

Research Ethics Education Needs Assessment Survey of the Toronto Academic Health Sciences Network

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Background

- Research and Education in Research Ethics Working Group (RE)²
- Within the University of Toronto Joint Centre for Bioethics (JCB)
- Members from U of T and Toronto Academic Health Sciences Network (TAHSN) institutions (affiliated teaching and community hospitals)
- **MISSION:** To advance empirical research and educational activities in research ethics.



Background (2)

- As its first initiative, (RE)² launched a web portal to serve initially as a repository of TAHSN research ethics educational information.
<http://reportal.jointcentreforbioethics.ca/>
- To prioritize educational needs of researchers and research ethics personnel within TASHN, (RE)² developed a survey instrument to capture information that could be used to enhance the educational portal and other research ethics resources.



Methods

- The needs assessment survey instrument was partially adapted from surveys developed by other research ethics working groups, including the Association of Research Ethics Committees of the United Kingdom.
- The survey was designed to capture:
 - Information regarding participants' involvement with research ethics;
 - Past educational levels in research ethics;
 - Current opportunities for education;
 - The educational needs of participants.



Methods (2)

- It was determined that the activity was Quality Assessment/Quality Improvement.
- A link to the survey on SurveyMonkey was sent through a listserv of the Office of the Vice-Dean, Research and International Relations, Faculty of Medicine at the University of Toronto, reaching several stakeholder groups within TASHN, including:
 - Researchers involved in human subjects research;
 - REB members and chairs;
 - REB administrators.
- Data were anonymous and unidentifiable.
- Survey was open for participation between July and November of 2009.



TAHSN Institutions

- | TAHSN Members/Full Affiliation | Associate Members |
|---|--|
| <ul style="list-style-type: none">• Baycrest Centre for Geriatric Care• Bloorview Kids Rehab• Centre for Addiction and Mental Health• Mount Sinai Hospital• St. Michael's Hospital• Sunnybrook Health Sciences Centre• The Hospital for Sick Children• Toronto Rehabilitation Institute• University Health Network• Women's College Hospital• The University of Toronto | <ul style="list-style-type: none">• North York General Hospital• St. Joseph's Health Centre• Toronto East General Hospital |



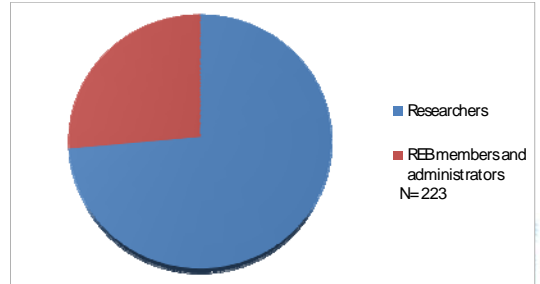
Results - Demographics

- 225 individuals participated in the study.
- 2 participants did not identify themselves as any category of stakeholder and were therefore excluded from the data presented here.
- 2 main stakeholder categories:
 - Researchers: researchers, research staff, students
 - REB members and administrators: included researchers who self-identified as REB members also



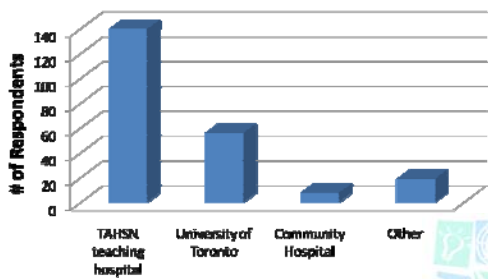
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Participant Groups



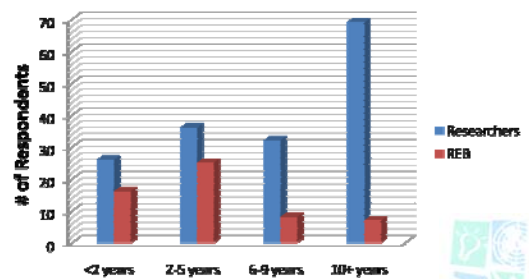
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Primary Affiliation



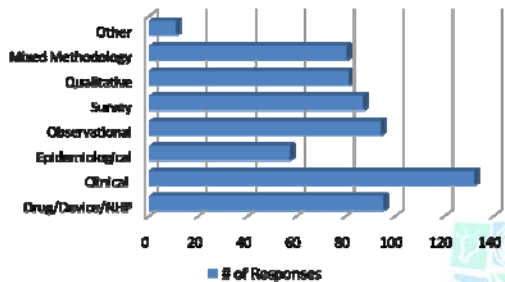
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Years of Experience



