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& SURGEONS OF ALBERTA

STANDARDS OF PRACTICE

~~Human~~ Health Research

Commented [CD1]: Title changed to align with the Canadian Institutes of Health Research.

Under Review: ~~No~~Yes
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The ***Standards of Practice*** of the College of Physicians & Surgeons of Alberta ("CPSA") are the **minimum** standards of professional behavior and ethical conduct expected of all regulated members registered in Alberta. Standards of Practice are enforceable under the *Health Professions Act* and will be referenced in the management of complaints and in discipline hearings. CPSA also provides **Advice to the Profession** to support the implementation of the Standards of Practice.

Note: a glossary of terms can be found at the end of this document. Glossary terms are indicated in teal with a "G" throughout this document.

PREAMBLE

~~1.~~ This standard applies to any regulated member involved in ~~human~~ health ~~research~~research[G], as identified through a current and recognized screening tool: as of Mar. 2025, ARECCI (A pRoject Ethics Community Consensus Initiative) is the recommended tool.

Regulated members who perform health research are encouraged to complete the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) CORE-2022 Course on Research Ethics and are expected to be familiar with relevant published statements concerning the conduct of research, including the Canadian Medical Association's (CMA) *Code of Ethics and Professionalism* and any other provincial and national requirements.[1]

Related standards, additional information and general advice can be found in the companion resources listed at the end of this document.

STANDARD

1. A regulated member who intends to conduct ~~human~~ health research **must**~~:~~:

~~2.~~a. comply with the *Health Information Act*, including ~~to submit~~submitting a proposal ~~for review by~~to a research ethics board in the Province of Alberta~~. Such boards include:~~ for review;

Commented [CD2]: Clause 1 of current version of the standard.

Commented [CD3]: Added based on CPSBC's *Conflict of Interest* Practice Standard.

[1] From CMPA's "Before starting a clinical research trial" (Aug. 2022) – accessed Apr. 2025

Terms used in the Standards of Practice:
- "Regulated member" means any person who is registered or who is required to be registered as a member of this College. The College regulates physicians, surgeons and osteopaths.
- "Must" refers to a mandatory requirement.
- "May" means that the physician may exercise reasonable discretion.
- "Patient" includes, where applicable, the patient's legal guardian or substitute decision maker.

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i. such boards include:

~~a.~~1. Health Research Ethics Board of Alberta ~~(HREBA)~~(HREBA)

2. ~~A regulated member **must**~~ Conjoint Health Research Ethics Board (CHREB), University of Calgary

3. Health Research Ethics Board (HREB), University of Alberta;

b. follow all applicable *Standards of Practice* (e.g., the *Conflicts of Interest* standard of practice);

~~3.~~ have approval from a research ethics board before commencing ~~human~~ health research~~.~~

~~4. A regulated member participating in human health research **must:**~~

~~a. ensure the welfare of any patient involved in the research study is the primary concern throughout the duration of the study;~~

~~b.~~c. ~~disclose to patients that the study has been reviewed by an ethics board, where appropriate;~~[2] and ~~relevant conditions imposed;~~

~~c.~~d. comply with the requirements of the research ethics board as ~~it relates~~they relate to initial and ongoing review of the research study~~; and~~.

~~d. disclose any potential or actual conflicts of interest to the research ethics board.~~

Commented [CD4]: Clause 4(d) of current version of the standard..

Commented [CD5]: Clause 3 of current version of the standard..

Commented [CD6]: These are requirements of research ethics boards, making these clauses redundant.

Commented [CD7]: Clause 4(c) of current version of the standard..

Commented [CD8]: This is also a requirement of research ethics board and is also redundant.

[2] To determine application of ethics review/approval is necessary, please refer to the ARECCI tool.

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2. A regulated member recruiting or enlisting participants for health research **must not:**

   a. charge the participant any fees; or

   b. ask the participant to contribute to the research costs.[3]

Commented [CD9]: From CPSM's *Research* standard of practice to protect the public.

GLOSSARY

Health research: any research that aims to improve human health by leading to improved disease diagnoses, more effective treatment options or a strengthened health care system.[4]

ACKNOWLEDGEMENTS

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RELATED STANDARDS OF PRACTICE

- *Code of Ethics & Professionalism*
- *Conflict of Interest*
- *Relationships with Industry*
- *Informed Consent*

COMPANION RESOURCES

- Advice to the Profession documents:
  - Conflict of Interest
  - Informed Consent for Adults
  - Informed Consent for Minors
- Alberta Clinical Research Consortium
- ARECCI Ethics Screening Tool
- CMPA:

[3] CPSM's *Research* Standard of Practice (Sep. 2023) – accessed Apr. 2025.
[4] From the Canadian Institutes of Health Research's "What is health research?" (Nov. 2023) – accessed Apr. 2025.

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  - Before starting a clinical research trial
  - Medical-legal issues to consider with research contracts
  - Physicians and research: Understanding your obligations
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (CIHR, NSERC, SSHRCC)

[i] ~~As of this date, the recommended tool is the ARECCI (A pRoject Ethics Community Consensus Initiative).~~