
CPI Newsletter – October 2017

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2017-18 CPI roster: *Chair* — Penny Riggs, COALS • *Vice Chair* — David Threadgill, *Veterinary Medicine* • *AgriLife Extension* — Craig Carpenter, Gaylon Morgan • *AgriLife Research* — Michael Brewer, Ambika Chandra, Fugen Dou, Lee Tarpley • *Architecture* — Ergun Akleman • *Bush School* — Kent Portney • COALS — Fuller Bazer, Russell Cross, Martin Dickman, Micky Eubanks, Elizabeth Pierson, David Stelly • *Education* — Oi-Man Kwok, Jeffrey Liew • *Engineering* — Jorge Alvarado, Ulisses Braga-Neto, Zachary Grasley, Melissa Grunlan, Tony Hsieh Sheng-Jen, Daniel Jiménez, Jodie Lutkenhaus, Ramesh Talreja • *Geosciences* — Alejandro Orsi, Pamela Plotkin, Brendan Roark • *IBT/PHARM/RCHI* — Julian Hurdle • *Law* — Susan Fortney • *Liberal Arts* — Steve Maren, Harland Prechel • *Medicine* — Vytas Bankaitis, Kayla Bayless • *Science* — Darren DePoy, Michael Hall, Christian Hilty, Alexei Safonov, Frank Sottile • *SPH* — Jane Bolin • *TAMU at Galveston* — R.J. David Wells • *TAMCD* — Jay Gropp • *TAMU at Qatar* — Othmane Bouhali • *TTI* — David Bierling, Mike Lukuc, Dennis Perkinson • *University Libraries* — Bruce Herbert • *Veterinary Medicine* — Loren Skow

The CPI is sponsored annually through equal funding from Texas A&M University, Texas A&M AgriLife, Texas A&M Engineering Experiment Station, and the Texas A&M Transportation Institute

Update from Dr. Penny Riggs, CPI Chair

Principal Investigators – The Council members had a productive session at the closed General Meeting in September. Thank you to all the PIs who provided input in the CPI survey. The comments provided will help shape CPI actions this year, and will also be utilized by SRS and research compliance to continue to assist PIs in enhancing the research environment for PIs. In addition, CPI has begun discussion and interaction with the Faculty Senate Research Committee, as well as administrators, about avenues to enhance opportunity and resources for those researchers who may not be well represented by CPI.

CPI will continue efforts to reduce administrative burden on PIs, and will emphasize communication, research infrastructure, and interdisciplinary research. Input from PIs has shaped CPI actions. We will continue to work on improvements, and to do a better job communicating about actions that are influenced by PI input.

October CPI News – The CPI executive committee met October 4, 2017, in preparation for today's meeting. Dr. Karen Butler-Purry provided a reminder about two VPR Fellow Positions that will focus on postdocs and core facilities. The deadline for submitting an application is October 16. The Division of Research highlighted several updates to Research Compliance, Biosafety & Export policies related to circulated shipping guidelines, controlled substances, and more. More information about these updates can be found on the flyers attached to the end of this newsletter.

Dr. Dimitris Lagoudas and Dr. Narasimha Annapareddy (Reddy) provided updates on Texas Engineering Experiment Station noting continuing renovations and new research partners and opportunities. They offered a reminder, **that Friday, November 3 is National Labs Day** on campus. This recruiting event offers an excellent opportunity for students to gain access to National Laboratories.

Dr. Craig Nessler provided the CPI-EC with an update from AgriLife Research. He highlighted the opening of the Wildlife and Fisheries building and ground breaking for a new Plant Pathology and Microbiology building. AgriLife Research is also involving faculty in discussion with several software companies regarding Big Data solutions for UAV and genomics data analyses.

Texas A&M Sponsored Research Services (SRS) is still undergoing an internal system audit that is examining processes, system policy and regulations as well as internal regulations. Currently SRS has only four open staff positions. This is welcome news in response to PI requests to reduce turnover at SRS.

Administrator Searches – Campus interviews are underway or approaching for several administrative positions. Everyone is encouraged to participate as much as your schedule allows. PI participation and input in the search process is valued and appreciated.

- Vice President and Associate Provost for Diversity campus interviews are nearing completion for four outstanding candidate. The advisory committee is chaired by Dr. Eleanor Green, and the search website can be found at <http://vpapdiversitysearch.tamu.edu/>.
- The Dean of Nursing search advisory committee, chaired by Dr. Joyce Alexander, has announced that 3 candidates will interview on campus beginning Oct 16. For details see the search website: <http://nursingsearch.tamu.edu/>.
- The search for Vice Chancellor and Dean of Agriculture and Life Sciences is ongoing, and chaired by Dr. Kathy Banks. The schedule for on campus interviews will be announced soon. More info can be found at the search website: <http://agrilife.org/vcdeansearch/>.
- The Vice President for Research (VPR) search advisory committee is chaired by Dr. John Gladysz and Dr. Patrick Louchouart. The search is ongoing. On campus interviews will likely be announced by the end of October. The search website can be found at <http://vprsearch.tamu.edu/>

CPI Contacts – The complete list of all CPI Representatives and the executive council for 2017-2018 can be found on the CPI website at <http://cpi.tamu.edu/membership>. All PIs are encouraged to communicate with their representatives to bring forward items of concern or interest for the research community. Please continue to bring research-related issues (and solutions) to my attention at CPI@tamu.edu, or contact me directly at riggs@tamu.edu or 979.862.7015.

The next general meeting will be held Wednesday, November 8. Contact Rebecca Luckey, rluckey@tamu.edu or 979.862.9166 for more information or to suggest agenda items for our monthly meetings.

