

OMIC DIGEST

Risks of Clinical Research

Anne M. Menke, RN, PhD, OMIC Risk Manager, and Kimberly Wynkoop, OMIC Legal Counsel

Clinical research is closely tied to the practice of medicine, and many physicians either participate in studies as investigators or refer patients for enrollment. While traditionally research was linked to academic institutions, it is increasingly being conducted in the offices of physicians who may work directly with pharmaceutical companies or device manufacturers. The Office for Human Research Protection (OHRP) has raised concerns that an increasingly commercialized and competitive research environment may erode informed consent and put research subjects at risk.¹ OMIC has had only two lawsuits related to clinical trials. This small number suggests that the protections for human research subjects codified in federal law are largely effective. Indeed, the OHRP

and Food and Drug Administration (FDA) monitor clinical trials and issue warning letters to investigators, institutional review boards (IRBs), and study sponsors who are not in compliance with these federal regulations.² These warning letters, together with OMIC malpractice claims and public hearings on the subject, provide valuable insights into the risks of clinical research and how to better manage those risks.

Recruitment and eligibility for clinical research

Sponsors of clinical research develop and seek regulatory approval for study protocols specifying elements such as study design and procedures, subject inclusion and exclusion criteria, risks and benefits, management of adverse events, and informed consent.

Investigators submit these protocols for IRB review and approval in order to begin the research activity. While recruitment takes place before any clinical intervention, IRBs pre-approve this process as well. IRBs ensure that recruitment methods, including advertising and payment for participation, are not coercive or unduly influential and do not overstate the benefits of the intervention. Investigators should be mindful of this when offering payment for participation to economically disadvantaged subjects. Similarly, they should be cautious when recruiting subjects who do not read or understand English, as they may not truly understand what they are being asked to do. The IRB may require that additional safeguards be in place when enrollment of such vulnerable persons is anticipated. Investigators should also be aware of the FDA guidance on enrollment of and special protections for certain populations (such as children and pregnant women).

Related to recruitment, eligibility determination presents additional concerns. Of the FDA warning letters to ophthalmologists we reviewed, all four cite failure to adhere to study

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Message from the Chair

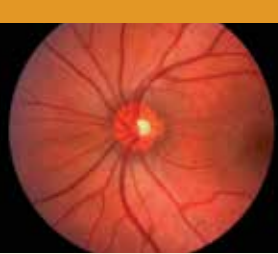
The Bean. Magnificent Mile. Deep dish pizza. There are a lot of things to like about my home town of Chicago. But for doctors, the inhospitable malpractice environment is not one of them. Perennially cited as one of the nation's "judicial hellholes," Cook County is a notoriously plaintiff-friendly venue with often unpredictable and seemingly unjustifiable jury awards. OMIC premiums for those of us practicing here reflect

this increased liability exposure, averaging \$17,000, well above the national average of \$9,500. Attempts at tort reform in Illinois have been about as successful as our Cubs in postseason.

To see the power of tort reform in action, one need only look west. California enacted what is now recognized as the gold standard for malpractice reform in 1975. This legislation, the Medical Injury Reform Compensation Act (MICRA), limits pain and suffering damages to \$250,000. It puts no caps on economic damages, which have continued to outpace inflation by more than double. Despite these increases, malpractice premiums for California physicians have

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Eye on OMIC



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OMIC
655 Beach Street
San Francisco, CA
94109-1336

PO Box 880610
San Francisco, CA
94188-0610

P 800.562.6642
F 415.771.7087
omic@omic.com
www.omic.com

Timothy J. Padovese
Editor-in-Chief

Paul Weber, JD, ARM
Executive Editor

Anne Menke, RN, PhD
Managing Editor

Kimberly Wynkoop, JD
Associate Editor

Ryan Bucsi
Contributing Editor

Betsy Kelley
Contributing Editor

Robert Widi
Contributing Editor

Linda Radigan
Production Manager

OMIC Increases Coverage Limit on Policy Benefits

We are pleased to announce that your standard policy benefit limits for regulatory and cyber exposures will be increased from \$50,000 to \$100,000 per policy year effective January 1, 2015. OMIC has monitored the exposures related to administrative practice activities, such as billing reimbursements for services and electronic storage and transmission of protected health information. In response to an expected rise in the number of Recovery Audit Contractor requests and an increase in the number of reported breaches, including lost and stolen laptops and devices, OMIC's Board decided to increase your coverage benefit to help reimburse for unexpected costs associated with these and similar events.

