

Insurance Investigator Initiated Clinical Research

Frequently Asked Questions (FAQs)

NSHA has worked with its broker and insurers and secured blanket research liability (RL) insurance for investigator-initiated clinical research being conducted at NSHA. The new insurance policy applies to research that is conducted at and administered by NSHA.

1. What is covered by the new RL insurance

- Research with respect to human subjects (including research on material of human origin and including data gathered from humans), for which a researcher interacts with human subjects and obtains NSHA Research Ethics Board (REB) Approval;
- All research projects reported to the insurer on an ongoing basis (reporting will be done by NSHA Research Services in collaboration with the NSHA REB); and

2. Who is covered by the new RL insurance?

- Any individual including but not limited to NSHA employees, students, consultants, researchers or physicians who
 - i. engage in research activities for and authorized by NSHA, and
 - ii. are acting under the direction of NSHA or pursuant to the terms of an appointment at NSHA.*

Research must be taking place at NSHA, have NSHA REB approval (as applicable) and be administered by NSHA

3. What is not covered by the new RL insurance?

- Research conducted at NSHA on behalf of and under the direction and control of other organizations (e.g., IWK, Dalhousie)

4. Are research studies with sites outside of Canada covered?

Possibly, yes. The RL insurance program is designed to cover research taking place worldwide. For proposed research intended to be conducted outside of Canada, additional information is required to be provided to the underwriter for review and approval. **It is important that you contact NSHA Research Services as early as possible if you are proposing to conduct research outside of Canada.**

5. When does this insurance coverage begin?

Coverage is in place for all relevant NSHA research that began on or after April 1, 2016.

6. What types of claims are covered?

- Physical or mental injury of research participants;
- Property damage;
- Personal injury, including libel, invasion of privacy and discrimination;
- Advertising liability;

7. What types of claims are not covered?

- Bodily injury or personal injury to NSHA researchers (employees, researchers, students, volunteers);
- Any claim from a research participant who did not sign a consent, except where legislation says consent is not required;
- Deliberate or criminal acts;
- Any research that continues after a regulatory body or REB orders a stop.

8. Will this insurance cost the investigator anything?

No, the costs associated with this RL insurance policy will be covered by NSHA. As stated above, coverage approval for research being proposed at sites outside of Canada will be determined by the insurer on a case by case basis.