

# Incentive Guidelines for Human Participant Research

## 1.0 PURPOSE

The purpose of this document is to provide guidance for researchers who plan to offer incentives for human research participation, as described in the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans TCPS 2 2018](#).

## 2.0 DEFINITIONS

**Coercion:** An extreme form of undue influence, involving a threat of harm or punishment for failure to participate. Coercion may negate the voluntariness of a decision to participate, or to remain, in a research project.

**Compensation:** Payment for one's time (e.g., minimum hourly wage).

**Gifts:** Token gestures and nominal in value (e.g., \$5 gift certificate, entry in a draw).

**Incentives:** Anything offered to participants, monetary or otherwise, for participation in research (incentives differ from reimbursements and compensation for injury).

**Lottery:** A chance to win a substantial prize.

**Reimbursement:** Payment to participants to ensure that they are not put at a direct, or indirect, financial disadvantage for the time and inconvenience of participation in research. Direct expenses refer to the costs incurred, while indirect expenses refer to losses that arise, because of research participation.

**Remuneration:** Payment for out-of-pocket expenses such as parking, travel, day care, and meals.

## 3.0 PROCEDURES

Because incentives are used to encourage participation in a research project, they are an important consideration in assessing voluntariness. If participants are to be offered incentives, the details must be provided to the REB. Incentives must be commensurate with the risks of participation and must not be so significant that it could be perceived to be an enticement to participate.

### 3.1 Incentives – General Research

3.1.1 Incentives are required to be appropriate in type and amount;

- 3.1.2 The onus is on the researcher to justify to GREB/HSREB the use of a particular incentive model and the level of incentives;
- 3.1.3 Incentives should not be so large or attractive as to encourage reckless disregard of risks;
- 3.1.4 Researchers and REBs should be sensitive to issues such as the economic circumstances of those in the pool of prospective participants, the age and decision-making capacity of participants, the customs and practices of the community, and the magnitude and probability of harms;
- 3.1.5 If the research project uses a lump-sum incentive for participation, the participant is entitled to the entire amount;
- 3.1.6 If a payment schedule is used, participants shall be paid in proportion to their participation;
- 3.1.7 Access to health care, education, and other services should not be prejudiced by the decision to participate (e.g., teachers should not recruit prospective participants from their classes or students under their supervision; physicians should ensure that continued clinical care is not linked to research participation);
- 3.1.8 Participants must be free to withdraw their consent to participate in the research at any time, and need not offer any reason for doing so, without suffering any disadvantage or reprisal, including withholding payment; If there is a time point at which participants may not withdraw their data (e.g., following the submission of an anonymous survey, following dissemination/publication), this limitation must be communicated to participants during the informed consent process ([TCPS 2 2018, Article 3.1](#));
- 3.1.9 The payment structure for research participation should not put undue pressure for participation to join or remain a part of the research project (i.e. payments that may cause participants to undertake actions that they would not ordinarily accept);
- 3.1.10 All processes regarding incentives should be clearly defined during the informed consent process.

### **3.2 Unequal Compensation**

- 3.2.1 Unequal compensations can result from: study design, compensation being tied to performance, and chance;
- 3.2.2 It is considered unethical to compensate participants differently if they contribute in a like manner to the research project;
- 3.2.3 A research design might require more extensive contribution of time and effort from some participants than others (e.g., short vs. long survey); and therefore differences in compensation must be justified to the REB;

- 3.2.4 Some studies may involve parents and their small children, who may be compensated differently;
- 3.2.5 Some First Nations expect compensation for Elders that differs in kind or extent from compensation for other participants;
- 3.2.6 Researchers may have valid reasons for wanting to tie compensation to some aspect of performance; however, these reasons must be justified to and cleared by the REB;
- 3.2.7 Participants should be informed on the LOI/CF and/or debriefed afterwards, if there is any prospect of their learning differences in compensation relative to other participants;

### **3.3 Lotteries**

- 3.3.1 Lotteries can be used to compensate participants, instead of having to give individual incentives for participation;
- 3.3.2 The maximum prize value must not exceed \$500;
- 3.3.3 Participants should be informed of the value of the prize and their odds of winning (i.e. number of participants entered in lottery), and be given an opportunity to opt out of the lottery during the informed consent process.

