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VOLUME V

FOCUS on Research

Digging for Data on Marijuana's Health Effects

Dr. Salomeh Keyhani has cringed many times the last few years with various news reports about the numerous assumed medical "benefits" of marijuana. She has heard commentators of esteemed media, such as NPR and the New York Times, praise the supposed positives of legalizing marijuana, from increasing tax revenues to remedying health problems.

It's not because she's conservative on hot topics. On the contrary – she's outspoken on many health care issues and written op-ed pieces regarding universal care and Medicare for all.

But as a physician and scientist, Keyhani is bothered by the misinformation or lack of information about the health effects and potential harms of marijuana.

While some research has shown that certain cannabis compounds can aid children with refractory seizures, quell nausea for patients undergoing chemotherapy or soothe some nerve pain, there is no evidence that it helps the vast majority of medical conditions for which it is touted.

"Marijuana is being promoted to the public as a harmless herbal remedy," said Keyhani, an NCIRE-supported researcher, SFVAHCS Staff Physician and UCSF Professor of Medicine, whose research over the years has concentrated on health care quality and policy.

Part of the problem is aggressive and unregulated advertising by a multi-billion dollar cannabis industry. "The important public policy benefits of decriminalization of



*Salomeh Keyhani, MD, MPH
Staff Physician, SFVAHCS
Associate Professor of Medicine, UCSF*

marijuana are being conflated with a message that marijuana is safe and harmless. Marijuana use is not harmless."

Another big problem – and, as a scientist, one she can address directly – is the dearth of evidence and investigation about the health effects of marijuana. "People believe things for which we have no proof," she said. "We need data."

Keyhani notes also that most of the studies that have found a benefit from cannabinoids have been based on pharmaceuticals, not plant-based or smoked marijuana.

Inspired by the need to fill a gaping hole in research and a commitment to some of her VA patients who smoke

While her previous studies included a general population, Keyhani now focuses on a population that is very vulnerable to the harms of using marijuana – adults 65 years and older. And Veterans are keys to her research.

marijuana while coping with various ailments, Keyhani now devotes much of her research to getting answers about health effects of marijuana use.

Her study in the September 2018 Annals of Internal Medicine revealed indeed that Americans' view of marijuana is more favorable than existing evidence supports. The survey of more than 16,000 adults found that over one-third believe that smoking marijuana prevents health problems; there is no evidence that marijuana "prevents" any condition and there is evidence that smoking any substance is harmful.

They also believe however, that marijuana is beneficial in treating insomnia, depression, and anxiety, for which efficacy and safety have not been established and possible harms may exist. In addition, a sizable number of those surveyed think that marijuana has no addiction potential and also suggest that secondhand smoke from marijuana is safer than secondhand smoke from tobacco, despite no evidence to support those beliefs.

While that report underscored the need for further research to understand the health effects of marijuana use, another study published in July of last year by Keyhani and co-researchers at SFVAHCS and UCSF, offered just the tip of an iceberg of the possible many harms. Their meta-analysis of existing studies found that smoking marijuana doubles a person's risk of developing a regular hacking cough and triples the risk of coughing up phlegm and wheezing.

Research concentrates on Older Adults.

While her previous studies included a general population, Keyhani now focuses on a population that is very vulnerable to the harms of using marijuana – adults 65 years and older. And Veterans are keys to her research.

The number of states in which marijuana is legal has grown to 33 for medicinal purposes and 11 for general use. In 2000, the prevalence of marijuana use among older adults was undetectable – zero percent, according to national surveys.

But in just the four years from 2013 to 2017, use among adults age 65 and over more than tripled from 1.4 percent

to 5.7 percent, suggesting use among older people might be increasing by 1 percent a year, said Keyhani.

She and SFVAHCS co-researchers are now conducting or constructing studies of Veterans to examine:

- Links between smoking marijuana and cardiovascular events among older adults with heart disease.
- Association between marijuana use and outcomes of fall-related injury, other injuries, altered mental status, mood disorders and respiratory infections. Falls, for example, are the number one cause of injury and death among older people and an important metric of health
- Whether older patients who use marijuana with other psychotropic drugs (opiates, benzodiazepines and sleep medications) are more likely to have adverse outcomes.

