



Clinical Trial Research News

From the Office of Clinical Research

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This newsletter is published on a bi-monthly basis and is designed to provide an information source for anyone interested in Clinical Research. Please contact Trish Berry if you would like to be added to / deleted from our mailing list.

Message from April Hughes

As many of you may already be aware, I will be leaving St. Boniface General Hospital at the end of September to join BC's Northern Health Authority as a Health Services Administrator. I am very grateful, and fortunate, to have had this opportunity to work with you in the development of various clinical research services and programs for the Winnipeg region and beyond. Please know that the Office of Clinical Research team will continue to assist you with consulting and facilitation of your projects. Thank you all very much for having included me in your research teams over these past 8 years. I wish you all the best with your future projects.

April

Announcement

Please be advised that September 7, 2007 will be Laura Nesmith's last day with the Office of Clinical Research.

Since July 2003, we have had the wonderful opportunity to work with Laura Nesmith as our Student Research Assistant. During her time with the OCR Laura's responsibilities expanded from providing administrative assistance to our Office staff to coordinating and conducting clinical research projects for Principal Investigators.

Laura is an exceptional individual. We wish her well with her future studies and all her future pursuits.

REVISED SOPs Coming Soon.....Effective Monday September 10, 2007

The Office of Clinical Research will be issuing new Standard Operating Procedures starting on Monday, September 10, 2007. More information regarding revisions to the SOPs, distribution/exchange of SOP manuals and signing of new SOP Agreements will be sent out soon.

The OCR would like to sincerely Thank Bunny Fontaine, Naomi Granke and Nicole Marten for all their time and expertise during the SOP review process.

Statistics and Medical Research

Graphical Presentation of Data: Summarizing Frequency Distributions

One of the most common statistical procedures is the graphing of data in order to summarize the distribution of scores of a variable in a research study. Four basic methods of graphing are commonly employed: histograms, frequency polygons, cumulative or ogive curves and box-and-whisker plots. Each graph supplies the researcher with important information for summarizing and interpreting the data.

Histograms

The creation of a histogram is one of the first stages in analyzing and interpreting data. Almost all statistical and spreadsheet computer software programs produce histograms as one of their graphical options. A histogram consists of two axes: a horizontal axis representing the scores of a variable in terms of intervals and a vertical axis representing the frequency or number of cases falling within each interval. Figure 1 shows a typical frequency histogram for cholesterol levels in a patient sample.

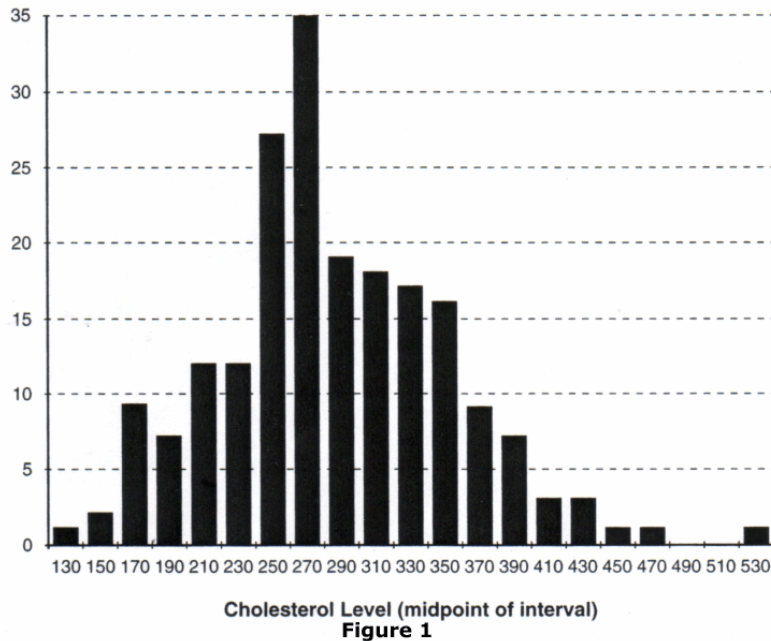


Figure 1

The vertical axis can be expressed in percentage or proportion as well as frequency. A percentage histogram is usually preferable to a frequency histogram since it is independent of sample size and allows a more meaningful comparison between different studies (since percentage is equivalent across studies). The histogram can be used with categorical, nominal and continuous data but yields the most information with continuous variables (e.g. heart rate). Inspection of a histogram tells the researcher the general shape of the data (normal, skewed, bimodal, etc.), the range of scores and the presence of outliers or extreme scores. Each of these indices will influence how the data will be treated in subsequent statistical analyses. For instance, a skewed distribution may require non-parametric analysis rather than parametric analysis.

