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GUIDANCE NOTES ON RESEARCH RISKS AND BENEFITS

INTRODUCTION

As research represents a step in the unknown, it can present certain risks to the participants as well as to the wider communities involved in the research. These risks may be known or unknown at the onset of research. This guidance note is intended to provide researchers with a conceptual framework for research risks, an understanding of the submission requirements related to risks, and the researcher's responsibility with respect to minimizing risks and balancing the risks and benefits in accordance with the core principles of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2): Respect for Persons, Concern for Welfare, and Justice.

GUIDANCE NOTE #1: DEFINITIONS

Risk: The possibility of the occurrence of harm. The level of foreseeable risk posed to participants by their involvement in research is assessed by considering the magnitude or seriousness of the harm and the probability that it will occur, whether to participants or to third parties.

Minimal Risk Research: Research in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research

Above Minimal Risk Research: Research in which the probability and magnitude of possible harms implied by participation in the research are greater than those encountered by participants in those aspects of their everyday life that relate to the research

Research-Attributable Risk: Risks that are specifically attributable to the research procedures.

GUIDANCE NOTE #2: REQUIRED INFORMATION FOR REB REVIEW

Researchers are required to inform the REB whether the research poses minimal risk or above minimal risk to the participants. In cases where there is above minimal risk, the researcher must clearly identify the ways that harms have been minimized and/or managed, and demonstrate that that the study poses a favourable balance of risks and benefits.

All known and reasonably foreseeable risks should be disclosed in the consent form. In cases where there is risk of harms to others (i.e. people other than the participant), such information must be disclosed as well.

2.1 Quantification of Risks

For risks relating to a clinical intervention, the specific percentages of the risks should be provided. These risks should match the harms specified in the protocol and investigator's brochure/product monograph. Such risks should be listed in descending

order of frequency. Risks may be grouped according to range if the range is sufficiently narrow.

Where no percentages are available, specific discussion about risks encountered in case series/case reports, preclinical studies, or studies involving similar procedures are required. If absolutely no relevant data about harms of the experimental procedures is available (e.g. a Phase I trial), Investigators are required to make their best effort to honestly inform participants about possible risks of participating in the research, even if they cannot be quantified. This quantification can be in the form of "for thirty participants, five experienced a particular side effect."

GUIDANCE NOTE #3: UNKNOWN INTERACTIONS WITH OTHER DRUGS

Researchers must disclose in the protocol and consent form whether the research necessitates that certain medication or treatments not be administered during the study so participants can evaluate this in the context of their current health.

GUIDANCE NOTE #3: STUDIES WASH-OUT PERIODS OR REQUIREMENTS FOR STOPPING MEDICATION

The consent from must explain the symptoms/signs that participants could experience from being taken off of any medication, and the potential impacts on their health.

GUIDANCE NOTE #4: HARMS REQUIRING SPECIAL COUNSELLING

If in the course of the research, there are tests that might have results that impact seriously on the research participant's health or have other serious implications (e.g. HIV, Hepatitis, or some genetic tests), appropriate pre- and post-test counselling services should be made available to that person, and, when appropriate, to their family members. The measures taken to ensure that counselling services are made available to research participants should be detailed in the protocol.

GUIDANCE NOTE #5: SOCIAL AND PSYCHOLOGICAL HARMS

Some research projects may present risks related to social harm, such as breaches of confidentiality, social stigmatization, threats to reputation, and/or psychological harms. In such cases, the protocol must detail what strategies are in place to minimize and/or manage such risks to participants and other affected individuals. For studies where the research activities are likely to reveal high levels of psychological distress (e.g., EQ-5D questionnaire), a rescue plan must be described in the protocol and consent form.

GUIDANCE NOTE #6: HARMS RELATED TO TESTING FOR REPORTABLE DISEASES

For studies that require testing for reportable communicable diseases, the consent form must explicitly inform the participants of potential for such reporting to occur. Refer to the BC Centre for Disease Control's list of reportable communicable diseases.

GUIDANCE NOTE #7: RISK OF NOT BEING ABLE TO RECEIVE STUDY TREATMENT FOLLOWING TERMINATION OF THE STUDY

For studies involving clinical treatments for chronic conditions, the possibility that participants will not be able to receive the treatment after the study ends should be disclosed in the consent form. Refer to the BC Common Clinical Informed Consent Form Template for specific wording.

GUIDANCE NOTE #8: Harms to Others

Any potential harms to individuals other than the participant (e.g. sexual partners, family members, etc.) that may arise from the study must be disclosed in the protocol and consent form.

The risk of any harms to pregnant women, to women who could become pregnant during the course of the research, or to men in relation to the reproductive capacity need to be disclosed in the consent form. In studies where such risks exist, the exclusion criteria on the consent form should explicitly indicate individuals intending to become pregnant or impregnate their partners.

GUIDANCE NOTE #9: Benefits

Research benefits can be direct, e.g. a health condition improves, or indirect, e.g. the research benefits a group to which the participant belongs. The protocol and consent form should specify the benefits to the participants. If there are no direct benefits to the participants from participating in the research, this must be stated explicitly. If any specific therapeutic benefits cannot be assured, but may be hoped for by the participant, state explicitly that the participant may or may not benefit from participation in the study.