

SURVEY B

INSTITUTIONAL REB REVIEW PROCESS

TO BE FILLED OUT BY EACH INSTITUTIONAL REB

REB GOVERNANCE

1. Is there an institutional policy for REB membership, terms of reference, terms of office etc.?

- No
 Yes

If yes, please attach a copy or provide the web link.

2. How many members on the REB? _____

3. What is the current gender balance?

_____ Males _____ Females

4. What is the expertise balance of the REB? (Numbers may add up to more than the number of REB members if there is multiplicity in expertise).

Number of members with expertise in Research _____

Number of members with a legal background _____

Number of members with an ethics background _____

Number of community members _____

Others _____

5. How is the REB Chair chosen? (If applicable, cite specific sections of the institutional policy.)

6. What are the terms of office?

Chair _____

Members _____

Not specified _____

7. Explain successful processes that you have used to recruit a community member of the REB.

8. Explain how you recruit other REB members. (If applicable, cite specific sections of the Institutional policy.)

9. Do you have difficulty seeking REB members?

- No
 Yes
- If yes, please check all that apply.

- Recruiting individuals with expertise in research methodologies
 Recruiting individuals who have formal training in ethics
 Recruiting qualified individuals who can commit the time
 Recruiting community members
 Other (Please explain.) _____

10. What decision-making process is used by the REB in giving ethics approval?

- Consensus
 Majority
 Other (Please specify.) _____

11. How often does the REB meet?

_____ times a month

Other (Please specify) _____

12. Are the meetings ...

- Scheduled
 Ad hoc as needed

13. What records does the REB keep and for what length of time? **Please check all that apply.**

TYPES OF RECORDS	LENGTH OF TIME (YEARS)
<input type="checkbox"/> Ethics review applications	
<input type="checkbox"/> Protocols	
<input type="checkbox"/> Minutes of meetings	
<input type="checkbox"/> Signed consent forms	
<input type="checkbox"/> Correspondence	
<input type="checkbox"/> Annual Reports	
<input type="checkbox"/> Adverse Event Reports	
<input type="checkbox"/> Case Monitoring	
<input type="checkbox"/> Amendments to Approvals	
<input type="checkbox"/> Other	

14. Describe the administrative support provided to the REB and what proportion of a full time position is spent by each person on REB related activities.

TYPE OF ADMINISTRATIVE SUPPORT	PROPORTION OF A FULL TIME POSITION

15. Please indicate any types of compensation provided to REB Chairs or members.

REB CHAIR	REB MEMBERS
<input type="checkbox"/> None	<input type="checkbox"/> None
<input type="checkbox"/> Release Time from Teaching	<input type="checkbox"/> Release Time from Teaching
<input type="checkbox"/> Honorarium	<input type="checkbox"/> Honorarium
<input type="checkbox"/> Travel Funds	<input type="checkbox"/> Travel Funds
<input type="checkbox"/> Other, please describe	<input type="checkbox"/> Other, please describe

16. Do REB members serve as an institutional resource on ethics issues in research involving humans?

- No
 Yes If yes, does the REB participate in any of the following activities?

Please check all that apply.

- Ethics training for graduate students
 Ethics training for faculty
 Ethics training for research partner organizations
 Development of ethics training materials for classroom use
 Other

REB PROCEDURES

17. When conducting ethics reviews, what guidelines are used? Please check all that are used by the REB.

- Institutional ethics review policy
 Tri-Council Policy Statement (TCPS)
 REB guidelines
 Institutional faculty handbook
 Good Clinical Practice – GCP (Health Canada)
 Action Plan from the Ministry of Health (QUEBEC)
 Civil Code (QUEBEC)
 Council for International Organizations of Medical Sciences (CIOMS)
 Canadian Psychological Association

Other _____

18. Does the REB collect information about the sources of funding for research that requires an ethical review?

- No
 Ad hoc basis
 Always

19. Provide the percentage of all ethics reviews (Full and expedited) by source of funding:

SOURCE OF FUNDING	PERCENTAGE
- external granting agency with peer review	
- external granting agency without peer review	
- internal support	
- contract research	
- unfunded research	
- Other	

20. Are there types of research that involve human participants that are not currently reviewed by the REB?

- No
 Yes If yes, please explain.

