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How Safe Is Safe? Insurance for Investigative Sites

By Norman M. Goldfarb and Michael Smith, Jr.

Insurance companies collect premiums from their many policy-holders. They use the premiums to pay out the few claims. Since, on average, premiums are paid before claims are made, insurance companies accumulate cash reserves, which they invest. Insurance companies thus have two principal sources of income: premiums and investment returns. When the number or size of claims increase, premiums generally go up. When investment returns increase (in a competitive insurance market), premiums generally go down. Insurance companies may initially price a policy high, and then reduce the premiums as it gets to know you better. It may also price it low to get your business, and then increase the premiums. At the end of the day, insurance companies generally operate with a break-even "loss ratio" (paid claims/premiums), paying all the other costs of running the business out of investment returns.

Potential losses include payment to the claimant, e.g., an injured subject, and defense costs, consisting mostly of fees to lawyers and experts. Defense costs often exceed the eventual payment to the claimant. In clinical research, settlements and court awards are very rare, but can run into the millions of dollars. With so much at stake, defense costs can also exceed $1 million.

Unlike companies in most other industries, insurance companies do not sell their product to just anyone. Potential customers must provide information – sometimes a lot of it – to the insurer. The insurer evaluates this information and, if it judges the risk acceptable, "underwrites the risk," i.e., offers the policy at a price it considers fair given your risk profile. If you think the price is too high, you may be able to obtain a lower price by providing additional information and arguments. The insurance company may also reduce its price if it is competing with other insurance companies for your business.

There are three types of insurance applicable to clinical research:

- Medical malpractice insurance covers bodily injury to research subjects
- Professional liability insurance covers financial harm to sponsors
- General liability insurance covers "slip and fall" injuries

Medical Malpractice Insurance

Medical malpractice ("med mal") insurance covers bodily injury to patients. Claims are rare, but awards and settlements are potentially huge. Many med mal policies exclude injuries from unapproved drugs and devices, i.e., in clinical trials. They may cover injuries resulting from "medical care of patients" but not clinical research. If an injured subject received a placebo, it was probably not medical care. If you do not have a prior professional relationship with an injured study subject, it is more difficult to argue that he/she is your patient. On the other hand, clinical research

may constitute medical care if there is no effective approved treatment for the subject's medical condition. Faced with a large potential loss, your insurer may interpret the policy very strictly. A clinical research "endorsement" on your policy will clarify your coverage and avoid the potential awkwardness of bankruptcy.

Physicians purchase med mal insurance to cover themselves personally and their staffs. If they are part of a larger business entity, e.g., a hospital or clinic, their personal insurance does not protect the business entity against claims. The business entity therefore needs its own med mal insurance.

Some states, such as California, Texas and Florida, cap non-economic med mal awards. Others are notorious for high awards. If you want to buy med mal insurance from a multi-state insurer, be sure they know you are in a state with a cap.

Professional Liability Insurance

Professional liability insurance, also known as "errors and omissions (E&O)" insurance, covers financial damages related to professional services. Coverage under a professional liability policy is triggered when a party claiming injury files a lawsuit against the insured party that rendered the professional service. For example, if a site enrolls ten of the subjects in a 100-subject study, and its data later proves to be unusable, the sponsor would have to extend the study to replace those subjects. The data may be unusable because a coordinator did not follow GCP or someone involved in the study was debarred by the FDA. The sponsor would incur the cost of running the additional subjects through the study – a multiple of the fees paid to the site. Its New Drug Application (NDA) to the FDA may also be delayed, potentially costing it millions of dollars in lost profits. If the sponsor were to be so inclined, it could sue the site for $10 million in damages.

If the site's budget is $5,000 per subject, its total revenue from the study is $50,000 (plus start-up fees). Its profits may have been $5,000 or less. If the site performed superbly on its last 499 studies, that $10 million claim could consume its accumulated profits, not even considering legal fees, damage to reputation, invitation for an FDA inspection, and management distraction.

Fortunately, claims of this type are very, very rare. It is unlikely that one of many sites on a study can cause enough damage – undetected until late in the study – to justify the expense of litigation and bad publicity for the sponsor. In addition to professional liability insurance, the site can protect itself from this potential liability by contractually capping potential damages to, for example, a fixed dollar amount or (a multiple of) the fees received.

General Liability Insurance

General liability insurance is generally bundled with property insurance. There are two categories of general liability risks:

- Premises liability includes bodily injuries to third-parties caused by the site's negligence. Slip-and-fall claims are a subject of humor, but, every year in the

United States, over 300,000 hospital patients are moderately to severely injured as the result of a fall. (Wall Street Journal, May 23, 2005)

- Personal and advertising injury (PI/AI) liability includes libel, slander, the use of another's advertising ideas in product advertising, and false detention or imprisonment. PA/AI may be relevant to a site if the investigator repeatedly criticizes a sponsor or study drug.

