Research and discovery is one of the core missions of Washington University and our Anesthesiology Department. We are excited to bring you a newsletter that straddles research conducted in all areas in the Washington University Department of Anesthesiology (WUDA). The practice of Anesthesiology is increasingly complex and far-reaching. The research interests of Anesthesiology span a broad clinical and scientific realm, and have the potential to affect much of medicine as a whole. Developments in basic and clinical science over the past decades have made the fundamental unsolved problems in Anesthesiology research (e.g. underpinnings of consciousness; mechanisms of sleep, sedation and general anesthesia; neurophysiology of pain and itch; neurobiology of addiction and analgesia; and pathophysiology of septic shock) scientifically tractable. Apart from the generation of new knowledge, an important goal at WUDA is to train a diverse group of anesthesiology scientists with appropriate scientific skills to enable them to address the research priorities in anesthesiology-related science across the translational continuum (T₀ through T₄). The figure below depicts broad research areas within WUDA. We intend to publish this newsletter twice a year. In each issue, we will be (i) providing useful information regarding research, (ii) showcasing some of the research accomplishments of both early stage and more senior researchers at WUDA, and (iii) shining the spotlight on some of the remarkable scientific accomplishments within the Department. WUDA is one of the world’s leading Anesthesiology research departments. As the research directors, we are excited about the many advances being spearheaded by scientists in our Department, and hope that readers of this newsletter will similarly feel proud and inspired. We encourage all of you to attend the upcoming Departmental academic evening on the April 20, 2018, at 6:00 p.m. where some of the current research conducted in WUDA will be showcased. We also hope that you will attend our premier annual C.R. Stephen Lecture, which this year features the dynamic speaker Vamsi Mootha. Dr. Mootha will discuss *Mitochondrial Systems Biology: Understanding the Whole from the Parts* at the lecture on April 11, 2018, at 4:00 p.m. in the Eric P. Newman Education Center. See you there!
<table>
<thead>
<tr>
<th><strong>Meet Your Research Staff</strong></th>
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</thead>
<tbody>
<tr>
<td><strong>Anne DeSchryver</strong>: Director of Research Administration - Anne is responsible for oversight of all financial &amp; administrative operations for the research divisions and centers (<a href="mailto:adeschryver@wustl.edu">adeschryver@wustl.edu</a>, 314-362-8376)</td>
</tr>
<tr>
<td><strong>Maureen Arends</strong>: Project Manager - Mo provides support for the INQUIRI &amp; DoCTR Division Chief, as well as faculty in INQUIRI &amp; DoCTR (<a href="mailto:arendsm@wustl.edu">arendsm@wustl.edu</a>, 314-273-2456)</td>
</tr>
<tr>
<td><strong>Jane Blood</strong>: Jane provides assistance for all components of clinical research including protocol development, study design, project management, database development, and general study oversight. Jane also supervises the pool of clinical research staff (<a href="mailto:jblood@wustl.edu">jblood@wustl.edu</a>, 314-747-5531)</td>
</tr>
<tr>
<td><strong>Jon Bucher</strong>: Research Administrator - Jon supervises the grants team and is responsible for all grant submissions, contracts, and post award activities, plus the handling of more complex grants including center and training grants (<a href="mailto:bucherj@wustl.edu">bucherj@wustl.edu</a>, 314-362-8649)</td>
</tr>
<tr>
<td><strong>Ellen Fischbach</strong>: Clinical Research Specialist - Ellen is responsible for the department's human subjects regulatory functions including IRB submissions, regulatory compliance, education and auditing (<a href="mailto:ellen@wustl.edu">ellen@wustl.edu</a>, 314-747-1709)</td>
</tr>
<tr>
<td><strong>Rob Gatewood</strong>: Grant Specialist II - Rob is responsible for financial reporting and IDs, as well as pre and post award grant activities (<a href="mailto:Robert.gatewood@wustl.edu">Robert.gatewood@wustl.edu</a>, 314-273-1743)</td>
</tr>
<tr>
<td><strong>Jodi Maslin</strong>: Manager of Administrative Services – Jodi is the administrative manager for the Center for Clinical Pharmacology (<a href="mailto:jmaslin@wustl.edu">jmaslin@wustl.edu</a>, 314-446-8126)</td>
</tr>
<tr>
<td><strong>Sherry McKinnon</strong>: Manager of Clinical Research - Sherry oversees all clinical / human subjects research regulatory activities &amp; also is a DoCTR project manager (<a href="mailto:smckinnon@wustl.edu">smckinnon@wustl.edu</a>, 314-286-1768)</td>
</tr>
<tr>
<td><strong>Katherine Mitchell</strong>: Manager of Administrative Services - Katherine handles payroll, sourcing, visas, HR onboarding, lab facilities, and oversees purchasing, pro cards, and misc. accounting functions (<a href="mailto:kmitchell@wustl.edu">kmitchell@wustl.edu</a>, 314-454-5979)</td>
</tr>
<tr>
<td><strong>Christina Saldivar</strong>: Sr. Department Accounting Coordinator - Christina handles purchasing / accounting, travel, check requests, pro cards, etc. for research faculty and trainees (<a href="mailto:csaldivar@wustl.edu">csaldivar@wustl.edu</a>, 314-362-8540)</td>
</tr>
<tr>
<td><strong>Amber Spies</strong>: Executive Secretary - Amber provides administrative support for the WUPC and DBR research division chief, support for the research admin office, and she coordinates the research seminar series and research faculty visits (<a href="mailto:spiesa@wustl.edu">spiesa@wustl.edu</a>, 314-747-1805)</td>
</tr>
</tbody>
</table>
### Center for Clinical Pharmacology – New Faculty

