

Clinical Trial Research News

From the Office of Clinical Research

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This newsletter is published on a quarterly basis and is designed to provide an information source for anyone interested in Clinical Research. Please contact Terry (237-2226) if you would like to be added to / deleted from our mailing list.

Announcement

International Clinical Trials Day
Wednesday, May 20, 2009
St. Boniface General Hospital Research Centre
8:30 AM to Noon
FREE
See attached poster for more details!

Statistics and Medical Research

Understanding Correlation

Correlation analysis is one of the most basic and widely used statistical methods in medical research. Although correlation is a relatively simple statistical procedure, it forms the basis of more advanced statistical methods such as linear and multiple regression, factor analysis, cluster analysis, path analysis, canonical correlation and discriminant function analysis.

Correlation techniques can be employed in exploratory, retrospective and prospective research studies. Essentially correlation is a procedure for quantifying the relationship between two or more variables by measuring the strength and direction of the relationship. The correlation coefficient (r) is usually expressed as a value ranging from -1.0 to +1.0. For example a $r = +.83$ indicates a strong positive relationship between two variables (say sodium intake and blood pressure) showing that as levels of one variable increase there is a corresponding increase in the values of the other variable. Negative correlation values indicate an inverse relationship between variables. Confidence intervals (usually 95% or 99%) can also be set up around a given r value through a transformation into a Fisher's z statistic, enabling a researcher to state the confidence that the population r falls between two specific values.

Types of Correlation Measures

Different types of correlation measures are used depending on the type of data and the nature of the variables in the study. It is important that researchers apply the proper measure of correlation when analyzing their data.

- Pearson correlation measures the relationship between two continuous variables.
- Spearman Rho and Kendall's Tau are non-parametric measures which quantify the relationship between two ordinal or ranked variables.
- Phi coefficient is used when both variables are nominal measurement and dichotomous.
- Contingency coefficient measures the relationship between two nominal variables that have more than two levels.
- Point-Biserial coefficient is used to correlate one dichotomous variable with one continuous variable.

Interpreting Correlation

The calculated r value between two variables can be evaluated for statistical significance to see if the relationship occurs by chance alone. Researchers need to be aware that the level of significance is strongly affected by the size of the sample. For example, with a small sample (n = 10) a correlation must be r = 0.63 or greater to be significant. But for large samples (n = 1000) even very small correlations (r = .195) may be statistically significant. In other words, a statistically significant correlation may be quite small and not particularly meaningful if the sample size is large enough.

The meaningfulness of a correlation coefficient can be determined by calculating the 'coefficient of determination' (r squared). This is a measure of the amount of variance that the variables share. For example, r = .20 is statistically significant for a large sample size = 1000 but the amount of variance accounted for by the relationship between the two variables is only r squared = .04 or 4%. Another 96% of variance is unaccounted for. A correlation of r = .70 is required to account for 50% shared variance between variables.

It is also important to understand that a statistically significant correlation between two variables does not imply cause and effect. It only indicates a non-causal association between variables. Other factors may be influencing the two variables in a complex interaction which would require a strictly controlled experimental design to delineate.

This article is authored by OCR statistical consultant Doug Staley. Doug teaches statistics at the School of Medical Rehabilitation, University of Manitoba and has conducted medical research at SBGH for more than 25 years. Readers are welcome to submit questions or suggest topics of interest.

Doug can be contacted by email: dstaley@mts.net or extension 2690.

Lab Services Form - Updated

Please find attached an updated Lab Services Form (which is to be completed and sent to Kris Ryan with all new protocols). Please discard the old form and replace with this one. An electronic version can be found under the heading templates at <http://www.sbrc.ca/content/blogcategory/86/131/>

The following is a quick example illustrating the best way to complete the section 2 regarding any tests (or procedures) that are "above standard of care" which are performed in-house (i.e. not at a central lab).

Laboratory	Test Names or Procedure:	Specific Visits (above standard of care)
Biochemistry:	TSH, Homocystein	Day 15 and Day 42 each cycle
Pathology:	All procedures	All Visits
Hematology:	D-Dimer	Cycle 3, Day 15

For protocol amendments that affect the lab contact Kris directly to confirm if the lab needs to "re-sign".

Questions? Contact: Kris Ryan - Research Lab Technician
 Tel: (204) 235-3935 Fax: (204) 231-2656
 E-Mail: kryan@sbgh.mb.ca

Message from the Bannatyne Campus Research Ethics Board

RE: Updated Research Ethics Board Submission Form (dated February 1, 2009) and Revised Clinical Trial Registry Information Sheet (updated February 1, 2009)

Bannatyne Campus Research Ethics Board Submission Form

The University of Manitoba Bannatyne Campus Research Ethics Board Submission Form has been updated to include the expanded definition of the types of trials that must be registered prior to the enrolment of the first participant to ensure subsequent publication of trial results. The International Committee of Journal Editors (ICMJE) recently adopted the World Health Organization's (WHO) definition of a clinical trial as follows:

"Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects of health outcomes."

Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

A few additional administrative changes have also been made which are all highlighted for ease of review.

Clinical Trial Registration Information Sheet

The information sheet about mandatory "Clinical Trial Registration" has also been updated in a question answer format to better clarify the requirements and instructions on how to register applicable trials. This information sheet can be found on The University of Manitoba, Bannatyne Campus Research Ethics Board website.

