

Table of Concordance: TCPS and Proposed Recommendations

| Original TCPS  | January 2008 Version  |
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| <p>A. Clinical Equipoise<br/>           B. Phases of Pharmaceutical Research<br/>           C. Multicentre Clinical Trials<br/>           D. Placebo-Controlled Studies<br/>           E. Analysis and Dissemination of the Results of Clinical Trials</p> <p><b>Article 7.3</b></p> <p><b>REBs shall examine the budgets of clinical trials to assure that ethical duties concerning conflict of interest are respected.</b></p> <p>Budgets for clinical trials usually are calculated by per capita costs—that is, the sponsor pays the researcher a fixed sum for each research subject recruited. Per capita payments raise ethical concerns because of the potential to place the researcher in a conflict between maximizing economic remuneration and serving the best health interests of subject-patients, especially if the researcher also holds a therapeutic or clinical or other fiduciary relationship with the subjects. Disclosure of the amount of the per capita payment, and other budgetary details, will assist the REB in assessing potential conflicts of interest, and may also assist the researcher in resolving them. As a general guide, per capita payments should be comparable to the physician’s or researcher’s usual professional fee. When trials take place within a public institution, such as a hospital or a long-term care facility, recovery of utilization costs for institutional and other resources (such as radiological and diagnostic services) should be considered essential, and should be in addition to any overhead charge stipulated by the institution.<br/>           Examination of the clinical trials within the ethical perspectives of the</p> | <p>A. Clinical Equipoise<br/>           B. Phases of Pharmaceutical Research<br/>           C. <u>Budgets, Contracts and Agreements</u><br/>           D. Multicentre Clinical Trials<br/>           E. Placebo-Controlled Studies<br/>           F. <u>Sharing New Information</u><br/>           G. Analysis and Dissemination of <u>the Data &amp; Results of Clinical Trials</u></p> <p><b><u>C. Budgets, Contracts and Agreements</u></b></p> <p><b>Article 7.3</b></p> <p><b>REBs shall <u>ensure that budgets, contracts and investigator agreements regarding clinical trials are properly examined to assure that ethical duties concerning conflict of interest are respected.</u></b></p> <p>Budgets for clinical trials are usually calculated by per capita costs— that is, the sponsor pays the researcher a fixed sum for each research subject recruited, <u>based on the length of time that the subject is on the study and the tests required by the trial. Unreasonable payments or undue inducements</u> raise ethical concerns because of the potential to place the researcher in a conflict between maximizing economic remuneration and serving the best health interests of subject-patients, especially if the researcher also holds a therapeutic or clinical or other fiduciary relationship with the subjects. Disclosure of the <u>kinds and amounts of the payments</u>, and other budgetary details, will assist the REB, <u>or other delegated body within the institution, to assess potential conflicts of interest</u>, and may also assist the researcher in resolving them. As a general guide, payments should be comparable to the physician’s or researcher’s usual professional fee <u>for the provision of comparable services</u>. When trials take place within a public institution, such as a hospital or a long-term care facility, recovery of utilization costs for institutional and other resources (such as</p> |

phases outlined above for clinical trials will assist REBs and researchers in identifying ethical issues that are both generic for all clinical trials and specific for a given trial.

*C. Multicentre Clinical Trials ...*

*D. Placebo-Controlled Studies ...*

**Article 7.4 The use of placebo controls...**

radiological and diagnostic services) should be considered essential, and should be in addition to any overhead charge stipulated by the institution.

The independent review of the investigator-industry contract should be undertaken by a duly composed REB, or by or under the auspices of another competent institutional authority that shares the results with the REB, as an integral part of the ethics review process. If done under the latter process, the review of contracts should be conducted in a manner that: (i) conforms to the special ethical duties, mandate and purposes of REB review, and (ii) consults with the REB when necessary.

