

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.

Announcements

Welcome!!!

The Office of Clinical Research is pleased to introduce the following new staff members;

Michael Sinaisky, B.Sc., CCRP – Associate Research Coordinator (phone: 235-3813)

Krista Vandewaeter – OCR Administrative Secretary and Recording Secretary for the RRC (phone: 235-3623)

Statistics and Medical Research

Testing a Research Hypothesis

One of the cornerstones of scientific research is the testing of research hypotheses through statistical methods. When a research hypothesis is clearly stated it is possible to use powerful statistical techniques to detect whether or not a significant relationship exists between variables or a significant difference exists between sample groups. Science typically employs two types of hypotheses: the null hypothesis and the alternative or research hypothesis.

The null hypothesis proposes that there is no relationship between variables or that there is no difference between groups (e.g. treatment versus control or placebo). The alternative hypothesis proposes that there is a significant relationship between variables or a significant difference between groups. The alternative hypothesis can be further divided into two categories: a directional alternative hypothesis (one-tailed test) or a non-directional alternative hypothesis (two-tailed test).

An example will help to clarify the distinction between the two types of alternative hypothesis. Let us say that we want to test whether a new treatment is effective in reducing blood pressure. The researcher designs a study comparing an experimental group (who receive the new treatment) and a control group (who are administered a placebo). The null hypothesis would state that there is no difference between the two groups in terms of blood pressure change. A non-directional alternative hypothesis would state that the treatment group will have either a significant increase or significant decrease in blood pressure compared to the control group. A directional alternative hypothesis would state that the treatment group will have a statistically significant decrease in blood pressure compared to the controls. In this example a directional alternative hypothesis is appropriate as, presumably, it would be unlikely that the new treatment would result in an increase in blood pressure in the treatment group.

One of the advantages of a directional or one-tailed test is that it is more powerful than a non-directional or two-tailed test because the value yielded by the statistical test does not have to be so large to be significant at a given level. However, the researcher must have a sound theoretical basis for the directional hypothesis. Typically the null hypothesis is the focus of the statistical test. If a significant difference between groups is found, the null hypothesis is rejected and the alternative hypothesis is accepted. If there is no significant difference between groups then the null hypothesis is accepted.

Statistics and Medical Research (continued)

This type of hypothesis testing leads to two types of statistical error, called a Type I error and a Type II error. A Type I error occurs when we reject a true null hypothesis, i.e. the data suggests (incorrectly) that a significant difference exists when in fact there is no difference. A Type I error is equivalent to a false positive finding. A Type II error is the opposite of a Type I error and is equivalent to a false negative finding. It occurs when we accept a false null hypothesis, i.e. the data show (incorrectly) that there is no difference between groups when in fact a real difference exists.

The probability of making a Type I error is called 'alpha' and can be decreased by altering the level of significance used in the statistical test. For instance, the researcher could set the alpha level at $p = .01$ rather than $p = .05$. In this case a Type I error would occur only 1% of the time.

The Type II error is called a 'Beta' error and is directly related to the power of a statistical test to detect real differences between groups: $\text{Power} = 1 - \text{Beta}$. To reduce Type I errors (and hence increase power) the researcher can use a more liberal level of significance, since there is an inverse relationship between Type I and Type II errors. There is a greater chance of finding significant results if you are willing to risk 5 chances in a 100 that you are wrong ($p = .05$) than if you are willing to risk 1 chance in 100 ($p = .01$).

The likelihood of a Type II error can also be reduced by increasing the sample size, decreasing sources of extraneous variation and increasing the effect size or impact of the independent variable. Decreasing the probability of one type of error increases the probability of the other type of error. Researchers must ask themselves which type of error they are willing to risk. This depends very much on the nature of the study. The researcher must decide whether a false positive (Type I error) or a false negative (Type II error) is more serious.

Statistics articles are 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.

