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Moving Ahead

Draft Report of the Experts Committee for Human Research Participant Protection in Canada

August 15, 2007

The consultation will be open from August 15, 2007 to November 30, 2007. All submissions must be sent electronically to the Sponsors' Table Secretariat at secretariat@hrppc-pphrc.ca.

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Le présent rapport est également disponible en français au www.hrppc-pphrc.ca

37 **Sponsors' Table for Human Research Participant Protection in Canada**
38 **Consultation Process**
39

40 The Sponsors= Table for Human Research Participant Protection in Canada, ([www.hrppc-](http://www.hrppc-pphrc.ca)
41 [pphrc.ca](http://www.hrppc-pphrc.ca)) is a group of organizations that shares a common interest in promoting research
42 involving humans that meets the highest standards in excellence and ethics. In large part,
43 research organizations in Canada operate to high ethical standards and involve the
44 dedication of many people. The current system of human research participant protection
45 faces increasing pressures related to issues such as governance, consistency, transparency
46 and public accountability. To address these pressures, the research community needs a
47 shared vision that will define and build a process that further develops a system to protect
48 research participants while facilitating research that is important to society. Given the
49 national and international implications, it is time for all players to work together toward
50 common objectives based on an open and transparent process.

51
52 Part of the Sponsors= Table process included the establishment of an Experts Committee
53 to provide independent analysis and recommendations. In September 2006 the Experts
54 Committee met for the first time. They have worked expeditiously in the months since
55 and have now submitted a draft report.

56
57 Before the Sponsors' Table organizations formally consider the contents and
58 recommendations of the Experts Committee's report, they wish to consult with each
59 members' constituent groups and/or stakeholders and other interested parties on its
60 content as well as on other pertinent issues. The Sponsors' Table has identified six
61 questions which provide a broad framework for this consultation process.

62
63 It is important to be clear that the Sponsors' Table organizations are not endorsing the
64 contents or recommendations of the Experts Committee's report at this time.

65
66

The consultation will be open from August 15, 2007 to
November 30, 2007. All submissions must be sent
electronically to the Sponsors' Table Secretariat at
secretariat@hrppc-pphrc.ca.

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69
70 The Experts Committee will have an opportunity to revise its draft report before
71 submitting a final version. The Sponsors' Table intends to communicate its action plan
72 as soon as possible after receiving the Experts Committee's final report.

73

74 The following questions are provided to guide you in forming your response to the report
75 *Moving Ahead*. Please feel free to comment on any part of the report and not limit your
76 reply to these questions.

77

78

79 1. How well is the Canadian system for the protection of human research
80 participants currently functioning? What are some of the most pressing concerns
81 or challenges? What elements are working best?

82 2. Is there need for improvements in the system?

83 If yes, for what reasons? What are the most pressing aspects of this need
84 (policy, standards, education, monitoring, accreditation, sanctions, other)?

85 What might be some of the consequences if the status quo remains in place
86 (e.g., for multi-jurisdictional research, policy harmonization, education, and
87 participant protection)?

88 3. How would you assess the arguments and recommendations of the report *Moving*
89 *Ahead*, in particular, that an independent organization be created with the three
90 primary functions of policy, education, and accreditation?

91 4. What would be the impact (positive and/or negative, including financial) on you
92 and/or your organization were an organization similar to the one proposed in the
93 report *Moving Ahead* be established? Are there alternative courses of action that
94 you would recommend?

95 5. What issues were not addressed in the report *Moving Ahead* that need to be
96 considered?

97 6. Looking at what could be done right now, or in the near future, what specific
98 actions would you recommend to improve the protection of human research
99 participants? Who should pay for what share of the financial costs in any change
100 to the system (e.g., policy, education, accreditation as cost recovery)? In the short
101 to medium term during a potential transition? In the longer term?

102

103

104 Thank you very much in advance for spending the time and energy to provide comments.

105

106 **Important Notice**

107

108 All submissions received by the Secretariat will be made available to organizations of the
109 Sponsors' Table, to members of the Experts Committee, and to an independent
110 contractor. For the current list of Sponsors' Table members please visit our web site,
111 www.hrppc-pphrc.ca.

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115	Table of Contents
116	Chairman’s Foreword
117	List of Acronyms
118	1. Preface
119	
120	2. Background
121	
122	2.1 Sponsors’ Table for Human Research Participant Protection in Canada
123	2.2 Experts Committee for Human Research Participant Protection in Canada
124	2.2.1 Experts Committee Mandate and Work Plan
125	2.3 Description of the Current System
126	2.4 Concerns about the Current System
127	2.5 Other Options Considered
128	2.5.1 Status Quo
129	2.5.2 Public Assurance System
130	2.5.3 Accreditation Models
131	2.5.3.1 AAHRPP’s Model of Accreditation
132	2.5.3.2 NCEHR’s Model of Accreditation
133	2.5.3.3 Strengths and Weakness of Accreditation
134	2.5.4 Replacing Institutional REBs by Regional REBs
135	2.5.5 Regulation through Federal Statute
136	2.5.6 US Accreditation
137	2.5.7 Canadian Council for Animal Care
138	2.5.8 Other International Developments
139	
140	3. An Overview of the Proposed New Canadian Oversight System for Research Involving
141	Humans
142	
143	3.1 Goals
144	3.2 Attributes
145	3.3 Functions
146	
147	4. The Canadian Council for the Protection of Human Research Participants (CCPHRP)
148	
149	4.1 Board of Directors
150	4.2 Members
151	4.3 Office of the Executive Director
152	4.4 Policy
153	4.5 Education
154	4.6 Accreditation
155	4.6.1 What Gets Accredited?
156	4.6.2 Accreditation Functions
157	4.7 Accreditation Panel

August 15, 2007

Open Call for Comments

158	4.8 The CCPHRP Organizational Chart
159	
160	5. Implementation of the System
161	5.1 Creating the CCPHRP
162	5.2 Financing the CCPHRP
163	5.3 Establishing the Reach of the System
164	5.4 Costs
165	5.5 Time Table
166	
167	6. Summary of Recommendations

168
169
170
171
172
173
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Chairman's Foreword

The Experts Committee for Human Research Participant Protection in Canada presents herewith its draft report and recommendations concerning the development of a new oversight system in Canada.

The draft report is the product of some ten months work. Beginning in September, 2006 the Committee held monthly face-to-face meetings which it supplemented by conference calls and the circulation of draft texts by various members.

During the course of its work the committee assessed the concerns with the existing Canadian oversight arrangements and then examined alternative models that might serve to deal effectively with these problems. It also arranged to receive briefings from a number of organizations with experience in its field, including the National Council on Ethics in Human Research (NCEHR), the Interagency Advisory Panel on Research Ethics (PRE), the Association for the Accreditation of Human Research Protection Programs, and the Canadian Council on Animal Care among others.

The approach used by the Committee was to build on much work (analysis, consultations and consensus-building) that had been done over the preceding decade, particularly by NCEHR and PRE. Its objective in developing its proposals was to achieve, not perfection, but workability. In the Committee's view, the most important thing at this stage is to put in place the best set of measures that can be devised and then let them evolve in the light of experience.

The Committee's conclusions and recommendations are set out in this report. The oversight system and organization that it proposes would, in the Committee's judgment, provide the most effective way of enhancing the protection of human research participants in Canada.

The stage has now been reached where the Committee wishes to obtain the views of the research community. Accordingly, it has joined with the Sponsors' Table in initiating a consultative process to elicit reactions to the proposals it has developed.

Comments on any or all of the elements of the report will be welcome. To the extent that those examining the report wish to express criticisms, the Committee would find it particularly helpful if concrete alternatives to its proposals could be provided.

Once the consultative process has run its course, by November 30, 2007, the Committee will meet to review the advice it has received and then to finalize its report.

Arthur Kroeger,
Chairman of the Experts Committee
June 30, 2007

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List of Acronyms

216	AAHRPP	Association for the Accreditation of Human Research Protection Programs
217	AUCC	Association of Universities and Colleges in Canada
218	CCPHRP	Canadian Council for the Protection of Human Research Participants
219	CCAC	Canadian Council for Animal Care
220	CIHR	Canadian Institutes of Health Research
221	CPSRIH	Canadian Policy Statement on Research Involving Humans
222	NCEHR	National Council on Ethics in Human Research
223	NSERC	Natural Sciences and Engineering Research Council
224	PEERH	Programs for Ensuring Ethical Research with Humans
225	PAS	Public Assurance System
226	PRE	Interagency Advisory Panel on Research Ethics
227	SSHRC	Social Sciences and Humanities Research Council
228	TCPS	Tri-Council Policy Statement
229	REB	Research Ethics Board

230 **1. Preface**

231 The governance of research involving humans in Canada is an evolving process that
232 requires ongoing review and revision. There have been a number of commissioned
233 reports on the state of affairs in Canada regarding the governance of research involving
234 humans. As early as 1995, the National Council on Bioethics in Human Research (now
235 the National Council on Ethics in Human Research, NCEHR) produced a report
236 documenting the challenges facing medical schools in Canada.¹ It details concerns that
237 resonate to this day. Also in 1995 there was the Deschamps report on the governance of
238 health research in Québec.² This report provided the foundation for the province's plan
239 of action for reform. During this time, the three federal granting agencies were
240 attempting to bring their separate research ethics policies together based on a set of
241 common principles for research involving humans. The publication in 1998 of the *Tri-*
242 *Council Policy Statement: Ethical Conduct of Research Involving Humans* (TCPS) is a
243 milestone in Canada of forging a unified approach to the research ethics policy.³ Two
244 subsequent reports, one by the Centre on Governance at the University of Ottawa⁴ and the
245 other by Michael McDonald and his colleagues⁵, further documented major concerns
246 with the governance of research involving humans in Canada. Other reports and
247 publications on various aspects of the governance of research involving humans have

¹ National Council on Bioethics in Human Research, "Protecting and Promoting the Human Research Subject: A Review of the Function of Research Ethics Boards in Canadian Faculties of Medicine", *Communiqué*, Winter, 1995, pp. 3-32.

² Pierre Deschamps, Patrick Vinay, and Sylvia Cruess, *Comité d'experts sur l'évaluation des mécanismes de contrôle en matière de recherche clinique*, Ministère de la Santé et des Services sociaux du Québec, 1995.

³ Available online at <http://pre.ethics.gc.ca/>

⁴ Centre on Governance, *Governance of the Ethical for Research Involving Human Subjects*, University of Ottawa, 2000.

⁵ Michael McDonald, et al, *The Governance of Research Involving Human Subjects*, Law Commission of Canada, 2000.