### **3.4 Queen's University Payments to Research Study Participants**

- 3.4.1 Queen's University must comply with Canada Revenue Agency and Research Funding Agency guidelines when issuing cash, near-cash, or non-cash items to research study participants;
- 3.4.2 The Queen's University Policy on payments to research study participants can be found: <http://www.queensu.ca/secretariat/policies/finance/payments-research-study-participants>;
- 3.4.3 For individual payments of \$250 or more, the participant's name, home mailing address and social insurance number must be obtained;
- 3.4.4 The Principal Investigator (PI) or delegate is responsible for the following in regards to payments to study participants:
  - Ensuring all necessary ethics approvals are in place and that payments are eligible under the applicable funding agency guidelines,
  - Approving payments (cash, near-cash, or non-cash) to study participants,
  - Safeguarding cash, near-cash, or non-cash items until distributed to study participants,
  - Issuing funds, near-cash, or non-cash items to study participants as required,
  - Reconciling advanced funds and repaying any unused funds by way of cash or cheque to the project from which the

advance was issued and promptly returning any unused funds,

- Maintaining appropriate supporting documentation of payments to participants in accordance with record retention requirements of CRA and funding agencies,
- Notifying Accounts Payable at [accounts.payable@queensu.ca](mailto:accounts.payable@queensu.ca) if a PI becomes aware that a participant will accumulate \$500 or more in study payments or other non-employment income.

### **3.5 Reimbursement/Remuneration**

3.5.1 Participants should be offered remuneration for out-of-pocket expenses, unless the PI can justify why it is not possible to do so;

3.5.2 Participants should be informed about the reimbursement/remuneration procedure, or lack thereof, during the informed consent process.

### **3.6 Incentives – Clinical Trials Phase I-VI**

3.6.1 For all phases: Researchers and REBs must ensure incentives for participation are not coercive, and patients do not accept risks they would otherwise refuse because of the incentives being offered;

3.6.2 **Phase I:** Generally includes participants with specific diseases for whom conventional therapy has failed. Researchers and REBs must ensure that participants are aware of the untested nature of the therapy;

3.6.3 **Phase II:** Generally includes participants whose therapeutic options have been exhausted;

- During the course of a Phase II clinical trial, patients will have access to a new drug that may provide clinical benefit. Researchers shall:

- a) as part of the consent process, provide details on access to the new drug upon trial completion; and
- b) make reasonable efforts to secure continued access to the drug following the Phase II trial, for those patients for whom the drug appears to be efficacious;

3.6.4 **Phase III:** Researchers and REBs should ensure that the care of patient-participants is not compromised in the random assignment to any arm of the trial (including the placebo arm). Researchers should also provide a plan for interim analysis of data, early unblinding of clinicians and/or patients, and/or ending the trial if the drug should prove ineffective or harmful;

3.6.5 **Phase IV:** Phase IV is valuable for assessing the long-term safety and effectiveness of marketed drugs and devices. Researchers and REBs should consider the financial terms between sponsors and

investigators, as these terms may create problems such as inappropriate prescription practices, billing practices, and/or inappropriate utilization of public resources.

## 4.0 ADDITIONAL NOTES

[TCPS 2 2018 Article 3.1 states:](#)

- a) Consent shall be given voluntarily.
- b) Consent can be withdrawn at any time.
- c) If a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials.

### **Application:**

“This Policy neither recommends nor discourages the use of incentives. The onus is on the researcher to justify to the REB the use of a particular model and the level of incentives... In considering the possibility of undue influence in research involving financial or other incentives, researchers and REBs should be sensitive to issues such as the economic circumstances of those in the pool of prospective participants, the age and decision-making capacity of participants, the customs and practices of the community, and the magnitude and probability of harms (see [Chapter 4, Section B](#))...

