

Pacemaker



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*Pacific Coast Conference
May 6-7, 2022*

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AMWA Northern California Chapter, 2022 Board of Directors

The Board members want to hear from you! Please reach out to any or all of us. You can reach us by email at the following addresses:
(*email addresses are spelled out to discourage spam*).

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Chapter Website: <https://amwancal.org/>



Letter From Our Chapter President Fae Koohestani

Dear fellow Chapter members,

I hope you and your loved ones are enjoying the relatively relaxed community environments around you after enduring a long hibernation because of the COVID-19 pandemic. Just looking at my ever-expanding to-do list for outdoor activities, such as attending concerts and visiting art galleries, I see that I've started to enjoy the postpandemic era! But I think I need to curb my enthusiasm and remember that I have a limited amount of energy and time to do what I love to do outside my home, to be grateful for the improved situation, and to be hopeful that with our collective efforts and a bit of understanding by Mother Nature (ie, evolving infectious microorganisms) we won't be back to hibernation again.

In spite of the difficult situation we faced and the uncertainty of the current circumstances, your elected Chapter officers continued to uphold the mission of our Chapter by actively participating in virtual meetings, discussing important issues, and handling a variety of tasks via email. Here is a summary of their collective efforts over the last two quarters of 2022.

- **Holding the Annual Membership Meeting:** Held on March 19; introduced the 2022 Chapter Officers; reviewed Chapter finances and the President's plan for the year, which involves optimizing Chapter procedures; learned about Platform Protocols used in oncology clinical trials in a presentation I gave.
- **Holding the Pacific Coast Conference (PCC):** Held over two days on May 6 and 7; covered a variety of educational topics by experts across different disciplines as main presentations and roundtables over a full day; commenced the first "Leadership" (coined by our own vice president, Mark Hagerty!) in a half-day gathering to provide a "learn and share" opportunity among AMWA Chapter leaders, and to support and educate emerging leaders; excellent teamwork by the PCC Committee members who spent many hours planning the event and passing the torch to their colleagues in the South Pacific Chapter for next year's conference.
- **Hiring a new webmaster:** In February, the very responsive Armeen Mahdian started supporting the IT needs of our Chapter website and officers as well as supporting events.
- **Electing a Program Committee Chair:** In June, Loni Anderson enthusiastically took on the mantle from Maggie Norris, who had kindly served as our interim Chair while the Board tried to fill the position.

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- **Major updates to Chapter communications procedures and support platforms:** Crystal Herron, Communications Committee Chair, has spearheaded the much-needed related efforts with support from the Communications Committee and Suzanne Canada, Membership Committee Chair.
- **Developing standard operating procedures (SOPs) for Board and Chair positions:** Spearheaded by Nancy Katz, Governance Committee Chair, and supported by past and present Board members.

Energized by great outcomes of our efforts over the last several months, your Chapter officers are currently working on the following:

- A virtual aperitif hour in late summer
- A dinner get-together of Chapter members in Denver, CO, during the 2022 AMWA National Conference (spearheaded by our Chapter volunteer, Yule Lee)
- An in-person gathering of Chapter members in fall or winter, the postpandemic era permitting (let's keep our fingers crossed!)
- Finalizing SOPs and developing Chapter-related work instructions
- Continuing work on the President's plan for the year
- Planning and conducting the 2023 Chapter election

We hope we can successfully accomplish what we have so far planned to do for the next two quarters of the year and share our plans with you in the next issue of the *Pacemaker*. Keep in mind that your ongoing support of Chapter officers and events has been key to our success. So please continue your support by attending our events, sharing your feedback and suggestions, volunteering in different capacities, renewing your membership, and spreading the word about our Chapter among your networks.

I would like to end my letter by appreciating the efforts made by *Pacemaker* Co-Editors Mimi Wessling and Michele Anderson to put this issue together and having it available for you to read. I also would like to thank all our volunteers who prepared the write-ups of PCC presentations.

Stay healthy, enjoy life as it presents itself to you. I look forward to seeing you at our next event and in Denver in November!

Fae Koohestani, MS, PhD
NorCal Chapter President



Editor's Note

In this issue of *Pacemaker* we've departed somewhat from our usual approach to content: We review the recent 2022 Pacific Coast Conference for our readers who weren't able to attend the webinar on May 6 and 7. The amount of information that our presenters offered was also so rich that even if it is a repeat for some of our readers who did attend the webinar, it has so much value. The variety of topics was astounding! In another first, we've decided to offer a recording of the PCC for purchase: See the details at the end of my Editor's Note.