248 emerged in recent years; some of which are discussed in more detail in this report.⁶

249 Taken together these reports indicate that the need for change in Canada is evident.

250

251 However, despite the broad recognition that the ethical oversight of research in Canada

252 must evolve, proposals for remedial measures have often proven controversial. Some

253 stakeholders have objected that strengthened and comprehensive ethical oversight could

254 constitute a bureaucratic burden that would impede the work of researchers. Concerns

255 have also been raised about the costs of an enhanced oversight system, and how such

256 costs might be met. In addition, some members of the social science and humanities

257 communities have objected to having what they regard as a biomedical system of

258 oversight applied to their work.⁷

259

260 In recent years there has been considerable discussion of concerns about the system, but

261 to date concrete actions to deal with them have fallen short of what is required. In

262 developing its proposal the Committee has been conscious of the need for greater

263 progress to be made in this area. Members of both the Committee and the Sponsors'

264 Table have reported a desire to move from studies and discussion to concrete action. The

265 decision by a Canadian university to seek accreditation by an American organization, the

⁶ For example, two reports that a Committee member received through an Access to Information Request; Trudo Lemmens, Chantal Beauvais, Loren Falkenberg, and Edith Deleury, "Report to the Three Granting Agencies from the Ethics Review Committee Regarding the Assessment of Institutional Policies with the TCPS" December 20, 2002 and the T. Douglas Kinsella and Edward W. Keyserlink "Review of the Clinical Ethics Research Board The University of British Columbia: Final Report" August 1, 2001.

⁷ On this issue in general see the consultation document, Interagency Advisory Panel on Research Ethics, Social Sciences and Humanities Research Ethics Special Working Committee, "Qualitative Research in the Context of the TCPS: A follow-up to the *Giving Voice to the Spectrum* report and a Discussion Paper" Secretariat on Research Ethics: Ottawa, 2007.

266 Association for the Accreditation of Human Research Protection Programs (AAHRPP)
267 tends to substantiate the claim of an urgent need for action.

268

269 In planning its work, the Committee decided at the outset that it should build upon the
270 extensive analytical work and consultations that have been carried out in past years, and
271 that it should put forward a plan for action. This is why the Committee chose *Moving*
272 *Ahead* as the title for its report.

273

274 The Committee has developed a proposal that draws upon the main elements of the
275 Social Sciences and Humanities Research Council (SSHRC) public assurance system and
276 NCEHR's proposal for an accreditation system, as well as other proposals that have been
277 advanced in recent years, with a view to both addressing the concerns with the current
278 system and eliciting broad support from the research community. It has also taken into
279 account ethical oversight measures that have been put in place by various organizations
280 and jurisdictions in Canada and internationally.

281

282 The Committee agreed that its work should be guided throughout by the need to protect
283 human participants in research. Accordingly, it defined its principal objective as being:

284

285 *to develop a Canadian oversight system for the protection of human research*
286 *participants that is effective, efficient, broadly applicable, and one in which*
287 *safeguards for participants are proportionate to the risks in each case.*

288

289 The Committee believes that, at the present juncture, what is primarily required is to put
290 in place the best system that can be devised, and then to allow it time to develop,
291 understanding that adjustments will be made over time in the light of experience. In
292 developing its proposal, the Committee has sought to attain, not perfection, but
293 workability. The Committee believes that if a system of the character described in this
294 report were put in place, and supported in good faith by stakeholders, it would come to
295 represent a significant advance in protecting human research participants.

296

297 This report is very much a collective product. Every member of the Committee
298 contributed to the contents during our frequent meetings. A number of members also
299 submitted draft texts that were then discussed and adjusted as the Committee considered
300 necessary before being incorporated into the text. While individual members of the
301 Committee may well hold views that diverge in some degree from this or that passage in
302 the report, all subscribe to the consensus the Committee has achieved.

303

304 **2. Background**

305 **2.1 Sponsors' Table for Human Research Participant Protection in Canada**

306

307 On June 21-22, 2005 the NCEHR convened a workshop of 54 stakeholders for the
308 purpose of reviewing and responding to the penultimate draft of "Promoting Ethical
309 Research with Humans" – the *Report of the Task Force for the Development of an*
310 *Accreditation System for Human Research Protection Programs*.⁸ In response to the
311 outcome of this workshop, a meeting was organized on September 16, 2005 by the Royal
312 College of Physicians and Surgeons which involved the College, the Association of

⁸ Available online at www.ncehr-cnerh.org

313 Universities and Colleges in Canada (AUCC), Health Canada and the three Canadian
314 federal research granting agencies (CIHR, SSHRC, and NSERC). At this meeting, of
315 what has become known as the ‘Sponsors’ Table’, it was agreed that,
316 ...it would be useful to establish an expert committee to look into a range of
317 governance models for the oversight of ethics in human research and to explore
318 issues including implementation and funding.⁹
319
320 Over the next several months, additional meetings of the Sponsors’ Table were held, and
321 its membership increased to include the following organizations:¹⁰

- 322 ○ Alberta Ministry of Health and Wellness,
- 323 ○ The Association of Canadian Academic Healthcare Organizations,
- 324 ○ The Association of Faculties of Medicine of Canada,
- 325 ○ The Association of Universities and Colleges of Canada,
- 326 ○ Canada's Research-Based Pharmaceutical Companies,
- 327 ○ The Canadian Federation for the Humanities and Social Sciences,
- 328 ○ The Canadian Institutes of Health Research,
- 329 ○ Fond de la recherche en santé du Québec,
- 330 ○ Health Canada,
- 331 ○ Health Charities Coalition of Canada,
- 332 ○ Research Canada,
- 333 ○ The Natural Sciences and Engineering Research Council,
- 334 ○ The Social Sciences and Humanities Research Council, and
- 335 ○ The Royal College of Physicians and Surgeons of Canada.

336 Terms of Reference for this group were adopted which stipulated the main objectives for
337 the Sponsors’ Table, namely:

- 338 ○ to establish an Experts Committee
- 339 ○ to engage other organizations sharing a common interest with the Sponsors’ Table
- 340 ○ to provide terms of reference for, and facilitate the activities of, the Experts
341 Committee
- 342 ○ to establish a Secretariat and select a Chair for the Experts Committee,

⁹ AUCC Update, October 12, 2005 Number 7

¹⁰ The Sponsors’ Table web site is www.hrppc-pphrc.ca

- 343 ○ to develop a common communications strategy for the Sponsors' Table, and
344 ○ to utilize individually and collectively the Experts Committee's findings and
345 recommendations to consider next steps.

346 The tenure of the Sponsors' Table was established at 3 years, from its inception in 2005.

347

348 **2.2 Experts Committee for Human Research Participant Protection in Canada**

349 In June 2006, the Sponsors' Table issued a call for nominations to the Experts
350 Committee. The key criterion for selection to the Committee was that members were to
351 be selected for their expertise, were not to be representative of any organization, and were
352 to serve as volunteers. The following areas of expertise were considered:

- 353 ○ Research Ethics
354 ○ Health Law
355 ○ Research Ethics Board Administration
356 ○ Research Ethics Board membership (Biomedical and Social Sciences /
357 humanities)
358 ○ Administration and Health Care
359 ○ Research Administration
360 ○ Accreditation Systems, and Standards Processes
361 ○ Social Sciences and Humanities Research and Methodologies
362 ○ Clinical Trials
363 ○ Clinical Research
364 ○ Natural Sciences Research

365 ○ Aboriginal Research

366 ○ Research Participant Perspective

367 Consideration was also given to the overall balance of perspectives, as well as regional,
368 linguistic and gender representation.

369 Mr. Arthur Kroeger, Companion of the Order of Canada, was invited by the Sponsors’
370 Table to Chair the Committee. Mr. Kroeger had previously served as Deputy Minister of
371 six federal government departments. He was Chairman of the Public Policy Forum from
372 1992 to 1994, and since 1999 has been Chair of the Canadian Policy Research Networks.
373 Mr. Kroeger also served as Chancellor of Carleton University for nine years. The
374 Committee consisted of the following members:

375 Professor John R.G. Challis, Vice President (Research) and Associate Provost, University
376 of Toronto

377 Dr. Karen Cohen, Associate Executive Director, Canadian Psychological Association

378 Mr. Jack Corman, President/Secretary, Institutional Review Board (IRB) Services Inc.

379 Me. Pierre Deschamps, Avocat, Faculté de droit, L’Université McGill

380 Dr. Jocelyn Downie, Canada Research Chair in Health Law and Policy, Dalhousie
381 University

382 Dr. Serge Gauthier, Chair, Faculty of Medicine Ethics Institutional Review Board,
383 McGill University

384 Ms. Patricia Lindley, Director, Office of Research Ethics Administration, Dalhousie
385 University

386 Dr. Deborah C. Poff, Professor of Philosophy and Political Science, University of
387 Northern British Columbia

388 Dr. Dorothy Pringle, Professor of Nursing, University of Toronto

389 Dr. Vincent Sacco, Professor, Department of Sociology, Queen's University

390 Dr. Hal Weinberg, Director, Office of Research Ethics, Simon Fraser University

391 Mrs. Marianne Vanderwel, Director, R&D Oversight - GCP and Pharmacovigilance,
392 Pfizer Inc.

393 Dr. Jonathan C. Yau, University of Calgary

394 In addition, Dr. Peter Monette, of Health Canada provided Secretariat support.

395

396 **2.2.1 Experts Committee Mandate and Work Plan**

397 In its direction to the Committee, the Sponsors' Table articulated the following mandate:

398 To provide expert advice on the development of a system for human research
399 participant protection in Canada, considering accreditation and alternative models,
400 and taking into account different levels and types of risk in research. This process
401 will include an assessment of existing means of ensuring human research
402 participant protection for various types of research and of the gaps that such a
403 system would address.¹¹

404 The following work plan was adopted by the Committee:

- 405 ○ Monthly face-to-face meetings
- 406 ○ Invited presentations¹²
- 407 ○ Discussion and analysis of presented materials
- 408 ○ Review of relevant literature / documentation

¹¹ Information on the Experts Committee and its terms of reference can be found online at www.hrppc-pphrc.ca

¹² Presentations were made to the Committee by the following organizations: National Council for Ethics of Human Research (NCEHR), Interagency Advisory Panel on Research Ethics (PRE), Canadian Council on Animal Care (CCAC), US Office for Human Research Protections (OHRP), Association for the Accreditation of Human Research Protection Programs (AAHRPP), Social Sciences and Humanities Research Council, Canadian Council for Health Services Accreditation (CCHSA), and Dr. Sue Dodds of the University of Wollongong, AUS.

- 409 ○ Drafting of an Interim Final Report
- 410 ○ Public consultations on the Interim Final Report
- 411 ○ Final Report

412 On behalf of the Committee, Health Canada contracted consultants with the Government
413 Consulting Services to conduct the technical work of developing a draft costing model for
414 the proposed recommendations. The consultants worked with a subcommittee in
415 establishing the cost estimates.

416 The tenure of the Committee was given as 2 years. However, from the outset, the
417 objective of the Committee was to complete its work thoroughly but expeditiously, and to
418 produce a draft final report within 9 months of the first meeting. Ongoing communication
419 between the Committee and the Sponsors' Table was carried out through monthly
420 meetings between the Chairs of each body. In addition, two meetings were held by the
421 Chair and the Secretariat with members of the Sponsors' Table.