These studies are possible because of rich VA research and medical record databases, some of which document marijuana use of its patients. Pilot studies by Keyhani also have shown that researchers can carve out important cohorts of Veterans – marijuana users and non-users – willing to be interviewed and studied.

"Without data, policymakers will be unable to provide accurate information to the public, and clinicians will be unable to have evidence-based discussions with their patients."

These studies are critical toward filling a very important gap in information about marijuana and its help or harm to health. "Without data, policymakers will be unable to provide accurate information to the public, and clinicians will be unable to have evidence-based discussions with their patients," said Keyhani.

Q and A: An Interview with Dr. Anne Schafer



Anne Schafer, MD
Chief of Endocrinology and Metabolism, SFVAHCS
Associate Professor of Medicine
and Epidemiology and Biostatistics, UCSF

Q: You are a “homegrown” SFVAHCS physician/scientist. How did you end up here?

A: I came to San Francisco when I started medical school at UCSF, and I stayed for my internal medicine residency and endocrinology fellowship training. Training at UCSF includes inpatient and outpatient rotations at the SFVAHCS, and my VA experiences had a particularly strong impact on me. First, the SFVAHCS Medical Service is celebrated for its commitment to education; its attending physicians are revered for their teaching. Second, I felt a connection to Veterans’ issues and care, as my grandfather’s career was in the Air Force, and my dad’s time as a Navy physician shaped his clinical neurology career. Third, the Endocrinology and Metabolism Section at the SFVAHCS has special clinical and research strengths in osteoporosis and metabolic bone disease, the areas that became my focus. Following my fellowship training in endocrinology, I extended my research training through a VA Fellowship in the Health Issues of Women Veterans. I then received a five-year VA Career Development Award, and with that I really made the SFVAHCS my profes-

sional home. In July, I became Chief of the Endocrinology and Metabolism Section. I’m excited to build and strengthen the section in the upcoming years.

Q: How did you arrive to your current research focus?

A: I entered medical school with a strong interest in women’s health issues and ambulatory care. I found myself drawn to physiology and internal medicine while a medical student, and I realized that endocrinology brought together those developing interests of mine. While a resident, I pursued a research program focused initially on osteoporosis treatment, then expanding to include the interplay of bone, fat, and glucose metabolism. As I did so, I found on my clinic schedule an increasing number of obese adults who were undergoing or had undergone bariatric surgery for weight loss. I puzzled over those who had postoperative abnormalities in calcium metabolism and even low bone mass and fracture. I began constructing a research program that would address the needs of this patient population, and also, more broadly, use bariatric surgery as a model to understand the skeletal effects of obesity and weight loss.

Q: How is this research significant to Veterans and the general population?

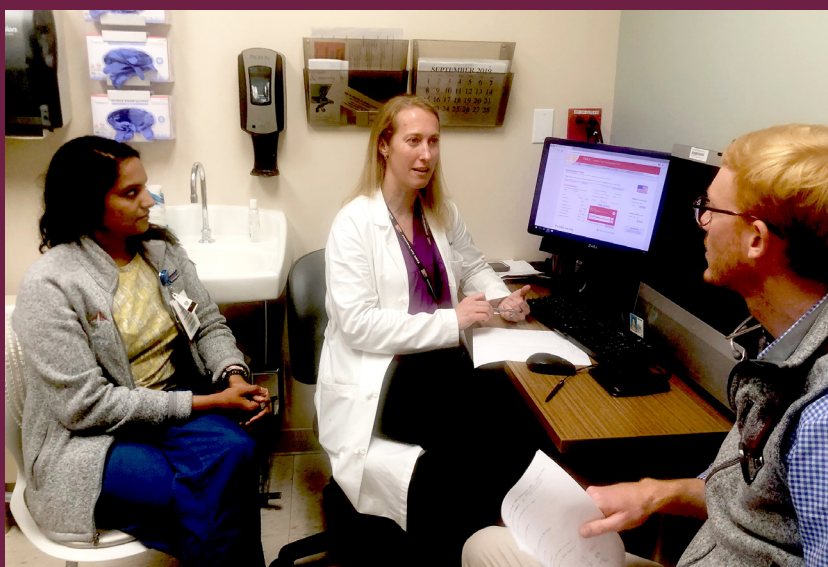
A: Obesity and osteoporosis are both extremely common chronic illnesses. Obesity is more prevalent among Veterans who use the VA for health care than it is in the general population. Osteoporosis has tremendous medical and economic impact due to morbidity and mortality caused by fractures: Among Veterans, mortality 12 months after a hip fracture is 32% for men and 18% for women. Treating obesity and preventing fractures both must be priorities of the VA and of general society.