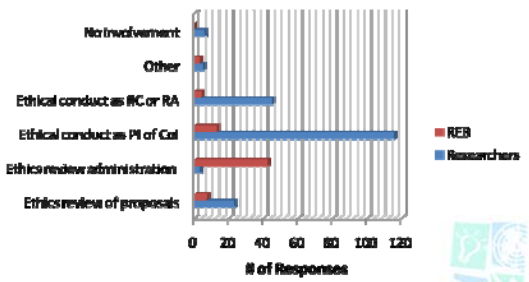
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Types of Research



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Involvement in Research Ethics



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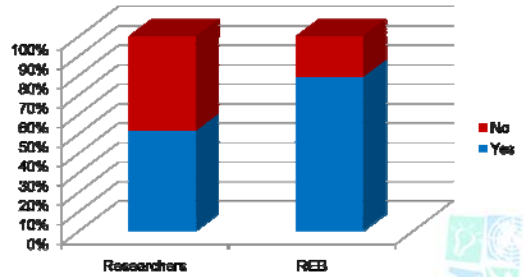
Results – RE Education

- Current amounts of RE education
- Perspectives on sufficient amounts
- Barriers to access
- Topics and methods of RE education



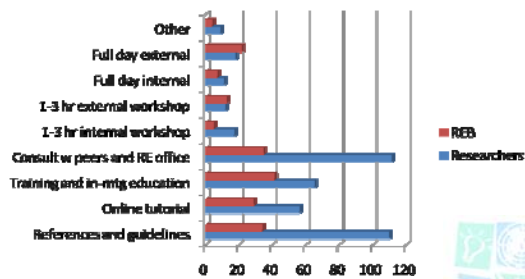
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Completion of TCPS Tutorial



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Types of RE Activities Attended



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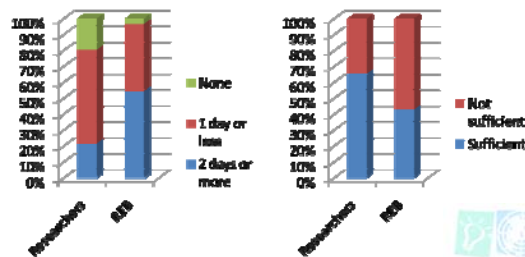
Types of RE Activities Attended (2)

- Types described:
 - Brown bag lunch series
 - Issues in Clinical Research
 - GCP course
 - Research on RE
 - REO workshops/lectures
 - NIH online tutorial
 - CAREB, NCEHR, SoCRA, OHRP conferences/workshops
 - REB retreats and dinners
 - Programs at universities and colleges – McMaster, Humber College
 - Websites – PRE, NCEHR, U of T



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Amount of Time on RE Education



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Amount of Time on RE Education (2)

Researcher quotes:

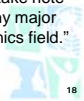
"Basically, the research education is adequate but one always benefits from additional updates."

"I can always learn more."

"My only involvement in ethics seems to be in completing REBs in order to undertake research. I'm sure the field has changed and there is more information available which would be useful for me to know."

"Significantly under prepared and at the mercy of my keepers."

"My many years of experience allow me to incrementally take note of new developments and policies. Also, I have not had any major shifts in my research which would force entering a new ethics field."



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Amount of Time on RE Education (3)

REB members/administrators:

"Would like to get further training to be able to add as much to being an REB member as possible."

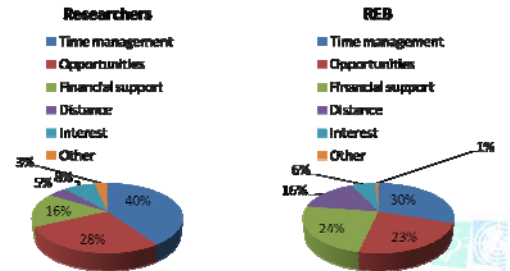
"Things are always changing and it is important to know of the latest findings and any new areas that are of concern."

"I am a lay member of an REB and believe I am most useful to it by bringing my understanding of ethics based primarily on my knowledge and experience of ethical matters outside of the REB to the meetings. However, I do consider having completed the tutorial an essential part of my ethics education for this role."

"It's certainly always apparent, when taking part in anything educational, that so much more could be available and coordinated. So many people are essentially "reinventing the wheel" at their own institutions and not yet sharing resources, educational and otherwise."

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Barriers to RE Education



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Barriers to RE Education (2)

Researchers:

"A well-thought out REB application procedure should be intuitive, logical and self-explanatory. Please tidy up your act and streamline your procedures rather than waste more research time with 'educating' us."

