RCM&D

July 2012

Pushing Back on Risk:
The Importance of Contractual Review

By Karen Byank Mathura, RN, JD, CPHRM

Life Science companies often "live and die" by their contracts. Whether they are negotiating language in an indemnification paragraph or drafting and redrafting a pivotal informed consent document, both legal and risk management issues come into play on a daily basis.

Contracts from a Risk Manager's Perspective

As a claim and risk management consultant who is a registered nurse and medical malpractice defense attorney by training, I have reviewed numerous Life Science contracts. Although the majority of the documents are legally sound and insulate the client from future legal action, many are lacking from a risk management perspective.

Hold Harmless Provisions

Hold harmless provisions or indemnity language can be found in virtually all Life Science contracts. These provisions are essential as they act to shift risk or apportion risk in a contract and act as extremely effective risk transfer tools. These provisions include the conditions agreed upon by an individual or corporation accepting all future responsibilities, including costs and claims, which may arise from the transactions, activities, events or agreements in a particular study or protocol.

Life Science companies will typically see one, two or three of these hold harmless provisions in their contracts. These include the obligation to "defend", meaning that the company will be required to pay the other party's legal expenses as it defends itself against a third party claim; the obligation to "indemnify", meaning to compensate someone for loss or damage; and the obligation to "hold harmless" the other party, meaning that one party will accept liability, thereby eliminating liability for the other party. At minimum, Life Science companies should ensure that they are not agreeing to unilaterally indemnify, defend and hold harmless a respective party.

Standard Hold Harmless Provisions

At minimum, Life Science companies should ensure that they are not agreeing to unilaterally indemnify, defend and hold harmless a respective party.

- **Defend** – the company will be required to pay the other party's legal expenses as it defends itself against a third party claim
- **Indemnify** – to compensate someone for loss or damage
- **Hold Harmless** (the other party) – one party will accept liability, thereby eliminating liability for the other party

RCM&D

Bilateral Indemnification

Bilateral indemnification or mutual provisions grant both parties a right of indemnity if held liable for the acts or omissions of the other. In other words, each party respectively carries the potential liability associated with their own personnel, acts and products. At minimum, this indemnification language should be closely reviewed by an attorney and risk manager or an attorney and outside risk consultant.

What Your Informed Consent Document Should Include

By definition, informed consent is the permission that a patient must provide in order to undergo a medical or surgical treatment or to participate in an experiment after he or she understands the risks involved. The majority of litigation surrounding Life Science companies in clinical trial mode stems from participants alleging that they were not adequately apprised of the risks of a particular study and entered into the study "blindly".

A Life Science company should ensure that its informed consent document includes, at minimum, the following:

- A simply stated purpose of the study
- The number of subjects involved in the study
- The duration of subject's participation
- Procedures to be followed
- A simply stated, but thorough description of risks and discomforts
- A description of potential, currently unforeseeable risks
- Benefits, if any, to the test subjects
- Alternative procedures of courses of available treatment
- That participation is voluntary
- Disclosure of any new findings throughout the study
- The costs involved
- The schedule of compensation for participation
- Compensation for medical treatment if injury occurs during the study
- Sponsor/clinical investigator contact information
- Confidentiality of subject's medical records
- Reasons for participation termination
- Subject's withdrawal from study
- Exculpatory language suggestions that the sponsor or any party is excused from liability.

Informed Consent Documents

- Comprehensive, yet simple and clear to avoid misinterpretations
- Outline purpose, procedures and risks foremost
- Consider future litigation defenses
- Eliminate uncommon, non-layman terms:
  - Hypertension → *High Blood Pressure*
  - Systemic → *Whole Body*
  - Hypercalemia → *Increased Potassium*

It is critical that this document is legible and easy to understand. As feasibility permits, the document should be concise and to the point.

Use Non-Technical Terms for Informed Consent

There is controversy surrounding the “reading level” for which the informed consent document should be tailored, but overall, junior high reading and comprehension levels provide a sound baseline. In addition, companies should attempt to limit the sheer amount of information that potential subjects are expected to read and understand. Key risk management suggestions for an informed consent document include eliminating uncommon, non-layman terms such as “hypertension” when you could use “high blood pressure”, “systemic” when you could use “whole body”, or “hypercalemia” when you could use “increased potassium”, just to name a few.

When finalizing the document, you should attempt to “fast forward” several years into the future and imagine how the company would defend an informed consent or battery type of claim for any given study. If the terminology is difficult and the study is complex, it certainly helps that there was adequate time provided to obtain the consent and that there was ample opportunity provided for questions and corresponding feedback. Informed consent documents should be all-encompassing, simple and concise as possible.

Conclusion

It is essential that Life Science companies pay close attention to all of their contracts and should particularly study indemnification language and informed consent documents from risk management and risk transfer tool standpoints.

Author Information

Karen Mathura serves as a Risk Management and Claims Consultant for RCM&D. Utilizing her experiences as a Registered Nurse and Attorney, Karen has worked at litigation firms, defending physicians and hospitals against claims of negligence.

About Us

A leader among the privately-held insurance advisory firms in the country, RCM&D provides strategic insurance consulting, risk management and employee benefits services to diverse clients. With more than 300 professionals and six locations throughout Maryland, Pennsylvania and Virginia, we combine vast experience, specialized expertise and personal attention to deliver solutions individually tailored to each client’s needs.

For More Information

Contact Karen Mathura at KMathura@RCMD.com.