

# Annual Report of the Nipissing University Research Ethics Board

4 October 2011

Dr. Sharon Rich  
Vice-President, Academic and Research (Interim)  
Nipissing University

Dear Dr. Rich,

As NUREB Chair, I am pleased to submit this 2010-2011 report through you to the Board of Governors. I thank you also for your unwavering support of NUREB over the past year.

This report includes the number of applications reviewed, a generic description of ethics issues/concerns that have been addressed in the past year and, where necessary, recommendations concerning changes to this policy or to the procedures for conducting an ethics review.

## Number of Proposals Reviewed and Approved

The number of applications reviewed, with comparison to the previous three years, is as follows:

PROTOCOLS REVIEWED	2007-08	2008-09	2009-10	2010-11
Faculty – research	42	53	57	68
Faculty – course assignments	4	6	4	3
Graduate students	24	36	26	18
Undergraduate students	30	23	19	30
Administration	1	1	0	4
Institutional approval	0	0	5	3
Renewals and/or modifications	0	13	27	24
TOTAL	101	132	138	150

The number of faculty research protocols, and renewals/modifications to existing protocols continue to increase.

The statistics for 2010-11 include a number of summer submissions: Faculty research (5), Faculty course assignment (1), Graduate students (2), and Institutional approval (1).

The number of applications approved, conditionally approved, approved with modifications, still outstanding and rejected during the past four years follows:

	2007-8	2008-9	2009-10	2010-11
Approved without modification	56	33	43	36
Approved conditionally	0	17	56	87
Modifications requested – subsequently approved	44	65	28	14
Modifications requested – still outstanding	0	0	10*	13*
Modifications requested – abandoned		8		
Modifications requested – irregularities		3		
Rejected	1	1	1	0
TOTAL	101	132	138	150

\*This number was left unchanged to allow comparison with this point in the year. Six of the 10 still outstanding a year ago were revised, resubmitted and approved; the other 4 were abandoned.

Applications which are complete and submitted well in advance of the deadline, by researchers who are thoroughly familiar with the TCPS - Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - usually result in fewer modifications and delays (and makes more efficient use of volunteer NUREB reviewers' time).

For this reason, NUREB will require by 1 April 2012 that all researchers must submit with their protocol proof of completing the TCPS 2 online tutorial.

## Concerns

### 1. Institutional Conflict of Interest

In providing administrative support to NUREB, we understand that the REB Coordinator now has an arm's length relationship with your office (NUREB clerical duties are now supervised by the Assistant Vice-President, Research and Graduate Studies).

This avoids the appearance of an institutional conflict of interest and makes the likelihood of administrative interference less likely. (No interference has occurred.)

## 2. Monitoring

A year ago, I was able to report that I worked with the REB Coordinator in 2009-10 to ensure that NUREB receive Final Reports of completed research projects. Previously, NUREB had never attempted even this minimal monitoring of approved protocols.

Unfortunately, with the turnover of REB Coordinator personnel in 2010-11, this was not possible in 2010-11.

I hope we can restore this monitoring function in the year ahead. REB oversight continues throughout the life of a research project.

## 3. Support – Staffing & Technology

The REB Coordinator has become a demanding job over the past two years, NUREB duties competing with numerous higher-priority responsibilities. The position nominally requires a half-time commitment, but much of this is repetitive, tedious manual work that entails considerable overtime.

We need to modernize in order to more consistently monitor NUREB-approved research and make better use of our dedicated staff.

Since 2007 the REB Coordinator has used a simple Microsoft Excel spreadsheet to manually keep track of REB protocols.

Two years ago, I reported to VPAR Aspevig that Nipissing University did not appear to have the resources to develop the kind of database we needed. The REB Coordinator and I had been advised by in-house specialists that this would take at least two years, unless it became identified as a higher

priority in the University. InfoEd software, for example, cost US\$182K plus annual fees of US\$54K, while an in-house build required a year or more of dedicated human resources.

A year ago I reported to your predecessor that the REB Coordinator and I again participated in meetings to discuss a database that would meet REB/ACC needs, allowing the Coordinator to generate reports, send out notices and facilitate ongoing monitoring.

Microsoft SharePoint was mentioned a year ago as a possible mechanism for sharing REB data among authorized personnel.

This now seems to be a viable solution.

### REB Coordinator Duties

The REB Coordinator performs the following routine tasks:

Protocols (signed hard copy plus digital copy) are due the first Friday of the month. The Coordinator reads each one. If protocols have any missing or incomplete information, the Coordinator notifies the researcher (and the faculty supervisor in the case of students) via email, noting what is still required and informing her/them that the protocol will consequently be reviewed the following month.

Once a protocol is complete, the protocol and all attachments are assigned a protocol number referencing the year, month, consecutive number and the surname of the principal investigator (e.g., 2010-09-01 Smith). Faculty, undergraduate and graduate student protocols are distinguished by addressing the file label as FAC, STU, ADMIN, MEd, MA, etc.

The e-copy is assigned the same protocol number and saved in a designated e-file.

If the research involves no more than minimal risk, the protocols are forwarded by e-mail to two NUREB members for review, two weeks prior to meetings (if the REB Coordinator's other duties permit) in order to give the reviewers sufficient time to review the files.

