RS0400 – RESEARCH IN MEDICAL EMERGENCIES

Interior Health would like to recognize and acknowledge the traditional, ancestral, and unceded territories of the Dãkelh Dené, Ktunaxa, Nlaka'pamux, Secwépemc, St'át'imc, Syilx, and Tŝilhqot'in Nations, where we live, learn, collaborate and work together.

Interior Health recognizes that diversity in the workplace shapes values, attitudes, expectations, perception of self and others and in turn impacts behaviors in the workplace. The dimensions of a diverse workplace includes the protected characteristics under the human rights code of: race, color, ancestry, place of origin, political belief, religion, marital status, family status, physical disability, mental disability, sex, sexual orientation, gender identity or expression, age, criminal or summary conviction unrelated to employment.

1.0 PURPOSE

To describe the actions of the Interior Health (IH) Research Ethics Board (REB) for the ethical review of research in which the participant is having a medical emergency.

2.0 DEFINITIONS

TERM	DEFINITION
Authorized third party:	*Any person with the necessary legal authority to make decisions on behalf of a prospective participant who lacks the Capacity to Consent to participate, or to continue to participate, in a particular research project. An individual who is recognized by the institutional policy as acceptable for providing Consent in the non-research context to the procedures involved in the research will be considered a legally Authorized representative for the purposes of the research.*
Capacity	*The ability of prospective or actual participants to understand relevant information presented (e.g. purpose of the research, foreseeable risks, and potential benefits), and to appreciate the potential consequences of any decision they make based upon this information.*
Consent:	*An indication of agreement by an individual to become a participant in a research project. The term Consent implies free (also referred to as voluntary), informed and ongoing Consent.*

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3.0 POLICY

3.1 Research in medical emergencies requires additional consideration and/or there may be federally mandated determinations that the REB is required to make and document.

3.2 Research in medical emergencies must have REB approval prior to implementation. This may be provided by the Chair or Designee.

3.2.1 Prior to approving such research, the REB must ascertain that:

3.2.1.1 a formal research protocol exists,

3.2.1.2 a serious threat to the prospective participant requires immediate intervention,

3.2.1.3 the researcher or health care provider is qualified to provide the experimental treatment,

3.2.1.4 all standard known efficacious treatment has been administered, and

3.2.1.5 the patient or third party has provided informed Consent.

3.2.2 The researcher must justify to the REB the reasons why an exception to obtaining informed Consent from participants is required. Consent may also be waived if adequate attempts have been made to locate an Authorized Third Party and have failed.

3.2.3 Subject to all applicable legal and regulatory requirements, research involving medical emergencies shall be conducted only if it addresses the emergency needs of the individuals involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves medical emergencies to be carried out without the Consent of participants, or of their Authorized Third Party, if ALL of the following apply:

3.2.3.1 A serious threat to the prospective participant requires immediate intervention; and

3.2.3.2 Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the participant in comparison with standard care; and

3.2.3.3 Either the risk of harm is not greater than that involved in standard therapeutic care, or it is clearly justified by the potential for direct benefit to the participant; and

3.2.3.4 The prospective participant is unconscious or lacks Capacity to understand risks, methods and purposes of the research project; and

3.2.3.5 Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and

3.2.3.6 No relevant prior directive by the participant is known to exist.

3.2.4 When a previously incapacitated participant regains Capacity or when an Authorized Third Party is found, free and informed Consent will be sought for continuation in the project and for subsequent research-related procedures.

3.2.5 The Chair or Designee will inform the researcher of his/her responsibility to report to the REB the outcome of the treatment together with any serious adverse events associated with it in a written report to be submitted no later than **7 days** from the time of the event. See policy *RR0900 Safety and Serious Adverse Events Reporting*.

3.2.6 If a research study is subject to the US Food and Drug Administration regulations and involves an exception to informed Consent for emergency research, the REB shall review and comply with the provisions of 21CFR50.

4.0 PROCEDURES

4.1 The REB will follow procedures for the ethical review of any research involving participant as identified in section 3.1 of this policy per Research Ethics Policies RR0300 Initial Review of Research and RR0400 Amendments.

RS0400 – RESEARCH IN MEDICAL EMERGENCIES

5.0 REFERENCES

1. Canadian Institutes of Health Research, Natural Sciences and Engineering Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2022.

2. Interior Health. (2021). Research Policy Manual: RR0300 Initial Review of Research.

3. Interior Health. (2021). Research Policy Manual: RR0400 Amendments.

4. Interior Health. (2022). Research Policy Manual: RR0900 Safety and Adverse Events Reporting.

5. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), ICH Harmonized Guideline, Integrated Addendum to ICH E6(R1); *Guideline for Good Clinical Practice*, E6(R2), November 9, 2016.

6. UBC Office of Research Ethics. (2018). Standard Operating Procedure 502: Special Categories of Research

7. US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46).

8. US Food and Drug Administration Code of Federal Regulations, Title 21, Volume 1:
   - Part 50, Protection of Human Subjects, (21CFR50).
   - Part 56, Institutional Review Boards, (21CFR56).