**Dr. Tom Burris:** Dr. Burris joined us on March 1, 2018.  
http://www.clinicalpharmstl.org/research/Burris.html

**Dr. Susruta Majumdar:** Dr. Majumdar will join us on July 1, 2018  
http://www.clinicalpharmstl.org/research/majumdar.html

### NIH Funding News

National Institutes of Health Director Francis S. Collins announced on April 4 the launch of the HEAL (Helping to End Addiction Long-term) Initiative, to speed scientific solutions to address the national opioid crisis. NIH will significantly increase funding to bolster research on opioid misuse and addiction as well as pain with an investment of $1.1 billion in FY2018, made possible by the FY 2018 Consolidated Appropriations Act, which provides $500 million for opioid addiction research. HEAL will bolster research to inform better addiction prevention strategies through enhanced pain management and improve treatments for opioid misuse disorder and addiction. For more information, please read the NIH announcement about this important research initiative.


This represents a near doubling of funding for research on pain and opioid misuse/addiction. Given the robust focus in basic science, translational and clinical research on pain and opioid misuse in our department, this represents a huge opportunity for our investigators. If you have research projects or ideas in these areas, now is the time to apply!

### FY18 Awarded Grants (as of 2/28/18)

<table>
<thead>
<tr>
<th>PI</th>
<th>Funding Agency</th>
<th>Title of Grant</th>
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<tbody>
<tr>
<td>Amrita Aranake-Chrisinger</td>
<td>Foundation for Anesthesia Education</td>
<td>The association between postoperative delirium and intermediate-term postoperative</td>
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<tr>
<td>Yu-Qing Cao</td>
<td>NIH – R01</td>
<td>Regulation of Trigeminal Nocieption by TRESK Channels</td>
</tr>
<tr>
<td>Yu-Qing Cao</td>
<td>DOD</td>
<td>Validating Peripheral CCI2 and CCR2 as Novel Targets for Chronic Migraine Therapeutics</td>
</tr>
<tr>
<td>Daniel Castro</td>
<td>NIH – F32</td>
<td>Dissecting the role and mechanisms of MU opioid receptors in nucleus accumbens</td>
</tr>
<tr>
<td>Laura Cavallone</td>
<td>ICTS</td>
<td>Dissection of pain-induced modulation of prescription opioid use – pilot study</td>
</tr>
<tr>
<td>Wayland Cheng</td>
<td>NIH – K08</td>
<td>Characterizing neurosteroid binding in the GABAA receptor using top-down mass spectrometry</td>
</tr>
<tr>
<td>Wayland Cheng</td>
<td>IARS</td>
<td>The structural basis of neurosteroid binding to the GABA(A) receptor</td>
</tr>
<tr>
<td>Wayland Cheng</td>
<td>CIMED P&amp;F</td>
<td>Characterizing Lipid and Anesthetic Interactions with Pentameric Ligand Gated Ion Channels using Native Mass Spectrometry</td>
</tr>
<tr>
<td>Name</td>
<td>Funding/Partner</td>
<td>Project Description</td>
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<tr>
<td>Robert Gereau</td>
<td>NIH – U18 Supplement</td>
<td>Soft, conformal wireless optoelectronic systems</td>
</tr>
<tr>
<td>Robert Gereau</td>
<td>NIH – R56</td>
<td>Mechanisms of Central Sensitization</td>
</tr>
<tr>
<td>TJ Graetz</td>
<td>BJHF</td>
