

## TITLE

**MANAGING EMERGENCY MEDICAL SERVICES RESEARCH AND OTHER KNOWLEDGE GENERATING ACTIVITIES**

## SCOPE

Provincial: Emergency Medical Services

## DOCUMENT #

ITM-EMS-2

## APPROVAL AUTHORITY

Senior Provincial Director and Chief Paramedic

## INITIAL EFFECTIVE DATE

June 30, 2017

## SPONSOR

EMS Research Committee

## REVISION EFFECTIVE DATE

Not applicable

## PARENT DOCUMENT TITLE, TYPE, AND NUMBER

Not applicable

## SCHEDULED REVIEW DATE

June 30, 2020

**NOTE:** The first appearance of terms in bold in the body of this document (except titles) are defined terms – please refer to the Definitions section.

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**OBJECTIVES**

- To ensure that Emergency Medical Services (EMS) **knowledge generating activities** in Alberta Health Services (AHS) EMS (e.g. **research**, quality improvement, and evaluation projects) are done in an ethically responsible manner and meet the required organizational expectations, resources and approvals.

**PRINCIPLES**

- AHS EMS supports knowledge generating activities that will improve and protect the health of the citizens of Alberta through the enhancement of: patient safety, clinical care, and organizational effectiveness and efficiency.
- Research, quality improvement, and evaluation projects are all important activities designed to generate new knowledge and ultimately improve the safety, effectiveness and efficiency of care provided to Albertans.
- It is important that in the process of creating new knowledge EMS patients, staff, and management are respected and protected. Patients and their information must be respected and protected by **EMS staff** in accordance with legislation, broader AHS policy, accreditation standards, and professional responsibilities.
- Projects in the context of this policy are activities that have a distinct beginning and end. Other activities that do not meet these criteria, such as on-going performance monitoring and quality assurance activities are not included. Similarly, activities that are routinely performed in the course of supervising individual staff are also not included.

## APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staffs, students, volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary).

## ELEMENTS

### 1. Managing Knowledge Generating Activities

1.1 All AHS EMS staff shall:

- a) Ensure that all collected **patient information** is protected and not disclosed without permission or consent, in compliance with Alberta's Health Information Act.
- b) Ensure Secure Record Locations are only accessed to perform required duties.
- c) For those supplying data for a research project, only disclose the requested information outlined in the signed **AHS Research Agreement** as per the stipulations set-out in that agreement.
- d) Take the **A pProject Ethics Community Consensus Initiative (ARECCI)** Level One training course if they will be leading a project. If this is not possible the project lead should ensure their supervisor is aware.
- e) Use the ARECCI Ethics Screening Tool to determine if the project constitutes research or if it is a **quality improvement or evaluation project**:
  - (i) If the project constitutes research it must be submitted to the **AHS EMS Knowledge Generating Project Support and Review Committee**.
  - (ii) If the project constitutes new Quality Improvement or Evaluation:
    - Proceed with projects that have Minimal Risk (risk scores 0 to 7).
    - Submit projects with Somewhat More Than Minimal Risk (risk scores of 8 to 46): to an AHS EMS Second Opinion Reviewer if available. If a Second Opinion Reviewer is not available the project may be submitted to a reviewer from the Evaluation Services or the ARECCI hub.
    - For projects with Definitely Greater Than Minimal Risk (risk scores 47 or greater) consider consulting with the AHS EMS

Knowledge Generating Project Support and Review Committee and submit to the appropriate director.

- Report results of any Knowledge Generating Activity to the AHS EMS Knowledge Generating Project Support and Review Committee the AHS project registry (if available) and other key stakeholders in order for knowledge translation to occur.

1.2 AHS EMS Second Opinion Reviewers shall:

- a) Complete the Alberta Innovates Health Solutions ARECCI Second Opinion Reviewer Project Ethics Course.
- b) Use the ARECCI Ethics Screening Tool to confirm that the project constitutes:
  - (i) A quality improvement and evaluation initiative.
  - (ii) Research:
    - If the project constitutes a research initiative the Second Opinion Reviewer shall direct the project lead to submit it to the EMS Knowledge Generating Project Support and Review Committee.
- c) Offer advice and recommendations to leaders of Quality Improvement and Evaluation Projects with Somewhat More Than Minimal Risk to strengthen ethics in their project and notify senior management of significant risks.

## 2. Managing Quality Improvement or Evaluation Projects

2.1 All EMS staff that are leading a quality improvement or evaluation project shall:

- a) Consult the AHS Quality and Safety Management Approach.
- b) Follow the ARECCI Guidelines for Quality Improvement and Evaluation Projects.