Frequency Polygons

Another way of constructing a graphical frequency distribution is the frequency or percentage polygon. Instead of bars, as in the histogram, straight lines are used to connect the midpoints of each interval. Figure 2 depicts a frequency polygon for the cholesterol data reported earlier in Figure 1.

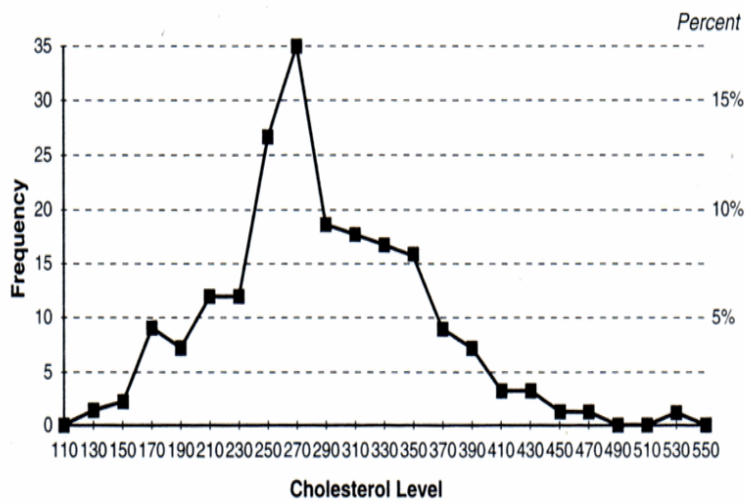


Figure 2

Frequency polygons should not be used with categorical variables as they suggest an underlying continuity of the data where none exists. A histogram should be used to display such data. When comparing two or more distributions of scores within the same graph (e.g. experimental group and control group), frequency polygons are more effective than histograms as they make visual comparison of the two distributions much easier.

Cumulative or Ogive Curves

A cumulative frequency distribution shows the number of scores falling below a certain point on a scale of scores. It is usually constructed from a frequency distribution by a process of successive addition of scores until all the scores have been accumulated. Figure 3 illustrates a cumulative curve for the cholesterol data.

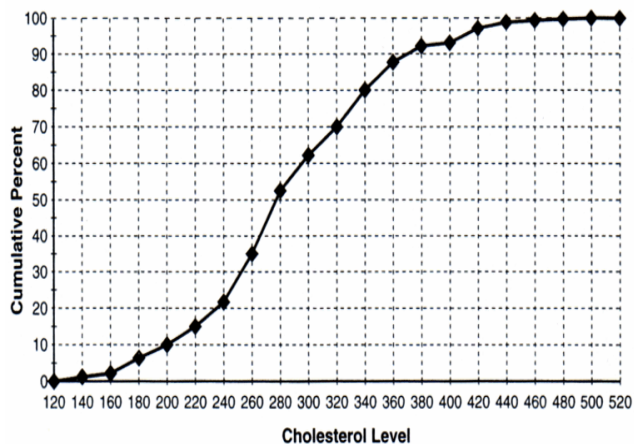
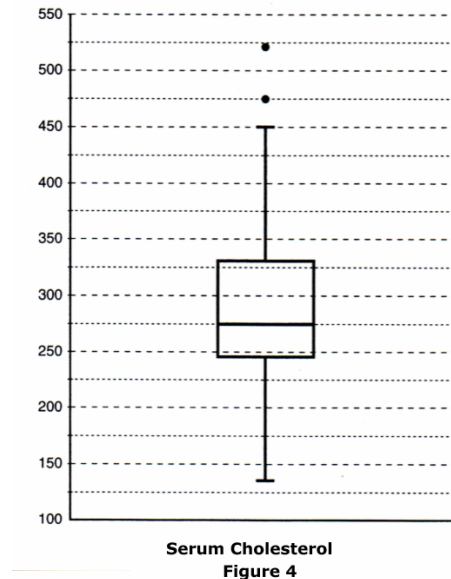


Figure 3

The cumulative curve provides a useful and efficient method for determining percentiles. For instance, in Figure 3 we can see that 70% of the sample have cholesterol levels below 320 Mg DL and 10% have levels below 200.