"As research ethics is not my primary research area, funding for workshops and/or meetings on research ethics would not be supported by my research grants. Time is always an issue."

"Educational opportunities that I am aware of are generally not relevant to my needs."

"Most research ethics education is not relevant to real world research."

"I do not think that they are needed, and if introduced will cost research in Toronto massive amounts of funding. This funding would be better spent to help junior researchers learn how to prepare proper grant applications. In my experience, this is what junior researchers in Toronto need the most."

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Barriers to RE Education (3)

"At this point, I really could not care less. I believe that I am quite capable of devising an ethically sound research design without REB training. The other way around, I don't believe that we have any evidence that the REB roadblocks that have been put up in recent years have in any way improved research quality or productivity at the U of T."

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Barriers to RE Education (4)

REB:

"Research ethics, as an institutional activity, is still not valued enough to allow the release from other activities. So most REB members and Chairs are balancing other roles (professor, clinician, administrator) and not able to have "free" time for self-reflection, professional development, etc."

"Institution seeing the value for us to attend."

"Retired, with limited personal income, and do not live in Toronto so transportation and accommodation are limiting factors."

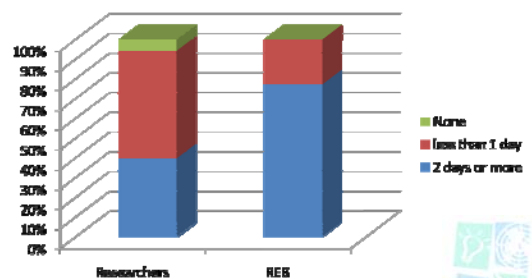
"To attend courses/tutorials that are pre-scheduled is very difficult, ie. getting time away from work, family etc."

"Either self-paced courses or on-line formats would be very useful."

"I am always looking for these opportunities and would attend more if I was aware of them."

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Sufficient Amount of RE Education



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Topics for RE Education

- RE principles
- Governance
- Ethical decision making
- Responsible conduct
- Authorship
- Principles of ethics review
- REB procedures and practices
- Identification of risks and benefits
- Informed consent
- Privacy and confidentiality
- Data management
- Conflict of interest
- Pharmaceutical research
- Quantitative design
- Statistics
- Qualitative design
- Student research
- Continuing ethics review
- Multi-centre research
- Capacity
- QA/QI vs. research
- Special populations
- Community-based research
- Internet research
- Handling deviations and SAEs
- Databases and biobanks
- Return of results
- Genetics and genomics
- Emergent technologies
- Other

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Top 10 topics

For Researchers:

1. Data management
2. Ethical decision making
3. Informed consent
4. RE principles and theories
5. Responsible conduct
6. Multi-centre research
7. REB procedures and practices
8. Privacy and confidentiality
9. Authorship
10. QA/QI vs. research

For REB:

1. Ethical decision making (2)
2. RE principles and theories (4)
3. Privacy and confidentiality (8)
4. REB procedures and practices (7)
5. QA/QI vs. research (10)
6. Informed consent (3)
7. Principles of ethics review
8. Identification of risks and benefits
9. Data management (1)
10. Conflict of interest

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RE Education Formats

- Reference materials or links
- 1-3 hr online tutorial
- 1-3 hr workshop
- ½ day workshop
- Full day internal workshop
- Full day external workshop
- 2-3 day conference
- Podcasts/vodcasts
- Web lecture
- Blog
- Message boards
- Web interactive modules
- Consultations with peers or RE Office
- Other

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Top 5 Education Formats

Researchers

1. Reference materials or links
2. 1-3 hour online tutorial
3. Consultation with peers or RE Office
4. 1-3 hour workshop
5. Web lecture

REB

1. 1-3 hour online tutorial (2)
2. ½ day workshop
3. Consultation with peers or RE Office (3)
4. Web interactive modules
5. 1-3 hour workshop (4)

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Comments about Survey and Portal

Researchers:

"... and some more time wasted on an REB activity. Honestly, please think about cutting back rather than expanding the REB offerings. We need simple, quick-moving procedures to allow for creative research to happen. Training should not even be necessary! Alternatively, bring back the more open-ended protocols that used to give blanket approval to lines of research, so that researchers did not have to apply again and again for each specific project."

"An ongoing issue is that the review procedures seem unnecessarily cumbersome for minimal risk studies - discourages us from incorporating research into coursework, etc. Also, requirement for yearly reviews seems excessive for limited risk student projects."