<td>Ventricular Assist Device Anti-Factor Xa (VAD-AntiX) monitoring study: A Prospective Randomized Feasibility Trial</td>
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<tr>
<td>Jose Grajales-Reyes</td>
<td>NIH – F31</td>
<td>Genetic dissection of brainstem circuits and their role in persistent inflammation</td>
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<tr>
<td>Ryan Guffey</td>
<td>BJHF</td>
<td>PECS block vs. multimodal analgesia for prevention of persistent postoperative pain</td>
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<tr>
<td>Alex Hinker</td>
<td>Society for Obstetric Anesthesia and Perinatology (SOAP)</td>
<td>Investigation of the Pharmacodynamic and Pharmacokinetics of Epidural Methadone in Healthy Volunteers</td>
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<tr>
<td>Simon Haroutounian</td>
<td>NIH – R01</td>
<td>5-HT3 receptor antagonists for neuropathic pain</td>
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<tr>
<td>Richard Hotchkiss</td>
<td>Bristol Myers Squibb</td>
<td>Explore potential mechanisms of action and potential signaling pathways for anti</td>
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<tr>
<td>Richard Hotchkiss</td>
<td>LEIDOS, NIH</td>
<td>Evaluation of Leidos peptopeptide inhibitor of PD-1/PD-L1 binding in murine sepsis</td>
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<tr>
<td>Richard Hotchkiss</td>
<td>NIH – R35</td>
<td>Enhancing Innate and Adaptive Immunity to Improve Sepsis Survival</td>
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<tr>
<td>Ellen Lockhart</td>
<td>ResMed Foundation</td>
<td>Fetal Growth Restriction and Obstructive Sleep Apnea Study</td>
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<tr>
<td>Aaron David Mickle</td>
<td>NIH – F32</td>
<td>Closed loop wireless monitoring and optogenetic modulation of bladder function</td>
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<tr>
<td>Michael Montana</td>
<td>Pharmaceutical Research and Manufacturers of America</td>
<td>Opioid sensitivity in adults with treated and untreated obstructive sleep apnea</td>
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<tr>
<td>Jose Moron-Concepcion</td>
<td>Brain &amp; Behavior Research Foundation</td>
<td>Role of KAPPA opioid receptors in the comorbidity between pain and affective dis</td>
</tr>
<tr>
<td>Aaron Norris</td>
<td>Foundation for Anesthesia Education</td>
<td>Examination of isoflurant activated neural circuits</td>
</tr>
<tr>
<td>Sylar Spangler</td>
<td>NIH – F31</td>
<td>Cellular and molecular mechanisms of nociceptin opioid receptor regulation</td>
</tr>
</tbody>
</table>

**Anesthesiology Research News & Opportunities**

**Early Stage Anesthesiology Scholars**

The Early-Stage Anesthesiology Scholars (eSAS) is an evolving community led by trainees, for trainees. eSAS serves the interest of early-career anesthesiologist scientists, providing an academic home for developing scholars in anesthesiology.

The Third Annual Scholars Program at the AUA and IARS meeting in Chicago is scheduled for Saturday, April 28, 2018.

Please visit [www.esashq.org](http://www.esashq.org) for more information.

