

## RESEARCH ETHICS

# Informing research participants of research results: analysis of Canadian university based research ethics board policies

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**Background:** Despite potential benefits of the return of research results to research participants, the TriCouncil Policy Statement (TCPS), which reflects Canadian regulatory ethical requirements, does not require this. The policies of Canadian research ethics boards (REBs) are unknown.

**Objectives:** To examine the policies of Canadian university based REBs regarding returning results to research participants, and to ascertain if the presence/absence of a policy may be influenced by REB member composition.

**Design:** Email survey of the coordinators of Canadian university based REBs to determine the presence/absence of a policy on return of research results to research participants both during an ongoing study and at conclusion. REB coordinators were asked to return a copy of the policy or guidelines and to describe the member composition of their REB.

**Findings:** Of 50 REBs that were contacted 34 (68%) responded and 22 (64.7%) met the inclusion criteria. Two (9.1%) had a policy that governed the return of research results while on a study, and seven (31.8%) following the completion of a study. Presence of an ethicist or a lawyer on the REB did not influence the presence/absence of such policies. No REBs had specific guidelines describing how participants should be informed of results.

**Conclusions:** Most REBs did not require researchers to disclose study results to research participants either during or following a study. Thus this study identifies an ethical shortcoming in the conduct of human research in Canada. It has also demonstrated that there are no clear recommendations by REBs to facilitate the return of results to participants following research projects.

The practice of offering research results to research participants has received increasing attention and support in recent years from researchers, participants, and others involved in human research.<sup>1–4</sup> We and others have argued that this practice is fundamental to the ethical principle of respect for persons, as to offer research results to participants treats them in the highest regard.<sup>1–5</sup> Respect for persons requires that researchers take seriously the choices of autonomous persons, and that those who are capable of deciding for themselves are entitled to protection. In Canada, research involving humans must conform to the TriCouncil Policy Statement (TCPS) on research involving humans,<sup>6</sup> and is assessed for its ethical merit by local research ethics boards (REBs). Although respect for human dignity is a guiding ethical principle of the TCPS, the policy statement does not address the offer of disclosure of research results to research participants. In addition, the policies of university based REBs in Canada are largely unknown with respect to this issue.

We are primarily interested in two temporally and ethically distinct circumstances during which results may be returned to research participants. The first is during an ongoing research study, particularly a clinical trial, when new information that is obtained during the course of a study may influence the participant's willingness to remain enrolled. In abiding by one of the key aspects of consent, namely "disclosure", researchers are ethically required to provide these results such that participants may be able to re-consent to the study. The US Common Rule requires that participants of clinical trials be informed if new findings obtained during the course of a study may influence their willingness to continue in a study.<sup>7</sup> In Canada, there is no guidance in the TCPS on providing research results to participants during an ongoing study should the need arise,

stating only that REBs *may* require researchers to provide participants with additional information including<sup>6</sup>:

An assurance that new information will be provided to the subjects in a timely manner whenever such information is relevant to a subject's decision to continue or withdraw from participation.

There is, however, no guidance on when this additional information should be provided to research participants, leaving individual REBs to determine this. There is much debate surrounding what new information should be considered "significant".<sup>8–10</sup> While there is very little debate that a "statistically significant survival advantage" of one treatment arm or a major side effect in a clinical trial should be communicated to research participants there are other interim study results that are more debatable. Markman<sup>8</sup> has suggested that: "the question of what is or is not relevant information for clinical trial participants should not be left to the discretion of individual investigators", rather "general policies and more formal guidelines should be developed to protect the rights and autonomy of patients participating in clinical trials".

Thus, it becomes particularly important in the absence of clear guidelines on the part of the TCPS in Canada to determine whether local REBs have such guidelines to protect the rights of research participants during research studies.