21. Does the REB develop policies as well as review research projects?

- No
 Yes If yes, please explain.

22. How many full committee ethics reviews did the REB initiate in the last fiscal year (May 1 – April 30)? _____

23. How many expedited minimal risk ethics reviews did the REB initiate in the last fiscal year (May 1 – April 30)? _____

24. Provide your best estimate by percentage of the approval process for these ethics reviews.

APPROVAL PROCESS	PERCENTAGE ESTIMATION	
	Full Reviews	Expedited Reviews
- approved without modification		
- approved with minor modifications, such as editorial changes to the consent form or cover letter		
- approved with major modifications, such as research design or content of the informed consent process.		
- approved but subsequently approval rescinded		
- not approved		

- ongoing, no approval at this time		
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25. Who is responsible for reviewing and approving research projects deemed to be of minimal risk?

- Reviewed and approved by the REB committee
- Approved by the REB Committee
- Reviewed by the REB Chair
- Reviewed and approved by the REB Chair
- Reviewed by an REB subcommittee
- Reviewed and approved by an REB subcommittee
- Reviewed by the administrative staff for the REB
- Reviewed and approved by the administrative staff for the REB
- Other (Please explain.) _____

26. Please indicate how the REB deals with research design issues for both expedited and full review research proposals.

	EXPEDITED REVIEW	FULL REVIEW
Does the REB consider quality of research design?	<input type="checkbox"/> No If no, please go to next question. <input type="checkbox"/> Yes	<input type="checkbox"/> No If no, please go to next question. <input type="checkbox"/> Yes
If yes, who does the peer review?	<input type="checkbox"/> Accept peer review of external funder <input type="checkbox"/> REB reviews quality issues <input type="checkbox"/> Other	<input type="checkbox"/> Accept peer review of external funder <input type="checkbox"/> REB reviews quality issues <input type="checkbox"/> Other
Is the peer review process prescribed in the institutional ethics policy?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

27. Please indicate how continuing review/monitoring is carried out for both expedited and full review research proposals.

	EXPEDITED REVIEW	FULL REVIEW
Is there a person responsible for continuing review/monitoring of research projects?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

If yes, please indicate how continuing review/monitoring is carried out for both the expedited and full review of research proposals.	<input type="checkbox"/> Reviewed by the REB committee <input type="checkbox"/> Reviewed by the REB Chair <input type="checkbox"/> Reviewed by the Administrative staff for the REB <input type="checkbox"/> Other (please explain)	<input type="checkbox"/> Reviewed by the REB committee <input type="checkbox"/> Reviewed by the REB Chair <input type="checkbox"/> Reviewed by the Administrative staff for the REB <input type="checkbox"/> Other (please explain)
Please indicate which of the following activities are parts of the continuing review/monitoring process for research projects reviewed as minimal risk. Please check all that apply.	<input type="checkbox"/> Annual report <input type="checkbox"/> Adverse event reports <input type="checkbox"/> End of protocol/research project <input type="checkbox"/> Other (please explain)	<input type="checkbox"/> Annual report <input type="checkbox"/> Adverse event reports <input type="checkbox"/> End of protocol/research project <input type="checkbox"/> Other (please explain)
How are researchers informed of their responsibility to provide information for continuing review?	<input type="checkbox"/> Not informed <input type="checkbox"/> By the administrative staff for the REB <input type="checkbox"/> REB ethics approval letter <input type="checkbox"/> Institutional ethics policy <input type="checkbox"/> Other	<input type="checkbox"/> Not informed <input type="checkbox"/> By the administrative staff for the REB <input type="checkbox"/> REB ethics approval letter <input type="checkbox"/> Institutional ethics policy <input type="checkbox"/> Other
Is it obligatory for researchers to report to the REB any change in research design?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes

28. Does the REB consider conflict of interest issues?

- No
- Yes If yes, please indicate all types of conflict of interest that are considered.(Please reference institutional policy if applicable.)
- REB members conflict of interest with research being reviewed
- REB members' personal beliefs and values as they impact on judgments made about research topics
- Self-funded research
 - Pressures to publish for promotion, tenure, professional award, enhanced esteem
 - Financial incentives to researcher of family member
- Dual hats of physicians as researchers, teachers as researchers, teachers as graduate student researchers....
- Other (please explain) _____

29. What is the procedure for the evaluation of multi-centre proposals? **Please check all that apply.**

- No difference in procedures
- Evaluation by research location of principal investigators (PIs) is acceptable
- Handled on an ad hoc basis
- Have developed institutional level collaborative agreements
- Other _____

30. For protocols falling under the Good Clinical Practice Guidelines (GCP), does the REB follow a different review process?