<http://www.umanitoba.ca/faculties/medicine/research/ethics/>

http://www.umanitoba.ca/faculties/medicine/research/ethics/media/Clinical_Trial_Registration_Feb1_09.doc

Please note: Do not save the Form templates (including main submission form, SAE reports, Annual reports, etc) to your computer but rather visit our "Forms Consent Templates" page each time you submit. This will ensure you are using the latest version of the forms.

More major revisions are being drafted on for the main REB submission form to accommodate updated ethical and privacy guidelines.

If you have any questions with respect to mandatory clinical trial registration, please contact Shelly Rempel-Rossum at 789-3389.

Tri-Council Policy Statement (TCPS) - Update

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) was jointly developed in 1998 by Canada's three research agencies-the Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council of Canada (SSHRC). The Agencies formed the Panel in 2001 to interpret and promote the TCPS. The Panel's mandate is to ensure that the TCPS evolves to keep pace with changes in research and society at large.

In December 2008, the Interagency Advisory Panel on Research Ethics (the Panel) released a substantial revision to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) and began a cross-country consultation tour. The Panel held close to 30 consultations involving over 800 participants in 17 Canadian cities including Winnipeg on March 26, 2009. Individuals, groups and organizations provided a significant number of comments. March 31, 2009 marks the end of this phase of the consultation process.

The draft 2nd edition of the TCPS has been generally well received by Canada's research community. The Panel appreciates the high level of community engagement to date and welcomes the many excellent suggestions that have been received, which will significantly improve the final document.

1. Deadline for Written Comments on the Draft Extended to June 30, 2009

The Panel has decided to accept written comments until June 30, 2009 to accommodate the approval processes of several organizations and groups that wish to submit coordinated responses to the draft 2nd edition. The Panel encourages the submission of comments as soon as possible since it will begin the work of revision in April.

2. Release of Revised Version of the Draft for Comments: Autumn 2009

The Panel will release a revised version of the draft to the public for further comment in October. There will be a 45-day written consultation period. The Panel will then prepare a final draft based on those comments. In February 2010, the Panel will submit a final revision to the Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council of Canada (SSHRC) for their consideration.

The Panel values feedback from the research community and the Canadian public. You are invited to submit your comments in writing by mail to the address below, by fax to 613-996-7117, by e-mail to Draft2e@pre.ethics.gc.ca or with the consultation feedback form at <http://pre.ethics.gc.ca/eng/policy-politique/initiatives/feedback-retroaction/>

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) was jointly developed in 1998 by Canada's three research agencies-the Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council of Canada (SSHRC). The Agencies formed the Panel in 2001 to interpret and promote the TCPS. The Panel's mandate is to ensure that the TCPS evolves to keep pace with changes in research and society at large.

To order a print copy of the draft 2nd edition of the TCPS, send your request to Secretariat@pre.ethics.gc.ca <<mailto:Secretariat@pre.ethics.gc.ca>> or contact Terry Sawicz-Hanesiak (237-2226 or tsawicz@sbgh.mb.ca) for extra copies which are available at SBGH.

Research Review Committee at St. Boniface General Hospital

Deadlines for RRC Submission

April 29

May 27

Please note there is no RRC meeting in July

July 29

August 26

September 30

October 28

November 25

Meeting Date

May 6

June 3

August 5

September 2

October 7

November 4

December 2

Submissions to the RRC must be received in N1004 by 11:00 AM on the deadline date.

Contact the **RRC** at **235-3623** with any questions you may have regarding your RRC submission. Please always refer to the Office of Clinical Research and RRC web site for the most recent submission forms and updates.

<http://www.sbrca.ca/content/blogcategory/87/132/>

The Biomedical (BREB) / Health Research Ethics Board (HREB) Submissions

Deadline for REB Submissions

April 14

May 11

June 8

Please note there is no REB meeting in July

August 10

September 14

October 9

November 9

November 30

Meeting date

April 27

May 25

June 22

August 24

September 28

October 26

November 23

December 14

Contact **Ethics** at **789-3255** with any questions you may have regarding your REB submission. Please always refer to the Research Ethics Board web site for the most recent submission forms and updates.

<http://www.umanitoba.ca/faculties/medicine/research/ethics/index.html>

Education and Training Events

SoCRA Certification – Are you Interested in Writing your Exam in Winnipeg? – May 19/09 - 9 AM to 1 PM

REGISTRATION DEADLINE IS APRIL 7, 2009!

REGISTER ON-LINE AT: <http://www.socra.org>

The Society of Clinical Research Associates, Inc. (SoCRA) is a non-profit, professional organization dedicated to the continuing education and development of clinical research professionals. The express aim of SoCRA is to provide training and continuing education for clinical research professionals and to establish and maintain an international certification program for clinical research professionals.

Free ON-LINE Resources

If you haven't already, we highly recommend you consider subscribing to the **FREE** monthly e-mail "**Journal of Clinical Research Best Practices**". The monthly electronic journal has excellent articles and a hilarious monthly cartoon that many clinical research professionals can appreciate and relate to.

To subscribe, search the archives, or read the current edition go to:

<http://www.firstclinical.com/journal/contents.html>