OMIC was one of the first malpractice carriers to cover its policyholders for proceedings related to billing errors and other regulatory exposures. Over the years, the coverage has been continually expanded and enhanced to meet the changing exposures of our insureds' medical practice,

including the rapid move to electronic medical records. OMIC's standard professional liability policy now provides protection for 14 related events and proceedings.

Broad Regulatory Protection (BRP) reimburses insureds for legal expenses relating to regulatory proceedings, including billing errors, DEA, EMTALA, HIPAA, covered licensing, and STARK proceedings, and peer review. BRP also covers audit expenses related to billing errors proceedings and fines or penalties (where allowed by state law) related to billing errors, EMTALA, HIPAA, and STARK proceedings.

Cyber (eMD[®]) protection covers insureds for electronic media exposures and breaches. These include multimedia, security and privacy liabilities, privacy regulatory defense and penalties, security and privacy breach response costs, notification expenses, and support and credit monitoring expenses. eMD[®] also covers network asset protection and cyber extortion and terrorism.

Message from the Chair

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stayed below the national average, thus helping to keep healthcare costs down and retaining access for patients. Several other states have adopted similar legislation with correspondingly good results.

MICRA is now under attack. Californians will go to the polls in November to vote on an initiative that, among other things, proposes to more than quadruple the cap on pain and suffering damages to over \$1,000,000. Raising caps alone is not widely popular with voters, in part because it is expected to raise healthcare costs and limit access. To sweeten the deal, the plaintiff attorney bar has added two seemingly unrelated provisions: random and post-adverse event physician drug testing, and mandatory use of a cumbersome and non-secure statewide database of patient prescription information (CURES) in order to cut down on prescription drug abuse. Focus groups have shown these issues resonate with voters. And why shouldn't they? An informal poll of my own physician colleagues finds little resistance to drug testing. While most

did not relish the thought of submitting to such scrutiny, few could offer compelling arguments why physicians should be exempt from the same workplace drug testing as other high-stakes professions, such as pilots, police officers, or school bus drivers.

One can argue the pros and cons of physician drug testing, but we feel any such debate and vote should address this issue independently and not be a Trojan Horse for dismantling the nation's oldest and most successful initiative in tort reform.

OMIC insures 484 California ophthalmologists, over 10% of our entire insured base. As a nationwide carrier, we clearly see the impact MICRA has had on minimizing frivolous lawsuits and stabilizing malpractice premiums in California. For that reason, OMIC has chosen to support Californians Allied for Patient Protection (CAPP), a broad coalition of California-based physicians, hospitals, and other providers fighting to keep the provisions of MICRA in place.

Watch for this battle to spill over nationally in the coming weeks. The decision on Prop 46 will impact tort reform everywhere. We hope California voters will see through the smoke screen.

Tamara R. Fountain, MD, Chair of the Board

Ophthalmic Mutual Insurance Company



Research Liability and Coverage

Kimberly Wynkoop, OMIC Legal Counsel

OMIC's policy covers insureds for claims based on injuries arising from direct patient treatment by the insured or someone for whose actions the insured is liable. This includes injuries to patient-subjects in a clinical research setting as long as the research was conducted under and in accordance with an American IRB-approved protocol. In research-related claims, there are often multiple defendants and various theories of liability alleged. In order to understand how OMIC's coverage would apply to such claims, here are some real world examples.

In the wake of the Office for Human Research Protection's (OHRP's) criticisms of the SUPPORT study (see the *Lead* article for details), law firms put out feelers to attract SUPPORT participants for potential lawsuits, offering to evaluate their cases. There was a large pool of potential plaintiffs; 1,300 infants had participated in the study. By April 2013, at least one lawsuit, *Looney v. Moore*, a class action, was filed against the IRB members at the University of Alabama at Birmingham, the lead site in the study, as well as the principal investigator (PI) and the manufacturer of the pulse oximeters used in the study. While the plaintiffs had made medical malpractice allegations against all of the defendants except the manufacturer, they ended up dropping these specific "medmal type" allegations. The remaining allegations are negligence, negligence per se, and lack of informed consent against the IRB members; negligence, breach of fiduciary duty, and lack of informed consent against the PI; and products liability and negligence against the pulse oximeter manufacturer. The case has yet to proceed to trial.

