

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

**Thank-you to all who attended
International Clinical Trials Day
Wednesday, May 20, 2009**

**We have had several requests and are already making plans for next year
.....be sure to save the date.....
Thursday May 20, 2010**

Statistics and Medical Research

Creating an Excel Spreadsheet Data Base for Statistical Analysis

Although there are a number of spreadsheet programs suitable for the entering of data, Microsoft Excel is by far the most widely used by medical researchers. It is "user friendly" and Excel data can be readily imported to statistical programs such as SPSS or SAS for statistical analysis. Researchers typically use Excel spreadsheets for two primary purposes:

- Clinical notes which describe the progress of a research study (e.g, dates patients are seen, complications due to treatment, etc.)
- Creation of a data base for subsequent statistical analysis by SPSS or other statistical software programs.

The focus of the current article is the second application - development of a data base suitable for statistical analysis. In my role as a research and statistical consultant, I constantly deal with data spreadsheets created by both beginning and advanced researchers. Virtually all of the spreadsheets that I receive need to be modified before they are suitable for importation into SPSS for statistical analysis. Researchers tend to make the same basic mistakes which can be prevented through education and familiarity with the data formatting requirements of SPSS.

The Excel spreadsheet displays data as a row (1, 2, 3, 4 . . .) by column (A, B, C, D . . .) grid. The intersection of a given row and column is called a cell. It is equivalent to one subject's value on one specific variable. The number of rows and columns can be expanded to accommodate thousands of subjects and variables, meeting the requirements of all but the largest epidemiological studies (which require specialized data bases). Data is typically entered as Rows = subjects or cases and Columns = variables or measures.

Variable Names

In order to analyze data in SPSS, each column in the Excel spreadsheet must have a variable name. This is the first common mistake researchers make when setting up their spreadsheet - they don't name all their variables. A second requirement is that the variable names need to be listed in the first row, and only the first row, of the spreadsheet. If several rows are used to describe variables, these rows have to be merged into Row 1 before SPSS can read the variable names. A few other suggestions:

- The names of variables should begin with a letter rather than a number, although numbers and symbols may be included in the variable name (e.g. Age<40).
- Variable names should not be repeated and should only identify one column in the spreadsheet.
- Where possible, keep variable names relatively short (15 - 20 characters).
- Although abbreviations are fine, especially if they are in common usage (e.g. EKG), abbreviations which are highly technical or idiosyncratic to the particular researcher should be avoided if possible. They make communication of the data analysis output more difficult when others do not understand what the variable name means. And the researchers themselves may forget what the variable name indicates when revisiting their data at a later date.

Data Entry

Statistical analysis is based on *numbers* assigned to subjects and variables. The most common mistake when entering data into the Excel spreadsheet is to use syntax rather than numerical coding. For example, if gender is specified as male/female, these words will have to be converted to numbers before SPSS can perform statistical calculations. Although SPSS can recode syntax to numerical values, it is easier to code the variables as male = 1 and female = 2, or vice versa, when entering them as data in the spreadsheet. Some other suggestions and considerations:

- For missing data, leave a cell empty rather than entering a dot or dash or n/a or a number such as "99".
- The number of decimal places should be limited to two or three unless great precision of measurement is required.
- Binary data (e.g. yes/no) can be entered as either 0, 1 or 1, 2. I prefer the latter convention.
- Researchers often enter dates such 9/24/78 to indicate D.O.B or the date of the beginning of treatment. This type of data cannot be directly analyzed by SPSS and must be converted into a numerical value. Instead of D.O.B calculate age and enter that in the spreadsheet. Rather than entering two dates to indicate the beginning and end of treatment, calculate and enter the duration of treatment in days, weeks or months.

Variables with Multiple Outcome Categories

One of the challenges in analyzing research data involves variables with multiple outcome categories. An example is complications to a treatment regime where there may be as many as 10 - 20 possible categories. If possible, categories should be combined to reduce their number to a more analyzable level.

The situation is made more complex by the fact that variables such as medical complications and co morbid diagnoses may have multiple values for a given subject (6 or 7 complications, 3 or 4 diagnoses). Difficulties arise when the researcher enters all of the outcomes for a given subject in one cell. Even if each outcome category is assigned a numerical value (say 1 - 10), an array of numbers in a cell (2, 3, 5, 8) cannot be analyzed by SPSS in a coherent manner.

To properly analyze measures with multiple outcomes, it is necessary to create separate variables for each outcome and code them as no = 1 and yes = 2. If there are 10 possible outcomes for a variable, then there will be 10 new variables, each with a binary outcome (yes/no), yielding one value (1 or 2) in a given cell of the spreadsheet.