**Anesthesiology Clinical Trials Network Launch**

On May 1 2018, following the AUA, SOCCA and IARS meetings, there will be a symposium in Chicago to launch this initiative. The initiative provides a collaborative approach to Anesthesiology clinical and translational research and was endorsed by the following organizations: Associate of University Anesthesiologists (AUA), Early Stage Anesthesiology Scholars (eSAS), Foundation for Anesthesia Education and Research (FAER), International Anesthesia Research Society (IARS), and Society of Critical Care Anesthesiologists (SOCCA).
Please visit https://mpog.org/ctn/ for more information.

**Society for Neuroscience – Pain Research**

The 2017 annual meeting of the Society for Neuroscience was held November 11-15 in Washington, D.C. While at the meeting Drs. Gereau and Moron-Concepcion were able to take that great opportunity to meet with Senator Claire McCaskill’s staff about the need for increased funding for chronic pain research, specifically by creating a “Pain Initiative.” At this meeting, Drs. Gereau and Moron-Concepcion emphasized the importance of basic science in the search for new approaches to treat pain. Dr. Moron-Concepcion said of the opioid crisis, “but more money is needed to invest in basic research. We cannot find new approaches to pain when we don’t know what pain is doing to the brain.”


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**Save the Date**

*C.R. Stevens Lecture – April 11, 2018 at 4:00*

*Vamsi Mootha, MD*

*Eric P. Newman Education Center*

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Dr. Vamsi Mootha is an Investigator of the Howard Hughes Medical Institute and a Professor of Systems Biology and of Medicine at Harvard Medical School. His laboratory is based in the Department of Molecular Biology and Center for Genome Medicine at Massachusetts General Hospital. Dr. Mootha leads a research team dedicated to mitochondrial biology.

Dr. Mootha received his B.S. (with honors, with distinction) in Mathematical and Computational Science at Stanford University. He then received his M.D. (cum laude) from the Harvard-MIT Division of Health Sciences and Technology, where his thesis research focused on mitochondrial energetics. Following an internship and residency in Internal Medicine at Brigham and Women’s Hospital, he pursued postdoctoral training in genomics at the Whitehead Institute.

His research group consists of clinicians, computer scientists, and biologists, who work collaboratively to elucidate the network properties of mitochondria, and how these properties go awry in human disease. His work has led to the discovery of nearly 20 Mendelian disease genes, to the discovery that mitochondrial dysfunction is associated with the common form of type 2 diabetes mellitus, and to the discovery of all of the molecular components of the mitochondrial calcium uniporter. His team has also developed generic, computational tools that have been widely used in biomedical research.

Dr. Mootha has received a number of honors, including a MacArthur Foundation Fellowship, the Judson Daland Prize of the American Philosophical Society, The Keilin Medal of the Biochemical Society, a Padma Shri from the Government of India, and election to the National Academy of Sciences.
Anesthesiology’s Sixth Annual Academic Evening – April 20, 2018 at 6:00
Eric P. Newman Education Center, Great Rooms A & B
The Washington University Department of Anesthesiology would like to recognize the scientific work of its members at our Sixth Annual Academic Evening. This will be an evening of fellowship as well as an opportunity to view and discuss the work of our research colleagues.

Faculty investigators (PIs) and staff from our research divisions will be invited to participate in an “Open House.” This will be a dedicated area reserved for faculty and staff to present a poster representative of the research done by their group. If interested in participating, please send information to Becky Snider no later than April 9, 2018.

Trainees in our Department (undergrads, medical students, graduate students, residents, fellows and post-docs) are welcomed to submit abstracts for the competitive portion of the evening as well as participate in an informal walk-around poster session. Faculty and staff are not eligible to participate in the competitive portion of the evening.

Spotlight: How Central is Central Stroke Pain? The role of afferent input in post-stroke neuropathic pain: a prospective open-label pilot study
Haroutounian S, Ford AL, Frey K, Nikolaisen L, Finnerup NB, Kharasch ED, Karlsson P, Bottros MM

The journal Pain recently accepted a manuscript authored by Dr. Simon Haroutounian and colleagues, in which the authors hypothesized that central post-stroke pain is a result of misinterpretation of afferent sensory input by the sensitized neurons within the brain, rather than generated spontaneously by the damaged CNS neurons.