- No
- Yes If yes, please explain.

31. Has a recommendation by the REB to stop or alter a research proposal or protocol ever been stopped or ignored by your institution?

- No
- Yes

REB CONCERNS

32. Please indicate the REB level of concern and intensity of REB committee time for each of the selected area of the ethics review process.

Selected Areas of the Ethics Review Process	REB Level of Concern			REB Committee Time		
	Very Concerned 1	Somewhat Concerned 2	Not Concerned 3	Most Time 1	Some Time 2	Little Time 3
Consent Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Consent Procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• For competent individuals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• For vulnerable individuals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

• For collectives	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• For special populations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Qualitative research projects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participant recruitment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participant Exclusion Criteria	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
'Over researched' research participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Scholarly Review	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Risk Reduction	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Risk/Benefit Assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Legal Issues	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Deception	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Financial Aspects for Research participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Financial Aspects for researchers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Urgency of Timelines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Adequate Administrative Support	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Resource Impact of Ethics Reviews	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Continuing Review/Monitoring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

33. Provide an estimate of the amount of time spent by each of the following person(s) in carrying out ethics reviews during the last fiscal year (May 1- April 30)

Type of Activity	Amount of Time (HOURS)
Meetings of the full REB	
Meetings of Executive or Subcommittees	
By the Chair in administrative/preparative work	
By individual members reviewing proposals	
By individual members in background reading	

REB TRAINING

34. How do you train REB members?

- Orientation workshop for new members
- Ongoing training for REB members
- Written information only like ethics policies, Tri-Council policy
- Other

34.1 What opportunities are there for education?

RESEARCHER PROCEDURES FOR ETHICAL REVIEWS

35. Does the REB have specific guidelines for researchers when submitting a research project for ethics review?

- No
- Yes If yes, please provide a copy or the web link for the site-visit team.

36. Does the REB have specific guideline cover letters and consent forms for researchers when submitting a research project for ethics review?

- No
 Yes If yes, please provide a copy or the web link for the site-visit team.

37. On average, how long does it take from the time of an ethics review submission to approval? _____ (in weeks).

38. What factors impact the length of time?

- Difficulty to find time for the REB to meet
 Insufficient secretarial support
 Workload of the committee
 Poorly written applications
 Other (Please specify.) _____

39. In what ways do researchers interface with the REB?

- Written submissions only
 Make a presentation to the REB :
 At the researcher's request
 By invitation only
 Required to make a presentation in all cases
 Other _____

40. Are there established procedures to appeal a decision of the REB?

- No
 Yes If yes, please explain and answer 41.1 to 41.4.

41.1 What are the grounds for appeal?

41.2 By whom is the appeal heard?

41.3 What is its composition?

41.4 Has the mechanism ever been used?

41. Does the REB have a mechanism for obtaining feedback from researchers about the ethics review process?

- No
 Yes If yes, please explain.

42. Does the REB have a mechanism for obtaining feedback from research participants about the ethics review process?

- No
 Yes If yes, please explain.

43. Does the REB permit research participants to meet with the REB? Please check all that apply.

- Not applicable
- With REB support staff
- With REB chair
- Full REB Committee
- Other (Please explain.) _____

CONCLUDING THOUGHTS

44. Are there particular issues related to ethics reviews of human research that you are interested in discussing with the Site-Visit Team?

45. Do you have any reflections on the institutional process in the implementation of the *Tri-Council Policy Statement (TCPS)* or other guidelines that may be of interest to discuss with the Site-Visit Team?

Signed _____

Title _____

Institution _____

THANK YOU

WE LOOK FORWARD TO THE SITE VISIT