Q: What outside interests do you have?

A: I love to run, play the piano, and learn about local history, but I spend most of my time these days having fun with my daughters, ages 7 and 4.

Q: What would most people be surprised to know about you?

A: I married my high school sweetheart. Mike and I went on our first date when we were 15.



Dr. Anne Schafer with endocrinology fellow Dr. Tejaswi Kompala
and internal medicine resident Dr. Daniel Minter

Mythbusting the (NIH) Review Process



Lynn Pulliam, MS, PhD
Chief, Microbiology, Laboratory Medicine Service SFVAHCS
Professor of Laboratory Medicine and Medicine, UCSF

So, you are a new Investigator and want to submit your first NIH grant. Here are some things I have learned both as a Reviewer and as a Recipient of many reviews, both good and bad!

1. Find a home, NIH Institute, and a Study Section that best applies to your research. Check the NIH website for Program Announcements (PA) and Request For Applications (RFA). Often, they cross institutes (e.g., NIA, NIDA, NIMH), and one institute may have more money for your topic than another.

- Talk to the Staff Research Officer (SRO) to see if that study section covers your topic and let her/him know you are interested in submitting.
- Check out the members of the study section online. Do they know your topic? Know your audience.

2. Type of grant. Do you want to submit an R21, R03 or R01? Being a new Investigator helps in that the paylines are higher for you. Make sure the NIH (cover letter) knows you are an early stage Investigator (less than 10 years out from MD or PhD).

- The R21 is high risk, high gain, two years and less preliminary data plus defined amount of money.
- The R03 is up to two years with smaller budget and no preliminary data necessary (but some advised) and directs up to \$50K.
- The R01 will require more preliminary data than the R21.

3. Topics to include in your grant and review.

- The R01 will require more preliminary data than the R21. The study section will review your grant on five criteria and give each category a score of 1-9 with comments on the strengths and weaknesses of each category.

- Your final score is not the mean of these five but is usually based on the Approach score (the most critical). The areas include Significance, Investigator, Innovation, Approach and Environment. In addition, several other categories are evaluated including: Protection of Human Subjects if using, Inclusion Plans (gender, race), Animals, Biohazards, Resource Plans and Authentication of Key Biological and/or Chemical resources. Each of these must be addressed.
- In addition to the formal outline of a grant (Introduction, Significance, etc.), always include the following comments in your Experimental Design:

- ✓ Statistical analysis – do you have enough subjects/ animals and do you need a statistician
- ✓ Rigor and reproducibility - <http://grants.nih.gov/reproducibility/index.htm>
- ✓ Pitfalls and alternatives – you must include this but be careful because a Reviewer may use your pitfall as a weakness
- ✓ Timeline – at the end of the proposal, briefly show how Aims will flow within the timeline; what is done in each year?
- ✓ Are the Aims interdependent? A common criticism for an R01 is that if Aim 1 does not work, the rest of the grant is based on this and falls apart. Make sure Aims are focused on the same theme but somewhat independent.

4. NIH budget increases. Institutes fluctuate in their yearly budgets and increases. For example, National Institute of Aging (NIA) has an influx of new money to study Alzheimer's disease and dementias, and National Institute of Drug Abuse (NIDA) has new money to study drug abuse. It's important to study a topic that has funding!