Declaration of Helsinki – Updated in October 2008

In October 2008 the World Medical Association (WMA) held their General Assembly in Seoul, Korea and one major outcome of the meeting was a revised version of the Declaration of Helsinki. The revised version of the Declaration of Helsinki was adopted by the WMA and is now available at <http://www.wma.net/e/>

The current version contains several significant changes and any person involved in conducting research should become familiar with the revised document.

December 2008 issue of The First Clinical Research – Journal of Clinical Research Best Practices, has a link titled "What's New in GCP?" which provides a summary of the changes to the Declaration of Helsinki. The journal is free and can be located at <http://www.firstclinical.com/journal/contents.html>

Research Review Committee at St. Boniface General Hospital

Deadlines for RRC Submission

January 7
January 28
February 25
March 25
April 29
May 27

Meeting Date

January 14
February 4
March 4
April 1
May 6
June 3

Please note there is no RRC meeting in July

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/content/blogcategory/87/132/>

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

Deadline for REB Submissions

Meeting date

| | |
|------------|-------------|
| January 12 | January 26 |
| February 9 | February 23 |
| March 9 | March 23 |
| April 14 | April 27 |
| May 11 | May 25 |
| June 8 | June 22 |

Please note there is no REB meeting in July

| | |
|--------------|--------------|
| August 10 | August 24 |
| September 14 | September 28 |
| October 9 | October 26 |
| November 9 | November 23 |
| November 30 | 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

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.

To become certified

- In order to be considered for SoCRA certification, the applicant must be a current member of SoCRA working with GCP guidelines under IRB/EC/REB approved (or specifically exempted) protocols.
- SoCRA will not be able to consider candidates who are unable to provide the requested supporting documentation regarding their experience in clinical research.
- Any questions regarding the eligibility requirements should be directed to the SoCRA Administrative Office.

NOTE: Most candidates will be eligible under **Category 1**. If you have completed two (2) years of full-time employment as a clinical research professional in the past five years, you will **NOT** need to provide supporting documentation for your educational experience.

ELIGIBILITY CATEGORIES – The applicant's experience must fall under one of the following categories:

Category 1: Candidates having completed a **minimum of 2 years of full time employment** (or 3500 hours of part-time employment) during the past five years as a clinical research professional.

Category 2: Candidates holding a **degree in "Clinical Research"** from an Associate, Undergraduate or Graduate Degree Program **AND** having completed a **minimum of one year of full-time experience** (or 1750 hours part-time) during the past two years as a Clinical Research Professional.

Education and Training Events (continued)

Category 3: Candidates holding an **Undergraduate or Graduate Certificate in “Clinical Research”** with a curriculum of no less than 12 semester (credit) hours or totaling a minimum of 144 credit hours from an academic institution of higher learning (community college, college or university) **AND** holding an **Associate’s or Bachelor’s Degree in a science, health science, pharmacy or related field** **AND** having completed a minimum of **one year of full-time experience** (or 1750 hours part-time) during the past two years as a Clinical Research Professional.

We will be hosting another exam writing for SoCRA Certification here in Winnipeg at St. Boniface General Hospital on Tuesday May 19/09 from 9 AM to 1 PM.

More information is available at <http://www.socra.org> or contact Terry Sawicz-Hanesiak at 237-2226 tsawicz@sbgh.mb.ca .

Project Management for Clinical Research Professionals – February 2009

LSAM is organizing a two-day interactive “Project Management for Clinical Research Professionals Workshop” presented by ASKA RESEARCH to be held in February 2009;

This Workshop is Specifically Designed for Clinical Research Professionals who are:

- Project Managers and Project Leaders
- Line Managers or Directors who supervise Project Managers
- Clinical Research Professionals who are interested in learning more about clinical research project management or who may want to pursue project management career opportunities

More details to follow in 2009 or keep checking the website www.lsam.ca

DON'T FORGET TO SAVE THE DATE!

**Wednesday, May 20, 2009
International Clinical Trials Day**

More SBGH event details to following in 2009!

HAPPY NEW YEAR