422 While the Committee was guided by its mandate and initial directives from the Sponsors'
423 Table, its deliberations were conducted without intervention from that body. On March
424 23, 2007, an initial draft Report was provided to the Sponsors' Table and a number of
425 comments were received. This version of the Report contains additional material and
426 clarifications that were requested at the March 23rd meeting.

427 **2.3 Description of the Current System**

428 Currently in Canada no coherent system for oversight of research involving humans
429 exists.¹³ The conduct of such research is governed by what is effectively a complex
430 patchwork of regulations and guidelines, developed over time by a variety of agencies
431 and organizations, operating under various jurisdictions and mandates and, by and large,
432 independent of one another. The following is intended to illustrate this complexity
433 without being exhaustive of all elements of the current system.

434

435 *Research organizations* – some research organizations establish policies to regulate
436 research conducted under their auspices. Some hospitals, for example, make ethics
437 review a condition of physician privileges.

438

439 *Funders of research* – federal/provincial/territorial governments conduct or directly fund
440 research and, through policies, exercise some control over the ethics of such research.
441 Many different non-governmental organizations also fund research and, through terms of
442 their funding, also exercise some control. The three federal research granting agencies
443 (CIHR, SSHRC, and NSERC) make compliance with the TCPS a condition of funding.
444 Some provincial research funding agencies and some charities that fund research also
445 make compliance with the TCPS a condition of funding.

446

¹³ Two works that attempt a description of the complexity of the current system are Marie Hirtle, “The Governance of Research Involving Human Participants in Canada” *Health Law Journal*, 11, 2003, pp. 137-152 and Kathleen Cranley Glass and Trudo Lemmens, “Research Involving Humans” in Jocelyn Downie, Timothy Caulfield and Colleen Flood, *Canadian Health Law and Policy*, Butterworths: Markham, Second Edition, 2002, pp. 459-500.

447 *Sponsors of research* – sponsors of research take responsibility not only for financing
448 research but also for the initiation and management of research. Typical industry
449 sponsors of research in Canada include Canada’s Research-Based Pharmaceutical
450 Companies (Rx&D), Non-Prescription Drug Manufacturers Association of Canada,
451 BIOTECanada, and Medical Devices Canada. Industry makes compliance with national
452 or international regulatory requirements a condition of sponsorship and conducts routine
453 monitoring activities and audits of research sites.

454

455 *Governments* – Health Canada regulates research involving drugs, biologics, and medical
456 devices through the *Food and Drugs Act*, its regulations, and policy directives. The
457 *Assisted Human Reproductive Act* regulates research involving human embryos. Industry
458 Canada regulates research involving personal information through the *Personal*
459 *Information Protection and Electronics Documents Act*. Some provincial/territorial
460 governments regulate research through legislation that relates directly to the ethics review
461 of research (e.g., Québec and Newfoundland and Labrador), privacy legislation, and
462 various statutes that relate to the administration of the health care system (e.g., consent
463 legislation). In addition, research in Canada can be subject to oversight through
464 legislation from other countries if, for example, the research is directed toward the
465 approval of a new drug in those other countries or funded by foreign governments (e.g.,
466 studies regulated by the US Food And Drug Administration or funded by the US Health
467 and Human Services are subject to US regulatory requirements). Canadian researchers
468 can also be subject to oversight through legislation in other countries if, for example, they
469 are conducting research in those countries (e.g., an HIV drug trial in Nigeria).

470

471 *Professional organizations* – some professional organizations consider compliance with
472 research ethics policies as part of professional regulation. For example, the College of
473 Physicians and Surgeons of Alberta has made ethics review a condition for all Alberta
474 physicians conducting research.

475

476 *Journal editors* – a group of editors of leading medical journals have made compliance
477 with ethics guidelines a condition of publication in their journals.

478

479 *Courts* – Canadian courts play an oversight role with respect to research through torts,
480 contracts, and property law. For example, if a researcher failed to obtain free and
481 informed consent to participate in a research study, she could be sued by the research
482 participant for battery. Research Ethics Board (REB) members could be sued for
483 negligence if an REB failed to adequately review a consent form and a risk materialized
484 that clearly should have been, but was not, mentioned in the consent form.

485

486 The current situation then is complex- many players overseeing many other players
487 through the use of many instruments. There are significant gaps in this oversight
488 function – e.g., *some* research is subjected to oversight, *some* sponsors are governed
489 by *some* guidelines or regulations. And where conflicts and contradictions occur, no
490 mechanism exists to reconcile these differences, or to provide leadership and
491 guidance in the face of emerging ethical issues.

492

493 **2.4 Concerns about the Current System**

494 In recognition of the number of commissioned reports, articles and conference
495 presentations that have explored, analyzed, and described the range of problems or
496 challenges to the existing situation in Canada, the Committee believes it does not need to
497 repeat this work in great detail. Readers not familiar with this body of work are invited to
498 read through some of the literature cited in the footnotes.¹⁴ The Committee would,
499 however, like to identify the following problems as particularly acute and serious enough
500 to warrant the kind of reform we are proposing:

501

502 *Comprehensiveness of the System*

503 The current system does not cover all research involving humans across Canada. There
504 are many gaps in the system, including unfunded research, non-drug trials in physician's
505 offices, some community-based research, and some government and private sector
506 research. Indeed, Canada's definitive policy on the ethical conduct of research involving
507 humans, the TCPS, applies only to research conducted at institutions receiving funds
508 from the three federal research granting agencies, or where adopted by a particular
509 organization (e.g., the Alberta College of Physicians and Surgeons of Canada or the Nova
510 Scotia Health Research Foundation).

¹⁴ See, for example, Jocelyn Downie, "Contemporary Health Research: A Cautionary Tale" *Health Law Journal*, Special Edition, 2003, pp. 1-20; George F. Tomossy, David N. Weisstub and Serge Gauthier, "Regulating Ethical Research Involving Cognitively Impaired Elderly Subjects" in David Weisstub, S. Thomasma, Serge Gauthier, and George Tomossy, *Aging: Decisions at the End of Life*, Kluwer Academic Press: Dordrecht, 2001, pp. 227-254; Willy Carl Van den Hoonaard, *Walking the Tightrope: Ethical Issues for Qualitative Researchers*, University of Toronto Press: Toronto, 2002; Trudo Lemmens, "Federal Regulations of REB Review of Clinical Trials: A Modest but Easy Step towards an Accountable REB Review Structure in Canada" *Health Law Review*, 2005, 13, pp. 39-50; C. A. Schuppi and D. Fraser, "Factors Influencing the Effectiveness of Research Ethics" *Journal of Medical Ethics*, 33, 2007, pp. 294-301.

511

512 *Lack of Effective Coordination of Research Oversight*

513 Canada lacks a higher level coordination of the governance of research involving
514 humans. The result is that the current oversight 'system' is unnecessarily fragmented.
515 There is often inadequate transparency and effective public accountability. There often
516 appears to be confusion among key players regarding their roles and responsibilities
517 resulting in an inability to coordinate action to address ongoing problems and meet new
518 challenges.¹⁵ Since its inception, the Interagency Advisory Panel on Research Ethics
519 (PRE) has endeavoured to bring transparency and community engagement to the process
520 of ethics policy development, nevertheless, much remains to be done to achieve a sense
521 of cohesion and public accountability in the overall oversight process.

522

523 *Lack of Good Governance at the Organizational Level*

524 Some research organizations may not have in place good governance systems for the
525 research involving humans conducted under their auspices. Problems include a lack of
526 resources, inefficient REBs, ineffective or absent monitoring, a lack of organizational
527 knowledge of, and comprehensive policies governing research involving humans
528 activities, and a lack of transparency and accountability.

529

530 *Conflicts of Interest or Competing Interests*

531 Serious competing interests are evident throughout the system. For example, federal
532 research granting agencies promote research and at the same time are stewards of the

¹⁵ This is particularly troublesome given that REBs perform a central public function of human research participant protection. Despite the importance of this public function, it is often not fully recognized and supported at higher levels of government.

533 predominant research ethics policy in Canada. While the Councils regularly seek to
534 manage these dual responsibilities, a transfer of the regulatory function to an independent
535 body could serve to eliminate the difficulty inherent in the present situation. Though
536 some REB members may promote a culture of ethics to ensure that their organization
537 conducts research according to high ethical standards, other REB members may have
538 interests in specific research projects or, more commonly, may have interests in the
539 promotion of research within the organization which may be at odds with human research
540 protection. Though many organizations have made their REBs more structurally
541 independent, others may not have sufficient independence within their local
542 organizational structure to adequately protect research participants.

543

544 *Lack of Consistency among Research Ethics Policies and Guidelines*

545 The existing research ethics governance policy statements, guidelines, and regulations are
546 not consistent in all aspects of research involving humans. This means that research
547 conducted under the auspices of one set of guidelines may be subject to very different
548 rules when conducted under the auspices of another set of guidelines. Indeed, research
549 might be permitted in one context and not in another depending on the source of the
550 funding. In addition, it is important to recognize that Canadian researchers are active in
551 international research and a lack of consistency between Canadian and international
552 requirements may confuse researchers and REBs. Work is underway by PRE and others
553 to address the lack of harmonization across policies where it is appropriate. This may
554 result in a resolution of some of the current issues in the foreseeable future but the
555 challenges are sufficiently widespread to continue to require attention.

556

557 *Consistency and Duplication of Ethics Review*

558 There is concern about an unacceptable level of variability with respect to REB decisions
559 on the same or similar research applications. This is seen in multi-centre research where
560 some REBs may give disparate opinions on issues not related in any way to local context.
561 This variability may reflect: a lack of expertise among REB members; the strain REB
562 members face in reviewing too many applications; inconsistent interpretation of existing
563 policy and standards; or the lack of clear guidelines and standards for REBs.

564

565 Duplication of ethics review is a major impediment to the timely conduct of multi-centred
566 and collaborative research. Organizations uncertain about the rigour and competency of
567 other organizations' review processes generally require local review; a practice which can
568 result in a series of duplicative reviews taking many months. The result is an inflated
569 workload for REBs, and unacceptable, even destructive delays for researchers, with no
570 demonstrated increase in human research participant protection.

571

572 *Relevant Expertise of REB Members*

573 Related to consistency, there is a recognized problem with the relevant expertise of some
574 REB members. Some members of REBs are not sufficiently informed about the
575 requirements (including regulations, guidelines, and policies) appropriate to the nature of
576 the research being reviewed; some REBs do not have members with appropriate levels of
577 expertise (for example, in ethics, law, or specific research methods, e.g., qualitative
578 research). Chronic high turn-over rates on REBs are common, reflecting the heavy

579 workload borne by REB members, and the general lack of recognition given to this work
580 by organizations. The cost of this includes a lack of efficiency when REBs are on
581 continuous learning-curves, lack of consistency in REB reviews, over-reaching of REBs
582 due to uncertainty about the interpretation of guidelines and regulations, and failing to
583 follow the TCPS and other relevant guidelines and policies thereby failing to adequately
584 protect participants.

