

## EVCP Expresso ? August 2019

Dear Colleagues,

Once again, lives have been cut short and others forever changed due to another mass shooting in America. The 244<sup>th</sup> mass shooting of this year occurred on Sunday during what has traditionally been a fun-filled family festival in Gilroy, an event now forever tainted by tragedy. These senseless acts of violence must stop.

Simply put, gun violence is a public health crisis [1]. There is absolutely no reason for an assault weapon to be available to a civilian. Our colleagues at Zuckerberg San Francisco General are on the front line of this epidemic every day and see the impact on victims and families ? not just when it makes the news. So what can we do? We must remain vigilant, help strengthen our communities, and advocate for common-sense gun reform to end this madness.

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In the meantime, this month's *Expresso* brings you several significant topics, such as our shared responsibility for ensuring the safety and inclusion of our transgender colleagues and learners, as well as clinical trials process improvements and an update about the ban on fetal tissue in research.

- Improving Clinical Trials Activation Time: It takes a village
- Standing Up for Science: The importance of fetal tissue research
- Raising Our Voices: Being allies to the transgender community

Send me your feedback ? about something you've read or want to read about. Just drop me a note at [ExecutiveViceChancellor@ucsf.edu](mailto:ExecutiveViceChancellor@ucsf.edu) [2].

Thanks,  
Dan

## Improving Clinical Trials Activation Time: It takes a village

Let me begin by acknowledging a simple fact: the length of time it takes to activate a clinical trial at UCSF is too long. There are many steps to the activation process ? coverage analysis (making sure procedures are billed to the right place), contract review, budget development, and human subjects approval, to name the most critical, and each is complex and nuanced. Furthermore, compliance with financial and regulatory procedures during the activation process is critical to patient safety and the sustainability of the clinical trials enterprise. However, the time from submission of the protocol to opening of the trial often exceeds six

months at UCSF, and we all recognize that this translates into frustration for faculty and staff and, most importantly, fewer options for our patients. Lindsey Criswell, vice chancellor of research at UCSF, has made improving clinical trial activation time a top priority, and this has begun to show tangible results and improvements.

"UCSF has a fantastic group of administrative staff involved in the clinical trial activation process," says Lindsey. "My main focus has been to provide a vision of what success looks like, to bring leadership and frontline staff together to maximize collaboration, and secure adequate resources to implement the solutions they identify." A central partner in this effort has been UCSF's Program Management Office <sup>[3]</sup> (PMO), a fantastic in-house resource that helps groups attain operational efficiencies. To start, the PMO facilitated an intense three-day kaizen <sup>[4]</sup> (a business improvement process popularized in Japan) where a working group of faculty and staff dissected the entire clinical trial activation process into its individual steps. This process allowed the group to identify the core components of the activation process and how they can best be organized to maximize efficiency.

Following the kaizen, a clinical trials activation task force was convened to operationalize the kaizen findings. This has led to many important changes over the last six months:

- **New staffing.** We identified a need for additional staff in several departments of the clinical trials activation team and have secured funding from the chancellor to support these new positions. We've also hired a quality improvement and compliance officer focused on clinical trial activation to keep us on track both in compliance and activation time. And we are in the process of appointing a faculty director for clinical trials operations to provide a frontline faculty voice as we move forward. (More to come on this next month!)
- **New systems.** We have implemented navigation and task management systems linked to OnCore (our clinical trials management system) that will allow staff and faculty to track individual trials and determine where they are in the pipeline. This also will allow us to report out on how long it's taking to activate clinical trials, so we'll have good metrics to follow our progress.
- **New targets.** The Office of Research has set a target goal of 120 days from protocol submission to activation. There's a lot of work to do to get to that 120 day target, but we are already seeing early improvements in activation times in the Cancer Center (where metrics allow for comparisons).
- **New single point of contact.** We now have a single point of contact email account monitored and triaged by Winona Ward, director of the Office of Sponsored Research. Send an email to [clinicaltrialshelp@ucsf.edu](mailto:clinicaltrialshelp@ucsf.edu) <sup>[5]</sup> if you have questions about the status of your trial. **It's the most efficient way to get help.**
- **New name.** To reflect all of the above changes and our increased focus on activation time, the Office of Clinical Research has been renamed the Office of Clinical Trials Activation (OCTA).