A protocol involving more than minimum risk is sent to all NUREB members.

Each protocol is entered on the Excel spreadsheet, our manual tracking systems. Spreadsheet information includes: protocol number, date received, name of PI, category (Faculty, Student, MEd., Admin), reviewers' names and reviewers' responses (cut and pasted from their emailed reviewer forms).

The spreadsheet continues to be manually updated as it progresses through the review and approval process.

A draft agenda for the upcoming REB meeting is prepared. This includes: a listing of any Renewals, or Requests for Modifications approved since last meeting; a chart listing each of the protocols to be discussed at the upcoming REB meeting; and any other agenda items as discussed.

NUREB reviewers forward their responses via e-mail attachments prior to the REB meeting. The REB meets within two weeks of the submission deadline to discuss the protocols so a quick turnaround is required. The reviews for each protocol are printed and added to the respective file.

If protocols are approved by the reviewers, they do not require further discussion; there will be a motion at the meeting formally approving these pre-approved protocols.

If concerns are found by the reviewers, the protocols are discussed at the REB meeting. The agenda will be revised at this point showing approved protocols and/or protocols that require discussion.

After each REB meeting, the status of each protocol discussed and REB members' concerns are added to the spreadsheet.

Once a protocol is approved unconditionally, the spreadsheet is updated to show that a letter of certification has been completed and noting the protocol's expiry date.

In the case of approved protocols, approval is communicated to the researcher (as well as the faculty supervisor in the case of students) via e-mail. A letter of certification is prepared, a hard copy signed by the Chair,

mailed to the researcher (and a copy is provided to faculty supervisors in case of students). Another copy of the letter is added to the respective file.

Conditional approvals and requests for changes or additional information are communicated to the researcher (and the faculty supervisor in the case of students) via e-mail using a REB checklist that is cut and pasted into the body of the e-mail, noting any concerns with reference to specific sections in the protocol. These communications are printed and added to the respective file.

A complete revised signed protocol is resubmitted by the researcher to the REB Coordinator in both hard copy and e-copy. The protocol number is amended to show how many revisions were required prior to approval: e.g., 2010-09(1).

The REB Coordinator forwards the revised protocol to the original reviewers, usually for approval but sometimes there are additional requests as the reviewers are not yet satisfied, and another revision is required. In rare situations a researcher abandons a protocol. To protect reviewers' identities, the REB Coordinator acts as go-between. A paper trail is always printed and filed: protocols, attachments, reviews and correspondence.

Once all reviewers' concerns are satisfied, a letter of certification is prepared, signed by the Chair, mailed to the researcher (with a copy provided to faculty supervisors in the case of students) and filed.

Minutes are kept, formally prepared, forwarded to REB members for review and comment. Routine inquiries are answered. Researchers drop off their protocols

The REB e-mail address is checked periodically each day. Requests for information are received and answered.

The REB website is updated as required.

## A Secure SharePoint Site for NUREB

Over the next few months, the REB Coordinator will establish a secure password-protected Nipissing University site for NUREB.

This will reduce the number of repetitive, manual, time-consuming, cutting-and-pasting, copying, printing and filing tasks.

It will also facilitate reporting and monitoring.

Initially, the REB Coordinator will simply post agendas, notices, minutes, reviewer templates and other information for upcoming meetings.

NUREB members will simply be able to read and download.

As soon as possible, we will then streamline our procedures as follows:

a) researchers send their protocols and forms directly to the site (signed hard copy not required)

researchers can submit but not view

external researchers would first be assigned a user identity

b) REB Coordinator retrieves protocols and reviews them for completeness

c) Once it has been established by the REB Coordinator that the protocol is complete, SharePoint assigns it a number

REB Coordinator and Chair can view all materials on the site

d) REB Coordinator alerts the reviewers (two if minimal risk or all NUREB members if greater than minimal risk) which protocols are available for their review. Reviewers review the materials in SharePoint and provide their comments.

Protocols can only be viewed by REB Coordinator, Chair and assigned reviewers

- e) NUREB reviewers post their reviews to the secure site, generating a protocol-specific workflow that can be viewed by the REB Coordinator and Chair  
  
reviewers' identities are protected
- f) REB Coordinator communicates with researchers and reviewers through the secure site, using a separate stream, adding to the workflow for that specific numbered protocol  
  
e.g. when changes are required, when approval or conditional approval have been granted, and when reports or other information is required (e.g. where there is a complaint or an appeal)
- g) Revisions to the protocol, proof of institutional authorization and all additional information from the researcher become part of the protocol-specific workflow
- h) We hope that SharePoint will be able to prompt the researcher 60 days prior to expiry, alerting the researcher of the responsibility to submit a report and/or seek an extension

#### 4. Terms of Reference

As you requested, the Terms of Reference have been updated.

I regret that these are not available at this time, but will be submitted following the next NUREB meeting.

They will then be submitted to the Board of Governors, through you, for approval as an appendix to this report.

Should you have questions on any of these matters, I would be pleased to provide you with additional information.

With best wishes,

John S. Long, EdD  
Professor, Schulich School of Education  
and  
Chair, Nipissing University Research Ethics Board