*D. Multicentre Clinical Trials ...*

*E. Placebo-Controlled Studies ...*

**Article 7.4 The use of placebo controls...**

#### **F. Sharing New Information**

##### **Article 7.5**

**(a) If, in the course of a trial, new information arises that may be relevant to participants' free, informed and continuing consent to participation in the research, investigators should share the information, in a timely manner, with the REB and participants. The urgency of the timing should be commensurate with the potential seriousness of the risk raised by the information. In some circumstances, new information that arises after a trial may also need to be shared.**

Article 7.5 outlines an investigator's continuing duty to share new and relevant information from the clinical trial process with the REB and research participants. "New information" is information that may affect the willingness of a participant to continue in the trial, or that is otherwise relevant to participants' free, informed, and continuing consent (See

articles 2.1, 2.4(f)). To understand its particular relevance, the information needs to be considered from a participant-centered perspective. This sharing may also include new information that arises outside the trial when that information is relevant to the participant's informed and continuing participation. "New information" thus covers a range of matters that include, but is not limited to, the following:

changes to the research protocol;

new risk information, such as adverse events or safety data;

new information which shows benefits of one intervention over another;

new findings, including important non-trial information;

unanticipated problems involving therapeutic efficacy or recruitment issues.

Duties to report such new information to the REB lies with the sponsor and the investigator. The REB's interdisciplinary advice should help structure the breadth and timing of sharing the information with participants. The more serious and urgent the information, the more promptly it should be shared.

In those circumstances when significant risk/benefit information arises after the trial, and which may well affect the well-being or safety of former participants, the investigator should share the information with the REB. The REB and investigator should consider whether given the nature and urgency of the information, a reasonable former participant would, under the circumstances, consider the information relevant to his or her well-being and informed choices. If so, then reasonable steps should be taken to share the information in a meaningful and timely manner with former participants.

In the event that a researcher and REB were to disagree over the sharing of new information with participants, attempts to resolve the disagreement should involve recourse to the REB appeals process (see articles 1.10-1.11, above). The REB process should be cognizant of, and sensitive to, the urgency of the matter. Attempts to resolve disagreement about the scope and reach of disclosure should be guided by a paramount principle of protecting the safety and welfare of trial participants.

*(b) Nota: This proposed sub-article 7.5(b) outlines two options regarding a TCPS duty to share new clinical trials information with regulatory authorities. Both options address researcher and sponsor disagreement over reporting the new information to relevant regulatory authorities. Option A recognizes that the duty may arise, as a matter of professional conscience, given a number of factors. Option B outlines a special duty to report the information when a sponsor refuses to do so.*

**Option A (Good Conscience Clause): In exceptional instances of intractable disagreement, where all other reasonable measures have been exhausted, the principle of protecting the safety and welfare of patients should further guide researchers and REBs about the lengths to which they should go to share new, relevant and important information. If in good conscience, a researcher or REB, exercising independent and professional judgment, were to determine that sharing information likely would prevent significant harms to research participants, then the researcher or REB may reasonably conclude there is an ethical duty to do so, despite objections. The scope of the duty—what new information should be disclosed, when it should be disclosed, and to whom it should be disclosed—should be proportionate to the seriousness and urgency of the potential harm.**

Option A addresses exceptional circumstances that might arise, for example, if a research sponsor were to refuse to report to a regulatory authority new and significant information. In such circumstances, should the researcher or REB report the new information to regulatory authorities? In their deliberations on such matters, researchers and REBs should consider such factors as: whether the information is novel and significant or duplicative; the objective quality and nature of the information; the direct relevance of the information to participants' safety, welfare and continuing consent; whether relevant entities (sponsors, data safety monitoring boards, and REBs) have been afforded a reasonable opportunity to discharge their duties with respect to the information, and relevant regulatory duties.

