

GUIDANCE STATEMENT ON INCENTIVES

The relationship between risk and participation incentives. There are infamous examples in medical research where vulnerable populations (often economically disadvantaged) have been offered huge financial incentives to participate in extremely high risk research. Such practices are unethical insofar that 1) informed consent can be compromised due to voluntariness concerns, 2) potential participants may display poor judgment by disregarding or overlooking issues or risk, or 3) individuals may falsify or conceal personal information so as to qualify for participation. In social sciences and humanities research, the same potential exists; therefore, researchers must be extremely sensitive to the participant's situation when an incentive is offered.

The following questions and answer discussion is provided to assist researchers in preparing their application for ethics review.

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1. **Are incentives considered a form of undue influence or coercive offer to participate?** NO; TCPS2 (2014) distinctly separates “incentives”, “undue influence” and “coercion” from each other, and it is important to understand that those distinctions and definitions stand on their own.

However, “Because incentives are used to encourage participation in a research project, they are an important consideration in assessing voluntariness”, which is the overarching principle under discussion. As defined in TCPS2 (see appendix showing full text of quotes/definitions paraphrased below):

- **UNDUE INFLUENCE** has to do with recruitment by individuals where potential participants “...being recruited may feel constrained to follow the wishes of those who have some form of control over them” through pre-existing relationship, whether the power of control is authority-based, trust and dependency-based, or service-entitlement based.
- **COERCION** “...is a more extreme form of undue influence, involving a threat of harm or punishment for failure to participate.”
- **INCENTIVES** “...are anything offered to participants, monetary or otherwise, for participation in research (incentives differ from reimbursements and compensation for injury).”

It is the REB's job to examine each situation independently to determine—given the circumstances of the participant and the context of the research—whether “...Where incentives are offered to participants, they [are] so large or attractive as to encourage reckless disregard of risks.”

2. What is considered a modest incentive that is ethically acceptable? IT WILL VARY.

The REB looks at the personal circumstances of the participant, what is being required of their time and effort to participate, and the risks involved in participating. Researchers have to justify why they need or choose to offer incentives in order to attract participation in the first place, and if it cannot be justified it would not matter how small or how large the incentive is.

Even a small incentive to participants in certain situations, for example, might be considered unethical.

Reciprocity gifting or tokens of thanks are sometimes offered (e.g. tobacco and customary cash gifts to Elders in the Aboriginal research context) but are not usually considered incentives, as they are expressing expected social and customary respect in exchange for the participant's gift of knowledge that is being provided to the researcher.

Likewise, in the non-Aboriginal context, in smaller participant pools things provided such as "\$5 Tim Horton card, \$20 online bookstore cards, pizza lunch before or after interviews or focus groups and observations, donuts and coffee during activities, can be found acceptable as simple expression of thanks from the researcher to the participant, rather than an incentive to participate. The researcher must certainly declare their intentions to provide such small acknowledgements, and the REB will examine the circumstances to see if they are appropriate in relation to the context and whether they need or should be mentioned during recruitment; however, they are not necessarily considered "incentives" in the meaning defined by TCPS2.

The offering of a larger amount of cash or value of object in proportion to the amount of time and effort required to participate, or an opportunity to win a substantial prize, would definitely be considered to be incentives and would be examined by the REB to determine if they might meet the standard of encouraging "reckless disregard of risks". (Some might argue that in a study without risk, that standard of reckless disregard might never be met).

3. What are the boundaries for incentives, or range of participant numbers compared to acceptable incentive amounts? In past AU REB decisions involving average healthy citizens of Canada in minimal risk (or less than minimal risk) research, the AU REB has NOT been averse to individual incentives up to \$50 for interviews or focus groups lasting approximately two hours, multiple survey completion or record-keeping extending over a period of time (weeks or months). Likewise, up to \$100 for the same type of activities combined altogether has been successfully defended. These incentives generally occur in smaller studies of less than 40 participants, as that number of incentive payments can usually be administered economically and most researchers at AU are limited to \$5,000 or less in their internally-funded or self-funded research budgets.