To test this hypothesis, the study team prospectively recruited eight participants with definite central post-stroke pain affecting at least one extremity and measured spontaneous and evoked pain, neuropathic pain descriptors, and lidocaine plasma concentrations.

The researchers found the blockage of peripheral sensory input resulted in complete abolition of pain within 30 minutes in seven of the eight participants. All mechanical/thermal hypersensitivity was abolished by the nerve block.

The results suggest that it is unlikely that central post-stroke pain is autonomously generated within the central nervous system, but rather that this pain is dependent upon afferent input from the painful region of the periphery, and may be mediated by misinterpretation of peripheral sensory input by sensitized neurons in the central nervous system.

The accepted version of the article can be found at: http://fq5np7af6j.search.serialssolutions.com/?V=1.0&sid=PubMed:LinkOut&pmid=29570507

Department of Anesthesiology Research Speakers
The Department of Anesthesiology hosts over 25 research seminar speakers each year whose talks cross over the basic science, translational and clinical research spectrum. Unless otherwise noted, seminars are scheduled at 4:00 and held in the CSRB-NTA 401 Conference Room.
Upcoming speakers:

<table>
<thead>
<tr>
<th>Date</th>
<th>Speaker</th>
<th>Title</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>4/17/18</td>
<td>Joseph F. Cheer, PhD University of Maryland</td>
<td>Endogenous Cannabinoids and the Pursuit of Reward</td>
<td></td>
</tr>
<tr>
<td>5/8/18</td>
<td>Oluwaseun Johnson-Akeju, MD Harvard University</td>
<td>General Anesthesia, Sedation, and the Concept of Biomimetic Sleep</td>
<td></td>
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<tr>
<td>5/15/18</td>
<td>Pei Tang, PhD University of Pittsburgh</td>
<td>TBA</td>
<td></td>
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<tr>
<td>5/22/18</td>
<td>Chad Brummett, MD Univ of Michigan Med School</td>
<td>The Role of Acute Care Prescribing in The Opioid Epidemic</td>
<td>4:30 start</td>
</tr>
<tr>
<td>6/20/18</td>
<td>Alex Evers, MD</td>
<td>State of the Department</td>
<td>Grand Rounds 6:45 am Wohl Auditorium</td>
</tr>
<tr>
<td>6/26/18</td>
<td>C. Michael Crowder, MD, PhD University of Washing</td>
<td>Lost in Translation? The Role of Protein Synthesis in Hypoxic Injury</td>
<td>Grand Rounds 6:45 am Wohl Auditorium</td>
</tr>
<tr>
<td>7/10/18</td>
<td>Vivianne L. Tawfik, MD, PhD Stanford University</td>
<td>TBA</td>
<td>Grand Rounds 6:45 am Wohl Auditorium</td>
</tr>
<tr>
<td>9/18/18</td>
<td>Rebecca A. Aslakson, MD, PhD Johns Hopkins School of Medicine</td>
<td>TBA</td>
<td>Grand Rounds 6:45 am Wohl Auditorium</td>
</tr>
<tr>
<td>9/25/18</td>
<td>Isaac Chiu, PhD Harvard University</td>
<td>Bacterial Interactions with the Nervous System in Pain and Host Defense</td>
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<tr>
<td>10/30/18</td>
<td>Joshua Gordon, MD, PhD National Institute of Mental Health</td>
<td>TBA</td>
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<tr>
<td>11/13/18</td>
<td>Daniel Talmor, MD, MPH Beth Israel Deaconess Medical Center</td>
<td>Pulmonary physiology at the bedside</td>
<td>4:30 start</td>
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Research Faculty Q & A

Richard Hotchkiss, MD, PhD

1. **What happened in the course of schooling to influence you to choose Anesthesiology & Anesthesiology Research?**

I did an internal medicine residency first, and was drawn to the intensive care unit because the patients are the sickest there and how your management of the patients can really make the difference sometimes between life and death. I call the ICU the “crucible,” because it is a place of intense testing of the patient, the family and the physician, and your decisions can really affect outcomes. The ICU is an incredibly emotional and intense place and I enjoy trying to make a difference. It is also a great place for teaching.
My fellowship was a surgical ICU fellowship at Massachusetts General Hospital and the Anesthesiologist on the floor helped run the ICU. I was impressed with the caliber of the anesthesiologists and the level of the care they provided.

