

<b>Title</b>	Recruitment and Informed Consent Requirements
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## 1 PURPOSE

This standard operating procedure (SOP) describes the requirements for recruitment<sup>1</sup> and informed consent<sup>2</sup> (including waiver thereof), as well as the REB review of these requirements.

## 2 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

## 3 RESPONSIBILITIES

All REB members and designated REB staff are responsible for ensuring that the requirements of this SOP are met.

The Researcher is responsible for providing the REB with:

- Informed consent form in accordance with institutional templates,
- A description of the recruitment methods and recruitment materials (if applicable),<sup>3</sup> including all promotional materials<sup>4</sup> and social media components,
- A description of the informed consent process, with relevant forms,<sup>5</sup>
- Justification for any request for waiver of the usual consent process.

The Researcher and the research Sponsor, if any, are jointly responsible for ensuring that the consent form contains all of the required elements. The REB is responsible for verifying that the consent form (if applicable) contains the required elements.

The REB is responsible for determining whether<sup>6</sup>:

- Recruitment methods are appropriate,
- The informed consent process meets ethical and legal requirements,

<sup>1</sup> *Avis sur les conditions d'exercice des comités d'éthique de la recherche désignés ou institués par le Ministre de la Santé et des Services sociaux en vertu de l'article 21 du Code civil, Gazette officielle du Québec, Part I, vol. 35, 1998, hereafter "Avis", p. 1039; Plan d'action ministériel en éthique de la recherche et en intégrité scientifique, Ministère de la Santé et des Services sociaux du Québec (PAM), 1998, p. 23; Modèle de règles de fonctionnement d'un comité d'éthique de la recherche, Ministère de la Santé et des Services sociaux, DGAERA, 2004, hereafter "Modèle", s. 10.3.*

<sup>2</sup> *Avis, p. 1039; PAM, p. 23; Modèle, s. 10.3; Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter "TDR", s. 6.2.*

<sup>3</sup> *Modèle, s. 9.3.*

<sup>4</sup> *ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R1), Health Canada, 1997, hereafter "ICH GCP", s. 3.1.2.*

<sup>5</sup> *Modèle, s. 9.3; ICH GCP, s. 3.1.2.*

<sup>6</sup> *Avis, p. 1039; PAM, p. 23; Civil Code of Québec (CCQ), c. CCQ-1991, art. 20 and 21 para. 4; Modèle, s. 10.3 and 13.1; TDR, s. 6.2.2 and 6.2.5.*

- Informed consent exemptions or waivers are acceptable,
- The informed consent form contains all the required elements.

#### 4 DEFINITIONS

See Glossary of Terms.

#### 5 PROCEDURES

All procedures and documents concerning recruitment and consent must be described, justified, and submitted to REB review in accordance with the REB SOP on Initial Review.<sup>7</sup>

##### 5.1 REB Review of Recruitment Methods

- 5.1.1 Recruitment methods should be adapted to research objectives and to potential participants. When potential participants are also patients of the Clinician-researcher, measures must be taken to minimize therapeutic misconception. Special precautions must be taken when recruiting vulnerable individuals to ensure freedom of participation;
- 5.1.2 A Clinician-researcher in a therapeutic relationship with potential participants may approach patients directly, but in no way should they feel pressured or under any obligation to take part in the study. In such cases, consent should be obtained by someone other than the Researcher. "Ideally, treatment and research functions should be performed by different people. However, there may be instances in which the participants' best interests are served by having their primary care clinician involved in recruitment and consent. In these cases, the research proposal shall indicate what other measures will be taken to minimize therapeutic misconception"<sup>8</sup>;
- 5.1.3 The research project can be advertised to the public by various means, including social media, posters, and conferences;
- 5.1.4 Potential patient-participants should be contacted by someone from the health care facility where they received treatment;
- 5.1.5 The consultation of medical records to identify patients who might meet eligibility criteria requires either authorization from the Director of Professional Services (*DPS*) or consent. However, if research is part of the institution's legally defined mandate, neither of these is necessary.<sup>9</sup>

##### 5.2 REB Review of the Informed Consent Process

<sup>7</sup> *Modèle*, s. 9.3 and 10.3; TDR, s. 6.2.2, etc.

<sup>8</sup> Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2014 (TCPS2), art. 11.6, p. 163.

<sup>9</sup> Act Respecting Health Services and Social Services, CQLR, c. S-4.2, art. 88.

