# RESEARCH ETHICS BOARD
Non-Local Serious Adverse Event
Spreadsheet Guide (Excel 2007)

1) Open the file "Non-Local SAE Submission Spreadsheet."
   a) A Security Warning will pop up just above the spreadsheet with the message "Macros have been disabled." (as shown below)


   b) Click "Options" to bring up a Security Alert window. This window will inform you that you should not enable macros unless you trust the source of the file.
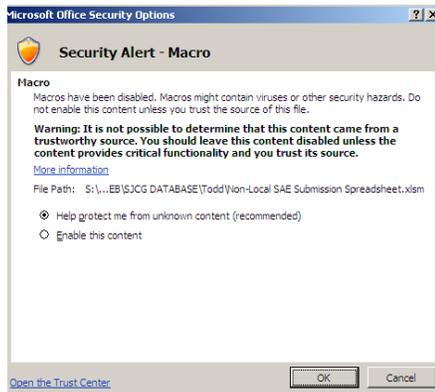

   c) In this case we do want to enable macros since the file source is trusted. Click "Enable this content." Finally, click "OK."
   d) The window will disappear and the spreadsheet will be displayed again.

2)
   a) With the spreadsheet open, you will notice that you need to fill in several values near the top of the screen: "Submission Date," "REB#," "Study Title," and "Principal Investigator." Click the square immediately to the right of Submission Date to select it. An arrow will appear as shown below:
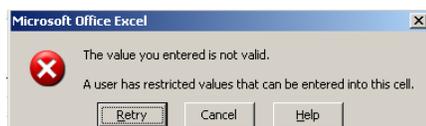

   b) Click the arrow to display a drop down list of all possible months. Select the appropriate month from the list.
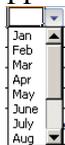
   c) Repeat this process to select a day and a year from the drop down lists.
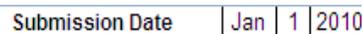
   d) Double-click the box beside "REB#." It will now allow you to type the seven-digit REB number. If you enter a number that is too short or too long an error message will appear as follows:

e) Finally, double-click the box beside "Study Title" to enter the study title, and double-click the box beside "Principal Investigator" to type in the Principal Investigator's title, first and last names. Once you are finished, the spreadsheet should look similar to the example below.

Submission Date	Jan	1	2010	
REB #	2010001			
Study Title			Example study	
Principal Investigator			Dr. John Doe	

3) You are now ready to enter SAEs into the spreadsheet.
   a) Double-click the box immediately below the Patient ID Number header (this should be row 16 column F). Type in the patient ID number. When you are finished, the spreadsheet should look similar to this picture:

   b) Next, fill in the date of the SAE in the following three boxes by using the drop-down lists provided. These drop-down lists work exactly the same as those used for the submission date at the top of the screen.

   c) Next double-click the box below "Adverse Event" and type in a description of the adverse event.

   d) After you have typed in the description, double-click the next box and click the arrow to display a drop down list of the event status. You can either enter "I" for "Initial" or the follow-up number.

   e) Next click the following box and select either "U" or "E" from the drop down list for unexpected or expected, respectively. By now your spreadsheet should look similar to the following picture:

f) Now double-click the next two boxes separately to specify the SAE relationship for reporting investigator and sponsor. Use the drop-down lists to select a word. If the word you are looking for isn't listed, simply double-click the box and type it in manually. When you are done the spreadsheet should look similar to this picture:

g) Next, double-click the box below SAE Type and specify the SAE type as 1, 2, or 3 from the drop-down list. The meaning of these values is listed at the top of the spreadsheet with a corresponding asterisk. If you choose SAE Type 1 or 2, you are finished entering the first SAE record (disregard **point h** below). If you choose SAE Type 3, you must specify the Type 3 SAE Changes in the last three columns as explained next.