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Comments about Survey and Portal (2)

"Everyone wants to "build" something but please recognize that established researchers are busy and mostly doing a good job in this area - adding further essentially useless demands is counterproductive. If it is "due diligence" that needs to be shown for those already researching keep it web-based and reasonable."

"I think it would be beneficial (but maybe not feasible) to make it mandatory for any staff involved in research to participate in a web-based interactive module on the responsible conduct of research."

"The most difficult piece related to TASHN still remains that the institutions still have different policies and requirements and it is a challenge to stay on top on the nuanced differences in multi-centre research."

"I think it's a great idea. Looking forward."

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Comments about Survey and Portal (3)

REB:

"Look forward to the Portal being up and running."

"I find as the only truly lay (i.e. no professional affiliation with hospitals or medical research or medical professionals) REB member, that my interpretation of what the scope of "ethical" and therefore worthy of comment is, is wider than that of other members in some cases. For example, I feel that I want a higher standard in fulfilling the requirement to respect the individual (potential participant) in regards to how the Information and Consent Forms are written. I understand that medical researchers are not writers and are under acute time pressures, but possibly they would get higher participation rates and greater commitment to their studies if the forms were written better, with the readers more in mind. This view seems to be deemed by other REB members as over-attention to unimportant details..."

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Discussion

- Good representation of researchers – almost equal for 10+ years experience and less than 10 years
- Representation of REB stakeholders not as heterogeneous, with the majority being administrators with 5 or less years of experience
- Diverse experience with research disciplines – majority had clinical research experience – either RCT or other types of clinical – but also significant amounts of qualitative, survey, observational and mixed methodology research
- Majority of researchers had RE experience in terms of ethical conduct as either a PI, Co-I, RA or RC
- Majority of REB respondents had ethics review as administrators
- Few respondents had experience conducting ethics review as REB members

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Discussion (2)

- Most participants in either group did complete the TCPS tutorial (60% for researchers, 80% for REB)
- Researchers and REBs rely mostly on references and guidelines and consultation with peers and the research ethics office as their current means of education
- However, the amount of time spent on RE education per year differs, with most researchers participating in less than 1 day per year (85%) and half of REB individuals participating in more than 2 days per year (50%)
- Barriers to education are similar in both groups: 30-40% respond time, 23-28% opportunities. 24% of REB respondents also feel that financial support from their institutions is a barrier
- RE topics of interest differ in the two groups: researchers mostly need research conduct focus; REBs need further specialized training for ethics review
- REB members do not feel that their work is perceived as valued by their institutions

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Discussion (3)

- 60% of researchers feel that they are involved in enough education, while 60% of REB respondents feel that their education is not sufficient
- Differing viewpoints on specific amount of education – 65% of researchers feel that <1 day per year sufficient; 75% of REB respondents feel that more than 2 days/year is needed. May be reflective of differing roles and daily experiences with research and RE
- Education formats not terribly different for the two groups. Researchers mostly want self-directed and easy access information. REBs want self-directed but also need interactive education, whether in person or online
- A very vocal minority of researchers are antagonistic to the REB and research ethics, including education
- Showing the relevance of RE and RE education to researchers is essential for buy-in

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Conclusions

Researchers and REB personnel have some similarities but some differences in terms of their educational needs: amount, format and topics

1. Amount

- a) Researchers want a minimum of RE education, preferably optional
- b) REBs want more RE education, with the support of institutions to allow them to attend as much as they feel they need
- c) REBs want greater information on what is being offered locally and nationally

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Conclusions (2)

2. Format

- a) Both groups want accessible information
- b) Researchers prefer education that is easy-access and self-directed, e.g. reference materials and links and online tutorials
- c) REBs want self-directed but also prefer face-to-face, discussion-based education, e.g. ½ day sessions, workshops

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Conclusions (3)

3. Topics

- a) Fundamentals are important to both groups.
- b) Researchers want information on how to conduct their research ethically and manage their data;
- c) REB members and administrators want education to help them in ethics review.



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Conclusions (4)

4. (RE)² will work with these results to develop aspects of the portal that will meet the needs of researchers and REB members and administrators.
5. Education sessions beyond technology will also be created to educate these stakeholders appropriately.



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Thanks to...

- Dr. Ross Upshur, Director, Joint Centre for Bioethics and the members of (RE)² who worked on this project from beginning to end
- Dr. Lorraine Ferris, Chair of the TAHSN Research Ethics Committee (TREC) for support (financial and logistical)
- Dr. Peter Lewis, Vice-Dean, Research and International Relations, Faculty of Medicine, University of Toronto



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