**FORM 4.1B GUIDANCE - EXPEDITED REVIEW**

Categories of Research That May Be Reviewed by the IDI REC through an Expedited Review

Procedure1

 *Applicability*

1. Research activities that
2. Present no more than minimal risk to human participants, and
3. Involve only procedures listed in one or more of the following categories, may be reviewed by the REC through the expedited review procedure. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human participants.
4. The categories in this list apply regardless of the age of participants, except as noted.
5. The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
6. The expedited review procedure may not be used for classified research involving human participants.
7. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the REC.
8. Categories one (1) through seven (7) pertain to both initial and continuing IDI REC review.

*Research Categories*

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
2. Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
3. Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labelling.
4. Collection of blood samples by finger stick, heel stick, ear stick, or venepuncture as follows:
5. From healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
6. From other adults and children2, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
7. Prospective collection of biological specimens for research purposes by non-invasive means. Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) un cannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labour; (h) supra- and sub gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
8. Collection of data through non-invasive procedures (not involving general anaesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
9. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
10. Collection of data from voice, video, digital, or image recordings made for research purposes.
11. Research on individual or group characteristics or behaviour (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviour) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
12. Continuing review of research previously approved by the convened REC as follows:
13. Where (a) the research is permanently closed to the enrolment of new participants; (b) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; or
14. Where no participants have been enrolled and no additional risks have been identified; or
15. Where the remaining research activities are limited to data analysis.
16. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories B through H do not apply but the REC has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

1 An expedited review procedure consists of a review of research involving human participants by the IDI REC chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IDI REC.

2 Children are defined as "persons who have not attained the legal age for consent to procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.