Box-and-Whisker Plots

The colourfully named box-and-whisker plot was developed by Tukey and is a simple and useful graph for exploring and summarizing an array of data. A box-and-whisker plot of the serum cholesterol levels is given in Figure 4.



The box describes the middle 50% of scores, ranging from the 25th percentile to the 75th percentile. The median or 50th percentile is denoted by a horizontal line inside the box. The two whiskers extend below and above the box to the lowest score and highest score, unless there are outliers, which are indicated by dots beyond the whiskers. Box-and-whisker plots are especially useful for comparing two or more distributions (e.g. patients and controls). Many statistical software computer programs (e.g. SPSS) produce box-and-whisker plots.

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 through the OCR or by email: dstaley@mts.net or extension 2690.



Lectures, Workshops and Conferences

Fall 2007 Clinical Research Lecture Series - U of M Bannatyne Campus

Interested in getting involved in Clinical Research? Clinical research refers to all research conducted with human subjects. These comprehensive lectures are specially designed for individuals with little to no previous research experience. The lectures will present an overview of the language of clinical research, project design and management, roles and responsibilities of the Investigator and the research staff, and the regulatory and ethical environment for the conduct of clinical research.

Due to over whelming response the October 18, 2007 lectures are full. If you would like to register for the remaining lectures on November 8, 2007 contact Terry Sawicz-Hanesiak, SBGH – Office of Clinical Research (204) 237-2226 or e-mail tsawicz@sbgh.mb.ca

DATE	TIME	LOCATION	TOPIC
Thursday, October 18, 2007	Lectures Full		Introduction to Clinical Research
Thursday, October 18, 2007	Registrations no longer being accepted		Clinical Research Ethics
Thursday, November 8, 2007	10:00 AM to Noon	Theatre C Basic Medical Sciences Building	Clinical Research Guidelines, Policies and Regulations
Thursday, November 8, 2007	1:30 PM to 3:30 PM	Theatre C Basic Medical Sciences Building	Clinical Research Project and Documentation Management

1) Introduction to Clinical Research (Lectures Full, Registrations no longer being accepted)

Interested in getting involved in Clinical Research? Clinical research refers to all research conducted with human subjects. This comprehensive introductory lecture is specially designed for individuals with little to no previous research experience. The course will present an overview of the language of clinical research, project design, roles and responsibilities of the Investigator and the research staff, and the regulatory and ethical environment for the conduct of clinical research.

2) Clinical Research Ethics (Lectures Full, Registrations no longer being accepted)

The history and principles of human research ethics and the “Tri-Council Policy Statement” will serve as the basis for this lecture. U of M Health and Biomedical Research Ethics Board structure, submission and review process will also be discussed.

3) Guidelines, Policies and Regulations in the Conduct of Clinical Research

This 2 hour lecture will review the regulatory environment that directs the developmental process for taking a drug from bench discovery through human research and on to market. An overview of the historical evolution of today’s regulatory environment will serve as the basis for why the regulations exist as they do. Quality control/monitoring and quality assurance/auditing will also be discussed.

Lecturers: Terry Sawicz-Hanesiak, Regulatory Affairs/Quality Assurance
Office of Clinical Research - St. Boniface General Hospital
Second Lecturer: TBD

Date: Thursday, November 8, 2007

Time: 10:00 AM to Noon

Location: Theatre C, Basic Medical Sciences Building, U of M Bannatyne Campus

4) Project and Documentation Management for Clinical Research

Rules, Roles and responsibilities will serve as the basis for project and documentation management of clinical research studies, be they drug, device or outcomes research. Topics covered will be:

- Pre-Study Planning, REB and Institutional Approvals
- Study Documents (Protocol, ICF, etc.)
- Source Documents and Data Collection Forms
- Informed Consent Process, Subject visits
- Study Close out

Lecturers: Terry Sawicz-Hanesiak, Regulatory Affairs/Quality Assurance
Office of Clinical Research - St. Boniface General Hospital
Second Lecturer: TBD