5. New and semi-new rules:

- Authentication of key biological and/or chemical resource must be addressed on a separate page. This includes reagents and cell lines. Where do you get them and how do you verify that they perform as expected?
- As of September 25, 2019, human fetal tissue cannot be used in new grants. This does not apply to stem cells.
- You must justify sex/gender choices for human AND animal studies.

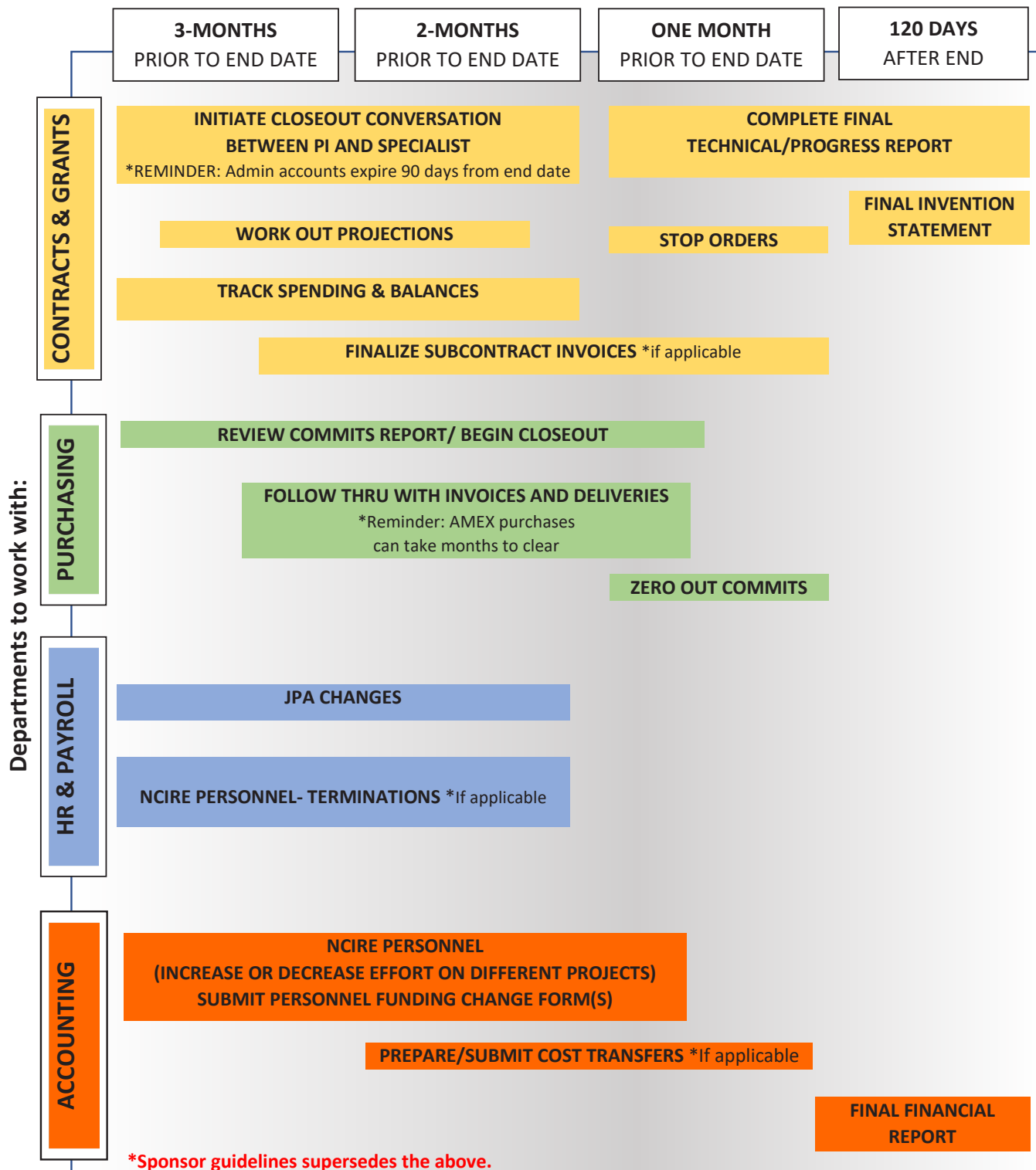
There are many seasoned PIs here at the San Francisco VA. Call them and ask for help. We are always willing to help you all be successful.