The second circumstance during which research results may be returned to participants is following completion of a

**Abbreviations:** CAREB, Canadian Association of Research Ethics Boards; REB, research ethics boards; TCPS, TriCouncil Policy Statement

research project. The offer to return research results to participants at study completion is based on the premise that respect for persons should continue following study closure to avoid treating research participants merely as a means to an end. Among other benefits a summary of results to research participants acts as an acknowledgement of the valuable contribution to research science that has been made by their participation. This practice of *offering* completed study results should be universal regardless of the nature of study (i.e. research in the social sciences, education, health fields, clinical trials, etc.) or of the possible future implications of the study results to the participant. The benefits of offering research results to research participants are numerous and have been described elsewhere.<sup>1, 2</sup>

There is growing support for the practice of offering research results to research participants. Partridge and Winer have supported the practice of offering results to participants of all clinical trials, not only when the results should offer a clear health benefit to the participants.<sup>2</sup> Mann has supported the assertion that research participants of clinical trials are entitled to know the results of research in keeping with an ethical requirement on the part of researchers to publicly disseminate trial results.<sup>11</sup> The International Ethical Guidelines for Biomedical Research Involving Human Subjects include providing results to subjects after study completion *essential* information for research subjects.<sup>12</sup> Studies have shown that research participants have a desire for research results, and in some cases wish to have the results even though they may be distressing.<sup>13-16</sup> We have previously shown that researchers within the Children's Oncology Group in the United States support the practice of offering results to participants at study conclusion, however they rarely offer research results to participants.<sup>17, 18</sup> In Canada, the TCPS states only that REBs *may* require researchers to provide participants with additional information including "The ways in which the results will be published, and how the subjects will be informed of the results of the research."<sup>6</sup> The TCPS provides no guidance on when this additional information should be provided to research participants, leaving this determination to be made by individual REBs.

REBs in Canada are responsible for ensuring the protection of research participants and the ethical conduct of researchers. Certain requirements are placed on the ethics committee membership by the TCPS to ensure the "expertise, multidisciplinary and independence essential to competent research ethics review"<sup>6</sup> including ensuring the committee is made up of at least one person knowledgeable in ethics, for biomedical research one person knowledgeable in the relevant law and at least one member recruited from the community, among other requirements. In the USA, research has shown that lay members from the community are underrepresented on IRBs and a significant majority of IRBs do not have a member who is a professional ethicist.<sup>19, 20</sup> No studies have been conducted to determine whether university based REBs in Canada are meeting the membership requirements of the TCPS and whether REB membership influences the policies and guidelines of university based REBs. We hypothesised that the presence of an ethicist or lawyer on the committee would increase the chances that an REB had a policy on disclosure of research results.

In the absence of TCPS guidelines instructing researchers under what circumstances they should be providing participants with interim study results, it is essential to determine whether this is provided by local REBs. It is also crucial to the universal offering of research results to all research participants at study completion to determine whether REBs in Canada currently require researchers to disclose results to participants. In addition we also wanted to determine if the

TCPS requirements for REB membership are upheld by REBs and whether this affects the policies and practices of REBs. We report here an examination of Canadian university based REBs with respect to existing written policies governing the return of research results to research participants. We also describe the membership composition of university based REBs and whether this influences the existence of a policy on disclosure of research results.

## METHODS

The IWK Health Centre Research Ethics Board (Halifax, Nova Scotia) approved the study. Consent to participate in the study was assumed by receipt of a completed survey. We sent an information letter to the participants of the study assuring confidentiality.

The REBs were recruited through a mailing list identified from the Canadian Association of Research Ethics Boards (CAREB) (the study was not sponsored by this group).<sup>21</sup> Inclusion criteria for participation in the study were members of CAREB belonging to a verifiable university based REB. Major hospitals with separate REBs and reciprocal agreements with university based REBs were also included in the study. REBs of primarily French speaking universities were excluded due to language limitations. All REBs that were not affiliated with a Canadian university were excluded.

CAREB is a national membership organisation intended to represent the interests of all Canadian REBs.<sup>21</sup> CAREB members include university based and non-university based institutions across Canada. The member contact list was accessed on 5 July 2003; 53 members were registered as of this date. Use of contact information for the members of CAREB for this study was approved by the CAREB board. Demographic information about the institutions was obtained from the internet.

The contact person for each REB registered as a member of CAREB was the REB coordinator in most cases. Where there was no REB coordinator listed, the contact was the REB chair. An email announcement to the REB coordinators was sent approximately one week before sending out the survey. An information letter and the survey were sent by email. Email reminders were sent at one, three, and six weeks, if no response had been received. As an incentive to participate in the study, participants were told that their names would be entered into a draw for an ethics text. The participants of this study were also given the opportunity to receive a summary of the results of the completed study.