**Option B (Special Duty to Report to Regulatory Authorities): In**

*E. Analysis and Dissemination of the Results of Clinical Trials*

exceptional circumstances, beyond those required under existing regulations, the ethical principles of avoiding harm and respecting participants' informed consent impose on researchers or REBs a special duty to share new safety-efficacy information with regulatory authorities. When sponsors refuse to report new and significant information that is relevant to the safety and welfare of participants, then researchers and/or REBs have a duty to do so. The more objectively relevant and urgent the information, the stronger the duty. Before REBs or researchers act on such duties, they should afford sponsors a reasonable opportunity for reporting the information to the appropriate regulatory authorities.

**G. Analysis and Dissemination of the Data and Results of Clinical Trials**

**Article 7.6**

**(a) Institutions and REBs should develop reasonable written policies regarding confidentiality clauses and publication clauses in research contracts between investigators and industry.**

A reasonable institutional policy should:

require that confidentiality and publication clauses be submitted to the responsible authority (e.g. REB, research administration) for determination of their adherence to the written policy of the institution;

require that the results of the review be shared with the REB as an integral part of the ethics review process.

provide that all confidentiality and publication clauses:  
be consistent with the investigator's duty to share new information from the clinical trial setting with REBs and trial participants in a timely manner, under articles 7.5 and 2.1(a);  
be reasonable in terms of any limitations or restrictions on the dissemination or communication of information;  
address data sharing/ownership; and

In many clinical trials, the sponsors obtain contractual rights to the initial analysis and interpretation of the resultant data. Researchers and REBs must ensure, however, that final analysis and interpretation of such data remain with the researchers, whose duty it is to ensure the integrity of their research. When stopping rules are required in Phase I, II and III clinical trials, monitoring of the interim results must be done independently. It should also be remembered that, with a stopping rule in place, long-term positive or negative effects might be masked by short-term harms or benefits.

Equally important, though sometimes difficult to achieve, is the researchers' duty to disseminate the analysis and interpretation of their results to the research community. Unfortunately, negative results and outcomes of research frequently are not published or disseminated. Silence on such results may foster inappropriate and potentially harmful clinical practices or needless and wasteful duplication. Researchers and REBs may exert pressure to alleviate this deficiency in the dissemination of research results by resisting publication bans proposed in research protocols, on the basis of ethical obligations of truthfulness and the integrity of research. Research journalists, journal editors, members of editorial peer review boards, sponsors and regulators should address this as an issue of scientific and ethical urgency.

address publication rights and authorship of the initial and subsequent reports in multicentre trials

**(b) Absolute bans on the dissemination of scientific information from clinical trials are ethically unacceptable. Confidentiality clauses or publication limitations that impose unduly broad limitations on either the content of the scientific information that may be disseminated or on the timing of that dissemination are presumed to be ethically unacceptable.**

In many clinical trials, the sponsors have contractual rights to the initial analysis and interpretation of the resultant data. These provisions are typically found in industry-investigator contracts that may not always be part of an REB review. To incorporate the analysis of these contractual provisions into modern interdisciplinary ethics review, articles 7.6(b) and 7.3 require (a) that institutions and REBs adopt reasonable written policies regarding such provisions; and (b) that contracts and relevant documents for proposed research be independently reviewed for their consistency with these policies and principles.

Article 7.6 is intended to ensure that any such contractual rights be reasonably balanced against the investigator's ethical and legal obligations to participants in trials and the scientific and public good in the dissemination of the data and results of research. For example, where stopping rules are in place, monitoring of the interim results must be done independently, for example, by an independent data safety monitoring board (DSMB). Properly composed and duly accountable DSMBs play an important role in ensuring independent overall analysis of clinical trial data and complement the role of the REB. It should also be remembered that, with a stopping rule in place, long-term positive or negative effects might be masked by short-term harms or benefits.