585

586 *Compliance*

587 There is the perception of a lack of compliance at many levels in the current system due
588 in part to a lack of public accountability. Some research organizations often do not
589 conduct adequate or, indeed, any monitoring of ongoing research after a project has been
590 given initial ethics approval. Research organizations often do not have systems in place
591 to monitor ongoing research and depend upon researchers to provide reports of problems.
592 Health Canada has direct jurisdiction over sponsors and researchers but only indirect
593 jurisdiction over REBs involved in regulated research. Although, Health Canada has
594 sporadically provided summary reports of its inspections, unlike regulators in the US, it
595 does not publish the compliance status of researchers or sponsors.

596

597 **2.5 Other Options Considered**

598

599 In Sections 3, 4, and 5 of this Report, the Committee presents its recommended option in
600 response to its mandate. In coming to its conclusions, however, the Committee
601 considered a number of options and variations on options. The following section

602 highlights some of these options and identifies the likely outcome of not responding to
603 the concerns identified in the previous section.

604

605

606 **2.5.1 Status Quo**

607

608 The Committee considered at length, but unanimously rejected, the suggestion that the
609 current situation required no reform, or only minor modification. We believe that a
610 fundamental reorganization is needed to ensure that those problems articulated in the
611 previous section can be adequately and responsibly addressed. In addition, we believe
612 that such change is critical if the Canadian research community is to cope with the ethical
613 challenges of a future which promises increasing technological complexity and
614 methodological invasiveness, and greater potential threats to individual privacy. In
615 addition, the Committee believes that the following will occur if the status quo is
616 retained:

617

618 ○ Canadian research organizations with strong links to the United States, especially
619 the National Institutes of Health, will seek US accreditation. Essentially, Canadian
620 taxpayers will be paying for US accreditation of some of their public institutions.

621

622 ○ There will be no effective resolution of the policy conflict of interest with the
623 Federal research granting agencies remaining the stewards of the TCPS.

624

625 ○ There will be little possibility of a pan-Canadian research ethics education
626 strategy (the importance of which has been widely endorsed) without a vehicle to
627 provide the necessary leadership.

- 628
629 ○ There will continue to be serious challenges to research given the lack of
630 coherence and coordination at a pan-Canadian level. Canadian researchers will
631 continue to face barriers to research especially for multi-centred research resulting
632 in less innovation and fewer benefits of research for Canadians.
- 633
- 634 ○ Given the competitiveness of international research, the continued lack of
635 consistency between Canadian and international requirements will maintain
636 barriers and diminish the attractiveness of Canada as a location for such research.
- 637
- 638 ○ There will be an erosion of public trust in research decreasing the willingness of
639 potential research participants to enroll in research, since there will be an
640 impression that Canadian research participants will not have their interests
641 sufficiently well protected.

642
643 **2.5.2 Public Assurance System**

644
645 Among other alternative approaches to governance and oversight, the Committee spent
646 some time considering the Public Assurance System (PAS) proposed by the SSHRC in
647 2001.¹⁶

648

649 In its early discussions, SSHRC posited the need for an asymmetric approach to
650 governance, given the diversity of disciplines and variability of risk which every
651 governance model needed to address. However, recognizing the inability to manage such
652 independent processes in other countries, SSHRC ultimately proposed one assurance

¹⁶ Available online at www.sshrc-crsh.gc.ca/

653 model for the oversight of all human participant research in Canada. The SSHRC
654 document states that,
655 ...an assurance system with broad flexibility and scope for all disciplines should
656 provide subjects with better protection, the public with immediate assurance, be
657 applicable to all disciplines and yet allow for more stringent oversight where
658 necessary, and promote remedial or formative development of the review process
659 in early stages of its implementation, and growth and refinement of the TCPS.¹⁷
660

661 As well, the SSHRC proposal noted that such a system, to be successful, had to be
662 accompanied by “a promotion of best practices and educational material and activities
663 that would consolidate and enhance the consistency of application of the TCPS across the
664 country while at the same time respecting the varied research disciplines and their
665 methodologies.”¹⁸

666

667 The proposed PAS model was to be voluntary and be based upon three documents: the
668 TCPS (understood as a living and evolving document); the institutional policies and
669 procedures implementing the TCPS; and the Memorandum of Understanding on the
670 Roles and Responsibilities between the three federal research granting agencies and
671 research institutions.

672

673 The main mechanism of oversight was to be annual reports and site visits that would be
674 monitored and implemented through the PRE and its Secretariat on Research Ethics.

675

676 In assessing the merits of the proposed PAS system, the Committee noted that it included:

¹⁷Ibid., p. 11.

¹⁸Ibid., p. 11.

- 677 ○ One system for research ethics for all institutions receiving funding from the three
678 federal research granting agencies
- 679 ○ A response to some of the gaps in existing systems of oversight
- 680 ○ The provision for a flexible, discipline specific approach
- 681 ○ A focus on the need to develop an educational plan to imbue the system with a
682 culture of ethics
- 683 ○ A diagnostic and formative approach rather than a punitive and top down
684 approach
- 685 ○ The identification of emerging issues and policy problems
- 686 ○ A respect for the autonomy and governance structures of research organizations
- 687 ○ Peer review
- 688 ○ Sanctions for infractions
- 689
- 690 The Committee considered and adopted a number of these points in its recommended
691 option. However, the PAS model was not recommended in its entirety because of the
692 limitations noted below:
- 693 ○ Its lack of standards and its highly flexible approach could result in inequity and
694 inconsistency in the direction given to institutions and REBs through the
695 assessment process
- 696 ○ The system would not be comprehensive in that it would continue to be under the
697 purview of the three federal research granting agencies and so not extend to other
698 research stakeholders in Canada

699 ○ It would not provide a vehicle for the coordination of policies across the various
700 sectors conducting research, i.e., in research organization not covered by an MOU
701 with the federal research granting agencies.

702 ○ It would lack authority to effect positive change or to deal with non-compliance

703

704 In brief, the PAS would not provide for sufficient reform to address existing gaps,
705 inconsistencies, and conflict of interest.

706

707 **2.5.3 Accreditation Models**

708

709 The Committee considered a number of accreditation models including NCEHR,
710 Canadian Council on Animal Care (CCAC), AAHRPP, and the Canadian Council for
711 Health Services Accreditation. The following discusses two models applicable to human
712 research.

713

714 **2.5.3.1 AAHRPP Model of Accreditation**

715

716 AAHRPP was incorporated as a non-profit organization in the United States in 2001 to
717 accredit Human Research Protection Programs in organizations that conduct or review
718 research with humans. Responding to increased public concern for protecting research
719 participants, AAHRPP accreditation seeks not only to ensure compliance with US federal
720 regulations, but to help organizations reach higher performance standards.

721

722 The Committee met with the Executive Director of AAHRPP and was briefed about its
723 creation, acceptance by the research community and challenges that it has faced. In
724 addition, the Committee membership included an AAHRPP Board member as well as

725 two members involved in professional accreditation who were resources to the
726 Committee on operational aspects of the accreditation process.

727

728 **2.5.3.2 NCEHR's Model of Accreditation**

729

730 In 1999, NCEHR established a Task Force to Study Models of Accreditation for Human

731 Research Protection Programs in Canada which reported on its deliberations in 2002.

732 This report addressed many of the advantages of accreditation and recommended a

733 system for Canada. Subsequently, a second Task Force was established to examine the

734 Development of an Accreditation System for Human Research Protection Programs.

735 This Task Force recommended that NCEHR take on the role of the Canadian accreditor

736 for human research.¹⁹ The Committee considered both reports from NCEHR and

737 arranged for the co-chairs of the second taskforce to present their model to Committee.

738 The Committee membership also included two members of the second NCEHR taskforce

739 and two members who had participated in the taskforce sub-committee on accreditation

740 standards.

741

742 **2.5.3.3 Strengths and Weakness of Accreditation**

743 Considering both the NCEHR and AAHRPP models together, the following will consider

744 the strengths and weaknesses of an option that only added a Canadian accreditation

745 process for human research in Canada.

746

747 The strengths of these accreditation models include:

¹⁹ Both reports are available online at www.ncehr-cnerh.org

- 748 ○ An accreditation system could be established that is proportionate, flexible and
749 adaptable allowing organizations to implement ethics review programs that are
750 suitable to their structure as well as the volume and nature of the research that
751 they conduct.
- 752 ○ While organizations would have flexibility in how they implement the standards
753 of accreditation, consistency in the interpretation of ethical and regulatory
754 requirements across organizations could also be enhanced.
- 755 ○ The system would be peer based both for establishing standards and assessing
756 organizations against the standards. By creating an inclusive environment, all
757 stakeholders involved in the governance, conduct, and review of research could
758 feel that their interests were represented.
- 759 ○ The accreditation system would be educational with the objective of continuous
760 quality improvement. The use of peers for the conduct of site visits would
761 support a culture of education and a community of practice across organizations
762 seeking accreditation, the community from which site visitors are selected, and
763 the accrediting body.
- 764 ○ Accreditation could enable the acceptance among organizations of each other's
765 review policies and procedures, facilitating a reduction in duplication and
766 inconsistencies in the review process.

767
768 The Committee identified the following weaknesses of an option that only added an
769 accreditation process to the current situation in Canada:

- 770 ○ The system would increase the burden of the current volunteer network as there
771 are a limited number of peers in Canada, who are qualified by training, education

- 772 and experience, to establish standards and assess organizations against the
773 standards.
- 774 ○ Although the accreditation system tries to manage the conflicts through the
775 application of clear standards, tensions that may occur between research
776 organizations and their REBs may not be resolved.
 - 777 ○ These accreditation systems are voluntary and, although they may become
778 mandatory at some point in the future, in the interim there will necessarily be a
779 two-tiered system of research organizations: those that are accredited and those
780 that are not.
 - 781 ○ The problem with the TCPS resting within the three federal research granting
782 agencies, and not being applicable to other research, would not be resolved.

783

784

785 **2.5.4 Replacing Institutional REBs by Regional REBs²⁰**

786

787 Another option the Committee reviewed involved the suggestion that REBs should be
788 removed from the research organizations and should instead function within a pan-
789 Canadian system of regional and national REBs. This argument is grounded in the belief
790 that independent REBs operating through such a system would address many of the
791 concerns outlined above in respect of the current concerns. The advantages of removing
792 the REBs from the organizations include the following:

793

²⁰ For sections 2.5.4 and 2.5.5, see Jocelyn Downie, “The Canadian Agency for the Oversight of Research Involving Humans: A Reform Proposal” *Accountability in Research*, 13, 2005, pp. 75-100.