Medical writers face a complex task: We have to be able to evaluate the underlying science and structure of studies, work with comments and suggestions from others. Sometimes we are faced with organizing an effective event or professional committee. The presentations on Friday offered depth of knowledge for the first challenge, and those on Saturday's "Leadership" provide structural bases for the second. Those two presentations drew on the experience of longtime AMWA NorCal members Sandra Ruhl and Nancy Katz. The roundtables provided an opportunity for exchange of ideas and supplied the interpersonal exchange that we all miss so much! The participants were rewarded in two

ways—information-wise and cooperation-wise. Thus, the two-day PCC 2022 program accomplished different goals, as Fae explains in her President's letter.

One section that I felt very timely I kept in the usual position is the Book Nook: Morgan Leafe's review of the medical ethicist Harriet Washington's most recent book, *Carte Blanche: The Erosion of Medical Consent*. Opening the book to the title of the first chapter reveals its saliency for the present COVID pandemic: "Informed Consent in the Time of Infection." How many physicians and health care workers have had to make decisions under extreme pressure when there were not enough hospital beds, not enough vaccine? When unproven medications were being touted? Washington provides perspective.

As promised, here's how to order a recording of the 2022 PCC

So you couldn't attend the Pacific Coast Conference (PCC) in May, but find yourself wishing you had access to the presentations and roundtables? Wish granted! For a small fee (\$30), Chapter members who did not register can access recordings of both days of the 2022 PCC. These materials will be available until December 31, 2022.

Send an email to treasurer@amwancal.org to receive the address to which you mail your \$30 check. (Sorry, no payments by credit card or PayPal). You will receive the link to all materials via email.



Presentations at the 2022 Pacific Coast Conference

Scary and Enlightening

Keynote Speaker: Gary Witherell

Writer: Barbara Arnoldussen

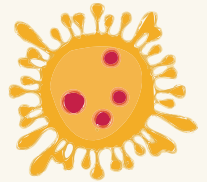
Biochemist Gary Witherell PhD launched the conference with a timely, in-depth look at the world of viruses. His talk, entitled "Catch Me If You Can: Science's Pursuit of Elusive Viruses," brought the audience up-to-date about natural immunity, vaccines, and COVID-19 decisions.



Discussing the viral components of COVID-19, Gary reasoned that virologists would have suggested national personal protective strategies very differently from what happened. COVID-19 has a surrounding lipoprotein envelope that makes it fragile, sensitive to air and UV light. "Virologists knew this virus was not going to be transmitted outdoors and was not going to be transmitted off surfaces," Gary announced. Following their expert opinion would not have closed outdoor recreation facilities and mandated "sanitizing things." Gary lamented, "No one was listening to the virologists."

Saving the otherwise negative situation are our immune responses, both innate and adaptive.

He estimated the herd immunity level at 70% to 95% infection, which could prevent the spread to the 5% to 30% uninfected individuals. His worst-case scenario combined both the lack of exposure and vaccines, a medical disaster that actually happened in Greece.



Gary discussed British researcher Neil Ferguson's computer simulation that predicted catastrophic death rates for COVID-19. This dire forecast resulted in lockdown strategies for the UK and the US. Real-time data showed that neither the lockdown severity nor duration reduced the death rate from COVID-19. But the lockdown produced other unintended consequences: 100,000 excess US deaths from suicide and substance abuse, missed medical care for TB or cancer, as well as excess deaths from increases in traffic accidents. The most worrisome prediction was the lockdown's deleterious effect of reducing exposure to all pathogens, with future increases in flu and respiratory deaths as well as more pediatric immune disorders.

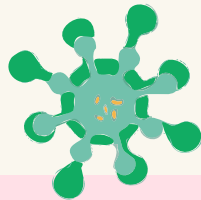


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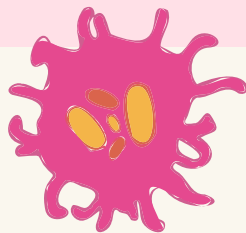


Gary included a humorous look at the “first clinical trial,” Dr. Edward Jenner’s work on the smallpox vaccine, with purported consent forms. He also described “Polio Paul” Alexander, an inspiring figure who has lived in an iron lung for the past 70 years. He listed the benefits of synthetic COVID-19 vaccines: one intranasal dose, with the possibility of rapid, inexpensive reformulation to respond to virus mutations

His fascinating lecture ended: “Due to natural immunity, vaccines, and the self-limiting nature of viruses:
THE HUMAN RACE WILL SURVIVE!”