Measures necessary for the effective discharge of the duties of researchers' and institutions to share new information and disseminate the analysis and interpretation of their results to the research community may need to be undertaken. Based on principles of the scientific process, respect for participant expectations and protection of the public good, research

*Requirement for Free and Informed Consent*

**Article 2.1**

scientists and institutions have an ethical responsibility to make reasonable efforts to disseminate publicly the results of research in a timely manner. Unfortunately, however, negative results and outcomes of research frequently are not published or disseminated. Silence on such results may lead to data suppression and publication bias and thus contribute to a series of harms: misinformed decision-making based on a mis-weighing of risks and benefits, inappropriate and potentially harmful clinical practices and injury to health, needless and wasteful duplication of research interventions on participants, fraud or deception in the clinical trials process and erosion of public trust and accountability in research. Research journalists, journal editors, members of editorial peer review boards, sponsors and regulators should continue to address this as an issue of scientific and ethical urgency. Clinical trials registries, editorial policies, ethical policy reforms, and revised national and institutional ethics policies all contribute to a multi-faceted approach to combating the ills of non-disclosure and the suppression of data in clinical research.

In the review process, the onus to justify significant restrictions on dissemination should lie on the researcher and, when appropriate, the sponsor. The reasonableness of the restrictions on either the content or timing of dissemination should be measured against the standards of the written institutional policies. For example, some existing university policies deem publication restrictions that exceed a reasonable time limit, e.g., 3-6 months after the close of the trial, to be unacceptable. Such written institutional policies should also address restrictions on the dissemination of particular kinds of information, such as information that may be considered proprietary/trade secret and information that participants would reasonably consider relevant to their welfare or safety. Consistent with Articles 2.1 and 7.5, restrictions on the latter are seldom, if ever, justified.

**A. Requirement for Free, Informed & Continuing Consent**

**Article 2.1**

**Free and informed consent encompasses a process that begins with a**

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| <p>(a) Research governed by this Policy (see Article 1.1) may begin only if (1) prospective subjects, or authorized third parties, have been given the opportunity to give free and informed consent about participation, and (2) their free and informed consent has been given and is maintained throughout their participation in the research. Articles 2.1(c), 2.3 and 2.8 provide exceptions to Article 2.1(a).</p> <p>(b) Evidence of free and informed consent ...</p> <p>Free and informed consent lies at the heart of ethical research involving human subjects. It encompasses a process that begins with the initial contact and carries through to the end of the involvement of research subjects in the project. As used in this Policy, the process of free and informed consent refers to the dialogue, information sharing and general process through which prospective subjects choose to participate in research involving themselves.</p> <p>Article 2.1(a) states the requirement in both ethics and law: to protect and promote human dignity. Ethical research involving humans requires free and informed consent. As elaborated more fully below, free and informed consent is exercised by an authorized third party for those who lack legal competence. ...</p> <p><b>Article 2.4</b></p> <p><b>Researchers shall provide, to prospective subjects or authorized third parties, full and frank disclosure of all information relevant to free and informed consent. Throughout the process of free and informed</b></p> | <p><b>researcher's initial contact with participants and which continues through to the end and sometimes beyond the research project. Throughout the process, researchers have a continuing duty to provide participants and REBs information relevant to the participant's free and informed consent to participate in the research.</b></p> <p>(a) Research governed by this Policy (see Article 1.1) may begin only if:</p> <p>(1) prospective subjects, or authorized third parties, have been given the opportunity to give free and informed consent about participation, and</p> <p>(2) their free and informed consent has been given and is maintained throughout their participation in the research. Articles 2.1(c), 2.3 and 2.8 provide exceptions to Article 2.1(a).</p> <p>(b) Evidence of free and informed consent....</p> <p>As used in this Policy, the process of free and informed consent refers to the dialogue, information sharing and general process through which prospective subjects choose to participate in research involving themselves.</p> <p>Article 2.1(a) states the requirement in both ethics and law: to protect and promote human dignity. Ethical research involving humans requires free and informed consent. As elaborated more fully below, free and informed consent is exercised by an authorized third party for those who lack legal competence. ...</p> <p><b>Article 2.4</b></p> <p><b>Researchers shall provide, to prospective subjects or authorized third parties, full and frank disclosure of all information relevant to free and informed consent. Throughout the free and informed consent process,</b></p> |
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consent, the researcher must ensure that prospective subjects are given adequate opportunities to discuss and contemplate their participation. Subject to the exception in Article 2.1(c), at the commencement of the process of free and informed consent, researchers or their qualified designated representatives shall provide prospective subjects with the following:

