Research Indemnification and Liability

Presented to McMaster University by Stewart Roberts
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Research and Insurance

• Research Contracts
  – Indemnity Clauses
  – Insurance Coverage
  – Risk Management Input

• Liability Issues Associated with Clinical Trials

• Related Entities
Contract Clauses

Indemnification

1. SPONSOR hereby agrees to indemnify, defend, land hold harmless The Board of Trustees of the University, their respective trustees, directors, employees, agents, subcontractors, and students (“Indemnitees”) from any liability, damage, loss, or expense (including reasonable attorneys’ fees and expenses of litigation) incurred by or imposed upon the Indemnitees or any one of them in connection with any claims, suits, actions, demands, or judgements arising out of or connected with this Agreement or the Research done under this Agreement, except to the extent that such liability is due to the gross negligence and willful misconduct of University.

2. The provisions of this clause shall survive termination of this Agreement.
Insurance

1. University shall procure and maintain during the term of the Agreement comprehensive liability insurance in an amount not less than $5,000,000 per occurrence.

2. SPONSOR shall procure and maintain during the term of this Agreement comprehensive liability and product liability insurance to the full amount of SPONSOR insurance limits, but in no event less than $5,000,000 per occurrence. Such insurance shall include University, their trustees, directors, employees, agents, subcontractors, and students as additional insureds with respect to this Agreement. This insurance shall be written to cover claims incurred, discovered, manifested, or made during or after the expiration of this Agreement.
3. Prior to the execution of the Agreement, each party shall provide the other with a Certificate of Insurance evidencing primary coverage and requiring 30 days prior written notice of cancellation of material change. Each party will advise the other in writing, that it maintains excess liability coverage over primary insurance for at least the minimum limits set forth above. Conditions of the Certificate of Insurance will be subject to approval in advance.

4. If SPONSOR’S insurance is written on a claims made basis, as opposed to an occurrence basis, SPONSOR shall guarantee that it will purchase “tail” coverage and/or a retrospective coverage provision to provide continuation and uninterrupted of coverage of all claims.
Publication

1. The basic objective of research activities at University is the generation of new knowledge and its expeditious for the public’s benefit. SPONSOR will provide all reasonable cooperation with University in meeting this objective.

2. As a matter of basic academic policy, University retains the right at its discretion to publish freely any results of the Research. University agrees to provide SPONSOR a copy of any manuscript at the time it is submitted for publication. SPONSOR may review the manuscript:

   (a) To ascertain whether SPONSOR’s confidential information would be disclosed by the publication;
(b) To identify potentially patentable Technology so that appropriate steps may be taken to protect such Technology; and

(c) To confirm that the privacy rights of the individuals are adequately protected.

SPONSOR will provide comments, if any, within 30 days of receipt of manuscript. If patentable Technology is disclosed in the manuscript, SPONSOR will promptly advise University whether it requests University to file and prosecute a patent application.
3. University will give SPONSOR the option of receiving an acknowledgment in such publication for its sponsorship of the Research.
Contract Clauses

Publicity

SPONSOR shall not identify University in any products, publicity, promotion, promotional advertising, or other promotional materials to be disseminated to the public, or use any trademark, service mark, trade name, logo, or symbol that is representative of University or its entities, whether registered or not, or use the name, title, likeness, or statement of any University faculty member, employee, or student, without University prior written consent. Any use of University name shall be limited to statements of fact and shall not imply endorsement by University of SPONSOR’s products or services.
No Warranties

University makes no warranties, express or implied, as to any matter whatsoever, including, without limitation, the results of the research or any invention, process or product, whether tangible or intangible, conceived, discovered, or developed under this agreement; or the ownership, merchantability, or fitness for a particular purpose of the research or any such invention or product. University shall not be liable for any direct, consequential, or other damages suffered by SPONSOR, any licensee, or any others including, but not limited to, damages arising from loss of data or delay or termination of the research, or from the use of the results of the research, or any such invention or product. The provisions of this clause shall survive termination of this agreement.
Liability Issues Associated with Clinical Trials

Ethics review
• inadequate review process
• materials provided to ethics review committee incomplete or inaccurate
• ethics review done after research started

Intellectual Property Rights disputes
• ownership
• publication
• use of research material (confidential) in subsequent work
Liability Issues Associated with Clinical Trials

Subjects
- informed consent incomplete
- inadequate subject screening

Start-Up/New Sponsor Entities
- lack of adequate insurance
- lack of experience
- lack of management skills
- lack of assets

Fraudulent Research and lack of oversight by the Institution
Related Entities

The Policy covers claims brought against the University. It does not cover separately incorporated entities that are wholly or part owned by the University.

Separate entities need their own liability coverage.