Our Keynote Speaker **Gary Witherell** combines experience in clinical, nonclinical, and drug-discovery scientific research with a commitment to quality medical writing. He is Founder, President, and Head of Medical Writing at MediSyntax. One characteristic that not many of us can claim is having a scientific tree that goes back eight generations to Louis Pasteur.



Clinical Trial Protocols: Writing for Audiences

Presenter: Karen Henry
Writer: Fae Koohestani

Medical writers tend to reuse content from approved protocols for writing new protocols. While this approach helps maintain standardized language across protocols, saves time and effort, and ensures what to include, it often leads to errors impacting the overall study.



Karen Henry’s extensive experience with clinical trials shows that this copy-and-paste approach not only is the root cause of including nonrelevant information, but also leads to missed information or inconsistencies throughout a document. These errors result in irregularities in the study conduct due to lack of understanding by/clarity for the audience. The lack of clear procedures can result in potential risks to patient safety, data integrity, additional costs, and poor trial compliance. It is, therefore, essential to write a protocol per ICH guidelines, which takes all four protocol audiences into consideration: (1) regulatory authorities; (2) investigators and site personnel; (3) independent review boards or ethics committees; and (4) the sponsor itself.

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Because each element of the protocol—from the general information on page 1 to the schedule of assessments and references—contains information for some if not all audiences, the highest standards of quality control should be implemented to avoid errors impacting site budgets, recruitment of eligible subjects, randomization and treatment of subjects, efficacy and safety assessments, as well as approval of the protocol by ethics committees and regulatory authorities.

Building Meaningful Relationships and a Positive Reputation With Your Clients and Colleagues

Presenter: Crystal Herron

Writer: Bridget Mazzini

If you're looking for an opportunity this summer to enhance your professional relationships and communication skills, check out Crystal Herron's presentation for the 2022 Pacific Coast Conference (PCC) Crystal anchors it with a quote from billionaire Warren Buffet: "It takes 20 years to build a reputation and 5 minutes to ruin it. If you think about that, you'll do things differently."

Crystal's presentation provided a toolkit for doing things differently.

In this 45-minute session, Crystal lays out a road map for building collaborative work relationships. Far from presenting an exposé on team-building exercises, she takes a pragmatic look at the elements that foster meaningful work relationships. She then follows through with definitive actions that can help professional relationships be more authentic and mutually rewarding, ultimately leading to better communication outcomes and professional satisfaction. Crystal provides sound principles for building trust, fostering collaboration, and addressing conflict. She also suggests ideas for using technology to help strengthen and solidify communication by creating email and text templates and keeping notes on client preferences.



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Crystal makes a convincing case that subtle differences in your approach to people can make a significant difference in your effectiveness as well as your professional fulfillment.

Drawing from personal experience as well as wisdom from business and relationship thought leaders, Crystal discusses:

- Key elements of meaningful relationships
- Traits that foster collaboration
- Strategies to strengthen meaningful relationships
- Factors to help resolve conflict
- Management systems to help with your relationships

In the weeks since I attended the PCC, I've already used some of these techniques and given a great deal of thought to others that I anticipate trying.

Crystal's presentation can be viewed by purchasing the recording if you missed the webinar (see the Editor's Note for details). Listen in and discover the advantages of asking for advice rather than for feedback, the importance of psychological safety in the work setting, how to write a power thank you (my personal favorite), and how the platinum rule differs from the golden rule.

You can find Crystal Herron at crystal.herron@redwoodink.com
[linkedin.com/in/crystalherron/](https://www.linkedin.com/in/crystalherron/)

Emerging Regulatory Challenges and Expectations in Drug Development

Presenter: Lisa Sauer

Writer: Leslie Kowitz

Accelerated Approvals—Pandemic—War! The last two years presented extraordinary global challenges. The pharmaceutical industry and the FDA were no exceptions. Lisa Sauer shared her insights on oncology treatments and how they were affected by the FDA's response to crises.

Current Themes within FDA and Oncology

Originally initiated in the 1990s, the FDA's Accelerated Approval (AA) program was created largely in response to the HIV-AIDS crisis. The program was later expanded to include oncology to expedite approvals for promising drugs. The FDA has increased its scrutiny of these drugs because they are often hard to confirm and the standard-of-care can quickly become outdated. Accelerated approvals are conditional: They require a confirmatory trial at a later date that demonstrates benefit to receive full approval status. Because the FDA can withdraw the approval if the benefit is not later confirmed, sponsors have been voluntarily withdrawing their approvals for failure to show efficacy or failing to complete the follow-up trials rather than wait for the FDA to rescind approval.