- (a) Information that the individual is being invited to participate in a research project;
- (b) A comprehensible statement of the research purpose, the identity of the researcher, the expected duration and nature of participation, and a description of research procedures;
- (c) A comprehensible description of reasonably foreseeable harms and benefits that may arise from research participation, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm;
- (d) An assurance that prospective subjects are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether or not to continue to participate; and
- (e) The possibility of commercialization of research findings, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors.

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The measures to be undertaken to publish or otherwise make publicly available the results of the research.

...

... Article 2.4(f) requires that researchers provide a reasonable explanation of the measures to be undertaken to publish and otherwise disseminate the results of the research. Beyond the ethical obligation to do so in such areas as clinical trials (see articles 7.6(a) and 7.6(b) below), this requirement is grounded on the reasonable expectation of participants in research that the results will be published or otherwise disseminated in the public domain to advance societal knowledge.

**Table 1: Additional information that may be required for some projects**

1. ...

10. The ways in which the research results will be published, and how the subjects will be informed of the results of the research.

B1. Authority of the REB

**Article 1.2**

**The institution in which research involving human subjects is carried out shall mandate the REB to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human subjects that is conducted within, or by members of, the institution, using the considerations set forth in this Policy as the minimum standard.**

The authority of the REB should be delegated through the institution's normal process of governance. In defining the REB's mandate and authority, the institution must make clear the jurisdiction of the REB and its relationship to other relevant bodies or authorities. Institutions must ensure that REBs have the appropriate financial and administrative

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**B1. Purpose and Authority of the REB**

**Article 1.2**

**(a) The primary purpose of REB review is to protect the dignity, well-being, rights and safety of research participants.**

**(b) The institution in which research involving human subjects is carried out shall mandate the REB to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human subjects which is conducted within, or by members of, the institution, using the considerations set forth in this Policy as the minimum standard.**

Article 1.2(a) indicates the primary purpose of human research ethics review. Respecting the dignity and protecting the rights of participants reflect fundamental values in research ethics. Those values will sometimes conflict with others, such as the societal good that may derive from research. The value conflict is endemic in REB review, as recognized in the ethics framework of the TCPS. Under the framework, the functions of REB review need to be exercised and applied thoughtfully to diverse research contexts. Those contexts range from the safety risks posed by health science research to critical social sciences research the purpose of which is to critique those under study.

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independence to fulfil their primary duties. ...

### *F. Review Procedures for Ongoing Research*

#### **Article 1.13**

**(a) Ongoing research shall be subject to continuing ethics review. The rigour of the review should be in accordance with a proportionate approach to ethics assessment.**

**(b) As part of each research proposal submitted for REB review, the researcher shall propose to the REB the continuing review process deemed appropriate for that project.**

**(c) Normally, continuing review should consist of at least the submission of a succinct annual status report to the REB. The REB shall be promptly notified when the project concludes.**

Beyond scrutinizing reports, the REB itself should not normally carry out the continuing ethics review, except in specific cases where the REB believes that it is best suited to intervene. For research posing significant risks, the REB should receive reports on the progress of the research project at intervals to be predetermined. These reports should include an assessment of how closely the researcher and the research team have complied with the ethical safeguards initially proposed.

In accordance with the principle of proportionate review, research that exposes subjects to minimal risk or less requires only a minimal review process. The continuing review of research exceeding the threshold of minimal risk that is referred to in Article 1.13(b), in addition to annual review (Article 1.13(c)) might include:

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As part of continuing ethics review, researchers should fulfill their responsibilities for continuing consent and the reporting of new information that arises in clinical trials, consistent with articles 2.1 and 7.5.