Date: Thursday, November 8, 2007

Time: 1:30 PM to 3:30 PM

Location: Theatre C, Basic Medical Sciences Building, U of M Bannatyne Campus

For more information or to register for the lectures contact:
Terry Sawicz-Hanesiak, SBGH – Office of Clinical Research
(204) 237-2226 or e-mail tsawicz@sbgh.mb.ca

Good Clinical Practice Workshop

Date: Tuesday, October 30, 2007

Time: 8:30 – 4:00 pm

In response to several requests, the Office of Clinical Research is considering presenting another full day Good Clinical Practice workshop.

The cost to attend the one day workshop would be \$150 (breakfast, lunch and break refreshments are included).

Monitoring Clinical Research Workshop:

Date: Wednesday, November 14, 2007

Time: 8:30 to 4:00 pm

Date: Thursday, November 15, 2007

Time: 8:30 to 12:00 Noon

In response to several requests, the Office of Clinical Research is considering developing a 1-½ day workshop on monitoring Clinical Research Studies. This course will focus on use of forms for hands-on monitoring, and the rationale for monitoring practices. The workshop would be open to anyone who has experience working in Clinical Research and has taken some form of GCP training.

Registration will be limited to 20 participants. For more information or to have your name placed on the waiting list please contact Terry Sawicz-Hanesiak, SBGH – Office of Clinical Research (204) 237-2226 or e-mail tsawicz@sbgh.mb.ca

2007 CURRENT ISSUES IN CLINICAL RESEARCH

**September 18-19, 2007
Minneapolis Convention Center, Minneapolis, Minnesota**

A co-sponsored program of Mayo Clinical Trial Services, Center for Translational Science Activities (CTSA) Education Resources, and the University of Minnesota Academic Health Center, Office of Clinical Research.

This conference will provide a comprehensive look at the responsibilities and processes of clinical research performance. It will include information on individualized medicine, vulnerable subjects, recruitment of minority populations, budgeting, responsibilities between principal investigators and clinical research coordinators, and study design. A presentation will also be given on the genomics collaboration between the University of Minnesota and Mayo Clinic. The two day conference will balance common interest topics in general sessions with specific clinical research and management issues in breakout sessions. Time will be allotted at the end of each presentation for questions and discussion.

This program is designed for clinical research professionals, including principal investigators, study coordinators, nurses, and other research personnel involved in managing and coordinating clinical research.

For a complete agenda, more information about the faculty, and to register for the conference, please click on the following link:

www.mayocts.com/research (<http://www.mayocts.com/research/>)

Protecting People While Increasing Knowledge: Ethics in Health Research, Evaluation and Quality Improvement

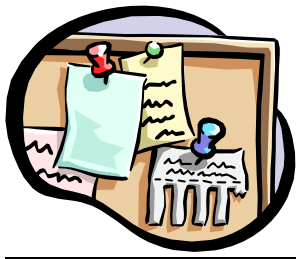
May 4-6, 2008 in Calgary, Alberta

This is a national conference on managing the ethics oversight of a spectrum of knowledge generating activities in Canada's health care and research system; research, quality improvement (QI), quality assurance (QA) and program evaluation (PE).

Please see Poster at end of Newsletter for full details.



Notice Board



Global Central Labs at PPD has switched to flatboxes that require assembly. The **Biochemistry Lab** at St. Boniface General Hospital will not accept these flatboxes and the extra work they require for assembly. The lab has some extra pre-assembled boxes from a previous study, however, when these run out we need another solution.

There are a few alternatives...

- 1) When you have a study involved with this particular central lab, you could possibly negotiate for a pre-assembled box to be supplied.
- 2) The study coordinator could arrange to have these boxes assembled for the lab.
- 3) The study could purchase alternative pre-assembled boxes.

Any questions or concerns can be forwarded to:

Kris Ryan, Research Lab Technician
St. Boniface General Hospital
Dept. of Biochemistry – Rm L3012
409 Tache Avenue
Winnipeg, MB R2H 2A6
Tel: (204) 235-3935
Fax: (204) 231-2656
Email: kryan@sbgh.mb.ca

Attached Memos

Whistleblower Protection Act

The Legislative Assembly of Manitoba recently proclaimed *Bill 34. The Public Interest and Disclosure Act* (also known as the “Whistleblower Protection Act”). Ginette Abraham, Patient Relations Officer has been appointed the Designated Officer for SBGH.