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Dose optimization is another hot topic. The FDA has focused its attention on dosing by ensuring Sponsors choose the lowest effective dose, which exposes patients to less toxicity than the previous approach (maximum tolerated dose). Now, when Sponsors receive a “Safe to Proceed” letter, it comes with a long list of data requests to satisfy questions on how the dose was chosen, including nonclinical, pharmacodynamic, and pharmacokinetic data.

Handling Crises

In 2020, the clinical oncology world ground to a halt because of the global COVID-19 pandemic. Clinical sites shut down and all health efforts turned to providing pandemic services. Drugs and materials were in short supply and some shortages continue to this day. The FDA quickly responded and issued guidance to clinical trial Sponsors, which added flexibility by allowing the use of telemedicine and drugs shipped directly to patients’ homes, in addition to handling concomitant COVID-19 vaccines. These allowances are considered deviations and must be documented, but the FDA quickly provided a path forward for clinical trials that were already in progress. Sauer believes COVID-19 has given us a unique opportunity to assess the impact of the pandemic on clinical trials—essentially an experiment

within an experiment. The FDA is interested in how the new allowances affected the conduct and outcome of clinical trials, and the Agency will be providing guidance on how to report this in the final clinical study reports.

Just on the heels of COVID-19, another crisis has affected many patients—the Russian invasion of Ukraine in February 2022. More clinical trial sites have opened in Ukraine in recent years, but the fighting has devastated and displaced so many people and caused shutdowns and shortages. Similar to the shift in focus for COVID, all efforts in Ukraine are focused on safety and security. One day we will look back on this period and be grateful for the combined efforts of the FDA and dedicated professionals who kept persevering to get new treatments to patients under these dire circumstances.

Lisa Sauer is the Senior VP of Regulatory Affairs & Quality Assurance at the biopharmaceutical company Exelixis, Inc., in Alameda, CA. Over the last 25 years of experience, she has led the company’s multiple approvals for two commercial products worldwide and is currently planning regulatory strategies for the development plans of new drugs in the pipeline.

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Show Me the Money: The Treasurer's Duties

Presenter: Sandy Ruhl

Writer: Mark Hagerty

For many, the scariest office in any nonprofit is the treasurer's. Handling the Chapter's money can seem unnerving. This well-attended session of the 2022 Pacific Coast Conference aimed to calm these fears. Sandy Ruhl is familiar with several roles in AMWA NorCal's Chapter, including the treasurer's. She spoke about the most practical aspects of how to do this important job:

- Establishing and managing bank accounts, including who needs access
- Watching the ebb and flow of funds, distributing checks, and receiving deposits
- Reporting Treasury status to the Chapter and National, including templates to use
- Keeping required records
- Maintaining federal tax-exempt status and filing how-to's with the IRS

Sandy also offered tips about filing California taxes and detailed the intricacies of our nonprofit status. My favorite tip: Visit the County Clerk's office in person and bring your papers and patience when you go.

The session split its time about 50/50 between the presentation and Q&A. Sandy spoke with humble experience, with tips to other chapters to avoid the obstacles she bumped into as she developed her best practices. Who knew that banking practices in different states could raise so much emotion? The answer is: Treasurers knew. The New England Chapter was actively interested and participative. Several participants' "war stories" emerged that brought Sandy's practices to life, and attendees seemed grateful for the advance instruction. Sandy's intent was to help others learn what she has learned, with perhaps less effort.

This session offered a "Treasurer's Trove" of helpful and practical information for what is arguably the most complicated officer position in the Chapter.

Sandy Ruhl had extensive experience as a nurse and in clinical research in different environments and roles—she then transitioned into freelance medical writing and quality control. AMWA NorCal has relied on Sandy formerly as Vice President, Program Committee Chair, President and now as Treasurer, representative to the AMWA National Chapter Advisory Council, and Pacific Coast Conference Committee Co-Chair.



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Putting Our House in Order: Bylaws, SOPs, and All the Rest

*Presenter: Nancy R. Katz, PhD, MWC,
Chair, NorCal Governance Committee
Writer: Bridget Mazzini*

Encouraging Chapters to develop bylaws and standard operating procedures (SOPs) has been a priority of AMWA National for over a decade. NorCal member and Chapter leader Nancy Katz was instrumental in creating our Chapter bylaws that provide guidance and structure to assist our Board of Directors (BOD) in responsible Chapter governance.