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| <p>Formal review of the process of free and informed consent;<br/> Establishment of a safety monitoring committee;<br/> Periodic review by a third party of the documents generated by the study;<br/> Review of reports of adverse events;<br/> Review of patients' charts; or<br/> A random audit of the process of free and informed consent.</p> <p>Other models of a continuing ethics review may be designed by researchers and REBs to fit particular circumstances.</p> <p>The process of a continuing ethics review should be understood as a collective responsibility, to be carried out with a common interest in maintaining the highest ethical and scientific standards. Research institutions should strive to educate researchers on the process of a continuing ethics review through workshops, seminars and other educational opportunities.</p> <p><b>TCPS Ethics Framework</b></p> <p><b>E. Academic Freedoms and Responsibilities</b></p> <p>Researchers enjoy, and should continue to enjoy, important freedoms and privileges. To secure the maximum benefits from research, society needs to ensure that researchers have certain freedoms. It is for this reason that researchers and their academic institutions uphold the principles of academic freedom and the independence of the higher education research community. These freedoms include freedom of inquiry and the right to disseminate the results thereof, freedom to challenge conventional thought, freedom from institutional censorship, and the privilege of conducting research on human subjects with public monies, trust and support. However, researchers and institutions also recognize that with freedom comes responsibility, including the responsibility to ensure that research involving human subjects meets high scientific and ethical standards. The researcher's commitment to the advancement of knowledge also implies duties of honest and thoughtful inquiry, rigorous analysis, and accountability for the use of professional standards. Thus, peer review of research proposals, the findings and their interpretation contribute to</p> | <p>Formal review of the free and informed consent process,<br/> Establishment of a safety monitoring committee,<br/> Periodic review by a third party of the documents generated by the study,<br/> Review of reports of adverse events,<br/> Review of patients' charts, or<br/> A random audit of the free and informed consent process</p> <p>Other models of a continuing ethics review may be designed by researchers and REBs to fit particular circumstances.</p> <p>The process of a continuing ethics review should be understood as a collective responsibility, to be carried out with a common interest in maintaining the highest ethical and scientific standards. Research institutions should strive to educate researchers on the process of a continuing ethics review through workshops, seminars and other educational opportunities.</p> <p><b>TCPS Ethics Framework</b></p> <p><b>E. Academic Freedoms and Responsibilities</b></p> <p>Researchers enjoy, and should continue to enjoy, important freedoms and privileges. To secure the maximum benefits from research, society needs to ensure that researchers have certain freedoms. It is for this reason that researchers and their academic institutions uphold the principles of academic freedom and the independence of the higher education research community. These freedoms include freedom of inquiry and the right to disseminate the results thereof, freedom to challenge conventional thought, freedom from institutional censorship, and the privilege of conducting research on human subjects with public monies, trust and support. However, researchers and institutions also recognize that with freedom comes responsibility, including the responsibility to ensure that research involving human subjects meets high scientific and ethical standards. <u>The commitment of researchers and institutions to the advancement of knowledge through scientific and scholarly inquiry entails duties of honest and thoughtful inquiry, rigorous analysis and accountability to participants, peers and society. That broad accountability includes a responsibility to</u></p> |
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accountability, both to colleagues and to society.

Review of the ethics of research helps ensure a more general accountability to society. Accountability, moreover, requires that the whole process should always be open to critical assessment and debate.

make reasonable efforts to disseminate or otherwise make publicly available the results of research, in a manner respectful of disciplinary and cultural contexts.

Peer review of research proposals, research findings and their interpretation contribute to accountability, both to colleagues and to society. Review of the ethics of research helps ensure a more general accountability to society. Accountability, moreover, requires that the whole process should always be open to critical assessment and scientific and public debate.