- 794 ○ greater efficiency for multi-centre studies because, with the centralization of
795 administration, researchers in such studies will not have to respond to multiple
796 conflicting REB reviews;
797
- 798 ○ greater consistency because, again with the centralization of administration, there
799 will be consistent operating procedures across regional REBs and better
800 communication between REBs;
801
- 802 ○ fewer conflicts of interests within REBs since members would not face a potential
803 conflict of obligations to research participants and to their host institution. The
804 regional REB would not report to any specific research organization thus
805 resolving a potential existing structural conflict of interest when institutional
806 REBs report to their office of Vice President of Research.
807
- 808 The Committee rejected this option in part because of the following limitations:
- 809 ○ the logistical challenges in developing a system that would need to draw upon the
810 methodological expertise that exists within institutions without having the
811 financial resources to do so. Currently, the costs are borne by the institutions that
812 provide the administration and the review expertise.
- 813 ○ the continuing requirement for ethical review of student research that would still
814 need to be provided by universities and colleges
- 815 ○ the loss of the ‘virtuous learning loop’ that can exist when the research
816 community is engaged in the ethical review of the research it conducts.

- 817 ○ potential for greater bureaucratization of the ethics review function in Canada
818 ○ institutional liability for the review and conduct of research remains an
819 outstanding issue
820 ○ loss of local knowledge about both the researchers and the context of the research
821 including other organizational policies and procedures that would apply to the
822 conduct of research.

823

824 **2.5.5 Regulation through Federal Statute**

825 The Committee also considered the argument that all research involving humans should
826 be regulated in Canada by way of a federal statute. This argument is grounded in the
827 belief that federal legislation would address many of the concerns outlined above in
828 respect of the current challenges. The advantages of federal legislation include the
829 following:

830

- 831 ○ the force of law would increase compliance with the rules governing research
832 involving humans
833 ○ depending on how the statute was written, the comprehensiveness of coverage of
834 the rules could be increased as all research could be captured through the
835 legislation
836 ○ there would be greater consistency across the country as it would not be left to
837 provincial/territorial governments to fill the current oversight gaps
838 ○ the situation would be avoided where some jurisdictions would have lower
839 standards than others and thus provide lesser protection for research participants.

840 Such a situation may create an additional problem of some research funders,
841 sponsors, or researchers only wishing to support or conduct research in
842 jurisdictions with weaker standards

- 843 ○ savings would be realized as researchers conducting research in multiple
844 jurisdictions would not need to spend resources to comply with a series of
845 different rules established by the various provinces and territories
- 846 ○ accountability would be increased as the oversight system would be made
847 accountable directly to Parliament.

848

849 Notwithstanding these benefits, the Committee rejected this option as being unrealistic at
850 this time, given the political and constitutional obstacles and the lengthy time-frame that
851 pursuing a statutory solution could pose. The Committee is of the opinion that, strong
852 support from members of the Sponsors' Table, and the endorsement by its member
853 organizations, can be an effective lever in broadly implementing the comprehensive
854 reform proposed by the Committee. However, the Committee also realizes that should
855 this endorsement not be achieved, a federal statute may be the only alternative to address
856 the current lack of systemic oversight for human research in Canada

857

858 **2.5.6 US Accreditation**

859 Some have suggested that Canada does not need to develop its own accreditation system
860 since it can easily rely upon the current system developed in the US. The Committee has
861 rejected this view because of the following considerations:

862

- 863 ○ US accreditation would ultimately hold Canadian research organizations
864 accountable to standards developed from different social, political, educational
865 and healthcare contexts. Canadian research organizations need to operate within
866 different contexts of culture and social policy and need to respond to a different
867 set of legislation, policies, and guidelines than US research organizations.²¹
868
- 869 ○ Simply relying upon the US or other international accreditation processes is the
870 easy way out of a complex situation. It does not show the type of leadership that
871 Canadians expect from those responsible for its public institutions or for the
872 protection of Canadians.
873
- 874 ○ Relying solely upon the US accreditation system is a serious issue of sovereignty.
875 A number of Canadian research organizations and governments have developed a
876 uniquely Canadian system that meets international expectations. Further
877 developing and enhancing this system is the responsibility of all Canadian
878 research organizations and stakeholders.
879
- 880 ○ Relying only on an accreditation function leaves many concerns in the area of
881 policy and education unaddressed.
882

²¹ Although accreditation is important to international mobility and partnerships in research and practice, this can best be achieved through the mutual recognition of national accreditation systems. As a recent example, as of February 2007, the American Psychological Association, supported by over 75% of accredited doctoral and internship programs in professional psychology in Canada, voted to stop its accreditation activities in Canada. Canadian programs are now accredited by the Canadian Psychological Association which has been accrediting in Canada for 22 years.

883 ○ The costs of participating in and sustaining the US system are considerable as will
884 likely be the costs for a Canadian system. However, in the latter case, Canadian
885 funds remain in Canada and contribute to building the expertise and the system
886 for human research participant protection.

887 For these reasons, the Committee believes that this option is not viable especially in the
888 long term.

889

890 **2.5.7 Canadian Council on Animal Care**

891

892 The Committee received a presentation by the Canadian Council on Animal Care
893 (CCAC). While human research is arguably more ethically and legally complex, the
894 Committee considered the option of recommending an organization with a structure
895 similar to the CCAC.²² The CCAC model has a number of advantages including:

896

- 897 ○ Promotes partnership with research organizations and a community of practice in
898 Canada
- 899 ○ Successfully promotes a culture of good animal practice and care
- 900 ○ Provides effective leadership in Canada
- 901 ○ Provides national education workshops and supports local educational activities
- 902 ○ Has been a driver in promoting behavioural change amongst investigators
- 903 ○ Facilitates development among policy, education and certification processes while
904 minimizing conflict of interests
- 905 ○ Has broad stakeholder and volunteer base

²² For a detailed comparison of the governance structure for animal research and human research, see Catherine Schuppi and Michael McDonald, “Contrasting Modes of Governance for the Protection of Humans and Animals in Canada: Lessons for Reform” *Health Law Review*, 13, 2005, pp. 97-106.

- 906 ○ Has developed an effective compliance mechanism through its capacity to remove
907 the certificate of good animal practice
- 908 ○ Promotes continuous quality improvement within its organization through
909 appropriate feedback loops between policy generation, education, and compliance
910 activities
- 911 ○ Is nationally and internationally recognized and respected.

912

913 The Committee does not accept the option of simply reproducing the CCAC model for
914 human research. However, the CCAC model does provide the following insights to be
915 considered for a similar organization for human research:

916

- 917 ○ Financial support for the organization should not be linked to the federal research
918 granting agencies although it may be linked to the federal government
- 919 ○ Stronger links would need to be developed between the organization and
920 provincial and national regulatory bodies
- 921 ○ Greater consistency would be needed among site visitors to promote equitable
922 application of the evaluation process
- 923 ○ More effective compliance mechanisms would be needed (e.g., alternatives to the
924 MOU used by the Tri-Councils)
- 925 ○ Broader reach, going beyond Tri-Council funded research, would be needed.

926

927 In summary, the Committee is of the view that the CCAC model has many attractive
928 features that should be incorporated into an oversight system for human research. The
929 Committee's recommended model borrows some elements of the CCAC model.

930

931 **2.5.8 Other International Developments**

932 It is important to point out that in addition to the US, other countries also have
933 accreditation systems. New Zealand has had an accreditation system for ethics
934 committees for some time. Under the *Health Research Council Act* (1990), the
935 accreditation of ethics committees in New Zealand allows for the delegation of ethics
936 review to local ethics committees. However, this system does not have a site visit
937 program. In the UK, the National Research Ethics Services is responsible for the
938 accreditation of research ethics committees operating within the National Health Services
939 system. This accreditation program includes site visits and assessment according to
940 published standards. This system was established in response to the *EU Clinical Trial*
941 *Directive 2001/20/EC of the European Parliament and the Council of the European*
942 *Union* which has implications for the operation of ethics committees in relation to clinical
943 trials of investigational medicinal products. The National Health Services extends its
944 accreditation program for all research involving humans under its auspices. At this time,
945 it is difficult to assess how many more national governments will develop accreditation
946 programs. The recommendations included in this report offer an opportunity for Canada
947 to take a global leadership role in developing its own accreditation system that could be a
948 model for other nations interested in promoting high ethical standards in research
949 involving humans.

950

951 3. An Overview of the Proposed New Canadian System of Oversight for Research
952 Involving Humans

953

954 The Committee is of the view that research involving humans in Canada should be

955 governed by a single system. This system should apply to research in all disciplines,

956 should bring all oversight functions together into one organization, and should apply to as

957 much research as possible.

958

959 *One Oversight System* – The Committee believes that there is validity to the concerns

960 expressed by some in the social sciences and humanities communities that, in practice,

961 the current Canadian policy framework of the TCPS was not designed (and has not

962 operated) with a great enough understanding of, or sensitivity to, social sciences and

963 humanities research. However, the Committee believes that it is possible to design a

964 system with an understanding of, and sensitivity to, all kinds of research and that there is

965 not, in principle, any reason for having different systems of oversight apply to different

966 kinds of research classified according to type such as qualitative or quantitative, or

967 discipline. Not only is there high risk biomedical research and low risk social science

968 and humanities research, there is also low risk biomedical research and high risk social

969 science and humanities research. Therefore, while it is reasonable to argue that the level

970 of scrutiny applied to research should vary by level of risk, it is not reasonable to argue

971 that it should vary by type or discipline. The Committee takes the view that all research

972 involving humans is about discovery and enhancing understanding of phenomena that

973 affect or are affected by humans. Risk to humans by participating in each research study

974 must be calibrated by both the researchers who design and conduct it and by members of

975 REBs who review and approve it. A single oversight system contributes to this
976 calibration by setting standards that address how risk should be assessed and how the
977 type and level of protection based on the level of risk should be determined to protect
978 participants for all types of research. During the process of accreditation, site assessors
979 apply these standards when reviewing decisions that have been taken by REBs and by
980 observing REBs in action. The assessors scrutinize the application of standards for
981 assessing risk and its implications for protective activities. This allows the assessors to
982 identify when appropriate assessment of risk and its consequences are in place, and when
983 risk is unjustifiably minimized or equally unjustifiably exaggerated. Patterns of the two
984 inappropriate types of risk assessment can be described and remedial actions prescribed.

985

986 *Functions* – the Committee believes that the three oversight functions of policy,
987 education, and accreditation should be brought together into one organization. While
988 concerns might be raised about conflicts of interest, the Committee believes that the
989 potential conflicts are manageable and that the potential benefits of bringing the three
990 functions together outweigh the potential risks. The arguments in support of this position
991 are found earlier in this Report in the discussion of the alternative models of accreditation
992 alone and later in this Report in the discussion of the education function.

993

994 *Scope* – while it might be argued that having a single system apply to all research
995 involving humans conducted in Canada is the ideal, the Committee is of the view that the
996 federal legislation that would be required to realize this ideal is not a viable option at
997 present. That said, the Committee is of the view that the closest approximation of the

998 ideal should be sought and, therefore, all those with the authority to mandate adherence to
999 the proposed system should do so in order to have the system reach as much research as
1000 possible.