Because OMIC's policy does not cover insureds for their work on IRBs or manufacturing liability, we will examine more closely the allegations against the PI. This is a hypothetical coverage analysis as OMIC does not insure any defendants in this case.

The negligence allegations against the PI focus on his negligence in designing an "unethical and flawed" experiment that targeted vulnerable people in violation of state and federal standards and failing to ensure the informed consent form disclosed all risks and details of the "experiment" in order for subjects to make an informed decision whether to participate. The breach of fiduciary duty count states that the PI had both a researcher-subject and physician-patient relationship with the infants. In these relationships, he had a duty to disclose all information material to the decision to give consent. The specific lack of informed consent allegation states the PI did not prepare the informed consent form in compliance with legal and ethical norms and the subjects would not have participated had they been fully informed. As you can see, the crux of the case against the PI is the failure to obtain informed consent. While the plaintiffs dropped the allegations of negligence in the diagnosis, treatment, care and monitoring of the patients, the informed consent deficiencies coupled with injury to the plaintiffs would likely trigger medical professional liability coverage. However, if there was no physician-patient relationship and an insured was sued for designing a flawed informed consent form that was used by other researchers, there would be no direct patient treatment and therefore no coverage.

Another insured was faced with a research based claim when a patient-subject experienced a retinal tear after globe perforation (see the *Lead* article for more details). What protected the insured, in addition to adhering to the study protocol, properly managing the adverse event, and maintaining insurance with OMIC, was having in place an indemnification agreement with the study sponsor. Such agreements place the burden of defending the researcher and paying damages to the claimant on the sponsor. They should state that the sponsor will defend, indemnify, and hold the researcher harmless. The protection should extend to the research institute, owners, officers, directors, physicians, employees, and agents as appropriate. They should relieve the researcher of responsibility for any liability or loss arising from any claims, demands, suits, actions, or judgments. Sponsors will likely want to limit the indemnification to claims resulting from adverse effects of their products and exclude indemnification for negligence, malpractice, gross negligence, or willful conduct of the researcher, including failure to comply with applicable laws or the terms of the study protocol. They may also want to retain the right to settle the claim or take it to trial. You should consult with an attorney in order to secure the most advantageous terms. (OMIC will work with the sponsor to apportion coverage based on the agreement and the insured's policy provisions.) The sponsor may also want you to indemnify them for your negligence or misconduct. Remember that your OMIC policy excludes such contractual liability. OMIC will defend and indemnify you, but not a third party, for claims based on your professional services.

enrollment criteria. When FDA staff conducted an investigation of one ophthalmologist, they found that 75% of the subjects did not meet inclusion criteria. In two of the letters related to one research center, the FDA found that scans taken to document the presence of the qualifying disease were performed incorrectly, indicating that the subjects may not have been eligible for the study. Another investigation showed that subjects did not meet visual acuity inclusion criteria. Investigators who receive warning letters face possible exclusion from research if concerns raised in the letter are not promptly and adequately addressed. They may also face lawsuits for negligence if the subjects of their research are harmed by investigational treatment for which they did not meet eligibility criteria, just as a physician would if a patient was injured during unnecessary surgery outside of research.

Benefits of adherence to study protocols

As the warning letters regularly state, adhering to study protocols protects subjects and ensures the integrity and quality of the data generated from the research. It can also protect investigators who are sued when subjects experience adverse events. For example, an OMIC-insured ophthalmologist recommended that his patient, who had age-related macular degeneration, enter a clinical trial being conducted at his office to test the effectiveness of a depot steroid injection. On the last injection of the study protocol, the cannula entered the globe, leading to a retinal break and tear. Unhappy with her final visual acuity of 20/80, the patient sued the pharmaceutical company as well as an OMIC-insured medical entity and two OMIC-insured ophthalmologists, one of whom was the study director. Experts reviewing the care determined that the insureds had properly enrolled the subject in the trial, obtained

informed consent, complied with the study protocol, performed the procedure, and managed the adverse event. The experts noted that the study sponsor knew that scarring from prior injections made subsequent procedures more difficult. They concluded that while the injury was due to the study drug and procedure, the insureds met the standard of care. The defense attorneys contacted the sponsor, who had signed an agreement with the insured group to indemnify, defend, and hold them harmless for any adverse effect of the drug on a subject as long as they complied with the protocol and met the standard of care. The sponsor accepted the experts' review and agreed to settle the case in exchange for a dismissal of the ophthalmologists and entity. Physicians engaged in clinical trials of drugs and devices can benefit from such agreements with study sponsors. Please see *Policy Issues* for more details.