h) If the SAE is of type 3, double-click the box below Protocol to specify if changes should be made to the protocol. The only options in the drop-down list are "Yes" or "No." Repeat this process to specify "Yes" or "No" for changes to the consent and investigator brochure. When you are finished, the spreadsheet should look similar to the picture below:

4) You have now entered a record into the spreadsheet in row 16. Each row in the spreadsheet should correspond to ONE patient. **The exception would be if a single patient had multiple events on the same day with different relationships and SAE type**. In this case, use a new row to enter additional event and related information but **do not** repeat the patient ID number or date of SAE (leave blank). If you would like to enter a new patient, double-click the first box in the next available row and repeat the instructions listed above from **Step 3.** If you enter a lot of records into the spreadsheet, you will notice that the column headers (rows 13, 14, and 15) will stay frozen in place even if you scroll up and down. This will help you remember what values to place in each column.

5) When you are ready, print out the spreadsheet. If the error message shown below appears, this means you haven't finished entering values in the box at the top of the screen. Follow the instructions in **Step 2** to fill in these values.
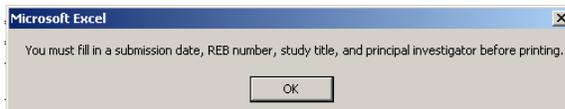
6) Once you are able to print successfully, you will notice that a few extra rows will pop up near the top of the screen as shown below. These rows will appear on the first page of your print-out for the principal investigator and research ethics board chair to sign. When you are ready, print out the document.

Person Completing Form: _____	For Research Ethics Board use only:
I acknowledge that I have read the information provided on the Serious Adverse Event(s) identified below and have assessed the safety significance of patients.	On behalf of the Thunder Bay Regional Health Sciences Centre Research Ethics Board, I acknowledge receipt of the below noted SAEs.
Principal Investigator Signature _____ Date: _____	Chair Signature: _____ Date: _____

7) Now you must save the electronic version of the spreadsheet. Click the Office Button at the top left corner of the screen to display the menu, and hover your mouse over "Save As." As you can see below, a list of different file formats will appear. Simply click the "Save As" button or click "Excel Macro-Enabled Workbook."

8) The screen shown below will appear. Change the file name to the format "REB#" "PI Last Name" "NLSAE" "Date." For example, "2010001 Doe NLSAE 2010Mar01". When you are finished, make sure you are saving the file somewhere you will remember and click "Save."
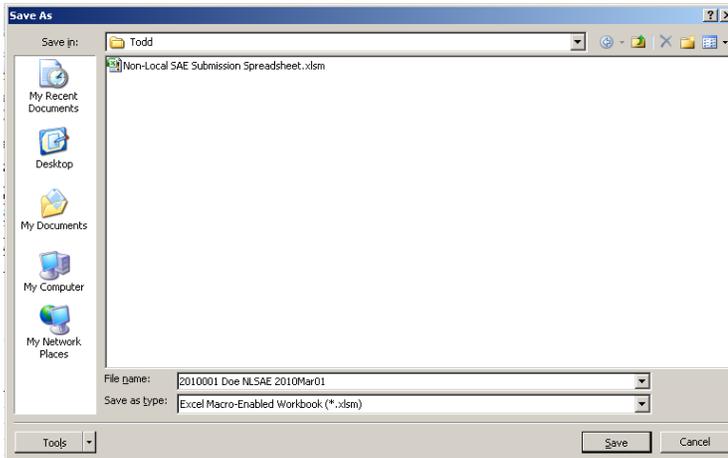
9) Email the Excel Macro-Enabled Workbook file that you just created to SJCG_REO@tbh.net. Mail one hard copy with Principal Investigator's signature to the Research Ethics Office

<u>Notes</u>

1) It is recommended that you save your work often to prevent any data loss.
2) If any difficult results during data entry, save what you have completed and contact the Research Ethics Office for assistance.   Often we can resolve issues without loss of work.
   Email: SJCG_REO@tbh.net   **Work Phone: (**807) 346-3697