The survey was developed by the authors based on the objectives of the project. The survey solicited the presence or absence of an REB policy or guidelines (or a section of guidelines or policies) that governed the return of research results to research participants during an ongoing research project and/or following the completion of a study. REB coordinators were asked to send copies of their institutional REB guidelines or policies regarding the return of research results to research participants, if these guidelines existed. The survey also solicited demographic features of the REB including the size of the REB, the number of trained lawyers, number of trained ethicists, and members trained in biomedical research law and number of community members. We used Excel to store the information from the completed questionnaires and Epi Info (Centers for Disease Control, Atlanta, GA) for the statistical analysis. We analysed the data with descriptive techniques.

## RESULTS

CAREB had 53 members at the time of the study. Emails sent to three of the REBs were undeliverable; these REBs were excluded from the study. Of the 50 REBs that were contacted 34 (68%) responded and 22 of these (64.7%) were eligible for

**Table 1** Comparison of research ethics boards included in the study with those excluded and non-responders by geographic location (province)

Province	Responded to survey	Did not respond to survey or (did not meet inclusion criteria*)
Alberta	2	1 (2)
British Columbia	2	1 (1)
Manitoba	3	1 (0)
New Brunswick	1	0 (0)
Newfoundland	1	0 (0)
Nova Scotia	3	3 (1)
Ontario	10	6 (5)
Prince Edward Island	0	1 (0)
Quebec	0	1 (3)
Saskatchewan	0	2 (0)
Total	22	28

\*Inclusion criteria: members of Canadian Association of Research Ethics Boards belonging to a verifiable English speaking university based

the study. Of those that responded and were excluded three were REBs from primarily French speaking universities; five were not university based REBs nor had a reciprocal agreement with a university REB; and four of the REB listings were duplicate listings or listings of a REB that did not exist. These ineligible responses are not included in this analysis. The coordinators who responded on behalf of the REBs represented 17 different universities, 18.5% of the total 92 universities in Canada as listed by the Association of Universities and Colleges (AUCC). The university REBs represented in this study were located in seven of the 10 (70%) Canadian provinces. There are no universities or colleges in three Canadian territories. Tables 1 and 2 compare those REBs that responded and were included in the study with those that did not respond or were excluded by geographic location and institution size, respectively.

**Research ethics board policies**

Table 3 shows the number of REBs that had a policy that governed the return of research results while on a study and a policy that governed the return of research results following completion of the study.

REB coordinators who responded that policies existed at their institutions regarding the return of research results to research participants were asked to submit a copy of the policy. The two REBs with policies on the return of research results while on a study were from the same institution. One REB coordinator at this institution responded for both REBs indicating that there were no strict requirements that study

**Table 2** Comparison of research ethics boards included in this study with those excluded and non-responders by size of institution (number of students)

Total no of students in 2004	Responded to survey	Did not respond to survey or (did not meet inclusion criteria*)
<10 000	4	3 (2)
10 000–19 999	6	4 (1)
20 000–29 999	9	3 (1)
30 000–39 999	3	2 (3)
>40 000	0	2 (1)
Not affiliated with university	0	2 (4)
Total	22	28

\*Inclusion criteria: members of Canadian Association of Research Ethics Boards belonging to a verifiable English university-based research ethics board.

**Table 3** Research ethics boards (REBs) with policies on disclosure of research results to participants

	University based REBs (n = 22)
Policy to return results while on a study, n (%)	2 (9.1)
Policy to return results following completion of study, n (%)	7 (31.8)
Policies to return results while on a study and following completion of study, n (%)	0 (0)

results be provided to research subjects. These REBs, however, do have guidelines that discuss studies using diagnostic tests, and the consent form guidelines remind researchers to deal with the issue.

Seven REB coordinators responded that their REB had a policy or guidelines regarding the return of research results to participants following the completion of a research project. All included either an excerpt of the policy or guideline, an internet link to the policy or attached their complete REB policy. Of this number, only one REB coordinator attached an REB policy describing the requirement of researchers to return research results. The other six REBs had a statement in the application for ethics approval requiring a description of how the results would be returned to research participants. One of these REBs also had a statement about accessing the results of the study in a sample consent form. The only REB with a policy on return of research results following completion of the study required that requests for ethics approval include a description of how the results will be disseminated and how the participants will be informed of the results.

On detailed review of the policies that required disclosure of results following completion of the study, none of the REBs indicated when the results should be offered, the need for peer review before disclosure, or in what form the results should be returned (that is, summary of results or raw data). None of the REBs required researchers to budget for the cost of returning results or of maintaining contact with the participants.