1001

1002 It should be emphasized that, while the Committee recommends a unified approach, this
1003 approach can and should be flexible and the system should ensure that the oversight is
1004 proportionate to the volume and nature of research, as well as the level of risk for
1005 participants.

1006

1007 **3.1 Goals**

1008

1009 Following from its mission to provide protection for human participants in research, the
1010 Committee defined the following goals for the oversight system:

1011

1012 ○ ensure that the rights of research participants are respected

1013

1014 ○ ensure the safety of research participants

1015

1016 ○ promote the well being of Canadians

1017

○ build and maintain trust among research funders, researchers, research

1018

organizations, research participants, and the Canadian public

1019

○ equitably balance the harms and benefits of research

1020

○ recognize the importance of, and facilitate the conduct of research

1021

○ reduce or avoid duplication and inconsistencies with existing rules and procedures

1022

governing human research

1023

○ promote the development of a culture of ethics in research, rather than mere

1024

conformity to a body of rules

1025

1026 **3.2 Attributes**

1027 The Committee agreed that a system with these goals should have the following

1028 attributes:

- 1029 ○ be comprehensive and broadly applicable to all types of human research
- 1030 regardless of funding source
- 1031 ○ be respectful of the division of powers among federal, provincial, and territorial
- 1032 governments
- 1033 ○ be flexible and permit safeguards for participants to be tailored to the character of
- 1034 the proposed research
- 1035 ○ be peer-participatory in all functions
- 1036 ○ be inclusive of all stakeholders
- 1037 ○ be publicly accountable
- 1038 ○ be administratively and financially efficient

1039

1040 **3.3 Functions**

1041 The Committee concluded that the Canadian oversight system should be responsible for

1042 three functions that follow from these goals and attributes:

- 1043 ○ policy
- 1044 ○ education
- 1045 ○ accreditation

1046

1047 The Committee also concluded that these functions should be exercised together in such a
1048 way as to produce continuous improvements in the system. Together they will offer the
1049 following benefits:

1050 For organizations:

- 1051 ○ A culture of responsible conduct of research would be promoted within the
1052 organization at all levels.
- 1053 ○ Risk to research participants would be reduced.
- 1054 ○ More effective processes that are proportionate to the volume and nature
1055 of research conducted by the organization are encouraged.
- 1056 ○ Increased confidence that all applicable ethical and regulatory
1057 requirements are met.
- 1058 ○ A basis for mutual recognition of other organizations involved in multi-
1059 center research is provided.

1060 For researchers:

- 1061 ○ Fewer duplicate reviews for multi-centre research.
- 1062 ○ Improved stability and competence in the organizational REB system.
- 1063 ○ Enhanced efficiency in the administrative aspects of ethics review.
- 1064 ○ Improved access to tools for education in research ethics for themselves
1065 and for trainees.
- 1066 ○ Greater transparency and, ultimately, coherence to requirements through
1067 the application of standards.
- 1068

1069 For sponsors of research:

1093

1094 **4. The Canadian Council for the Protection of Human Research Participants**
1095 **(CCPHRP)**

1096
1097 The Committee recommends that a Council be established as a non-governmental
1098 organization under the *Corporations Act* operating collaboratively with those involved in
1099 the conduct or review of research, including research participants. It should have the
1100 following organizational structure.

1101

1102 **4.1 Board of Directors**

1103 The Council should have a Board of Directors of up to 15 individuals appointed for their
1104 expertise relevant to the conduct and oversight of research involving humans. They
1105 should serve as individuals and not as representatives of specific organizations.

1106

1107 The Board of Directors should be responsible for providing organizational policy
1108 direction to the Council and for approving its budgets. It should select the Executive
1109 Director, provide guidance to him/her on major issues, and do annual performance
1110 reviews. The organizational culture embraced and fostered by the Board should be one
1111 that promotes achieving the mission and goals of the organization in a tangible and
1112 fiscally accountable manner.

1113

1114 **4.2 Members**

1115 The Board of Directors would be directly accountable to a body of Members whose
1116 function would be analogous to those of shareholders under the *Canada Corporations*

1117 *Act.* They would appoint the Board of Directors, appoint the auditor of the Council, and
1118 periodically receive reports and financial statements of the Council.
1119 Decisions about the composition of the Members should in the first instance be made by
1120 the Sponsors' Table. The Members should be drawn from organizations committed to
1121 fostering human research participant protection in Canada. In the interests of
1122 workability, the number of Members might best be in the range of 15-20. In addition to
1123 providing a line of accountability for the Board, the Members could promote the interests
1124 of the Council through collaboration with the research community in general.
1125 While the Council would be directly accountable to the Members, it would also, albeit
1126 less formally, be accountable to the Canadian public, Parliament, the
1127 federal/provincial/territorial governments and legislatures, and other stakeholders.

1128

1129 **4.3 Office of the Executive Director**

1130 The Office of the Executive Director should include the normal leadership and
1131 operational duties of such a position including the quality assurance for the Council itself.
1132 The Committee is of the view that the Council should adopt quality assurance principles
1133 which will allow it to evolve and quickly adapt to the needs and concerns of all of the
1134 relevant stakeholders.

1135

1136 Another key role for the Executive Director should be the establishment of
1137 communications from the outset with all of those involved with research. The debate
1138 over systems of oversight that has taken place in the past decade or so has seen a number
1139 of different proposals advanced at one time or another. To ensure that misapprehensions

1140 are kept to a minimum as the Council's work program takes shape, it will need to
1141 communicate clearly about what it is and is not going to do. It will also be important that
1142 the communications be multilateral; organizations and individuals of the research
1143 community, as well as research participants and the public, should be given an
1144 opportunity to feed into the evolution of the Council.

1145

1146 **4.4 Policy**

1147 The Committee considers it important, in the interests of achieving maximum coherence,
1148 that the functions of policy development, education, standard setting, and accreditation
1149 should all be vested in the same organization. The Council should be responsible for the
1150 development and interpretation of the Canadian policy statement as well as other
1151 Canadian policies for research involving humans focusing on the protection of human
1152 participants. This recommendation would address the concern with the TCPS resting
1153 under the auspices of the federal research granting agencies. Allowing for the Council to
1154 steward the policy would facilitate a broader representation in terms of its development
1155 and a wider application in terms of its use.

1156

1157 In order to avoid a policy vacuum at the outset, the Council should adopt as its initial
1158 policy base the TCPS, which it should re-name the Canadian Policy Statement on
1159 Research Involving Humans (CPSRIH).

1160

1161 From this initial policy base, the Council should then identify and move quickly to put in
1162 place such modifications as it may judge necessary for the purpose of making the

1163 CPSRIH more broadly applicable to all types of research involving humans in Canada.
1164 Particular attention should be paid to ensuring that the CPSRIH reflects an understanding
1165 and appreciation of the significant differences among various disciplines and that it
1166 moves beyond the real or apparent biomedical focus of previous policy statements and
1167 guidelines.

1168

1169 In undertaking revisions to the CPSRIH, the Council should address issues that have in
1170 the past given rise to difficulties in the implementation of the TCPS, particularly in
1171 relation to the social sciences and humanities research community. Specifically, attention
1172 should be given to the definition of human research requiring ethics review, the concept
1173 of minimal risk, the different kinds of ethics review (e.g., expedited vs. full review), and
1174 ways of giving practical expression to the concept of proportionality. Particular attention
1175 should be paid to ensuring that the CPSRIH reflects an understanding and appreciation of
1176 the significant differences between various disciplines and moves beyond the real or
1177 apparent biomedical focus of previous policy statements and guidelines. In pursuing these
1178 issues, the Council should make particular efforts to build on the substantial amount of
1179 research, writing, and consultation done by the PRE as well as other organizations
1180 involved in research ethics.

1181

1182 The Council should also ensure that its work intersects with and supports that of federal,
1183 provincial, and territorial governments as well as other relevant bodies such as those that
1184 accredit hospitals and professional educational programs. Specifically, the Council
1185 should examine areas where the CPSRIH could be in conflict with other research

1186 governance instruments. Where there is determined to be conflict, the Council should
1187 seek to resolve it, where possible and appropriate, through harmonization initiatives with
1188 the relevant authorities and/or through revisions to the CPSRIH. Interpretive notices
1189 should be released as this work develops.

1190

1191 Relations with governments and regulatory systems (e.g., the *Food and Drugs Act* and
1192 Regulations) will require particular attention. The Committee hopes that through dialogue
1193 the Council and governments would, in many cases, arrive at ways to harmonize their
1194 respective policies. Ultimately, however, a prerogative of governments is that they are
1195 entitled to the final word about whether and in what degree they will modify their
1196 governance instruments. Where they choose not to do so, the normal principles of
1197 democratic accountability would apply; their publics would judge, favourably or
1198 unfavourably, the decisions that governments have taken.

1199

1200 The Council should also ensure that, where appropriate, there is consistency with
1201 international regulatory requirements that impact some research activities in Canada. For
1202 example, over 500 organizations hold a US Federal-Wide Assurance in Canada
1203 (http://www.hhs.gov/ohrp/assurances_index.html). This means that these organizations
1204 have agreed to adhere to US regulations of the Department of Health and Human
1205 Services. For research involving drugs and medical devices, there are international
1206 efforts to harmonize the regulatory requirements by the International Conference on
1207 Harmonization (www.ich.org) and the Global Harmonization Task Force (www.ghtf.org),
1208 respectively. While European regulations are not directly applicable in Canada, certain

1209 aspects of European clinical trial and privacy directives have impacted those who sponsor
1210 or conduct international research. Therefore, it is important that, where appropriate, the
1211 Council establish policies that are consistent with the international regulatory
1212 environment, so that Canada will continue to attract and retain international research.

1213

1214 The Council should also undertake revisions to the CPSRIH on an ongoing basis in areas
1215 where it finds that the CPSRIH needs development either because specific provisions
1216 require reform or necessary provisions are missing. Such revisions must be done through
1217 regular consultations with the research community affected by the changes and with the
1218 Canadian public.

1219

1220 Especially during the initial years, the Council should make particular effort to build on
1221 the substantial amount of research, writing, consultation, and actions that has been
1222 undertaken by the PRE as well as other organizations involved in research ethics.

1223

1224 **4.5 Education**

1225 The Council should provide the leadership for the development of a Canadian education
1226 strategy that would identify the needs of the research community and the public in terms
1227 of research ethics. The Council should also provide educational opportunities, in various
1228 formats, on the CPSRIH as well as emerging research ethics issues.

1229

1230 Its educational programs on research ethics should serve to avoid duplication of effort
1231 among institutions currently providing educational opportunities. The Council's

1232 education services could relieve part of the burden that currently rests on under-resourced
1233 REBs to develop and provide educational programs for their members, and for
1234 researchers, research services staff, and others. Importantly, public education about
1235 research ethics principles, the rights of research participants, and the nature of the
1236 oversight system should help to build the public's trust in the human research enterprise.
1237 The work of the Council should build upon the substantial work already done by NCEHR
1238 and many other organizations.