Where larger incentives are generally seen is the area of online surveys, where a draw is used and the odds of winning are clearly stated. Where offering and distributing \$5 or \$10 gift cards to several hundred participants would be a time-consuming and costly endeavor, it

often makes more administrative sense to the researchers to offer a draw for one or more higher value prizes. In terms of incentives, the theory is that individuals might not make the time to do a 10-minute survey for a \$10 gift card, but for a 1 in 100 chance to win one of two \$500 cash prizes or items of equal value, those same individuals might feel it was worth taking the time to look at, and perhaps participate in, the survey. In those studies, researchers are generally looking for large numbers of participants to validate results, most studies have no risk to participation, and they take less than 30 minutes to complete. The generalized risk of identification of individual participation (loss of privacy and confidentiality of participation) is minimized by collection of the participant's contact information for draw purposes separately from their answers to the survey, and the contact information is destroyed immediately after the draw—so the actual survey answers are not connected to an individual respondent, and there is no list of participants maintained.

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- 4. Are financial incentives ethically acceptable under certain circumstances (e.g. overseas participants, where mailing an incentive gift might be impossible), and how much of an incentive would be considered appropriate?** YES. Incentives are considered by the REB under the same guidance—whether they are cash or objects of equal value—here or in another country. Researchers need to provide the necessary background information to justify the choice they are proposing including the cultural and economic circumstances of their proposed participants along with any other influencing circumstances including disclosure of corporate sponsorship and advertising.

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- 5. Is there any criteria for incentives that can be applied consistently across all applications?** NO. As noted in previous answers, the REB looks at each case individually AND it is the researcher's responsibility to present the arguments supporting the choices being proposed.

An amount proportionate to the time required to participate that is equivalent to the minimal hourly wage of the participant pool has been discussed at least once in past determinations as a way of assessing a maximum value for smaller study incentives for individual interviews, focus groups, and workshop observations. The idea behind this is that the individual would not profit from volunteering to participate in the research (nor would the value of their time be ignored). However, every participant pool will be different, and some will be economically cross-sectored, so even that standard can only be argued in certain circumstances.

Short, casual, anonymous surveys administered in-person (e.g. on the street as people are exiting a mall) or online are a totally different recruitment environment and participation commitment for the individual, and often the recruitment will be more sales-like to attract response, thus employing instant incentives (small gift cards) or larger draw incentives to catch the attention of prospective participants in a larger subject pool.

In evaluating draw (prize) incentives, a specified value is required to be assigned to the

prize whether it is cash or an object, and the chances of winning must be stated. Most recent AU REB approvals have seen \$500 to \$800 as the upper limit of value for an individual prize, whereas a few years ago that amount was \$300. Some researchers have opted to provide better odds by paring down the size of the prize and offering more than one within the same level of budget.

CONCLUSION: TCPS2 is a living document that has been designed to provide guidance on decisions to be made by REBs which are composed deliberately by a number of individuals possessing specific types of knowledge who will reflect current social, scientific, and community values, and whose responsibility is to place the interests of the participant first while not placing "...unnecessary impediments...[on] ethical research". There are very few hard and fast 'rules', but principles and guiding statements do exist so that the group's reflection and decision-making on each case has a basis for interpretation and substantiation.

For those seeking answers in the context of preparing a research award application at the same time as an ethics application, the foregoing illustrations about the types of decisions the REB at AU has made in the past should be helpful. In the end, research funding review and research ethics review are two separate enterprises which must each emerge from, and with, their own constraints and reasons. As an independent board of the university, the REB must reflect and operate under the federal guidelines within an evolving context—in this case, in terms of incentives—which necessitates a fresh look at each application on the basis of the information provided by the researcher and their assessment of what is required to enable the success of their recruitment and the proceeding of the research. A research funding committee on the other hand, must design its decision constraints within a budget-based monetary award system and a context of recognizing the value and level of excellence of the research proposed in order to promote and encourage quality research. The REB cannot carte blanche set specific limitations for research incentives, as that would mean a sense of pre-determination on any ethics applications arising that are tied to a funding award or application and the consequent possibility of conflict of interest which is specifically to be avoided in order for the REB to remain compliant under the federal guidelines.

The following shows the full text of the TCPS2 (2014), Chapter 3, Article 3.1 quotes strewn throughout the answers above. Statements regarding AU REB decisions past and present are generalized across observation of the Board's decisions which have occurred during the past 13 years.