Hopefully, awareness of the need to structure the Excel spreadsheet data in a way that is compatible with the requirements of statistical programs such as SPSS will make the life of both the statistician and researcher much easier.

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, by email: dstaley@mts.net or directly at 237-2690.

Research Ethics Board Submission Forms - Updated

As of June 1, 2009, the Bannatyne Campus REB form has been updated at the request of The University of Manitoba Access & Privacy Office to ensure research sites and The University of Manitoba are in compliance with PHIA regulations. PHIA requires that all University of Manitoba employees, students, or agents who handle or are exposed to personal health information take PHIA Orientation and sign a pledge of confidentiality that acknowledges that they are bound by written policy and procedures.

There should be little if any impact for those individuals who are employees of the WRHA and have signed a Pledge of Confidentiality as a condition of employment. The University of Manitoba will accept the pledges and does not require that an additional pledge be signed specifically for The University of Manitoba. From an auditing perspective, it is suggested that sites retain a copy of these pledges or clearly document in standard operating procedures where the pledges are retained (e.g. employee records).

Revised question as provided from The University of Manitoba Access and Privacy Office:

The Personal Health Information Act (PHIA)

PHIA requires that all University of Manitoba employees, students, or agents who handle or are exposed to personal health information take PHIA Orientation and sign a pledge of confidentiality that acknowledges that they are bound by written policy and procedures.

Has PHIA Orientation and pledge-signing been completed by all employees, students, and agents?

Yes

No

If "No," the Principal Investigator should contact University of Manitoba Access & Privacy Coordinator's Office to make arrangements, fippa@umanitoba.ca.

Where all individuals have not completed PHIA Orientation and signed a pledge, and for the purpose of ensuring that they do, Principal Investigators' contact information will be provided to the University Access & Privacy Coordinator's Office.

A few minor editorial comments were also added to the Bannatyne Campus form and have been highlighted in yellow.

Researchers and study coordinators are reminded to check the REB websites with each new application to ensure the latest version of forms are being used.

If you any questions regarding the new update please contact;

Shelly Rempel-Rossum, Research Ethics Board Coordinator,
University of Manitoba Research Ethics Boards - Bannatyne Campus
Phone: (204) 789-3389, Fax: (204) 789-3414 or e-mail: remross@ms.umanitoba.ca

OR

Margaret (Maggie) Bowman
Coordinator - Human Ethics
University of Manitoba Research Ethics Boards – Fort Garry Campus
Phone: (204) 474-7122, Fax: (204) 269-7173 or e-mail margaret_bowman@umanitoba.ca

Interagency Advisory Panel on Research Ethics (PRE) – Call for Nominations

The Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC) are pleased to announce a public call for nominations for membership on the Interagency Advisory Panel on Research Ethics.

For this round of nominations, the Agencies particularly encourage nominations from individuals with ethics experience, expertise and knowledge of research involving human participants in the following areas:

- Biomedical, clinical research and /or other areas of health research;
- Humanities and/or social sciences research;
- Natural sciences and/or engineering research;
- Research ethics administration, i.e. coordination of research ethics boards (REBs);
- Law and/or ethics;
- Research participant and/or community perspectives;
- Research involving Aboriginal peoples.

Deadline: 18 September 2009

For further details, please consult the following website:

<http://www.pre.ethics.gc.ca/policy-politique/participation/nominations-candidatures-2009-06-09.aspx>

The Granting Agencies thank you in advance for your support in ensuring that this call for nominations benefits from as broad an outreach as possible.

Research Review Committee at St. Boniface General Hospital

Deadlines for RRC Submission

Meeting Date

Please note there is no RRC meeting in July

July 29	August 5
August 26	September 2
September 30	October 7
October 28	November 4
November 25	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

Meeting date

Please note there is no REB meeting in July

August 10	August 24
September 14	September 28
October 9 (Friday)	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

Clinical Research Lecture Series at St. Boniface General Hospital

Lecture Title	Date and Time	Location
Introduction to Clinical Research And Research Ethics	Thursday, November 5, 2009 1:30 PM to 3:30 PM	St. Boniface General Hospital – N1012
Good Clinical Practice (GCP) and Clinical Research Regulations	Thursday, November 19, 2009 1:30 PM to 3:30 PM	St. Boniface General Hospital – N1012
Clinical Research Project and Document Management	Thursday, December 3, 2009 1:30 PM to 3:30 PM	St. Boniface General Hospital – N1012

There is no charge to attend the lecture series. For more information or to register contact Terry Sawicz-Hanesiak at (204) 237-2226 or tsawicz@sbgh.mb.ca.

Other Winnipeg Training Events

For additional training information please refer to the on-line LSAM schedule at www.lsam.ca