**FORM 4.1A DETERMINATION OF QUALIFICATION FOR EXPEDITED REVIEW**

**Before determining whether or not the study meets the Criteria for Expedited Review, the reviewer must have completed the Primary Reviewer Worksheet (Form 402A)**

| **MINIMAL RISK DETERMINATION** | Yes | No | N/A |
| --- | --- | --- | --- |
| The probability and magnitude of harm or discomfort anticipated in the proposed research greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. |  |  |  |
| Could identification of the participants and/or their responses 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. |  |  |  |
| Or Is the research classified? |  |  |  |
| **DETERMINATION OF QUALIFICATION FOR EXPEDITED REVIEW** |  |  |  |
| Allowed procedures |  |  |  |
| 1. Clinical studies of drugs and medical devices *only* when condition a) or b) is met
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| 1. Research on drugs for which an investigational new drug application is not required. (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.)
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| 1. Research on medical devices for which
 |  |  |  |
| 1. an investigational device exemption application (21 CFR part 812) is not required; **or**
 |  |  |  |
| 1. the medical device is cleared/ approved for marketing and is being used in accordance with its cleared/approved labelling.
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| 1. Collection of blood samples by finger stick, heel stick, ear stick, or venepuncture as follows:
2. From healthy, non-pregnant adults who weigh at least 110 pounds, the amounts drawn do not exceed 550 ml in an 8 week period and collection does not occur more frequently than 2 times per week; **or**
 |  |  |  |
| 1. From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, the frequency with which it will be collected.
 |  |  |  |
| 1. The amount drawn does not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period **and**
 |  |  |  |
| 1. Collection does not occur more frequently than 2 times per week.
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| 1. Prospective collection of biological specimens for research purposes by non-invasive means.
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| 1. 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.
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| 1. 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).
 |  |  |  |
| 1. Collection of data from voice, video, digital, or image recordings made for research purposes.
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| 1. 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.
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| 1. Continuing review of research previously approved by the convened IDI REC as follows:
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| 1. the research is permanently closed to the enrolment of new participants; **and** all participants have completed all research-related interventions; **and** the research remains active only for long-term follow-up of participants; **or**
 |  |  |  |
| 1. Where no participants have been enrolled and no additional risks have been identified; **or**
2. Where the remaining research activities are limited to data analysis
 |  |  |  |
| 1. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories 2 through 8 do not apply but the IDI 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.
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**Comments**

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[ ]  No [ ] Yes

Does this study meet expedited review criteria?

IDI REC Administrator Date

IDI REC Reviewer Date