Informed consent for research

Physicians are familiar with the information that must be provided to patients during the informed consent process, such as the condition, procedure, risks, benefits, and alternatives. Federal regulations impose additional elements for research-related informed consent, including a statement on the purpose, duration, and experimental procedures of the research. The regulations also stipulate that consent for research must be sought only under circumstances where the subject has a sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence. To this effect, the form must state that participation is voluntary and that refusing or discontinuing participation will cause no loss or penalty.


The consent form must also address the extent to which the investigator intends to maintain the confidentiality

of records identifying the subject and the possibility, if applicable, that the FDA, sponsor, IRB, or other involved parties may inspect such records. Absolute protection of confidentiality by the FDA should not be promised or implied since disclosure to third parties may be required. The form should also alert subjects that their records automatically become part of the research database.

Additionally, consent forms must address what will happen and whether there is compensation if injury occurs (see *Hotline*). However, federal regulations expressly prohibit exculpatory language and clarify that subjects may not be asked or implied to waive their legal rights or release the investigator, sponsor, institution, or its agents from liability for negligence. Recent draft guidance clarifies that a waiver may be permissible if it does not free another from liability. This was a change in position for the government; for example, it is now permissible for a subject to waive his or her rights to compensation for biospecimens provided to investigators.

While not required, investigators should consider the potential effects that a financial relationship might have on the research or their interactions with subjects. They should consider including information in the consent document about the source of funding and financial arrangements for the research. They may also want to modify the consent process when a potential or actual conflict exists.

A written form including these essential components generally must be submitted for IRB review and approval as part of the study protocol. While IRBs have the final authority for ensuring the adequacy of the information in the consent document, the language does not always pass governmental muster. A recent controversy about a multisite pediatric clinical trial called SUPPORT (Surfactant, Positive Pressure, and Oxygenation Randomized Trial),



which tested the effects of varied oxygen levels on retinopathy of prematurity (ROP) and chronic lung disease, highlights the difficulty in ensuring the adequacy of the consent process. SUPPORT, conducted from 2004 to 2009, was sponsored by the National Institute of Health and approved by 23 IRBs. OHRP received and responded to a complaint one year after publication of the results. In the warning letter sent to the lead study site, OHRP claimed that the study consent form failed to describe the reasonably foreseeable risks of blindness, neurological damage, and death due to the random assignment of premature infants to higher or lower ranges of oxygen. While the study protocol discussed prior studies that raised concerns about the consequences of both high and low levels of oxygen on survival and brain, lung, and eye health, the “Risks” portion of the consent form did not include this information.

A number of physicians and ethicists responded to the warning letter in peer-reviewed journals, and organizations such as Public Citizen weighed in. The investigators argued that infants were at minimal risk since oxygen levels during the trial would be kept within the range provided in NICUs at the time. Conversely, OHRP found that randomly assigning and confining subjects to either the lower or upper portion of the range was not the same treatment most infants would have received had they not participated in the study. Therefore, the study intervention and attendant risk and potential benefits differed from those of the “standard of care.” SUPPORT critics, agreeing with OHRP, felt that the parents needed to be informed not only of known concerns about both high and low levels of oxygen, but that the pulse oximeter had been altered to hide the true oxygenation level from providers. OHRP acknowledged the need for better guidance on informed consent

for trials comparing known treatments and convened a public hearing in 2013 to gather input that will inform future regulations.

