

Two New Insurance Policies for Clinical Investigators

By Norman M. Goldfarb

Most clinical investigators are physicians with medical malpractice insurance. These insurance policies, however, may specifically exclude, or be ambiguous about, coverage of claims by clinical research subjects.^{1,2} The policies may cover the principal investigator, but not the entity or other personnel. Clinical research injury claims are uncommon, so the insurer may not know how to manage and defend a claim. It may utilize attorneys who are unfamiliar with clinical research concepts that are essential for a successful defense.

Fortunately, two new insurance policies have become available. Both are specifically designed for clinical research. One, from CTIC, combines coverage for both regular medical practice and clinical research. The other, from Lloyd's of London, covers only clinical research. As Table 1 on the next page demonstrates, the policies offer attractive but slightly different features. Insurance policies are highly technical documents, so a careful reading of any policy, along with advice from an experienced insurance professional, is highly advantageous. The information in this article is for guidance only.

How expensive is clinical research insurance?

Both insurance policies are priced ("underwritten") individually based on factors such as site location, type and phase of studies, and amount of clinical research revenue. However, we can do some hypothetical calculations:

Clinical research coverage under the CTIC policy may be cheaper than for a physician who requires malpractice insurance anyway for his/her regular medical practice. However, we can calculate the fully-allocated cost: Imagine a hypothetical medical practice earns \$300,000 per year, with half – \$150,000 – coming from clinical research. Assume the average fee per study subject is \$3,000. The physician/investigator would need to enroll and retain 50 subjects per year, or about one per week. Malpractice insurance costs vary wildly by specialty and state, but assume, for this example, that it is \$20,000 per year, of which half – \$10,000 – is allocated to clinical research. Insurance would thus cost \$200 per subject, or 6.7% of revenue.

Under the Lloyd's policy, assuming a minimum premium of \$7,500 for \$300,000 of clinical research revenue and an average fee per study subject of \$3,000, insurance would cost \$75/subject, or 2.5% of revenue.

Table 1. Insurance Policy Information

Policy Name	CTRIC Policy of Insurance	Clinical Research Liability Insurance (CRLI)
Insurance Company	Clinical Trials Reciprocal Insurance Company, A Risk Retention Group	Lloyd's of London
Brokers	In discussions	Yes, see below
Source	Clinical Trials Reciprocal Insurance Company	Commerce Insurance Services
Contact	David Reed, J.D.; Arif Khan, M.D.	Michael Smith, Jr.
Telephone	425.453.8833	973.659.6414
Email	david@ctric.com; arif@ctric.com	michael.smith.jr@yesinsure.com
Website	http://www.ctric.com/	http://insure.commerceonline.com/
Eligibility	M.D.s that derive at least 25% of revenue from clinical trials, their allied workers (licensed or not; employee or contract; full-time, part-time or temporary) and the entity that employs them	Research sites and site management organizations, including their subsidiaries, officers, directors and employees; CROs, CRAs, CRCs individually
Coverage	(a) Medical malpractice and (b) clinical research liabilities	(a) bodily injury liability, (b) errors & omissions financial liability, (c) expenses incurred in administrative proceedings (e.g., related to FDA disqualification), (d) expenses and civil monetary penalties arising from billing-related proceedings (e.g., unintentional Medicare double-billing), and (e) employment practices liability (e.g., wrongful termination) (extra premium)
Coverage amount (incident/aggregate)	\$1m/\$3m	\$1m/\$3m to \$5m/\$5m; higher limits may be available
Coverage period	Claims-made; tail coverage free upon insured's death, full disability or, after 5 years, retirement; prior acts coverage available	Claims-made and reported
Types of clinical trials	Drugs, medical devices, biologics, diagnostics	All
Entity coverage	Yes	Yes

Covered injury claims	Bodily injury, sickness, disease, mental injury, mental anguish, and privacy	Bodily injury, sickness, disease or death; property damage or loss (e.g., faints while driving home and crashes car); economic loss due to injury, e.g., lost wages; mental anguish; loss of companionship
Pricing	Normally lower than other medical malpractice policies; each policy is priced individually based on type and phase of studies, clinical research revenue, and location	\$7.5K minimum premium; each policy is priced individually based on type and phase of studies, clinical research revenue, and location
Regions	25+ states, including CA, FL, NJ, NY, PA and TX	Worldwide
Exclusions	Major invasive procedures or major surgery; ophthalmology, dermatology and similar surgery OK	None specifically
Deductible	None	Normally \$10,000/claim; lower with additional premium
Defense costs	Yes, unlimited; paid in addition to policy limits	Yes, within policy limits
Other	Company is owned and governed by active principal investigators; policy-holders are part owners of the Company, voting for the Board of Directors and potentially receiving dividends from profits. Lloyd's of London reinsures risk.	Endorsed by Association of Clinical Research Professionals (ACRP), Association for the Accreditation of Human Research Protection (AAHRPP), and Academy of Pharmaceutical Physicians and Investigators (APPI)

References

1. "How Safe is Safe? Insurance for Investigative Sites", Norman M. Goldfarb and Michael Smith, Jr., *Journal of Clinical Research Best Practices*, June 2005
2. "Will You Lose Your Medical Practice If Your Patient Is Injured During A Clinical Trial?", Norman M. Goldfarb, *Medical Malpractice Law & Strategy*, April and May 2005. Available at <http://www.firstclinical.com/resources/articles.html>

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