If you or your employees drive a personal or rented vehicle on study-related business, e.g., at investigator meetings, you may want to purchase a "hired and non-owned vehicle" rider (add-on) to your commercial general liability or automobile liability policy. This rider protects the corporate entity (not the driver) for any bodily injury or property damage resulting from use of a vehicle not owned by the corporate entity (e.g., an employee's personal automobile). This coverage is considered "excess", meaning it pays for damages over and beyond the liability coverage provided by the vehicle owner's personal automobile policy.

Some insurance companies no longer underwrite general liability policies for investigative sites because they judge the risk is not justified by the premiums. Those who do normally require evidence of med mal or professional liability coverage.

"Clinical Research" Insurance

A few insurers have tailored insurance policies specifically for the clinical research industry. These policies combine features of med mal and professional liability insurance. They require careful review. For example, the policy may cover the medical care costs (up to a limit) of an injured subject. However, if a subject is injured, he/she will probably look first to his or her insurance company. If the subject is coming after you, he/she may not have medical insurance, or may be claiming $5 million for pain and suffering, loss of income, etc.

Insurance Policies

Coverage under a liability policy is triggered one of two ways:

1. Occurrence-based: Policy responds if it is in force when the incident actually happens.
2. Claims-made-based: Policy responds if it is in force when claim for any prior incident is made.

Most general liability policies are of the occurrence type. Most med mal and E&O insurance policies are of the claims-made type. Claims-made policies are less expensive initially, since only claims for bodily injury happening on or after a predetermined date, the "retroactive date", are covered. However, over time they become more expensive as the timeframe they cover expands. (One might think that the premiums would decline as time passes without a claim, but one would be wrong.) If you change insurance carriers on a claims-made policy, the new insurer will generally honor the retroactive date of the previous policy, unless there are known instances that may give rise to future claims. If you cancel a claims-made

policy, it is wise to buy an extended reporting period, or "tail policy". This policy provides an additional period of time in which to report claims that occurred prior to policy termination. Tail policy time periods of 1-5 years are typical, although some carriers offer longer terms.

Insurance policies have coverage limits, for example, $1 million per incident and $3 million in aggregate during a one-year period. These limits include defense costs, which can easily exceed $1 million if a subject is seriously injured, so there may be nothing left for a settlement or award. Both the insurer and the insured are thus motivated to settle cases for less than the coverage limit, even if the claim is not legitimate.

If a sponsor requires insurance limits higher than your current policy covers, your insurance carrier may be willing to increase your policy limits. You can reduce the coverage when the study ends. You may want to include the increased insurance cost in your study budget. Your insurer will calculate the additional premium based on multiple factors; it may charge an additional 5%, 50% or 100%.

A good independent broker will explain the salient points of an insurance policy to you. Nevertheless, you should still read the policy yourself; you may discover important ambiguities or gaps in coverage.

Indemnification

In most clinical trial agreements, the sponsor agrees to defend, hold harmless, and indemnify the site if a subject is injured under certain circumstances. For example, if the subject sues the site because of an injury caused by the study drug, the sponsor will pay for all the defense and settlement or award costs. Indemnification language can be very tricky. For example, it may be voided if you do not follow the protocol with a *different* subject. Indemnification is not a substitute for med mal insurance.

Most indemnification clauses exclude claims that are due, even in part, to acts by the site that involve some degree of negligence, misconduct or violation of law or regulation. The legal definitions of negligence and misconduct vary by state and country, but their general import is clear: if you color too far out of the lines, you are on your own.

Some sponsors require "cross indemnification", or indemnification of the sponsor by the site for the site's errors. Institutional med mal insurance probably covers the legal costs associated with indemnification; personal med mal insurance probably does not. If you agree to cross-indemnify the sponsor, you may be able to limit your risk by capping your cross-indemnification liability to the extent of insurance coverage or to a specified amount.[1]

If you are uncertain whether the indemnification language in a clinical trial agreement is acceptable, ask your attorney and/or insurance broker to review it.

Sponsor Insurance

Sponsors carry clinical trial/product liability insurance to protect themselves from injury claims by subjects (not professional liability financial claims). This insurance is generally priced per subject, and can be very expensive. Factors influencing the cost of this coverage include the nature of the study drug or device, the study phase, and the location. Foreign countries often have their own insurance requirements for sponsors.