**University based CAREB member REB composition**

Table 4 shows the composition of the REBs as outlined by the TCPS grouped by total member size. Seven of the REBs (31.8%) in our study did not have a trained ethicist as a member. To determine whether there was an association between the absence of a trained ethicist as an REB member and the existence of a policy on returning results to participants following completion of the trial we used Fisher’s exact test. There was no statistical significance between either the absence of an REB member who is a trained ethicist and the absence of a policy, nor a significance between the presence of an REB member who is a trained ethicist and the presence of a policy (p = 0.387).

There was no lawyer on three of the REBs (13.6%) that we surveyed. We found no significance between the presence of a lawyer on the REBs in our study and the existence of an REB policy on disclosure of research results to participants following study completion (p = 0.209, Fisher’s exact test).

**DISCUSSION**

Adherence to the TCPS is required by universities in Canada to receive funding from federal agencies. The TCPS therefore sets a baseline ethical standard for the majority of human based research in Canada conducted at the university level. All those conducting research on humans are required to be familiar with the TCPS and the policies of their respective

**Table 4** Member composition of research ethics boards (REBs)

	Size of REB (no of members)				Total
	0-5	6-10	11-15	16-20	
REBs, n (%)	1 (4.3)	5 (21.7)	13 (56.5)	4 (17.4)	23
REBs with at least 1 ethicist, n	N/A	3	10	2	15
REBs with at least 1 lawyer, n	1	4	11*	4	20
REBs with at least 1 member with expertise in biomedical research, n	0	0	2	3	5
REBs with at least 1 community member, n	1	5	13	4	23
REBs with at least 2 community members, n	0	2	10	3	15
REBs with $\geq 3$ community members, n	0	0	5	0	5

\*Three REBs had two lawyers and one REB had four lawyers.

institutions, at a minimum. Although the ethical principles of the TCPS are generally supported, there has been much criticism in recent years that the TCPS provides little guidance to researchers and REBs.<sup>22</sup> A recent report describes, in particular, the absence of guidance in the areas of humanities and social science research.<sup>23</sup>

Article 2.4 of the TCPS outlines a table of information that *may* be required for *some* projects, which include how the subjects will be informed of the results of the research during the conduct of the study.<sup>6</sup> The TCPS provides no guidance however, with respect to which projects may require return of interim results to research participants nor does it describe how this process should occur.<sup>6</sup> In lieu of specific guidelines described by the TCPS, we were interested in whether individual REBs have guidelines or a policy describing how results should be returned to research participants. The majority of REBs that we surveyed did not have a policy or guidelines that described this practice of returning research results to participants during an ongoing trial. This is a particularly surprising finding given that there are circumstances during which researchers would be ethically mandated to provide results to research participants such that they may be able to re-consent to participate. Given that clear guidelines regarding disclosure of interim results to research participants are neither provided by the TCPS nor REBs leads one to assume either that REBs do not require researchers to describe how and under what circumstances they would return interim results to participants or that more likely enforcement of this ethical standard occurs on an ad hoc or case by case basis. These results indicate that there is a significant deficit in the current framework of regulation for the ethical conduct of human research and the protection of research participants during research studies.

A third of REBs indicated on our survey that they had policies supporting the return of research results following the completion of a trial, however, only one board actually had a policy and the others had statements embedded in their guidelines that required a description of how results should be returned on the ethics application form. The finding that the majority of REBs do not require researchers to return research results to participants is not unexpected given that research ethicists are only recently asserting this practice as a means of showing greater respect for research participants. It is, however, unexpected that those REBs who do have a policy requiring researchers to discuss how results will be returned to participants following study completion do not provide clearer guidelines on how this should occur.

Our group has previously published a set of guidelines for return of research results that seek to minimise the harms and maximise the benefits of this practice.<sup>1</sup> These guidelines include<sup>1 2 24</sup>:

- offering research results at the time of study enrolment

- disclosure following peer-review but prior to public disclosure
- participants should be presented with the harms and benefits of receiving the results
- researchers should budget for the cost of returning results including maintaining contact with research participants.

Most importantly, acceptance of the offer of research results by study participants should be voluntary and an informed decision. What is most surprising regarding those REBs in our study who in fact have policies requiring researchers to return results to participants is that it is not clearly stated in the policy that receipt of the results should be voluntary on the part of the participant. We believe that the process of returning research results should not be an ad hoc one, but rather an organised approach that provides comprehensive support appropriate to the potential consequences of receipt of research results to the participant. This requires guidelines and policies that are specific for the genre of research conducted, the potential harms to the participant and the requirement of the research participant population.