Several principles emerged from the articles and the public hearings. Subjects need to know the difference between the care they would normally get and the care that will be provided during the study as well as the purpose and consequence of randomization. An informative example was cited in some letters and comments. In the US trials, the risk section of the consent form stated that “Because all of the treatments proposed in the study are standard of care, there is no predictable increase of risk to your baby.” The oxygen study also took place in New Zealand (NZ), where it was known as the BOOST trial. The NZ consent form

explained that too low of an oxygen level could lead to an increase in the risk of death, poor growth, brain damage, or developmental problems, while too high of a level could lead to an increase in the risk of lung disease or ROP and blindness. US governmental representatives commented that the NZ consent form adequately addressed the foreseeable risks and met federal requirements, and most speakers acknowledged that it better informed the subjects’ parents.

1. DHHS OIG. “Recruiting Human Subjects: Pressures in Industry-Sponsored Clinical Trials.” <https://oig.hhs.gov/oei/reports/oei-01-97-00195.pdf>.

2. Most research involving human subjects is governed by the Federal Policy for the Protection of Human Subjects or “Common Rule” (45 CFR Part 46, Subpart A) and/or the FDA Protection of Human Subjects Regulations (21 CFR Parts 50 and 56).

HIPAA Research Protections

The HIPAA Privacy Rule requires specific safeguards for protected health information (PHI). HIPAA supplements federal human subject regulations, which also include protections for the privacy of subjects and the confidentiality of their information. Any state privacy laws that are more stringent than the Privacy Rule would also continue to apply.

- Can use/disclose PHI for research without individual authorization under limited circumstances:
 - Documented IRB approval if there is no more than minimal risk to the privacy of individuals.
 - Preparatory to research if PHI not removed from site.
 - Research on PHI of decedents with, if required, documentation of death of individual.
 - Limited data set with data use agreement.
- Compound authorizations are permitted.
 - Permission to use/disclose an individual’s PHI for a research study can be combined with consent to participate in the study or any other legal permission related to the study, or authorization for a different research activity, in one form.
 - If research-related treatment is conditioned on the receipt of one of the authorizations, then the form must clearly differentiate between the components and provide the option to opt in to the unconditioned research activity.
- Future use authorizations are permitted: must include adequate general description of future research purpose, but doesn’t have to be study specific.
- Can receive remuneration for permissible disclosure of PHI for research: limited to reasonable cost to prepare and transmit PHI.



Closed Claim Study



Allegation

Manipulating screening data for study eligibility, failure to supervise technician, and abandonment.

Disposition

Case settled for \$250,000.

Fraudulent Enrollment of Patient in Clinical Trial

Ryan Bucsi, OMIC Senior Litigation Analyst

Case summary

An OMIC insured was the principal site investigator (PSI) at an OMIC-insured research center during a clinical trial comparing the effectiveness of an anti-VEGF drug, focal laser photocoagulation, and steroids for the treatment of diabetic macular edema. Enrollment criteria included at least one eye showing definite retinal thickening involving the center of the macula due to diabetic macular edema on clinical exam and OCT central subfield ≥ 250 microns. A technician completed the OCT study; the PSI noted that it was off-center but assumed the subject could not keep her head still. Since the PSI's exam showed macular edema, the PSI accepted the subject for the trial, obtained informed consent, and proceeded to administer an intravitreal injection of an anti-VEGF medication in the right eye and a sham injection in the left. The patient was instructed to use an antibiotic drop as prophylaxis against infection. Two days later, the patient returned to the PSI complaining of a pressure ache in the right eye and decreased vision. The PSI noted CF vision and diagnosed endophthalmitis, which was treated with a vitreous tap and intravitreal and subconjunctival antibiotic injections. The patient's condition worsened the next day and surgical intervention was needed. As the patient did not have health insurance, the PSI called the study coordinating center (SCC) to see if it would pay for the treatment. When the PSI learned that no funds were available, the PSI referred the patient to a county facility for further treatment. A culture ultimately grew out a heavy growth of strep viridans. Despite a vitrectomy, the patient was left with LP vision in the right eye.

The insureds reported the adverse event to the SCC. A year later, the research center discovered and fired an employee for embezzlement. One year after that, the SCC conducted a review and noticed a significant number of off-center OCTs, all apparently manipulated or substituted by the fired employee. The research center did its own investigation and clarified to the SCC that it did not offer bonuses for enrolling subjects but suspected that the employee falsified the OCT scans in order to enroll as many subjects as

possible as part of her embezzlement scheme. The SCC's review also concluded, based upon a review of the OCTs and fundus photos, that many of the subjects did not have macular edema, thus calling into question the PSI's clinical skills. The owner of the research center wrote to all affected subjects. The letter to the injured patient stated that the fired employee had intentionally altered the testing to increase eligibility for the study, that the right eye did not require an injection, and that, if the injection had not been performed, the eye would not have developed an infection. The patient sent a written claim to the research center expressing an intent to file suit.