A sponsor conducting Phase I and II studies for drugs with moderate risk of injury can expect to pay at least $600 per subject for a policy with a $1,000,000 aggregate limit per year. The per-subject rate is typically lower for Phase III trials, but with significantly larger subject populations and the need for higher aggregate limits, the overall cost can easily exceed $100,000 annually.

Exclusions

Liability insurance policies cover claims that result from reckless acts and usually even gross negligence. However, they do not cover intentional or criminal acts. Other exclusions include workers compensation-related injuries and employment practices-related claims for discrimination and harassment.

Every insurance policy is different; there may be a reason why one policy is cheaper than another. Your insurance broker can advise you and obtain clarifications from the insurers. For example, damages resulting from the disclosure of sponsor confidential information or subject private health information may or may not be covered, depending on if (a) a financial loss resulted and (b) it meets the definition of a "professional service" as outlined in the policy.

Most professional liability insurance policies give the insurer the right to settle a claim at its discretion, even if an admission of fault is required and the professional loses his or her license as a result. Anyone who values his or her professional license will therefore review with care the policy's claims defense language.

The best way to avoid a claim is to conduct clinical research according to Good Clinical Practice in a safe facility. If there is a claim, you have a good defense against assertions of negligence or misconduct.

Some insurance companies are more financially sound than others. If excessive losses force an insurance company to go out of business, it will not be able to fully defend and pay all of the outstanding (and potential) claims. To be safe, buy insurance from companies that the A.M. Best Company has rated at least "A".

Insurance Brokers

Med mal insurance is often purchased directly from the insurer. Generally, however, you buy insurance through a broker. Insurance brokers can be either "captive," i.e., representing a single insurance company, or independent. Although they are paid sales commissions by the insurers, the broker is your representative. Their

reputation depends on good service in obtaining insurance and obtaining payment for claims. Larger brokers have more leverage with insurance companies.

A relatively small number of insurance brokers specialize in clinical research insurance, and only a few of those understand the needs of investigative sites, understand the pros and cons of the few policies available, and know how to tell your story to insurers. You can identify specialist insurance brokers by asking other sites for recommendations, or doing a keyword search on the web.

Self-insurance

There are two types of self-insurance: (a) a state-certified program and (b) no insurance. Self-insurance makes sense if the chance of a large loss is essentially zero. However, if there is a plausible chance of a catastrophic risk, self-insurance is like playing Russian roulette with your business. A better solution is probably to reduce the premium by raising the deductible to a level that will not put you out of business.

Inaccurate Information

If you did $250,000 of clinical research last year, and tell your insurer that you expect to do $250,000 of clinical research in the next year, but actually do $300,000 worth, the insurer will not penalize you for the inaccurate estimate. However, if you intentionally deceive your insurer about facts that matter, you may forfeit your coverage. Your broker can advise you when it is appropriate to notify your insurer of new information.

Certificates of Insurance

Sponsors sometimes require a certificate of insurance to prove that you have certain coverage. Your insurance broker should be able to obtain one from your insurer within a day or two, at no charge. Because the certificate is only a single page, it will not include "details" such as whether clinical research is covered by your med mal policy.

Additional Named Insured

Your sponsor may ask you to make it an "additional named insured" on one or more of your policies. The advantage to the sponsor is that it will then have most of the rights you have as the "primary insured." It does not make sense for a sponsor to be named an additional insured on a med mal or professional liability policy, because it is not providing medical services or professional services (to itself). There is some justification to name the sponsor as an additional insured on a general liability policy. For example, if a subject slips on your stairs and sues the sponsor, the general liability coverage afforded to the site automatically extends to protect the sponsor

company. It will be protected under the policy by virtue of the additional insured endorsement. Since it is your insurance policy, the sponsor will be more open to settling questionable claims.

Your general liability insurer may agree to make the sponsor an additional named insured. It may charge a fee for the service, which the sponsor should pay. However, your insurer may not agree because it does not want to risk getting involved in medical malpractice litigation.

Conclusion

Clinical research is a low-margin business. The next-to-last thing an investigative site needs is a big insurance bill. However, the last thing a site needs is a claim that puts it out of business.

Note:

1. For a more detailed discussion of this topic, see "Clinical Trial Injuries: Will Your Client Lose His/Her Medical Practice?", Norman M. Goldfarb, Medical Malpractice Law & Strategy, April and May, 2005. Available at http://www.firstclinical.com/resources/papers.html.

Norman M. Goldfarb is Managing Partner of First Clinical Research, a provider of a clinical research best practices consulting, training, implementation and research services. Contact him at (650) 465-0119 or ngoldfarb@firstclinical.com. Michael Smith, Jr. is Assistant Vice President at Commerce Insurance Services. Contact him at (973) 659-6414 or michael.smith.jr@yesinsure.com