- 5.2.1 The consent process should be adapted to research objectives and to potential participants. When potential participants are also patients of the Clinician-researcher, measures must be taken to minimize therapeutic misconception. Special precautions must be taken during the consent process when recruiting vulnerable individuals, to ensure freedom of participation;
- 5.2.2 REB members will review the proposed consent process to ensure that it follows institutional guidelines and all applicable regulations;
- 5.2.3 An REB review of the proposed consent process includes the following:
- Components of the recruitment process: how, when, where, and by whom potential participants are to be contacted, including any and all materials used (e.g. research fact sheets),<sup>10</sup>
  - Potential undue influence (power relationship, trust, dependency), evidence of coercion or incentives leading to underestimation of potential research risks, that could undermine free and informed consent,<sup>11</sup>
  - Manner in which the research is to be advertised,<sup>12</sup>
  - Specific measures related to the translation or interpretation of informed consent documents, in accordance with paragraph 5.4 of this SOP,
  - Specific and exceptional measures for safeguarding participant safety and privacy,
  - The Researcher's plans regarding the identification and disclosure of incidental findings, if any;
- 5.2.4 The REB usually requires written consent<sup>13</sup> on an REB-approved informed consent form, dated and signed by the participant or legal representative thereof and the person obtaining consent. Other means of obtaining consent (oral consent, deferred consent, field notes, implied consent by return of a questionnaire) may nonetheless be approved by the REB under certain circumstances<sup>14</sup>;
- 5.2.5 Minors aged 14 years and over may consent on their own to participate in a research study, if according to the REB, the risk is minimal and circumstances permit<sup>15</sup>;
- 5.2.6 In cases where research projects involve participants who do not have the capacity to consent, the REB will examine how the consent of the participant's legal representative is obtained and documented. The REB will ensure that, when required, assent is documented;

<sup>10</sup> *Modèle*, s. 10.3; TDR, s. 6.2.2, etc.; TCPS2, p. 26.

<sup>11</sup> *Modèle*, s. 10.3; TDR, s. 6.2.5, etc.; TCPS2, art. 3.1 (a); CCQ, art. 10 para. 2.

<sup>12</sup> *Modèle*, s. 9.3 and 10.3.

<sup>13</sup> CCQ, art. 24 para. 1; TCPS2, art. 3.12.

<sup>14</sup> "consent to research may be given otherwise than in writing if justified in the circumstances in the opinion of a research ethics committee. In such a case, the committee determines the proper manner, for evidential purposes, of obtaining consent" (CCQ, art. 24 para. 2).

<sup>15</sup> CCQ, art. 21 para. 5.

5.2.7 The REB may approve the use of any technological means it deems appropriate for the conduct of the consent process and its documentation;

5.2.8 Researchers are not required to obtain participant consent for the secondary use of non-identifying information.

### **5.3 REB Review of the Informed Consent Form**

5.3.1 The REB will review only those forms consistent with institutional templates;

5.3.2 When institutional templates are modified after an informed consent form has already been approved, the REB will inform the Researcher if it determines that the previously approved informed consent form must be revised and, when applicable, if participants need to be re-consented;

5.3.3 The REB will review proposed informed consent forms for clarity, language level (Grade 8), content, and inclusion of all required elements;

5.3.4 The REB will ensure that there is complete disclosure of all information required for informed decision-making. Such information generally includes:

- Logo of the institution,
- Bar code for relevant research information from the patient's medical records, for security purposes,
- Identity of the Researcher,
- Identity of the funding agency or Sponsor,
- Invitation to participate in a research project,<sup>16</sup>
- Statement of research objectives,
- Expected duration and nature of participation,
- Description of the research procedures,
- Explanation of the responsibilities of the participant, when relevant,<sup>17</sup>
- Description of potential benefits, both to the participants themselves and generally, that may arise from research participation,<sup>18</sup>
- Description of any and all risks associated with the research procedures indicating, where possible, severity and frequency thereof,

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<sup>16</sup> TCPS2, art. 3.2 (a).

<sup>17</sup> TCPS2, art. 3.2 (b).

<sup>18</sup> TCPS2, art. 3.2 (c).

- An assurance that prospective participants:
  - are under no obligation to participate,<sup>19</sup>
  - are free to withdraw, or to verbally withdraw their consent at any time, without prejudice to the care to which they are entitled or to their relationship with the medical team,<sup>20</sup>
  - will be given, in a timely manner throughout the course of the research project, information relevant to their decision to continue or withdraw from participation,<sup>21</sup>
  - will be given information on their right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal<sup>22</sup>;
- Circumstances not permitting withdrawal of data or human biological materials already collected,
- The manner in which the researcher informs the participant's primary physician of participation in the research, if applicable, and the manner in which the participant consents to have his/her primary physician informed,
- Information concerning the possibility of commercialization of research findings,<sup>23</sup>
- Real, potential or perceived conflicts of interest on the part of the researchers or any other relevant party, as reported to the REB, that the REB finds relevant to disclose to participants,<sup>24</sup>
- The methods used for dissemination of research results, including the safeguards for protecting participant privacy,<sup>25</sup>
- The identity and contact information of a designated representative who can explain the research to participants,<sup>26</sup>
- The identity and contact information of individuals outside the research team whom participants may contact regarding possible research-related issues,<sup>27</sup>
- Personal information collected about participants and for what purpose,<sup>28</sup>
- Specific authorization request to access the participant's Québec Health Record, where justified,<sup>29</sup>

<sup>19</sup> TCPS2, art. 3.2 (d).