Analysis

OMIC's retained expert opined that the claimant did not meet the criteria for either the study or off-label use of the drug. He also felt that the failure of the PSI to obtain a second OCT when the first was clearly off-center was below the standard of care. While the claimant alleged abandonment because the PSI did not provide all care needed for the endophthalmitis, the expert supported the PSI's management of the complication itself (see *Hotline* for a discussion of what care must be provided by an investigator). The claimant ultimately accepted a settlement on behalf of the research center for \$250,000.

Risk management principles

Ensuring that research subjects meet enrollment criteria protects the research subject, the investigator, and the data. The trial developers in this case built safety into the protocol for enrollment through redundancy: findings of edema were required on both clinical exam and OCT, so either a competent exam or an accurate OCT would have excluded this subject from the trial. A more cautious approach when faced with a questionable test result, such as repeating the OCT scan, may have helped the PSI determine that the patient was not qualified for the study. Improved employee oversight may also have helped the insureds ferret out the fraudulent actions of the employee and uncover the falsification of the OCT scans.



Adverse Events in Clinical Research

Anne M. Menke, RN, PhD, OMIC Risk Manager

Just as with care provided outside of research, subjects who participate in clinical trials can experience complications from the study intervention. Federal regulations use the term “adverse events” to describe these outcomes and define them in intentionally broad terms. In drug trials, for example, an adverse event would include any adverse change from the patient’s baseline condition, including any abnormal clinical laboratory test value, which occurs during the course of the study, whether related to the study medication or not. Management of adverse events in clinical research raises questions about who provides and pays for care when adverse events occur.

Q When is an investigator required to provide care for adverse events?

A The FDA issued a guidance document for investigators that contains non-binding recommendations.¹ It states that investigators should provide reasonable care for any adverse events related to trial participation. If the investigator does not possess the necessary expertise, the investigator should make sure that the subject is able to obtain the needed care from a qualified practitioner. The care should continue until any emergency condition related to the study intervention is resolved, whether the condition develops during the study or after it ends. The claimant in the *Closed Claim Study* alleged that the principal investigator (PI) abandoned her by referring her to a hospital after an adverse event occurred instead of performing the needed surgery herself. The PI was a retinal specialist

and had the requisite expertise to perform the vitrectomy. The subject, however, was unemployed and without insurance, and the PI, who was an employee of the research center, did not have the authority to provide care in these circumstances. Since endophthalmitis was a foreseeable risk of an intravitreal injection, the PI should have clarified in advance with the research center and the study coordinating center what care she would be authorized to provide in the case of an adverse event. Once she learned that the care she could provide was limited to office-based interventions, she should have identified retina specialists and hospitals willing to provide further care.

Q Who pays for the care in the case of an adverse event?

A Federal regulations governing informed consent stipulate that subjects who face more than minimal risk should be told what compensation and medical treatments, if any, are available for injuries arising from study procedures and where more information may be obtained. The claimant in the *Closed Claim Study* complained that the consent form contained conflicting information about what care would be provided. The form stated that tests related to the study would be free, but that the subject or subject’s insurance company would be responsible for the costs of study-related treatment, office visits, and general eye care. The consent form then went on to explain that some costs and treatment might not be covered by the subject’s health plan, but if they were not, they would be covered by the study. The claimant

informed the investigator at the outset that she had no insurance, and it appears that she believed the study would pay for her care. Her complaint letter did not reference a later section of the consent form, which stated that, in the event of an injury, she would receive medical treatment but would be responsible for the costs and that no money was available to compensate her for an injury. The form did not explain whether the risks detailed in the document were considered an injury. Consent forms can be confusing. The National Cancer Institute developed a research consent form template that meets federal requirements but uses simplified language. It states, in part, “The study sponsors will not pay for medical treatment if you are injured or hurt because you took part in this study. Your insurance company may not be willing to pay for injury from the study. If you have no insurance, you will be responsible for any costs [related to an injury].” The template further explains that if subjects feel an injury was a result of medical error, they keep all of their legal rights to seek payment for an injury even though they were in a study.² Ophthalmologists may benefit from using similar language to ensure that information about adverse events is clearly communicated in the protocol, consent form, and consent process.