REFERENCE: TCPS2 (2014), Chapter 3, Informed Consent

<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-epc2/chapter3-chapitre3/#toc03-1>

**A. General Principles: Consent Shall Be Given Voluntarily
Article 3.1**

Application (a) The voluntariness of consent is important because it respects human dignity and means that individuals have chosen to participate in research according to their own values, preferences and wishes.

The approach to recruitment is an important element in assuring voluntariness. In particular, how, when and where participants are approached, and who recruits them are important elements in assuring (or undermining) voluntariness. In considering the voluntariness of consent, REBs and researchers should be cognizant of situations where undue influence, coercion or the offer of incentives may undermine the voluntariness of a participant's consent to participate in research.

Undue Influence

Undue influence and manipulation may arise when prospective participants are recruited by individuals in a position of authority. The influence of power relationships (e.g., employers and employees, teachers and students, commanding officers and members of the military or correctional officers and prisoners) on the voluntariness of consent should be judged from the perspective of prospective participants, since the individuals being recruited may feel constrained to follow the wishes of those who have some form of control over them. This control may be physical, psychological, financial or professional, for example, and may involve offering some form of inducement or threatening some form of deprivation. In such situations, the control exerted in a power relationship may place undue pressure on the prospective participants. At the extreme, there can be no voluntariness if consent is secured by the order of authorities.

REBs and researchers should also pay particular attention to elements of trust and dependency in relationships (e.g., between physician and patient or between professor and student). These relationships can impose undue influence on the individual in the position of dependence to participate in research projects. Any relationship of dependency, even a nurturing one, may give rise to undue influence even if it is not applied overtly. There may be a greater risk of undue influence in situations of ongoing or significant dependency.

Pre-existing entitlements to care, education and other services should not be prejudiced by the decision of whether or not to participate in, or to withdraw from, a research project. Accordingly, for example, a physician should ensure that continued clinical care is not linked to research participation. Similarly, where students do not wish to participate in research studies for course credits, they should be offered a comparable alternative.

Coercion

Coercion is a more extreme form of undue influence, involving a threat of harm or punishment for failure to participate. Coercion would negate the voluntariness of a decision to participate, or to remain, in a research project.

Incentives

Incentives are anything offered to participants, monetary or otherwise, for participation in research (incentives differ from reimbursements and compensation for injury, which are discussed in [Article 3.2\[j\]](#)). Because incentives are used to encourage participation in a research project, they are an important consideration in assessing voluntariness. Where incentives are offered to participants, they should not be so large or attractive as to

encourage reckless disregard of risks. This is a particular consideration in the case of healthy volunteers for the early phases of clinical trials, as discussed in [Article 11.1](#). The offer of incentives in some contexts may be perceived by prospective participants as a way for them to gain favour or improve their situation. This may amount to undue inducement and thus negate the voluntariness of participants' consent.

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](#)). Guardians and authorized third parties should not receive incentives for arranging the involvement in research of the individual they represent. However, they may accept reasonable incentives or compensation on behalf of that individual, as long as these are suitable to the circumstances.

ADDITIONAL NOTE REGARDING RECENT AU POLICY (March 2015): *Employee Gift Expenditure Policy and Sponsorship, Donation and Non-Employee Gift Expenditure*

In March 2015, the university announced new financial policy with respect to the reporting requirements for the provision of 'gifts' to employees of AU and to non-employees. These policies govern the provision of all 'gifts' to employees and non-employees (including for research purposes). These new policies have implications to researchers who are proposing 'incentives' in their projects.

If the participants in your study happen to be AU employees, you will be required by Financial Services to provide the names of participants when submitting documentation for reimbursement of expenditures. There is no requirement to name the specific project that the participant was involved in or to explain the nature of the participation. However, this reporting requirement should be provided to participants in the informed consent process.

If the participants in your study are non-employees, you will not be required to provide participant names when submitting documentation for reimbursement of expenditures. Financial Services has confirmed that generic identifiers such as "research participant 1, 2, 3..." is sufficient. The 'purpose of gift' can be generally identified as 'research project'.