Your Risks in Clinical Trials – And How to Protect Yourself

Universities are hubs of innovation and hot beds of opportunity for medical advancements. In order to advance these medical discoveries from the lab to the general population, researchers must first evaluate the therapy, intervention or product on human patients in clinical trials. While we encourage the growth and development of ideas at our universities, we also want to protect the organization, including physicians and other staff from the liabilities that accompany this important work. To help manage these exposures, we look to risk management techniques, as well as an insurance program to transfer some of this risk.

What Are Your Risks?

As a study **sponsor**, you may be held liable for injuries alleged to have stemmed from participation in the trial. To help identify your risks, consider the following common allegations:

- Negligence in designing the study resulting in patient injury (**protocol liability**)
- Negligence in study conduct resulting in patient injury
- Negligence in failing to warn patients of the potential harmful effects of the study (**informed consent liability**)
- Negligence in failing to warn patients that the trial is experimental – and to properly set expectations of the results of the study (**informed consent liability**)
- Breach of patient privacy (**privacy liability**). Even if you choose to outsource patient recruitment and conduct of the trial to a third party organization, as party to the trial, you may still be brought into a suit for a privacy breach of patient health records.

Definitions

Clinical trial[1]
Any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes. Interventions include, but are not restricted to, drugs, radiopharmaceuticals, cells and other biological products, surgical procedures, radiologic procedures, devices, genetic therapies, natural health products, process-of-care changes, preventive care, manual therapies and psychotherapies. Clinical trials may also include questions that are not directly related to therapeutic goals in addition to those that directly evaluate the treatment of participants.

Informed Consent Form[2]
A document that describes the health risks and anticipated benefits of the trial to the study subject.

Protocol[2]
A document that describes the objectives, design, methodology, statistical considerations and organization of a clinical trial.

Sponsor[2]
Individual/organization that initiates and is responsible for a clinical trial. The sponsor must comply with obligations to regulatory bodies.

Outside of liabilities as a study sponsor, your risks may include financial loss liability. If you are working on behalf of an industry sponsor (such as a pharmaceutical company), they may bring a suit against you for negligence causing them a financial loss (**E&O liability**). For example, consider the allegation that an error/omission in your work caused a delay of their product to market, potentially jeopardizing millions of dollars the company has invested in product development.

How Can You Protect Your Organization?

1. **Mitigate the risk.**

   Due diligence and oversight throughout the trial can reduce the risk of potential clinical trial liability claims. Some loss reduction strategies include:

   - Ensuring all partners are qualified – including investigators, contract research organizations, ethics committee members
     - Background check
     - Clinical knowledge
     - Clinical trial experience
     - Appropriate education
   - Managing conflicts of interest
   - Ensuring global regulatory requirements are met
   - Ensuring ethical recruitment practices
   - Ensuring rigorous informed consent process
   - Ensuring proper monitoring throughout the trial

2. **Transfer the risk contractually**

   Ensure your contracts with partners have suitable indemnification clauses defining the scope of each party's commitments, and that appropriate insurance is in place such as financial loss errors & omissions liability insurance and medical professional liability insurance. Note that physicians may not be protected by the Canadian Medical Protective Association (CMPA) for their clinical trial activities, depending on the nature of the work.

3. **Transfer the risk via insurance**

   Consider the options of protecting the university's clinical trial exposure on a blanket global basis versus a per-trial basis.

   It is important to consider the risks that come along with being a driver of discovery and being at the forefront of innovation. Lack of diligence could result in adverse regulatory actions, suspensions, debarment, criminal actions, fines, penalties – translating to reputational damage and loss of funding. By developing a strategy on how to manage these risks with loss reduction and risk transfer techniques, you help keep the university on track in its trajectory of changing the world with success in research.

CURIE Liability Coverage for Clinical Trials

Coverage applies to the institution, faculty, staff and students involved in university clinical trials. The coverage does not apply to other separately incorporated entities that may be set up by the university. These entities will need their own insurance.

The coverage includes activities of "ethics review committees" including non-university members of those committees for both university and non-university reviews.

The coverage includes faculty who are members of the Canadian Medical Protective Association (CMPA) but it Is limited to claims brought in Canada by a Canadian resident (where CMPA does not provide coverage for such claims). CMPA also excludes non-resident claims whether brought in Canada or any other jurisdiction.

This coverage as it applies to CMPA members (only) excludes claims brought by non-resident – see endorsement exclusion 001 of the CGL policy. The non-resident exclusion does not apply to the institution or any other non CMPA member additional insured.

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[1]Frideres, J., & Ludwin, S. K. (2014). *TCPS 2 - Chapter 11: Panel on Research Ethics*. Retrieved 2018, from Panel on Research Ethics website: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter11-chapitre11/

[2]Health Canada. (2016, June 29). *Guidance Document For Clinical Trial Sponsors: Clinical Trial Applications*. Retrieved 05 01, 2018, from Health Canada website: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/clinical-trials/clinical-trial-sponsors-applications.html#a212

The Canadian Universities Reciprocal Insurance Exchange (CURIE) is dedicated to securing long-term, stable and economical property and casualty insurance coverage in response to the general and unique requirements of universities. If you wish to find out more information, please contact your office of Insurance / Risk Management or CURIE staff.