

Guidance: The difference between Clinical or Behavioural studies is not always clear. The final decision is at the discretion of the Boards. Please reach out to your REB if you have any questions around which study type should be selected for box 4.1.

Behavioural and social sciences projects intend to study the relationship between people and their surroundings, including how people interact with each other, their communities, and institutional systems. They include psychological phenomena such as emotions, biases, and motivations etc. Psychological therapy and counselling studies fall under behavioural research. Emergent design and community-based studies are considered social science and behavioural research unless a clinical intervention is involved. Common methods include, but are not limited to, interviews, focus groups, surveys, questionnaires, behavioural therapy workshops, experimental coaching, observations, and secondary use of data.

Behavioural and social sciences studies can be about health and include health care providers and patients, where the goal is **not** to modify direct patient clinical care (e.g. diagnosis, medication, or treatment). When clinical charts are being accessed for a behavioural study full patient consent is required. Retrospective medical chart review projects should be submitted using the Clinical application form.

Clinical research intends to evaluate the effects of one or more health-related interventions on health outcomes. Investigations include, but are not restricted to, drug administration, surgical procedures, radiologic procedures, devices, genetic therapies, cells and other biological products, radiopharmaceuticals, natural health products (NHPs), process-of-care changes, preventive care, manual therapies, and psychotherapies.

Health Canada and US FDA regulated research, research evaluating human anatomy, physiological outcomes and processes, medical chart reviews, secondary analysis of clinical data, biobanks and clinical data registries should be submitted as a Clinical application.

A clinical research project that also includes questionnaires or interviews as part of its methodology should be submitted to a Clinical Research Ethics Board.