1239

1240 We recognize that including both an education function and an accreditation function
1241 within a single organization can give rise to risks. For example, there would be a
1242 possibility of conflict of interest when the Council accredited and offered education (i.e.,
1243 the Council might require, or be seen to expect, accredited organizations to take
1244 education workshops that it offers, thereby compelling organizations to pay for other
1245 services provided by the Council). Also, there could be a risk that in some cases the
1246 education would merely "teach to the test" and therefore not perform a robust educational
1247 function. However, in common with others such as NCEHR and the CCAC, the
1248 Committee believes that the risks can be minimized, or avoided entirely, through the
1249 careful construction of management firewalls between the education and accreditation
1250 functions, and that the benefits of including both functions within the same council
1251 outweigh the risks.

1252

1253 In response to possible concerns, it is important to emphasize here that the Council
1254 should not have a monopoly on education; organizations should be free to obtain

1255 educational services from any source they chose. In addition, any accreditation standards
1256 regarding education should not be limited to educational programs that the Council
1257 offers.

1258

1259 **4.6 Accreditation**

1260 The Committee recommends an oversight system which includes the accreditation of
1261 organizations that conduct or review research with humans.

1262

1263 **4.6.1 What Gets Accredited?**

1264 The Committee recommends that research organizations organize their research
1265 participant protection policies and activities under the rubric of a single program.²³ The
1266 primary focus of an accreditation process should be Programs for Ensuring Ethical
1267 Research with Humans (PEERHs) situated within various kinds of organizations that are
1268 involved in any aspect of the conduct of human research. The PEERH should consist of
1269 an integrated program of functions and activities to ensure that the organization meets its
1270 responsibilities within the oversight system, with the primary objective of providing
1271 protection for research participants. The PEERH will also serve to guide the research
1272 organizations' continual quality improvement of processes related to the ethical conduct
1273 of research, and the ethical review process.

1274

1275 PEERHs should have the following integrated functions:

- 1276 ○ Policy and Administration
- 1277 ○ Education

²³ The notion of a PEERH is borrowed in part from NCEHR's 2006 Task Force report.

1278 ○ Review

1279 ○ Monitoring

1280 ○ Reporting

1281

1282 The Policy and Administration function would normally consist of an organization's
1283 policy or governance framework that clearly defines the roles and responsibilities at each
1284 level of the PEERH within the research organization. In addition it would encompass the
1285 administrative structures (e.g. Ethics Review Office) and procedural guidelines that
1286 provide support and direction for the educational, review, monitoring and reporting
1287 functions. A fundamental responsibility of the organization would be to ensure the
1288 adequate resourcing of this aspect of its PEERH.

1289

1290 The Educational function of the PEERH would be comprised of those activities and
1291 resources which were directed towards educating researchers, research ethics boards,
1292 institutional officials, administrators, and research participants in the fundamentals of
1293 ethical research and the ethics review process. These could consist of internally
1294 generated, or externally available, educational opportunities and materials such as
1295 workshops, retreats, handbooks and manuals.

1296

1297 The Review function of the PEERH would consist of all those structures and activities
1298 related to the scholarly and ethical review process. Conventionally, it would consist of the
1299 policies and procedures related to the operation of Research Ethics Boards (internal or
1300 external to the organization) which review the organization's human research, as well as

1301 other relevant bodies (e.g. Departmental Review Committees, Scientific Review
1302 Committees, and Appeal Boards).

1303

1304 The Monitoring function would include those activities and procedures which relate to
1305 the ongoing review of research, such as audit procedures or annual reports on individual
1306 research projects. In clinical trial research, it would also involve the review of serious
1307 adverse events reports, or reports from Data Safety Monitoring Boards.

1308

1309 The Reporting function would represent all those activities which relate to the internal
1310 and external accountability of the PEERH. This could consist of, for example, annual
1311 reports of the Research Ethics Office to the senior administrative official in the
1312 organization with overall responsibility for the PEERH, reports to Government (e.g.
1313 Health Canada) or other internal or external reporting arrangements.

1314

1315 The actual configuration of each PEERH would vary according to the nature and volume
1316 of the research conducted by the organization and its organizational structure. For
1317 example, a small health centre with few research proposals might have modest
1318 administrative support, engage the services of another research organization's REB or a
1319 private REB, and rely on on-line training modules for its researchers. A large university,
1320 on the other hand, might have several dedicated administrative staff, hold annual
1321 workshops for REB members and training sessions for junior researchers, and might have
1322 several REBs operating internally. In each case, the same functional capacity of the

1323 program would exist, but in a manner proportional to the nature and quantity of human
1324 research being carried out.

1325

1326 The Council should accredit the PEERHs of the following types of organizations:

- 1327 ○ public and private organizations with their own institutional REBs
- 1328 ○ public and private organizations that conduct human research but do not have
1329 their own REB
- 1330 ○ public and private organizations that offer non-institutional REB services to
1331 others.

1332 In general, an organization should have only one PEERH although that PEERH may have
1333 several modules that include different REBs. For example, one module may have an
1334 REB that deals with clinical trials and perhaps another module that deals with qualitative
1335 research proposals. The important element is that there are PEERH-wide policies that
1336 provide direction to all the modules and that the organization can be accredited as a
1337 whole.

1338

1339 The accreditation process should seek to be comprehensive from the outset, and its
1340 requirements be met by all organizations; there should be no grandfathering of existing
1341 organizations and no exceptions from the requirement for accreditation, e.g., for national,
1342 public, or private non-institutional REBs.

1343

1344 While the Council and the system proposed by the Committee would have overall
1345 responsibility for providing oversight, leadership and direction for issues related to

1346 human participants in research, responsibility for ensuring such protection must continue
1347 to rest with individuals and organizations engaged in research. The protection of research
1348 participants is everyone's business.

1349

1350 **4.6.2 Accreditation Functions**

1351

1352 In exercising its accreditation function, the Council should ensure the performance of the
1353 following functions:

1354 ○ standards, procedures, and guidance

1355 ○ assessment and monitoring

1356 ○ complaints

1357

1358 Standards for accreditation should be developed to be used in assessing conformity with
1359 the Council's policies. The standards development process could take as its starting point
1360 the important work done by NCEHR on the development of standards.

1361

1362 *Ad hoc* working groups should also be struck to advise on specific issues, and should
1363 consult representatives of the research community before giving formal status to new
1364 standards.

1365

1366 Procedures should be developed for accreditation. These should include such things as:

1367 ○ the steps an organization must complete in applying for and maintaining

1368 accreditation (e.g., complete an application or self-study, participate in a site

1369 visit, complete and submit annual reports)

- 1370 ○ what constitute the components of each step (e.g., what is included in the
1371 application forms or self studies; who makes up the site visit team and how
1372 they are trained; what has to occur during a site visit; how the site visit teams
1373 report on their findings; how the applicant organization provides feedback in
1374 response to that report; how accreditation decisions should be made; and how
1375 compliance with the accreditation standards should be monitored)
- 1376 ○ how applicants can appeal an adverse accreditation decision.

1377

1378 Finally, a guidance function should be performed. The Council should serve as a
1379 resource to organizations interested in developing or improving existing PEERHs, or as a
1380 preparatory step to the accreditation process. This will be particularly important during
1381 the initial years in which an accreditation system is being established in Canada. During
1382 the start-up period of the Council, the focus will likely be on procedural guidance, though
1383 some substantive guidance would also be required. As the accreditation process develops
1384 and gains more experience, there would likely be a shift toward more substantive
1385 guidance in areas such as interpretation of standards and the policies and procedures of
1386 accreditation.

1387

1388 Guidance should also be provided to applicants for accreditation about such areas as the
1389 interpretation of accreditation standards and about the policies and procedures of
1390 accreditation. However, applicants should not be directed with respect to how to
1391 organize or administer their PEERHs in a specific way. The intent of most accreditation
1392 standards is to develop a set of criteria to which all accredited programs are held

1393 accountable. However, there is often more than one way to meet the criteria. This
1394 operational flexibility, combined with guidance about what to do, will be essential to
1395 accommodating the different contexts within which successful programs operate. The
1396 guidance function should be responsive to researchers, research administrators, REB
1397 members, research institutions, research sponsors, government, research participants and
1398 the general public.

1399

1400 While the primary objective of accreditation is continual quality improvement, it will be
1401 necessary at times to deal with situations of non-compliance by accredited organizations,
1402 or organizations in the process of seeking accreditation. In responding to allegations of
1403 non-compliance, the Council should function under the principles of procedural fairness.
1404 In dealing with such cases, it should adopt a proportional approach which would involve
1405 a range of measures, including issuing warnings, mandating education programs, and,
1406 ultimately, withdrawing accreditation. Other penalties and enforcement mechanisms
1407 should be developed and clearly identified to ensure that research involving humans in
1408 Canada is carried out in accordance with the CPSRIH.

1409

1410 **4.7 Accreditation Panel**

1411 An Accreditation Panel should be established that is organizationally separate from the
1412 Accreditation function. It should be comprised of knowledgeable individuals and be
1413 responsible for making decisions about granting, maintaining, or withholding
1414 accreditation status on the basis of information provided to it by the site visit teams. The
1415 Accreditation Panel should report directly to the Board of Directors of the Council.

1416 **4.8 The CCPHRP’s Organizational Chart**

1417

1418

1419

1420

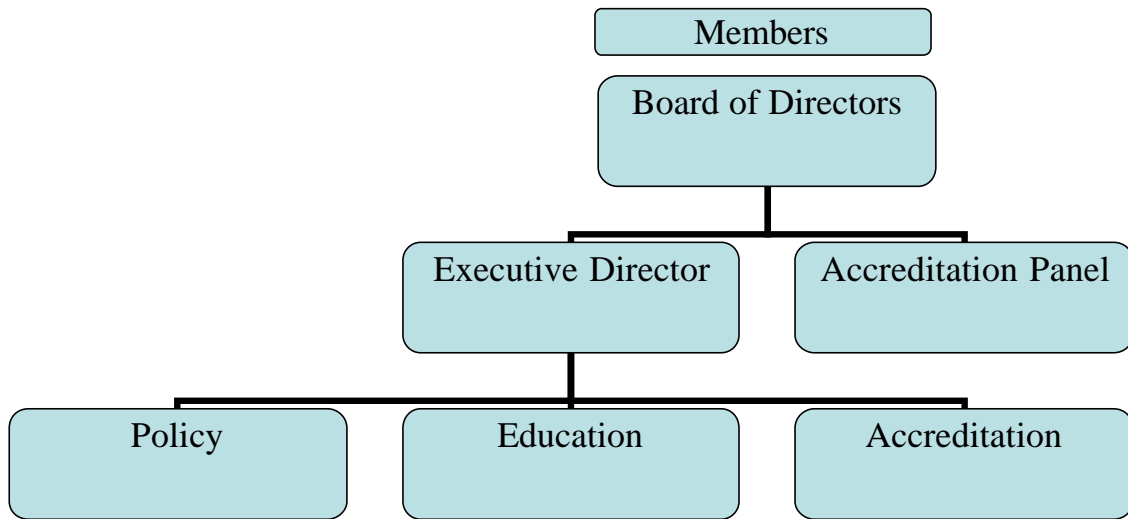
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1425



1426

1427 The Committee does not intend that the Council should grow into a large bureaucracy. In
 1428 particular, the Committee believes that the Council should make the fullest possible use
 1429 of peers (both volunteer and compensated) in carrying out its functions.