## 3. Managing Research Responsibilities

3.1 Prior to pursuing any research activities all **researchers** shall:

- a) Submit a written research proposal to the EMS Knowledge Generating Project Support and Review Committee.
- b) Acquire Ethics Approval from one of the following AHS recognized ethics committees within Alberta:
  - (i) Clinical Trials Committee (HREBA-CTC)

- (ii) Central and South Zone: Community Health Committee (HREBA-CHC)
  - (iii) Cancer Committee (HREBA-CC)
  - (iv) Calgary Zone: Conjoint Health **Research Ethics Board** (CHREB) (University of Calgary)
  - (v) Edmonton and North Zone: Health Research Ethics Board (HREB) (University of Alberta, Alberta Health Services and Covenant Health)
  - (vi) Or as designated by a AHS Research Administration representative.
- c) Complete a Health Information Act Section 54 Research Agreement coordinated by an AHS Research Administration representative.
- d) Only access information outlined in the AHS Research Agreement for the purposes outlined in that agreement.
- 3.2 Internal researchers shall:
- a) Submit a budget estimate for approval by all of the Executive Directors or Medical Directors of the impacted business areas of EMS through the AHS EMS Knowledge Generating Project Support and Review Committee. Researchers employed by Contracted Providers are considered internal researchers.
- 3.3 External researchers shall:
- a) Secure external funding from sources outside of AHS EMS for all aspects of the research project, including but not limited to, training, data collection, and compensation, except where EMS has agreed to cover these costs.
  - b) Ensure research proposals have relevance to AHS EMS and the provision of pre-hospital care.
- 3.4 AHS EMS Knowledge Generating Project Support and Review Committee (former Research Committee) shall:
- a) Review all knowledge generating projects where the primary purpose is research.
  - b) Review research proposals as outlined in the terms of reference.
  - c) Send information related to the project, which may include recommendations, to senior EMS leadership for review and approval.

- d) Ensure that the researchers are connected with AHS Research Administration to develop an AHS Research Agreement.
  - e) Ensure that all research projects have an appropriate ethics approval.
  - f) Ensure researchers and EMS staff only access the information set out in the signed AHS Research Agreement:
    - (i) Data system access may be provided when it is limited to the information set out in the signed AHS Research Agreement.
- 3.5 The AHS EMS Knowledge Generating Project Support and Review Committee may:
- a) Conduct audits to ensure only the information required by Knowledge Generating Projects and Research Agreements are accessed by researchers.

## DEFINITIONS

**A pRoject Ethics Community Consensus Initiative' (ARECCI)** means A pRoject Ethics Community Consensus Initiative.

**AHS EMS Knowledge Generating Project Support and Review Committee** means the provincial EMS committee designated to perform a review of research, quality improvement and evaluation projects (formerly called the AHS EMS Research Committee). In the case of research, an operational review will be performed to assess the risk, impact, and benefit of participating. This information, sometimes with specific recommendations will be sent to senior leadership for decision. In the case of quality improvement and evaluation projects, ensure that the project meets the highest standards of ethical conduct as outlined in the ARECCI tools.

**AHS Research Agreement** means an agreement (including clinical trials agreements) between a Researcher and AHS to ensure compliance with legislation, AHS policies and procedures, and any conditions imposed by AHS SPECIFICALLY TO THE RESEARCH STUDY.

**EMS staff** means all AHS EMS direct delivery providers, contract service provider staff and EMS students.

**Knowledge generating activities** means any inquiry, investigation, project, protocol, study, or trial that is related to the health of individuals or communities, that involves people or their health information, and that takes place in a community, a health organization, a service delivery organization, or an individual practice within the province.

**Patient information** means all personal and medical information collected during an event.

**Quality improvement or evaluation project** means quality improvement (QI) and evaluation projects that have a distinct beginning and end. ARECCI excludes quality assurance (QA) under the umbrella term QI and evaluation projects. QA is excluded because QA relates to issues of

compliance and ongoing monitoring activities, and not to the broader sense of projects which have a beginning and an end.

**Research** means an activity whose purpose is to contribute to the growing body of knowledge regarding health and/or health systems that is generally accessible through standard search procedures of academic literature. Research does not include activities related to quality improvement, program evaluation, or education of health services providers.

**Research Ethics Board** means a board or committee designated under the Health Information Act (Alberta) which is responsible for assessing the ethics of individual Research Proposals, requiring or waiving individual consents, and ensuring the Researcher applies adequate safeguards to protect the identity of the individuals.

**Researchers** means all eligible individuals conducting Research (including employees, independent contractors, medical, dental, podiatry, and midwifery staff, and other health professionals, students, and volunteers), employed by, appointed by, or representing AHS, individuals using AHS resources to conduct Research.

## REFERENCES

- Alberta Health Services Governance Documents:
  - *Consent to Treatment/Procedure(s) Policy (#PRR-01)*
  - *Disclosure of Harm Procedure (#PS-95-01)*
  - *Forms Management Directive*
  - *Information Technology Acceptable Use Policy (#1109)*
- Alberta Health Services Resources:
  - AHS Records Management IM-07
  - ePCR Documentation Procedures
  - QSAM
  - Records Retention Schedule IM-07-01
  - Procedure: Records Destruction IM-07-02
  - Procedure: Transitory Records IM-07-03
  - Procedure: Legal Hold IM-07-04
- Non-Alberta Health Services Documents:
  - Accreditation Canada EMS Standards: <http://insite.albertahealthservices.ca/974.asp>
  - Alberta Innovates Health Solutions
  - ARECCI This tool can be found at:<http://hreba.ca/home-2/a-project-ethics-community-consensus-initiative/>
  - *Freedom of Information and Personal Privacy Act (FOIPP)*
  - *Health Information Act (HIA)*
  - *Protection and Individual Privacy of Electronic Documents Act (PIPEDA)*

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