<sup>20</sup> CCQ, art. 24 para. 3; TCPS2, art. 3.1 (b) and 3.2 (d).

<sup>21</sup> TDR, s. 6.2.5.4; TCPS2, art. 3.1 (b) and 3.2 (d).

<sup>22</sup> TCPS2, art. 3.1 (c) and 3.2 (d).

<sup>23</sup> TCPS2, art. 3.2 (e).

<sup>24</sup> TCPS2, art. 3.2 (e).

<sup>25</sup> TDR, s. 6.2.6.7; TCPS2, art. 3.2 (f).

<sup>26</sup> TCPS2, art. 3.2 (g).

<sup>27</sup> TCPS2, art. 3.2 (h).

<sup>28</sup> TCPS2, art. 3.2 (i); Act Respecting Health Services and Social Services, CQLR, c. S-4.2, art. 19; Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information, CQLR, c. A -2.1, art. 53, 59, 125; CCQ, art. 35 and 37; *Modèle*, s. 10.3; TDR, s. 6.2.4, etc.

<sup>29</sup> CCQ, art. 35 and 37.

- A description of how confidentiality will be protected, as adapted for each research project from the confidentiality clause of the institution's template,<sup>30</sup>
- Planned or anticipated secondary uses of the data and samples obtained in the course of the primary research project,
- Financial compensation and reimbursement for participation-related expenses,
- Compensation for injury,<sup>31</sup>
- Information on stopping rules and situations where researchers might remove participants<sup>32</sup>;

5.3.5 The REB may require a separate consent form for optional procedures or sub- studies (e.g. tissue, blood, genetic testing or specimen banking).

#### **5.4 Language Requirements for Informed Consent**

5.4.1 Except when justified as deemed appropriate by the REB, informed consent forms should be available in both French and English.

5.4.2 If applicable/acceptable, a qualified interpreter – fluent in French or English as well as in the research participant's native language – orally interprets the REB-approved consent form to the research participant. The interpreter should be an impartial person. When the person obtaining consent is assisted by an interpreter, the interpreter must sign and date the consent form;

5.4.3 The REB requires that the research team attests to the accuracy of translated informed consent forms or requires an attestation from the translator certifying that the translated informed consent accurately reflects the contents of the REB-approved informed consent form;

5.4.4 If a research participant asks that the informed consent form be read to him/her, an impartial witness must be present during the reading and the entire informed consent discussion. Consent is documented, and the impartial witness attests that the information was accurately explained to the research participant and that consent was given by the research participant;

5.4.5 Where a participant cannot express consent by signing, consent may be given verbally or with a written mark, provided that a witness is present and attests to it in writing.

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<sup>30</sup> TCPS2, art. 3.2 (i).

<sup>31</sup> TCPS2, art. 3.2 (j); ICH GCP, s. 3.1.9.

<sup>32</sup> TCPS2, art. 3.2 (l); TDR, s. 6.2.3.2.

## 5.5 Changes to Information Relevant to Consent for Ongoing and Completed Research Participants

The REB will review and approve: any new information to be provided to participants of ongoing research, the disclosure of potential long-term health effects during or after participation in a research project, as well as any changes to the consent form related to the transmission of new information to participants<sup>33</sup>;

5.5.1 The Researcher must inform research participants of any new information that might affect their willingness to continue participating in the research or that may affect their long-term health, even if they have completed their participation in the research (e.g. significant changes to the research or potential risks thereof)<sup>34</sup>;

5.5.2 The REB will determine:

- The nature of the new information to be given to ongoing participants and the required documentation,
- Whether a modified consent form is required for incorporating the updated information,
- The process by which to allow participants to reconsider whether or not to continue participating in the research<sup>35</sup>;

5.5.3 If applicable, ongoing consent may be obtained orally by contacting the research participant by phone, providing the updated information, and documenting their agreement to continue<sup>36</sup>;

5.5.4 The Researcher must inform former research participants of any new information that may be relevant to their long-term health by contacting them via phone or mail or in person, as applicable.

## 5.6 Waiver or Alteration of Informed Consent

5.6.1 The REB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, provided that the Researcher submits satisfactory justification thereof and that the REB finds and documents the following:

- The regulatory guidance framework for research and all previously expressed wishes support the waiver,
- The research involves no more than minimal risk to the participants,<sup>37</sup>
- It is impossible, practically impossible, or inopportune to seek consent or to obtain fully informed consent,

<sup>33</sup> *Modèle*, s. 10.4.