Nancy now chairs the NorCal Governance Committee tasked with developing Chapter SOPs. In this presentation, she shared freely the ups and downs of pinning down exactly what it is we do and putting it in writing.

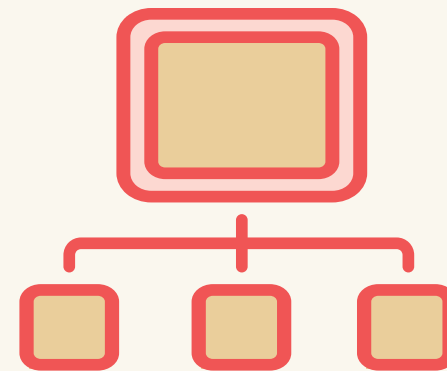
It seems so simple:

- Ask what do we do and how do we do it
- Write it down
- Not too general, not too specific
- Choose a template: many are easily accessible on the internet

- Establish a process for writing, approving, modifying, and managing SOPs.

Sounds straightforward, right? Yet even a seasoned medical writer like Nancy, whose microscopic attention to detail seems inherent in her DNA, suggests writing SOPs is just slightly preferable to getting a root canal.

While tedious for sure, there is a bright side. Nancy notes there is an art and a science to writing SOPs. It's not just about punctuation: There is judgment and finesse in defining and communicating, step by step, how to accomplish something. A side benefit Nancy notes: There is community to be found working on a project like SOPs and potential leadership growth for individuals who participate.



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Benefits include:

- Appreciation of a group's complexity of roles, responsibilities, and policies
- Awareness of this complexity and the importance of putting processes in writing
- Provides references for processes and scaffolding for operations
- Promotes smooth transitions to onboarding leaders

Nancy closed with an invitation to NorCal

Chapter members:



We know what we do and mostly how we do it.

Help us get our house in order!

Join the Governance Committee! No experience required. It is a great learning experience and chance to get to know fellow members.

Nancy also generously provided her contact information for AMWA members, including those outside our Chapter, to consult with her.

Contact Nancy at: bylaws-procedures-chair@amwancal.

A medical writer for over 25 years, **Nancy R. Katz** is President of the Illyria Consulting Group, Inc, which provides eCTD-compliant documents to the biopharmaceutical industry. She has also devoted time as the former President of AMWA NorCal and now chairs the chapter's Governance Committee.



Carte Blanche: The Erosion of Medical Consent

Reviewed by Morgan Leafe, MD

Renowned medical ethicist Harriet A. Washington explores the current status of consent in the U.S. medical research system in her latest book, *Carte Blanche: The Erosion of Medical Consent*. It will come as no surprise to those who are familiar with her previous work, including the award-winning *Medical Apartheid*, that Washington digs deep with her investigative work in *Carte Blanche* and unveils the disturbing truth behind yet another realm of the medical world that leaves members of historically marginalized groups in significant danger when seeking medical care.

...a must-read for all, but especially those who work in the health care system...

personnel and the use of synthetic blood products and dangerous hypothermia protocols mainly on Black patient populations to demonstrate the largely unpublicized ways in which patient consent is easily removed from research protocols—often leaving patients unaware that their rights have been violated.

Washington highlights modern medical experiments such as the administration of the anthrax vaccine to military



But wait, you might be thinking (as I did). What about Nuremberg? What about Institutional Review Boards (IRBs)? We are led to believe our modern medical research system has checks and balances in place that prevent the administration of

an experimental medication to or performance of an unapproved procedure on an unsuspecting patient. However, Washington outlines legal loopholes created in 1996 that make this exact scenario not only possible but a reality that has occurred regularly since then.

Carte Blanche is a must-read for all, but especially those who work in the health care system in any capacity. Even those of us who have spent our entire careers engulfed in the U.S. health care system may be unaware of the many ways in

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which it fails its most vulnerable participants. Washington's deep dive into the topic of consent and research should be a rallying cry to us all that the current system is unacceptable and warrants significant scrutiny and a complete overhaul.

Morgan Leafe, MD, MHA is double board-certified physician, medical writer, editor, and copywriter. She runs her own successful freelancing business offering an array of services including medical education, patient education, executive resume writing, journalism, copywriting, and board review. Morgan also offers career counseling to physicians interested in transitioning to the medical writing field.



Thanks for reading Pacemaker. We encourage you to contact us and look forward to hearing your ideas. Our emails are listed on the [Chapter Website](#) and on the first page of the Pacemaker.