2. **What brought you to Washington University?**

I went to medical school at University of Virginia and residency at Emory University, and then my ICU fellowship at Massachusetts General Hospital, where I met Dr. Alex Evers.

Dr. Owens spoke with a group of us at Massachusetts General about the opportunities available at Washington University; that he was building up the program here and it sounded like it was a great place to come work. However, it was really running into Dr. Evers at a scientific meeting, where he told me that Washington University was really a wonderful institution and that he was having extraordinary time here because there were wonderful opportunities to do a lot of research. I could tell that Washington University was a great place to be.

3. **What is the focus of your current research?**

My current research is focusing on immunotherapy; we are trying to boost the patient’s immune system to help them fight infections, specifically, we work on sepsis, which is the number one cause of death in the surgical ICU.

4. **Is there a particular award or achievement that is most gratifying?**

Watching the progression of the research that I have been involved with and taking it from the animal/mouse studies into clinical trials of therapies that we determined could be beneficial in humans. It has taken a long time, and a lot of people said it should have happened much sooner, but we have moved from the bench to the bedside and are now doing clinical trials with drugs that we are hopeful and excited about.

5. **If you weren’t a doctor/researcher what would you like to be doing?**

I would like to be a middle or high school history teacher. I really enjoy teaching and I really like kids that age and think I could really make a difference.

6. **What is the best advice you’ve received?**

Try to think about how to apply your research to the patient and how it can influence patient care. That helps give you some passion and helps remind you of the ultimate goal. I was told to always keep that in the back of my mind.

7. **What advice would you give to those who are early in their research career?**

a. Work on something that is important to you. If you believe it is important, and you feel passionate about it, that old saying to find something you love and you will never work a day in your life becomes a reality.

b. Find and work with a great mentor. It is very important to choose wisely. I have watched many investigators make mistakes on that and you can spend a long time with a mentor who is not devoted to spending time on you and your career.

c. When setting up your lab, it is very important to make the people in your lab feel as if they are part of the team, that everyone on the team succeeds, and that everyone is part of one mission. Treat everyone like family and how you would want to be treated. I think that is critical in any lab’s success.

d. Stay focused. I’ve seen many investigators fail because they try to do too many things.
e. Never neglect your family. This is incredibly important, because if your family isn’t doing well, you won’t be doing well. Family should be first; research and career second.

8. **What do you consider your biggest contribution to science?**
   I think the jury is still out on that whether I’ve made any contribution to science, but I do feel there is a good chance that the immune-based therapies we are testing now will make a big difference in people’s lives.

### Regulatory & Compliance News

**Epic and Research**

If you are receiving emails titled as above, you need to complete the survey (a link is provided in the email) or forward the message to a delegate (study coordinator) to complete the survey for you. This is required because you have an active study that includes a drug or device intervention or a billing component. These studies must be built into EPIC.

You will continue to receive emails weekly until the surveys are completed (3 reminders).

If you would like ordering and recruitment built into Epic please let Ellen Fischbach or Sherry McKinnon know and they can modify the study application to get this IRB approved for you.

**CT.gov – Frequently Asked Questions**

**Why is entry to CT.gov required?**
- It is required by Federal law (FDAAA 801), and regulations (42 CFR Part 11), which mandate registration and results submission for “applicable clinical trials”
- It is required for most medical journals
- It is the expectation for NIH-supported clinical trials

**Is there another registry we can use besides CT.gov?**
While there are other registries, Washington University uses CT.gov exclusively.

**Which studies need to be registered on CT.gov?**
The study must fall into all 4 points below and be initiated on or after January 18, 2017:

1. Interventional studies (Clinical Trials)
2. If any of the following apply:
   a. Is at least one study site located in the USA
   b. Is the study conducted under a US FDA Investigation Drug or Device
   c. Does the study involve a drug, biological, or device product manufactured in and exported from the USA to another country?
3. The study evaluates at least one drug, biological or device product regulated by the US FDA
4. The study is a Phase 2, 3, or 4 of a drug/biologic product, or the study is not a device feasibility study

Please refer to the ClinicalTrials.gov checklist: [https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf](https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf)
Ellen Fischbach and Sherry McKinnon can also assist you with making the determination.
What does CT.gov consider study start date?
The date the first participant is enrolled.