<sup>34</sup> TCPS2, art. 3.3.

<sup>35</sup> Consent may be withdrawn at any time, even verbally (CCQ, art. 24 para. 3).

<sup>36</sup> CCQ, art. 24 para. 2.

<sup>37</sup> TCPS2, art. 3.7A (a).



- The waiver or alteration is unlikely to adversely affect the well-being of the participants or their relations,<sup>38</sup>
- The research could not practicably be carried out without the waiver or alteration,<sup>39</sup>
- The information is used in a manner that will ensure its confidentiality,<sup>40</sup>
- Whenever appropriate, participants will be provided with additional pertinent information after participation;

5.6.2 The REB may allow research in health emergencies, by obtaining deferred informed consent of the participant or of his/her authorized third party, provided that the Researcher submits satisfactory justification thereof and that the REB finds and documents the following<sup>41</sup>:

- The regulatory guidance framework for research supports the waiver,
- A serious threat to the prospective participant requires immediate intervention,
- Either no standard efficacious care exists, or the research offers a real possibility of direct benefit to the participant in comparison with standard care,
- Either the risk of harm is not greater than that involved in standard therapeutic care, or it is clearly justified by the potential for direct benefit to the participant,
- The prospective participant is unconscious or lacks the capacity to understand the risks, methods and purpose of the research project,
- Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so, and
- No relevant prior directive by the participant is known to exist;
- Informed consent will be sought in a timely fashion as soon as the participant regains decisional capacity or a legal representative is found, as a condition of continued participation.

## 5.7 Consent for Research Involving Individuals Who Lack Capacity

5.7.1 For research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB must ensure that at a minimum the following conditions are met:

- Insofar as possible, the Researcher will involve those participants who lack the capacity to consent on their own behalf in the decision-making process. Assent will be documented.<sup>42</sup> Any

<sup>38</sup> TCPS2, art. 3.7A (b).

<sup>39</sup> TCPS2, art. 3.7A (c).

<sup>40</sup> The REB ensures respect for the legal framework for the protection of privacy and confidentiality of personal information: *Modèle*, s. 10.3; TDR, s. 6.2.4, etc.; Act Respecting Health Services and Social Services, CQLR, c. S-4.2, art. 19 and 19.2; Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information, CQLR, c. A -2.1, art. 53, 59, 125; CCQ, art. 35 and 37; Québec Charter of Human Rights and Freedoms, c. C -12, art. 5.

<sup>41</sup> TCPS2, art. 3.8.

<sup>42</sup> TCPS2, art. 3.9.

participant who dissents while understanding the nature and consequences of the study may not participate in the research,<sup>43</sup>

- The Researcher seeks consent from the prospective participant’s legal representative.<sup>44</sup> This legal representative cannot be the Researcher or any other member of the research team,<sup>45</sup>
- Whether or not the research affects the integrity of the prospective participant:
  - The Researcher demonstrates that, if the research involves only one participant, it is being carried out for his/her health; if the research involves a group of participants, it is being carried out for the benefit of persons of the same age, disease, or disability characteristics as the participant group,<sup>46</sup>
  - The inherent risks of the research, considering the participant’s state of health and personal condition, shall not be out of proportion to the benefits one can reasonably expect,<sup>47</sup>

5.7.2 When authorization for participation was granted by an authorized third party, and the participant acquires or regains capacity during the research, the Researcher will seek the participant’s consent, insofar as possible, as a condition of continued participation.<sup>48</sup>

## 6 REFERENCES

See footnotes.

## 7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
REB-SOP 404.001	N.A.	Original version
REB-SOP 404.001-1	2020-03-20	5.1.5: “Quebec Public Health Department” corrected for “Director of Professional Services”
REB-SOP 404.001-2	2024-10-15	Revisions to informed consent forms after changes to institutional templates

## 8 APPENDICES

<sup>43</sup> CCQ, art. 21 para. 3.

<sup>44</sup> CCQ, art. 21 para. 5 and 6. Maintaining consent on an ongoing basis: TCPS2, art. 3.3 and 3.9 (b).

<sup>45</sup> TCPS2, art. 3.9 (c).

<sup>46</sup> *Modèle*, s. 10.3; TCPS2, art. 3.9 (d). Research interfering with the integrity of the person: CCQ, art. 21 para. 2.

<sup>47</sup> *Modèle*, s. 10.3; EPTC2, art. 3.9 (d). Research interfering with the integrity of the person: CCQ, art. 10 and 21 para. 1.

<sup>48</sup> TCPS2, art. 3.9 (e).