Reviewer Contacts:

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Thomas Neylan, MD; ext 26961; thomas.neylan@ucsf.edu
Robert Nissenson, PhD; ext 23323; robert.nissenson@ucsf.edu

Contracts and Grants

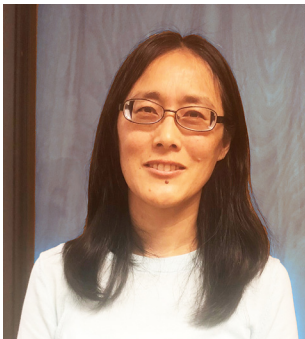
NCIRE Project Closeout Process



Created by Elaine Quitiquit-Palmer

Did You Know?

Accounting



Jian Pu, Accounting Manager

Jian Pu was promoted to Accounting Manager in July to oversee Accounts Payable, Accounts Receivable, Payroll, and other Accounting functions. She has been with NCIRE since 2006, and her primary role involves providing accounting and financial support to ensure adequate internal controls in accordance with GAAP, preparing monthly and year-end financial statements and analyses, and assisting in preparation of annual fiscal budget. We are lucky to have Jian as part of our team!

Purchasing

Bio-Rad Laboratories, Inc. is now available as a punch out vendor in NCIRE's requisitioning system ReQlogic. Our pricing will be visible once you add items to your cart.

You may also reference promo codes or quote numbers given by the representative when building your cart for additional savings.

Should you not be able to find some items through punch out or have any questions, please contact your NCIRE Buyer, or our Purchasing Team at: <http://www.purchasing@ncire.org>.

New Cellphone Policy

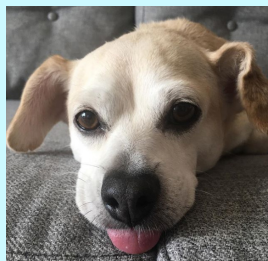
NCIRE recognizes that certain designated staff may occasionally be required to make business telephone calls and send and receive business e-mail or text messages using their personal devices. The purpose of the policy is to establish guidelines for providing reimbursement of expenses for the use of personal devices which are used in part for business purposes.

This policy applies to items personally procured such as cellular phones and other mobile connective devices/WIFI. NCIRE will provide a monthly stipend of \$50/month. With justification, payment amounts more than the \$50 stipend may be paid. Please refer to the Accounting Cellphone Policy for full details.

In the Helix



*Rakita Singh
Research & Development
Safety Officer*



*Kimberly Hutchison
Administrative Analyst
Research Associate, Tech*



*Charles Angelo Dangerfield
Materials Handler II
Buyer II*

Q: What's the first career you dreamed about as a kid?

A: I dreamed of becoming a doctor since I was a kid. I was always fascinated to learn how the human body works and to use that knowledge to help others. Although I didn't become a doctor, I am happy to work closely with doctors and researchers whose contribution to improve health care is so remarkable. It's an incredible experience for me to be able to help ensure the safe work environment for those who help others.

Q: What are you currently reading, or binge-watching?

A: I'm currently reading "Make Ink: A Forager's Guide to Natural Inkmaking" by Jason Logan. This is such a handy resource and I am looking forward to experimenting with different types of materials found around the area.

I've just finished binge-watching Good Omens, and now I'm really just waiting for the next season of Stranger Things to come out!

Q: What are you currently reading, or binge-watching?

A: I just finished reading "Astrophysics for People in a Hurry", by Neil deGrasse Tyson. It's a very interesting read. It's more of a refresher course on evolution, and it makes you look at life from a different perspective.

I'm currently binge-watching InkMaster, and Warrior. Everyone loves Bruce Lee.

HR Spotlight

Be Prepared

The San Francisco Bay Area is a region that is highly vulnerable to natural hazards like earthquakes, wildfires, and severe weather. It is vital to prepare for the unexpected and you should have the tools and plans in place to care for you and your family when an emergency arises.