There is clearly a need to provide research results in an organised well thought out process when the potential harms associated with receiving the results, including psychological harm to the participant are potentially great. There is currently very little information to indicate how research participants feel about receiving research results. The few studies that have been performed were on small numbers of participants.<sup>13-16</sup> More research is needed to determine how best to disseminate results from the perspective of the participant. The attitudes of researchers toward the practice of offering results to participants following research projects is also relatively unknown. Di Blasi *et al* surveyed investigators of placebo controlled randomised trials to determine whether participants were informed of their treatment allocation at trial closure and the study results at study closure.<sup>25</sup> They found that 45% of the 107 investigators who were surveyed informed participants of their treatment allocation and of those who informed participants of the treatment arm 67% (32 of 48) also informed participants of the study results.<sup>25</sup> A total of 9% of the participants who were not informed of their treatment arm were informed of the study results. Although investigators were not specifically questioned about their reasons for not providing results, several investigators offered their reasons including<sup>25</sup>:

- the results were “too distant in time” and “rather old news”
- it was difficult to trace patients
- the results were unclear
- none of the patients asked
- they were never asked by their sponsors
- most of the uninformed participants were dead.

It is difficult to determine from this study how many of the investigators contributed to the responses outlined in the paper, however the responses do point to the need for guidance in this area to provide researchers with mechanisms to maintain contact with participants, and the best ways to offer and disseminate results to participants.

Our group has provided a detailed review of the considerations that are required for universal offering of research results.<sup>24</sup> This review analyses the costs associated with dissemination taking into consideration the intrinsic study risk, the consequences of disclosure of the results, and the logistics of contacting participants to disclose results.<sup>24</sup> It is encouraging to see that some REBs at Canadian universities are considering this practice essential in the ethical conduct of research however, clearer guidelines are required to ensure that beneficence is the goal and that no harm is done to participants. Most importantly more research is needed to determine how best to disseminate results from the perspective of the participant.

The TCPS broadly outlines the required REB composition.<sup>6</sup> We found in our study that the composition of REBs varies considerably from institution to institution. The composition of REBs did not meet the minimal requirements for legal or ethical expertise as mandated by the TCPS in a significant minority (31.8% had no ethicist, 13.6% had no lawyer). Although we did not find that the absence of either legal expertise or ethical expertise influenced the existence of an REB policy governing the return of results following completion of a study, further research is needed to determine whether REB member composition influences other REB policies. All REBs reported adequate community member representation, potentially an important impetus to the support and development of policy for the return of research results to participants in the community.

The sample size of our study was relatively small, however major institutions from across the country as well as institutions from the most populated provinces in Canada (Ontario, British Columbia) were well represented. The results of our study are therefore representative of a large proportion of the university based research that is occurring in Canada. There were no apparent differences in responder universities compared to those that did not respond based on geographic location and institution size. It is also unlikely that non-responders had a policy on returning results to research participants as one would assume that they would be more apt to demonstrate it. We did not survey francophone REBs or non-university based REBs. The absence of a comprehensive organisation of REBs across Canada limited our efforts to survey all REBs. In the future, targeted assessment of hospital based and industry REBs will greatly facilitate research in the field of research ethics policy. This is particularly important given the significant amount of research that takes place outside universities in Canada. In addition, the composition of REB committees changes with time. Therefore, the current presence or absence of various disciplines such as ethics or law, may not be tightly linked to the thoroughness of ethics policies for each board.

## CONCLUSIONS

Our findings are important as they demonstrate significant gaps in university based REB policy. The absence of a requirement by most REBs in this study to offer to provide new or significant information that may inform the ongoing consent of participants in research is concerning. The lack of requirement of researchers to do so is an affront to the process and provision of consent, which should remain valid throughout the experimental process. While REBs would be expected to require researchers to respect the withdrawal of consent during a study, research participants should be

entitled to be informed of new information that would allow them to make their decision in an informed manner. On the whole, research ethics boards across Canada require clearer and more specific guidelines and policies to facilitate the return of research results to research participants following study completion such that researchers who choose to share results are provided with appropriate supports to minimise harms to the participant. Most importantly, REBs should only endorse the return of research results at study completion when it is a voluntary informed choice made by the participant. Further research is required to determine how research participants feel about receiving results at study completion and how best to disseminate results to participants.

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