What does CT.gov consider the primary completion date?
This is the date final data are collected for the primary outcome measure. This is typically the date of the final participant visit or follow-up participant interview for the study.

What does CT.gov consider the study completion date?
This is the date the final participant was examined or received an intervention for purposes of collection of data for the primary and secondary outcome measures and adverse events (for example, last participant’s last visit). This definition applies if the clinical study concluded according to the pre-specified protocol or was terminated.

What are the deadlines for CT.gov?
Registration: The study must be registered within 21 days of enrolling first participant.
Results: Results must be submitted no later than 1 year after final data collection for the primary outcome measure (primary completion date).

Are there consequences for non-compliance of Clinicaltrials.gov governance?
Yes, non-compliance can lead to suspension or termination of grant or contract, can affect future funding decisions, and your record in Clinicaltrials.gov will be marked as non-compliant. There may also be monetary penalties.

What information do I need to enter the results?
There are 4 modules to complete when entering the results of a study:
1. Participant Flow: This is a summary of participants’ progress through each stage of the study by assignment group.
2. Baseline Characteristics: This section lists the demographic and baseline measures by arm/randomization group and for the entire population of participants in the study.
3. Outcome Measures and Statistical Analysis: This is the summary of data for each primary and secondary outcome measures.
4. Adverse Events: This section includes a summary of anticipated and unanticipated events that were collected during the study.

A full list of data points can be found on the Clinical Research SharePoint drive located at https://collaboration.wustl.edu/depts/anest/Anesthesiology/ClinicalResearch

Who is responsible for maintaining the CT.gov registration?
Registration: The PI will start the registration of the study so that he/she is considered the “owner” of the record. Once the registration is started, the regulatory specialist can take over and complete the registration.
Results: The PI is responsible for entering results of the study as the person completing this entry must have a thorough understanding of the methods and results of the study.

Inviting a Summer Student to Participate in Your Clinical Research Study?
Please contact Ellen Fischbach or Sherry McKinnon no later than May 20, 2018 to start the process of obtaining IRB approval. You will need the following information:
- Start date
Research Happening

- The study for which the study will be affiliated
- Student’s contact information and CV
- The program in which the student is participating
- Training plan – Sherry and Ellen can provide a template

**Good Clinical Practice (GCP) Training**

Effective January 1, 2017, Washington University enacted a policy that requires all research team members (any person listed on a study in the myIRB system) have GCP training every 3 years. The GCP Certification is designed to give the researcher a basic understanding of the regulations and requirements for research using investigational (not approved by FDA) drugs or devices. To get your GCP training up-to-date: Logon to Learn at Work ([https://learnatwork.wustl.edu](https://learnatwork.wustl.edu)) and search for GCP.

Once completed, please e-mail your certificate to Ellen Fischbach or Sherry McKinnon for tracking. The Washington University policy is located at [https://research.wustl.edu/good-clinical-practices/#Frequency](https://research.wustl.edu/good-clinical-practices/#Frequency)

**SharePoint Site**

Clinical Research now has a SharePoint site; located at [https://collaboration.wustl.edu/depts/anest/Anesthesiology/ClinicalResearch](https://collaboration.wustl.edu/depts/anest/Anesthesiology/ClinicalResearch)

This SharePoint site will house commonly used forms and policies for Anesthesiology Clinical Research. We welcome your input for information you will find most useful.

## Recent Articles for Researchers

1. **Authorship and Team Science**

2. **NIH Policies on Experimental Studies with Humans**
   [https://www.nature.com/articles/s41562-017-0265-4](https://www.nature.com/articles/s41562-017-0265-4)

3. **Not Your Parent’s NIH Clinical Trial**
   [https://www.nature.com/articles/s41562-017-0262-7](https://www.nature.com/articles/s41562-017-0262-7)

What would you like to see in future newsletters?

Please contact Ellen Fischbach at 314-747-1709 or ellen@wustl.edu