Please see attached memo dated July 6, 2007 for further information.

Critical Incident Reporting and Learning Process

A new WRHA process to improve patient safety and the reporting of critical incidents (CI) is now in effect. This process is intended to “ensure timely, comprehensive and factual reporting and investigation of CIs in order to promote learning and enhance patient safety through the implementation of system improvements” (WRHA policy # 10.50.040). This new process ensures that the responsibilities as outlined in The Regional Health Authorities Amendment and Manitoba Evidence Amendment Act are fully supported.

Please see attached memo dated July 9, 2007 for further information.

Bannatyne Campus Research Ethics Board - Fees

Invoices for BREB and HREB fees for the August meeting will state "Canadian Funds Preferred". The office has been advised from Accounts Receivable at the U of M that payment of REB fees in American funds is acceptable. The hope is that remittances will be received sooner and without complications or "work-arounds". Contact Lorna Pankratz, Secretary, REB Bannatyne Campus at (204)789-3255 if you have any questions

PHIA Requirements for Databases

The following information regarding PHIA compliance and databases used for research has been prepared in response to recent questions. Please share it with your staff, investigators and colleagues. If you have any questions or concerns regarding your database compliance, please contact:

Shirley Guinn
Manager Health Records
St. Boniface General Hospital
E-Mail: squinn@sbgh.mb.ca
Phone: (204) 237-2909
Fax: (204) 231-0323

Requirements for PHIA Compliance of Databases

If a database contains identifiable personal health information, then this database must be PHIA compliant under the Personal Health Information Regulation, amendment 142/2005.

If identifiable personal health information has been replaced in the database with a Code, then PHIA compliancy is not required.

In order for a database that contains identifiable personal health information to be PHIA compliant, the associated system must create and maintain an electronic or manual record of user activity.

PHIA regulation 142 /2005 defines a record of user activity as follows:

Record of User Activity – means a record about access to personal health information maintained on an electronic system, which identifies the following:

- a) Individuals whose personal health information has been accessed.
- b) Persons who accessed personal health information
- c) When personal health information was accessed
- d) The electronic information system or component of the system in which personal health information was accessed.
- e) Whether personal health information that has been accessed is subsequently disclosed under section 22 of PHIA.

The record of user activity must be maintained for at least three years and a least one audit of the record of user activity must be conducted before the record is destroyed.

A record of user activity is not required if the personal health information is only demographic or is information that qualifies or further describes information listed below:

Name
Signature
Address
Telecommunications information

Sex
 Date of birth
 Date of death
 Family Associations
 Eligibility for health care coverage
 Jurisdiction of residence
 Manitoba Health Identification Number (PHIN)
 A unique identifier equivalent to the PHIN assigned by another
 Jurisdiction that pays for health care
 A unique identifier assigned by a trustee, when accessed by that trustee (Eg. MRN)
 A non-Canadian unique health identification number

Requirements for PHIA Compliancy of Databases

In order to prevent unauthorized access to databases that contain personal health information, it is important that you also implement appropriate security measures as follows:

1. Password protect your database.
2. Never permanently store a database that contains identifiable personal health information on a mobile device such as a laptop computer or a blackberry.
3. Databases that contain personal health information can never be emailed to another person using an internet email address unless the information is encrypted.
4. Ensure that you are familiar with the PHIA policy VI-331 PHIA – Security and Storage of Personal Health Information which is located in the St. Boniface General Hospital Administrative Manual on the SBGH Intranet site.

Research Review Committee at St. Boniface Hospital

Deadlines for RRC Submission

August 29, 2007
 September 26, 2007
 October 31, 2007
 November 28, 2007

Meeting Date

September 5, 2007
 October 3, 2007
 November 7, 2007
 December 5, 2007

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

Deadline for REB Submissions

September 10, 2007
 October 15, 2007
 November 9, 2007 (Friday)
 November 26, 2007

Meeting date

September 24, 2007
 October 29, 2007
 November 26, 2007
 December 10, 2007

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