1430

1431

1432 The Committee recognizes that the creation of an organization along the lines
 1433 recommended in this report would raise questions about the future of PRE and NCEHR.

1434

1435 PRE was created in 2001 by the three federal research granting agencies to carry forward
 1436 the development of the TCPS. It has done valuable work in implementation,
 1437 interpretation, education and evolution related to the TCPS, and is scheduled to bring
 1438 forward a number of proposals for revisions and additions to the TCPS in 2008. The three
 1439 federal research granting agencies are members of the Sponsors’ Table and so will be

1440 participating in discussions about the recommendations in this Report. Accordingly, they
1441 will be in a position to decide what the future of PRE should be if, as the Committee is
1442 proposing, the TCPS and its future development are to become the responsibility of the
1443 Council described in this Report.

1444

1445 In the case of NCEHR, it is an independent organization and not a member of the
1446 Sponsors' Table. Its future is, therefore, not a matter on which the Experts Committee
1447 could appropriately make recommendations. Nevertheless, the Committee wishes to
1448 record in this Report its high regard for the work that NCEHR has done in past years, as
1449 evidenced by the proposals first developed by NCEHR a number of which have
1450 influenced the Committee's recommendations. Subject to the views of NCEHR and its
1451 supporters, the Committee believes that the incorporation of the expertise and knowledge
1452 represented by individual members of NCEHR into the proposed Council could be a
1453 major contribution to making the Council a functioning reality at an early date. More
1454 generally, the Committee wishes to record its view that, one way or another, the valuable
1455 work done by NCEHR and its network of dedicated volunteers must not be lost in the
1456 transition to the new oversight system.

1457

1458 **5. Implementation of the System**

1459 **5.1 Creating the CCPHRP**

1460 The Committee recommends that the organizations of the Sponsors' Table, along with
1461 other appropriate organizations, appoint a panel of experts in the research community to
1462 serve as a Selection Panel. There should be an open call for applications for membership

1463 on the Board with the goal of maximizing expertise and managing competing interests
1464 and obligations. From these applications, the Selection Panel should then name a set of
1465 individuals who would apply for a Charter for the Corporation and serve as the first
1466 Board of Directors.

1467

1468 **5.2 Financing the CCPHRP**

1469 The Council should initially be funded by the federal government through a single
1470 transfer covering the costs of operating during a period of three years. The objective
1471 would be to ensure that during the start-up period the Council would be able to focus
1472 entirely on substantive issues without being continuously concerned about fund raising.

1473

1474 Towards the end of the three-year period, an assessment of the Council's progress should
1475 be conducted. Participants of this assessment, in addition to the Council, should be the
1476 federal/provincial/territorial governments and non-governmental stakeholders. Part of the
1477 assessment should be creating means of funding the Council in the long term including
1478 considerations of potential revenue streams. It is possible, for example, that the
1479 accreditation function could become self-funding. However, the Committee would
1480 caution against a result whereby the policy and education functions are self-funded and a
1481 system that relies too heavily on volunteerism from the peer community – peer
1482 engagement will be critical to the success and legitimacy of the new system but the new
1483 system must not add to the already overwhelming volunteerism burden.

1484

1485 **5.3 Establishing the Reach of the System**

1486 Given the constitutional division of powers among governments in Canada and the
1487 resulting political realities, the Committee has developed its proposal on the assumption
1488 that the new oversight system would not have a statutory base that would make its
1489 adoption compulsory. It follows that if a new system of country-wide oversight is to
1490 become a reality, it will need the active support of the major stakeholders.

1491

1492 The organizations of the Sponsors' Table (and others as well) will, therefore, have the
1493 principal responsibility for determining whether Canada is to have a more coherent,
1494 comprehensive, and effective oversight system for the protection of human research
1495 participants. Collectively, they are in a position to exert considerable influence because
1496 of their respective responsibilities for research that is:

- 1497 ○ conducted at institutions receiving federal funds;
- 1498 ○ funded by all federal departments or agencies;
- 1499 ○ conducted by governments;
- 1500 ○ subject to regulation by provincial governments;
- 1501 ○ conducted at institutions receiving funding from any of the bodies represented at
1502 the Sponsors' Table;
- 1503 ○ funded, or conducted by any of the bodies represented at the Sponsors' Table;
- 1504 ○ regulated through statutes such as the *Food and Drugs Act*, and by federal,
1505 provincial, and territorial legislation;
- 1506 ○ conducted by individuals who are licensed, regulated or accredited by
1507 professional organizations.

1508 This approach would capture almost all human research conducted in Canada or by
1509 Canadian researchers – without legislation by governments. In addition, as the oversight
1510 system takes root and its standards become widely accepted, peer pressure will likely
1511 become an important factor in inducing all organizations to participate within the system
1512 as a means of placing themselves on an equal footing with their peers. Furthermore, it
1513 would strengthen the argument that participation within the system constitutes the
1514 standard of care for the purposes of negligence law and would thereby expand the reach
1515 of the system even beyond these levels to all research in Canada. In summary, then, the
1516 willingness of major stakeholders, such as those at the Sponsors' Table, to use the
1517 substantial levers at their disposal is essential for the success of the proposed Council.

1518

1519 **5.4 Costs**

1520 To put in place a comprehensive system to address the problems identified earlier in this
1521 report would clearly require additional resources, as well as additional effort on the part
1522 of system participants. In order to develop a sense of the resources that could be
1523 required, Health Canada retained the services of the Government Consulting Services to
1524 develop a costing model. A sub-group of the Committee worked with the consultants on
1525 specific aspects of the cost estimates. The full report is available on the Sponsors'
1526 Table's web site, www.hrppc-pphrc.ca.

1527

1528 The model developed by the consultants found that a Council with all the responsibilities
1529 proposed in this report could require, when fully operational, an annual budget of \$9-10
1530 million and a staff of 51.

1531

1532 The consultant's model provides an important reference point for future discussions about
1533 the establishment and functions of the Council. However, several comments are called
1534 for.

1535

1536 First, a useful point of comparison is the Canadian Council on Animal Care (CCAC).

1537 The CCAC has a strong image as a highly effective and respected organization that

1538 serves Canada well. If we look at the proposed outline budget for the CCPHRP, it is

1539 about five times as large as the CCAC budget (\$9-10 million vs. \$2 million). If we look

1540 at the diversity, complexity, size and scope of all manner of human participant research

1541 compared with research involving animals, it seems clear that a factor of five is not at all

1542 out of line.

1543

1544 Second, not all the resources in the consultants' model would be incremental. For

1545 example, expenditures by PRE and NCEHR combined come to about \$2 million per year

1546 at present. In the event that the functions of these organizations would be transferred to

1547 the Council at some point in the future, their resource needs would be met within the

1548 overall levels identified by the consultants.

1549

1550 Third, in the process of establishing the Council, the Board of Directors and the

1551 Executive Director would need to make judgments about the number of staff and contract

1552 personnel required, at what stage, and at what levels of remuneration. It is possible that

1553 opportunities for economies could be found in this process. In addition, the phasing in of

1554 some functions could mitigate the requirement for some resources in the initial years. For
1555 reasons set out earlier, the Committee is of the view that the three functions of policy,
1556 education, and accreditation should all be assigned to the Council. But, decisions could
1557 be made during the implementation process as to the pace and scale at which each of
1558 these functions should be implemented.

1559

1560 It is also possible that savings could be found in other areas of the research ethics
1561 enterprise if the Council were created. For example, there is much expertise and
1562 programming around research ethics education. The Council could provide an
1563 educational program at low cost or assist in coordinating access to educational programs
1564 created by various universities and others so organizations needing to initiate or improve
1565 their education on ethics would not have to start from scratch and absorb the
1566 developmental costs involved. Among other possibilities could be the achievement of
1567 efficiencies through the establishment of reciprocity arrangements among accredited
1568 REBs so multi-site studies do not have to be reviewed by all the participating REBs. The
1569 latter would save time and effort of the REBs and reduce frustration and time of
1570 researchers.

1571

1572 All of this having been said, the Committee wishes to underline the importance of the
1573 new Council being provided with resources sufficient to enable it to discharge its
1574 responsibilities. An over-zealous pursuit of economies could defeat the purpose of
1575 creating the Council in the first place.

1576 The consultants were not asked to consider the expenses that research organizations
1577 might have to incur to meet the accreditation standards, as this would be impossible to
1578 estimate without first establishing the standards themselves. In this regard, however, it
1579 would be appropriate for eligible research institutions to treat the costs of an accreditation
1580 process to protect human participants as legitimate expenses under the Government of
1581 Canada's Indirect Costs Program. The Committee recommends that the Indirect Costs
1582 Program be given additional resources by the government to assist research institutions in
1583 meeting any cost increases associated with accreditation.

1584

1585 **5.5 Timetable**

1586 A realistic assessment of the time required to create the Council and to put in place the
1587 comprehensive system could be three years. Steps that have to be taken include
1588 incorporating the Council under the *Canada Corporations Act*, obtaining bridge financing
1589 from the federal government, nominating the Selection Panel, establishing the Board of
1590 Directors and the Members to whom they would be accountable, recruiting staff,
1591 completing standards, and developing educational tools, among other activities.

1592

1593 There are no evident shortcuts to this process. That being said, the likely time required to
1594 get the new arrangements into place constitutes a compelling reason for making as early a
1595 start as possible.

1596

1597 **6. Summary of Recommendations**

1598

1599 1. That the Sponsors' Table, together with other interested stakeholders, engage in a

1600 process that builds upon their cooperative efforts and immediately implement the

1601 Committee's proposal for a Canadian Council for the Protection of Human Research

1602 Participants.

1603

1604 2. That the Canadian Council for the Protection of Human Research Participants be

1605 entrusted with the three interrelated functions of policy, education, and accreditation.

1606

1607 3. That the federal government provide the necessary bridge financing for the Council

1608 and that members of the Sponsors' Table, together with other interested stakeholders,

1609 establish a permanent funding arrangement for the Council such as grants through the

1610 federal government's Indirect Costs Program.

1611

1612 4. That organizations of the Sponsors' Table, together with other interested stakeholders,

1613 establish policies that require all of those who fall within their respective jurisdictions to

1614 recognize the Council's authority, purpose, and functions and most specifically, to

1615 require all research involving humans conducted in Canada or by Canadian researchers to

1616 receive prospective ethical review and ongoing oversight from an REB following the

1617 CPSRIH and operating within an accredited PEERH.