GET A KIT

Keep basic supplies in an easy-to-carry emergency preparedness kit that you can use at home or take with you in case you must evacuate.

Start building your kit with list that can be found on <https://www.ready.gov/build-a-kit>

MAKE A PLAN

Identify out-of-area emergency contacts. Decide where to reunite with loved ones after a disaster in case phone lines are down. Write your plan on an emergency contact card and store in your phone along with important numbers for emergency resources in your area. Use the tips on this link <https://www.ready.gov/make-a-plan> to start making your plan!

Desk/Office Emergency Kit

- Flashlight with extra batteries
- Bottled water
- Food (granola bars, energy bars, etc.)
- Hand sanitizer/sanitary towelettes
- Battery powered or hand-crank radio
- Whistle
- Portable cellphone charger
- Dust mask
- Meeting place location
- Exit and fire extinguisher locations

BE INFORMED

Discuss how to prepare and safely respond when you are at work or at home. Make sure you're informed of how the notification systems in your area work. Review information on this link: <https://www.ready.gov/be-informed> to be prepared to respond to different emergency situations.

Harassment Prevention Training

Effective January 2019, California has passed a law requiring all employees to complete sexual harassment and abusive conduct prevention training. You should have received an email from Cal Chamber regarding taking this training. Training is mandatory for all NCIRE employees and must be completed by October 31, 2019.

You should have received an email from Cal Chamber with login instructions. Please check your spam folder or login by clicking <https://calchamber.elogiclearning.com/Login.aspx>. Your username will be your NCIRE email address. If you have any questions regarding the training, please contact Theresa.gio@ncire.org.

Message from the Chief Executive Officer



Fall is upon us; watching the seasons change at the SFVAHCS campus is always a delight.

In September the affiliation between NCIRE and UCSF was finalized, this agreement is effective for the next five years. The NCIRE core office has had a few personnel updates: after 16 years, Executive Assistant Linda Acton, has retired, and Rita Fabrizio has assumed that role. NCIRE's Controller Joanna Zhao has assumed the role of Secretary and Treasurer for the NCIRE Board.

Fiscal Year 2019 has ended; I would like to share highlights related to federal grants. As of 9/30/19, there were 164 applications submitted to federal sponsors, both as prime and subcontract proposals. This represents 44% growth from 2018, for which there were 114 submissions. The number of new federal awards for the period ending 9/30/19 was 32, an increase of 28% from 2018, for which there were 25 new awards.

Industry Research at NCIRE is accomplished via a Cooperative Research and Development Agreement (CRADA).

In 2019, there were 11 new agreements, in contrast to 2018 with 20 new agreements. This area is of keen interest, as a compliment to the existing research portfolio. Providing new, innovative therapies to patients is important as it offers options; these goals can be accomplished via Industry Research.

This newsletter is generated by a dedicated team who is focused on bringing time-sensitive, newsworthy updates to the research community. If you have any suggestions for content, please let us know. There is an opportunity to collect a reader surprise for the first 5 people who contact dna@ncire.org.

Rebecca Rosales, MBA, CRA

Chief Executive Officer

Share your thoughts (rebecca.rosales@ncire.org)

Increase to Indirect Costs associated with Industry-Sponsored Research

Effective January 1, 2020, there will be an increase in the indirect cost rate associated with all industry-sponsored research (Clinical/Research/Trials). The new rate will be 35%. This change is based on the need to keep the rate in step with the actual administrative costs associated with managing this type of research.

About NCIRE

NCIRE has One Mission, One Goal: Veterans Health. We sustain a scientific community of clinicians and researchers and support over 200 researchers who have joint faculty appointments at the University of California, San Francisco (UCSF) and the San Francisco VA Health Care System (SFVAHCS) and are working to foster innovation through leadership in the field of Veterans health research. Our broad portfolio of projects receives generous support from the National Institutes of Health, the Department of Defense, and individual donors, making us the largest nonprofit research institute devoted to Veterans health in the US. NCIRE is a 501(c)3 nonprofit. (Tax ID #94-3084159). Visit NCIRE at www.ncire.org.



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We welcome your input. Please send comments to dna@ncire.org.