(b) To maintain the element of voluntariness, participants shall be free to withdraw their consent to participate in the research at any time, and need not offer any reason for doing so. The participant should not suffer any disadvantage or reprisal for withdrawing nor should any payment due prior to the point of withdrawal be withheld. If the research project used a lump-sum incentive for participation, the participant is entitled to the entire amount. If a payment schedule is used, participants shall be paid in proportion to their participation.

(c) The consent process should set out any circumstances that do not allow withdrawal of data or human biological materials once collected....Researchers must provide a rationale to the REB for using collection methods that do not permit subsequent withdrawal of data or human biological materials. Where the terms of the research do not allow for withdrawal of their data or human biological materials, the identity of the participants shall be protected at all times during the project and after its completion. Participants shall also be informed that it is impracticable, if not impossible, to withdraw results once they have been published or otherwise disseminated.”

### **Clarification on the Use of Incentives from the Panel of Research Ethics (PRE)**

Queen’s University requested clarification about the use of incentives from the [Panel of Research Ethics \(PRE\)](#) based on second edition of the *Tri-Council Policy Statement*:

*Ethical Conduct for Research Involving Humans* on 2016AUG12 and the specific questions and responses from PRE are noted below:

**1. If the participant withdraws at any point for whatever reason whatsoever after the research has started, is the participant entitled to the lump sum compensation?**

- Respect for persons, one of three Core Principles of TCPS2 (2014), translates in part into the right of participants to voluntarily decide to participate and to their right to withdraw at any time. As stated in Application of Article 3.1, “(b) To maintain the element of voluntariness, participants shall be free to withdraw their consent to participate in the research at any time, and need not offer any reason for doing so...The participant should not suffer any disadvantage or reprisal for withdrawing nor should any payment due prior to the point of withdrawal be withheld.” If the compensation that the participant was informed of when consenting to participate was lump sum, then the participant is entitled to the lump sum compensation. If the compensation is based on a schedule where the participant is compensated proportionate to their participation, then the participant is entitled to the amount up to the point of their withdrawal.

**2. If the participant starts a survey or interview and answers nothing at all, is the participant entitled to the lump sum compensation?**

- If the participant submits the survey with nothing, and the design of survey/interview tool does not oblige the participant to provide an answer, the promised compensation will need to be provided to the participant – same as response to question 1 above, either lump sum or based on a schedule.

**3. Can researchers set up conditions to limit compensation if a participant doesn't finish at least a certain percentage of the expected participation?**

- Yes, a schedule can be developed to set minimum participation and to prorate the compensation based on participation.

**“It should be noted that TCPS2 (2014) “neither recommends nor discourages the use of incentives. The onus is on the researcher to justify to the REB the use of a particular model and the level of incentives.” (Application of Article 3.1).**

## 5.0 REFERENCES

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans TCPS2 (2018): <http://www.pre.ethics.gc.ca/eng/home.html>.
2. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans TCPS2 (2018):  
<http://www.pre.ethics.gc.ca/eng/home.html> Compensation of Human Research Participants (University of Alberta): [http://www.reo.ualberta.ca/en/Human-Research-Ethics/~media/reo/Human-Ethics-Files/Forms-Files/Guidelines-on-Compensation-of-Human-Research-Participants%20 March 2009.pdf/](http://www.reo.ualberta.ca/en/Human-Research-Ethics/~media/reo/Human-Ethics-Files/Forms-Files/Guidelines-on-Compensation-of-Human-Research-Participants%20March%202009.pdf/).
3. Guidelines for Compensation and Reimbursement of Research Participants (University of Toronto): <http://www.research.utoronto.ca/wp-content/uploads/2010/01/Guidelines-for-Compensation-and-Reimbursement-of-Research-Participants-Approved-Feb-16-11.pdf/>
4. The Queen's University Policy on payments to research study participants can be found: <http://www.queensu.ca/secretariat/policies/finance/payments-research-study-participants/>.
5. Detecting, Preventing, and Responding to “Fraudsters” in Internet Research: Ethics and Tradeoffs, Jennifer E. F. Teitcher, Walter O. Bockting, Ph.D., José A. Bauermeister, M.P.H., Ph.D., Chris J. Hoefler, Michael H. Miner, Ph.D., and Robert L. Klitzman, M.D.:  
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4669957/>.