

CONTINUING REVIEW MATRIX

Indicate the Level of Continuing Review with an **×** in only **ONE** of the boxes in the matrix below.

1. RESEARCH CATEGORY	2. LEVEL OF CONTINUING REVIEW			
	LEVEL I Adverse Events & Annual REB reports	LEVEL II Level I & Audit 10% of subjects	LEVEL III Levels I, II & Audit >10% of subjects; + -DSMC	LEVEL IV Level I to III & observe consent
A. Retrospective observational Studies involving personal health information NO patient contact	<input type="checkbox"/>			
B. Prospective observational studies: NO physical exams	<input type="checkbox"/>	<input type="checkbox"/>		
C. Prospective observational studies: Physical exams and physiological assessments without biological specimens		<input type="checkbox"/>	<input type="checkbox"/>	
D. Prospective observational studies: with biological specimens (blood, urine, tissue)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E. Clinical intervention trials (×) <input type="checkbox"/> Drug <input type="checkbox"/> Device <input type="checkbox"/> Surgical <input type="checkbox"/> Behavioural <input type="checkbox"/> Biologic <input type="checkbox"/> Natural Health Product		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

FOR CLINICAL INTERVENTION TRIALS ONLY: For drug, biologic, natural health product or device trials, indicate the **phase** of the trial (×).

Phase I <input type="checkbox"/> (initial use in humans; to determine the safest dose, route and schedule for a new drug; to identify toxic side effects)
Phase II <input type="checkbox"/> (to provide preliminary information about how well the drug works; to generate more information about safety and benefit of the drug)
Phase III <input type="checkbox"/> (to compare a new drug or combination of drugs or a procedure with the current standard therapy; to obtain additional safety and efficacy data)
Phase IV <input type="checkbox"/> (following regulatory approval of the drug; study drug is used for the approved indication; to determine if efficacy can be improved)

INSTRUCTIONS FOR COMPLETING THE MATRIX

STEP 1- Classify your study according to the Categories of Research A to E.

- Select only **ONE** category of research that includes the most invasive type of contact/intervention with the subjects in your study.

Categories of Research for the Continuing Review Matrix

A Chart Reviews (Retrospectively Collected Data)

- Review and analysis of previously collected data from health records information (e.g., retrospective chart studies)
- Information may be retrieved from Health Records charts, clinic charts, or study charts, or may be in internal or external computerized databases (e.g. Statistics Canada, OHIP, etc.)
- Purpose of review of records is to study the natural history or incidence of disease, diagnostic methods, prognostic studies, or collect pilot information
- Note that some of the information may be sensitive, including information of a confidential nature that might cause economic disadvantage (e.g., influence employability or insurability), or be socially stigmatizing in any way, thus may pose more potential risk to the research subject.
- The underlying principle for this type of research is that no contact, either by mail, email, telephone, or face-to-face interaction will be made with patients/research subjects.

B Prospective Studies using questionnaires, interviews and data contained in registries or databases

- May include: qualitative research, including focus groups regarding needs, or satisfaction with services
- May include program evaluation, health services research, health economics research, behavioural observation, outcome of disease, quality of life.
- The underlying principle for this type of research is that there is direct contact with patients/research subjects via telephone, mail, email, or face-to-face interview, however there is no physical, imaging, or neuro-cognitive examination of patients.

C Prospective observational studies involving patient examinations, without biological specimens.

- May include: natural history of disease, diagnostic methods, prognostic studies
- Could include physical examinations, Vision/hearing testing, Imaging
- Psychological and neurocognitive testing
- The underlying principle for this type of research is that there is direct contact with patients/research subjects which involves physical, imaging, or neurocognitive examination of patients.

D Prospective observational studies with biological specimens (e.g. blood, urine, tissue)

- Studies of mechanisms of disease
- May include: genetic, biochemical, morphological (e.g. microscopy of human tissue), and physiological (e.g. metabolism) studies
- Samples are identifiable/linked to a specific patient
- Usually includes more investigations than would be ordered for clinical purposes
- The underlying principle for this type of research is that there is direct contact with patients/research subjects which involves obtaining biological specimens from patients and/or research subjects.

E Clinical Intervention Trials involving drugs, devices, natural health products, behavioral interventions etc.

- Phase I, II, III, and IV studies * that prospectively study or compare therapies or diagnostic methods
- May include pharmacokinetic or pharmacodynamic studies
- May also include elements of Research Study Types A-D
- May use randomization, blinding or placebos
- The underlying principle for this type of research is that there is a diagnostic or therapeutic intervention involving research subjects.

STEP 2- Risk to Research Subjects:

- **Next, consider the degree of risk to the research subjects in your study.**

The following factors should be considered: subjects' diagnosis and stage of disease, age, sensitivity of information (e.g. HIV status, economic status), type of specimen(s) collected, novelty and invasiveness of intervention(s), number of interventions, study duration, study methodology (e.g. use of placebos, randomization), conflict of interest, research experience of PI, experience of clinical research staff.

STEP 3- Level of Continuing Review:

- **Select only ONE level of continuing review that corresponds with your category of research. Please note that continuing review is cumulative ie., all of the continuing review elements of lower risk categories also apply.**

Each level of Continuing Review is defined as follows:

Level I Annual Status Report (Renewal Form) to REB in addition to ongoing adverse event reporting

Level II Level I Requirements **and** Audit of 10% of enrolled subjects, including approvals, consents, protocol adherence, drug accountability and patient eligibility

Level III Level I and II Requirements **and** Audit of >10% of enrolled subjects (as in Level II), plus continuing review of adherence to treatment protocol, adverse events, pharmacy review, and data quality: A Data Safety Monitoring Committee (DSMC) may also be required.

Level IV Level I, II and III requirements plus observation of informed consent or interview of research subjects post-consent by the Clinical Research Monitor.

- **Phase 1:** Initial use in humans; to determine safest dose, route and schedule for a new drug, to identify toxic side effects.
- **Phase 2:** to provide preliminary information about how well the drug works; to generate more information about the safety and benefit of the drug; to study a new use of an approved drug.
- **Phase 3:** to compare a new drug or combination of drugs or a procedure with the current standard therapy; to obtain additional safety and efficacy data.
- **Phase 4:** following regulatory approval of the drug, the study drug is used for the approved indication to determine if efficacy can be improved.