Finally, we are collaborating with leadership in the Department of Medicine on a pilot program to explore other ways that we might organize more efficiently. For example, are there federated service models where components of the activation process could be managed in a standardized but decentralized way? "We have much more work to do," says Lindsey, "but I am confident that by working together, our outstanding clinical trials administrative leadership and staff will make clinical trial activation an efficient, compliant process that serves our research faculty and patients well."

Lindsey's team has my full support and I know they will be successful.

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## **Standing Up for Science: The importance of fetal tissue research**

If you're a researcher in the life sciences, you may have used fetal tissues at some point; at the very least, one of your colleagues has. These cells have unique and valuable properties. They're more flexible and less specialized than adult cells, and they can be grown easily in culture. They've been vital in gaining insight into disease and human development, developing vaccines, and advancing research and treatment in diseases and disorders as varied as childhood cancers, the Zika virus, rheumatoid arthritis, cystic fibrosis, and hemophilia.

That's why I felt both anger and dismay when I was alerted to a new Trump administration policy to limit federally funded fetal tissue research. Make no mistake: This is politics eclipsing science.

I applauded Chancellor Sam Hawgood's statement [\[6\]](#), which not only noted that the government was cancelling a \$2 million a year contract with UCSF, including research into cures for HIV, but also pointed out: "We believe this decision to be politically motivated, shortsighted, and not based on sound science."

Importantly, this fight is far from over, and we are not in it alone. UCSF stands with a veritable army of allies in science and academic medicine who oppose this policy. "UCSF is part of an extensive coalition that is committed to preserving federal support for fetal tissue research," says Natalie Alpert, UCSF's director of federal government relations. "Many academic medical centers engage in this research, including several others in the UC system, so it's a priority for the UC Office of the President, too." (UC President Janet Napolitano issued her own statement [\[7\]](#) in June.)

Other groups joining together include the International Society for Stem Cell Research (ISSCR), the Coalition for the Life Sciences (CLS) and the Association of American Medical Colleges (AAMC), as well as patient groups. In addition, Democrats in Congress are joining the fight, and the House of Representatives recently passed legislation that would block implementation of the new policy. However, the legislative fix faces an uncertain future in the Senate, and little likelihood of signature by the president.

Our own Keith Yamamoto, UCSF's vice chancellor for Science Policy and Strategy, "has been following this issue for several years," Natalie says. "Proactively, he's been going door-to-door and talking to members of Congress about the critical importance of fetal tissue research to scientific innovation." That effort will continue.

I'd like to point out one encouraging precedent, which you can see right here on our Parnassus campus: the Eli and Edythe Broad Center of Regeneration Medicine and Stem Cell Research at UCSF. It's that sleek, modern building, standing on stilts, and hugging the hillside beneath the eucalyptus trees behind the Health Sciences towers.

The building came about because of California's bold response to federal limits imposed on stem cell research in 2003. A year later, the state's voters passed Prop. 71, appropriating \$3 billion for stem cell research, and declaring such research a fundamental right under the state constitution. An excellent take on how California once again set the standard for the country is offered in this article by UCSF researcher Zachary Brown in *Scientific American* [8].

We're fortunate that House Speaker Nancy Pelosi and the rest of the Bay Area's delegation already support fetal tissue research, and they're working hard to restore the right to use it. Aided by CLS (which is chaired by Keith Yamamoto), our Congresswoman Jackie Speier (D-San Mateo) led 34 House Democrats in a letter to Health and Human Services HHS Secretary Alex Azar seeking the administration's rationale for imposing the new policy, and urging him to reverse it.

On April 22, 2017, the UCSF community gathered to stand up for science [9]. Given the ongoing assault on science by our administration, the need to stay on top of this issue and speak out has only grown.

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## **Raising Our Voices: Being allies to the transgender community**

Did you know that two of the key individuals who catalyzed the Stonewall riots [10] into a national movement commemorated annually during Pride were transgender women of color, Marsha P. Johnson and Sylvia Rivera [11]?

This past June marked the 50<sup>th</sup> anniversary of the Stonewall uprising. On the Friday preceding the San Francisco Pride parade, postdoctoral scholar Iris Young and many others participated in the 16<sup>th</sup> annual Trans March [12]. He explains, "It's the only place and time we get to be surrounded by a majority trans folks—it's a time to come together as a community to be seen and heard as the many people we actually are" the rest of the year many of us try not to be visible."