1. FDA. “Guidance for Industry: Investigator’s Responsibilities—Protecting the Rights, Safety, and Welfare of Study Subjects.” <http://www.fda.gov/downloads/Drugs/.../Guidances/UCM187772.pdf>.

2. National Cancer Institute. NCI Consent Form Template. <http://www.cancer.gov/clinicaltrials/conducting/simplification-of-informed-consent-docs/page 3>.



OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

655 Beach Street
San Francisco, CA 94109-1336

PO Box 880610
San Francisco, CA 94188-0610

OMIC has announced a 25% dividend credit to be applied to 2015 renewal premiums plus OMIC's competitive 2014 rates will be extended through 2015. Call 415.202.4628 or email getaquote@omic.com to take advantage of these savings.

Calendar of Events

OMIC continues its popular risk management program through 2014. Upon completion of an OMIC online course, CD/DVD, or live seminar, OMIC insureds receive one risk management premium discount per premium year to be applied upon renewal. For most programs, a 5% risk management discount is available; however, insureds who are members of a cooperative venture society (indicated by an asterisk) may earn an *additional discount* by participating in an approved OMIC risk management activity. Courses are also listed on the OMIC website, www.omic.com.

Contact Linda Nakamura at 800.562.6642, ext. 652, or lnakamura@omic.com for questions about OMIC's risk management seminars, CD/DVD recordings, or computer-based courses.

October

18 25 Years of Liability in Pediatric Ophthalmology and Strabismus plus Lessons to Learn: Pearls from Individual Cases (Course PED07). Pediatric Ophthalmology Subspecialty Day at Annual Meeting of the American Academy of Ophthalmology. Vista Room S406A, McCormick Place, Chicago, IL; 3:25–4:27 pm.

19 OMIC Medical Malpractice Cases. Young Ophthalmologists 2014 at Annual Meeting of the American Academy of Ophthalmology. Room S101B, McCormick Place, Chicago, IL; 12:25–12:40 pm.

19 2nd Annual Bruce E. Spivey, MD, Lecture in Risk Management and Patient Safety and OMIC Forum (SPE15). Annual Meeting of the American Academy of Ophthalmology. Room S406B, McCormick Place, Chicago, IL; 2–4 pm.

19 Identifying and Managing Unhappy Patients (Course 237). Annual Meeting of the American Academy of Ophthalmology. Room S106B, McCormick Place, Chicago, IL; 4:30–5:30 pm.

20 Why Take the Risk? How to Create an Effective Risk Management Strategy (SYM34). Annual Meeting of the American Academy of Ophthalmology. Room S403B, McCormick Place, Chicago, IL; 12:45–1:45 pm.

20 ROP Screening and Treatment: What You Wanted to Know But Were Afraid to Ask (Course 381). Annual Meeting of the American Academy of Ophthalmology. Room N140, McCormick Place, Chicago, IL; 2–4:15 pm.

November

10 OMIC Closed Claims. Northern Virginia Academy of Ophthalmology. Maggiano's Little Italy; Tyson's Corner,

McLean, VA; 6 pm. Contact Linda Nakamura at OMIC, 415.202.4652.

January

17 A Storm is Brewing: Lessons from Malpractice Studies. Cataract Surgery: Telling It Like It Is! Ritz-Carlton, Sarasota, FL; 1:15–2:30 pm. Register at <http://www.cstellingitlikeitis.com/index.html>. Sign in onsite.

17 Think Outside the Knife, Part 1. Hawaiian Eye 2015. Grand Wailea, Maui, HI; 9:45–10:15 am. Register at <http://www.healio.com/meeting/hawaiianeyemeeting/home>.

18 An Ophthalmologist, a Priest, and a Felon Walk into a Bar.... Hawaiian Eye 2015. Grand Wailea, Maui, HI; 9:30–10:15 am. Register at <http://www.healio.com/meeting/hawaiianeyemeeting/home>.