standards- Draft Guidance (FDA): This guidance presents standards for optimizing the quality of imaging when used to assess a trial’s primary endpoint or a component of that endpoint. The FDA has requested feedback on the draft guidance by May 4, 2015.

Clinical Outcomes Assessment Development and Implementation:Opportunities and Challenges Public Workshop (FDA): This public workshop will provide updates on accomplishments, challenges, and ongoing efforts in the use of clinical outcome assessments (COAs), and plan for the future of COA development and utilization in drug development programs. The workshop is available via webcast; persons interested in participating must register online by March 27, 2015.

Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care- Draft guidance (OHRP): This draft guidance applies to research involving human subjects conducted or supported by the Department of Health and Human Services (HHS). It focuses on reasonably foreseeable risks of research in studies whose purpose includes evaluating risks of treatments or procedures that are medically recognized standards of care, and explains how to apply the HHS Regulations 45 CFR Part 46 to such studies.

*Use of Electronic Informed Consent in Clinical Investigations - Draft guidance (FDA): Open for comment until May 8, 2015, this draft guidance provides recommendations for clinical investigators, sponsors, and institutional review boards (IRBs) on the use of electronic media and processes to obtain informed consent for FDA-regulated clinical investigations.

Alberta Research in Alberta

Clinical Research in Alberta

This month we’re featuring articles in the field of mental health.

- Influence of birth cohort on age of onset cluster analysis in bipolar I disorder.
- Effects of minocycline add-on treatment on brain morphometry and cerebral perfusion in recent-onset schizophrenia.
- Disability in bipolar I disorder: The 36-item World Health Organization Disability Assessment Schedule 2.0.
- Food for thought: understanding the value, variety and usage of management algorithms for major depressive disorder.
- Feasibility and acceptability of web-based enhanced relapse prevention for bipolar disorder (ERPonline): Trial protocol.
- Pilot study of cognitive remediation therapy on cognition in young people at clinical high risk of psychosis.
- Stress exposure and sensitivity in the clinical high-risk syndrome: initial findings from the North American Prodrome Longitudinal Study (NAPLS).
- Suicidal behaviours in adjustment disorder and depressive episode.

Each issue will highlight a research area that has been recently published by Alberta researchers.

Visit the ACRC website under Clinical Research Source for the full listing.

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