The Trans March is both a celebration and a demonstration against the injustices still facing the transgender community. For example, this year in rapid succession, three federal memos were issued that made it legal to (1) deny health insurance coverage of gender-affirming procedures, (2) allow health care providers (including emergency responders) to deny

treatment, and (3) allow homeless shelters to deny access, all on the basis of transgender identity. Factor in the increasing murders of transgender women of color, a military ban, bathroom bills, and efforts to remove recognition of and protections for transgender people under U.S. civil rights laws and there is a glaring urgency for cisgender folks like me to become better allies.

The burden to fight this battle should not lie solely on transgender people, many of whom are under assault personally, locally, and nationally. All of us who are privileged not to face these issues also need to be vocal both within and outside of UCSF. As a leading public institution dedicated to health, we must use our expertise to counter harmful misinformation about transgender and nonbinary people and to object when it is used to justify their exclusion or mistreatment. Iris says, "Right now, the loudest voices are in opposition to us, and it's more important than ever for allies to speak up." If you're aware of barriers at UCSF, I encourage you to reach out to the Lesbian, Gay, Bisexual and Transgender Resource Center or the LGBTQ Committee, which advises leadership on challenges and opportunities.

In California, we've made some progress. In February, I wrote about SB 179, California's Gender Recognition Act that recognized a nonbinary gender under California law. Here at UCSF, I'm proud we have the Center of Excellence for Transgender Health, as well as UCSF Transgender Care, which is led by Madeline Deutsch, associate professor in the Department of Family Community Medicine and practicing primary care specialist. Madeline is an international leader in establishing standards of care for transgender patients and guides many of our groundbreaking efforts in this area.

Change must happen on many levels. Where can an ally, like me, begin? **Learn** why pronouns matter and respect the use of the singular pronoun *they*. **Listen** when someone tells you their pronouns and include your own during introductions, for example in a meeting. **Include** pronouns in your signature block and bio. **Speak up** if you hear someone being referred to by an incorrect name or pronoun. Being an ally may take you out of your comfort zone, but stepping up for others is the right thing to do.

"Some people say they don't need to say their pronouns, but it's definitely a form of allyship," says Evolve Benton, equity and inclusion manager at the School of Medicine. "Then if someone else says 'they,' you'll think about that a little more so as to not misgender me and others."

Senén Mendoza, TETRAD graduate student, offers another perspective. "For me, gender remains an ongoing journey. I've experienced a lot of the challenges that the community faces. I'm passionate about the issue, because nonbinary genders are something that a lot of people don't encounter often and don't think about much. My goal is to educate and advocate for the LGBT community as a whole, especially for transgender students at UCSF."

CJ Frosch, an operations manager at UCSF Finance, and others have a few more suggestions on being an ally:

- **Incorporate nonbinary terminology.** Did you know that there is a gender-neutral honorific? It's Mx (pronounced "mix"). Be mindful when creating forms and surveys that gender, pronoun, and honorific fields include nonbinary options.
- **Don't deadname.** CJ explains, "It's the name that was assigned at birth that they don't identify by anymore. Hearing it can be extremely jarring and upsetting." Check the UCSF directory where individuals have the option to update their name. The [trans.ucsf.edu](https://trans.ucsf.edu)

[21] site offers tips to correct names on UCSF identification and in the directory. Keep in mind that some UCSF systems may reflect a deadname.

- **Make more restrooms gender-inclusive.** When only single-gender restrooms are available, transgender people are at higher risk of harassment and assault. “Every trans person I know has a story about being told they’re in the wrong room or being threatened or physically assaulted,” CJ says. UCSF is in the process of converting single-occupancy restrooms, and if you see one that isn’t, please tell Facilities [22]! We’re also improving signage to make them easier to find [14].
- **Increase representation:** Foster an inclusive environment for transgender people on committees and throughout our organization. During hiring and recruitment, communicate that UC’s non-discrimination policy includes gender expression, identity, and transition.
- **Reinforce the expectation:** Basic awareness training for departments and addressing any issues that arise immediately are critical. Tips and resources for allies and community are online [23]. Increased campuswide training will be rolled out this fall based on the work of the UCSF SB 179 Task Force [24].

We don’t have good numbers on how many transgender people are at UCSF, in part because many folks prefer not to disclose their identity. “A lot of people I know are “stealth.” They’re not always out as trans. We’re not always a visible minority,” says CJ. Note: while we should strive to ensure that everyone feels safe being visible, nondisclosure is an equally valid choice. We must respect everyone’s privacy by not outing them to others.

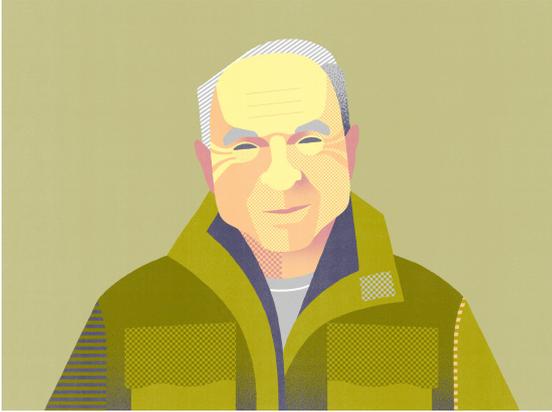
Evolve says, “I don’t think people are intentionally harmful. People at UCSF definitely try to be helpful. They’re some of the most caring people I’ve ever worked with. Because there are so many brilliant minds here, the ability to unlearn things can be a little hard for folks.”

CJ echoes the sentiment: “Ninety-nine percent of the time, folks at UCSF are the most well-intentioned people I’ve met out of anywhere that I have worked. I don’t question anybody’s intention when they ask for my gender. We’re UCSF. We are a university in San Francisco, known for its rich cultural diversity, and yet we have a long way to go. If anybody is going to be the front-runner, it should be us.”

I agree. Let’s lead the way to a more inclusive UCSF and world for our transgender and nonbinary community.

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## Dan’s Tip of the Month



I really enjoy listening to NPR's podcast How I Built

This with Guy Raz <sup>[25]</sup>. The weekly stories weave narrative journeys about innovators, entrepreneurs, and idealists and the movements they shaped. Recently, I heard the rebroadcast of Patagonia: Yvon Chouinard <sup>[26]</sup> ? a true pioneer who created a profitable yet meaningful corporate culture and business model that has transcended every aspect of his enterprise and elevated his people, service, and product. Key philosophy parallels with UCSF? Forge your own direction, learn by doing, do things differently, prioritize quality and longevity, work with motivated, independent people, and realize that a simplified, focused approach can lead to an abundant, prolific path. Check it out ? it's really enlightening!

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- [2] <mailto:ExecutiveViceChancellor@ucsf.edu>
- [3] <https://pmo.ucsf.edu/>
- [4] <https://en.wikipedia.org/wiki/Kaizen>
- [5] <mailto:clinicaltrialshelp@ucsf.edu>
- [6] <https://chancellor.ucsf.edu/blog/response-administrations-actions-fetal-tissue-research>
- [7] <https://www.universityofcalifornia.edu/press-room/uc-president-napolitano-s-statement-new-restrictions-regarding-fetal-tissue-research>
- [8] <https://blogs.scientificamerican.com/observations/a-bulwark-against-trumps-stem-cell-ban/>

- [9] <https://www.ucsf.edu/stand-science>
- [10] <https://evcprovost.ucsf.edu/evcp-expresso/201906#stonewall>
- [11] <https://sites.psu.edu/womeninhistory/2016/10/23/the-unsung-heroines-of-stonewall-marsha-p-johnson-and-sylvia-rivera/>
- [12] <http://www.transmarch.org/>
- [13] <https://www.merriam-webster.com/dictionary/cisgender>
- [14] <https://lgbt.ucsf.edu/gender-inclusive-restrooms>
- [15] <https://diversity.ucsf.edu/committees/3433696>
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- [23] <https://trans.ucsf.edu/allies-community>
- [24] <https://lgbt.ucsf.edu/gender-recognition-act>
- [25] <https://podcasts.apple.com/us/podcast/how-i-built-this-with-guy-raz/id1150510297>
- [26] <https://www.npr.org/2018/02/06/572558864/patagonia-yvon-chouinard>