Letter Regarding Hurricane Maria Recovery Efforts

This year's hurricane season has had a dramatic and devastating impact. As recovery efforts are underway in Texas and Florida, Puerto Rico is also struggling after experience heavy rainfall. Damage from the storm wiped out infrastructure, as well as an estimated 80% of the island's agricultural resources. We recently received correspondence about relief coordination efforts in Puerto Rico, and the writer asked that her letter be shared with CPI:

Howdy!

As you may know, Puerto Rico had a catastrophic category 4 hurricane (Maria) pass by last Wednesday, September 20th. Personally, I was not able to reach my family whom reside in the Northwest of the island till Monday September 25, 2017. Currently, there is no water, no power, no mobile communication, and a lack of fuel distribution. The power is not expected to come back for over 3 months.

As TAMU graduate student from Puerto Rico, I encourage you to pass this [link](#) to the CPI and/or VPR listserv to see if any Investigator is willing to provide aid for science in Puerto Rico. This program is being organized by Ciencia Puerto Rico; a powerful database-driven community website focused on users with interest in both Puerto Rico and science. Your help will be appreciated.

or copy: https://yalessurvey.qualtrics.com/jfe/form/SV_6YigLXts7kTr2YJ

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Office of the Vice President for Research Announces 2 Research Fellow Opportunities

The Office of the Vice President for Research is searching for two tenured faculty members to serve administrative appointments as Research Fellows. The deadline for submitting a CV is October 16, 2017.

Please see the attached PDF for the requirements and details associated with these two Research Fellows positions.

If you have any additional questions regarding the positions, contact Interim VPR Dr. Karen Butler-Purry directly at vpr@tamu.edu

Research Development Fund

Full applications are due October 23, 2017. More information is available at rdf.tamu.edu or email questions to rdf@tamu.edu.

National Biosafety Month

October is National Biosafety Month. This annual initiative was started in 2014 by NIH and other DHHS agencies to promote stewardship of the life sciences and biosafety awareness. Principal investigators play an important role with respect to biosafety in their laboratories and are responsible for developing comprehensive SOPs and ensuring all personnel are trained and familiar with these SOPs. Researchers (including students) working with biohazardous materials are encouraged to take this opportunity to reinforce their attention to biosafety policies, practices and procedures.

The Biosafety Occupational Health Program (BOHP) is an integral component of the Office of Biosafety within the Division of Research. BOHP serves all researchers who work with potentially infectious biohazards and/or animals in the context of their research, teaching or testing activities. Recently, the TAMU BOHP expanded its scope to include all health science center researchers at occupational risk of exposure to infectious biological materials or animals. BOHP can be reached at bohp@tamu.edu or 979-845-6649.

New International Research Program with FAPESP, São Paulo, Brazil

The Division of Research at Texas A&M University and the São Paulo Research Foundation, FAPESP, are pleased to announce a new Cooperation Agreement for Research aiming to implement scientific and technological cooperation through the funding of joint research projects between Texas A&M researchers and researchers from the State of Sao Paulo, Brazil.

The announcement for the TAMU-FAPESP Collaborative Research Grant program was released on **August 1, 2017**. The closing date for proposal submissions is **October 30, 2017**.

Funding for the Texas A&M principal investigator will be US\$10,000 per proposal per year. FAPESP will provide an equivalent amount of funding for their PIs.

One principal investigator is required from Texas A&M and the other from a public and/or private institution of higher education in the State of São Paulo.

Additional details will be announced as soon as they are available.

The São Paulo Research Foundation – FAPESP – is an independent public foundation with the mission to foster research and the scientific and technological development of the State of São Paulo. The agreement between Texas A&M and FAPESP is for a period of five years, which may be extended by mutual agreement between both institutions.

For additional information on the program, please contact Monica Bruno Holder, international programs coordinator, at m-holder@tamu.edu.

Water Security Symposium '17

The Division of research is hosting a research networking event over water security on Wednesday, November 8th from 1:30-4:40 pm in MSC, Room 2406A. PIs are invited to present their ongoing water-security related research in a 2-minute flash presentation.

More information about the Water Security Symposium can be found on the flyer attached to the end of the newsletter, or through this link: <http://vpr.tamu.edu/researchdevelopment/registrations/water-security-symposium>

NSF Broader Impacts Seminar and Expo

November 8, 1:00-4:30 p.m.

ILSB Auditorium and Lobby

This event, part of the new [Junior Faculty Proposal Writing Academy](#), will inform attendees about the strategies and considerations relevant to the Broader Impacts requirement of grant proposals submitted to the National Science Foundation (NSF) and will include a resource expo following the workshop.

1:00-2:30 – Seminar: A 90-minute seminar on how PIs can improve the competitiveness of their NSF proposals through the creation of a strong Broader Impacts component.

2:30-4:30 – Expo. A two-hour expo for PIs to visit with representatives of organizations and programs from the university with whom they can collaborate in the design and implementation of their future broader impacts and outreach strategies and activities.

The Expo is an opportunity to meet and form relationships with representatives who can assist faculty in creating and developing the broader impacts or outreach activities of their proposals.

While all **junior faculty** are encouraged to participate in this event, **senior faculty** and **post-docs** are welcome to attend. Principal investigators may also invite graduate students who are supporting critical components of their grant proposals.

Register at <https://u.tamu.edu/JFPWA-NSFBI> by **5:00 p.m. on Monday, November 6, 2017**.

NSF Biology Directorate implementing a “No-Deadline,” Full-proposal Submission Process for most programs

It was announced on Oct. 5, 2017 that the Directorate for Biological Sciences (BIO) at NSF “will implement a ‘no-deadline,’ full-proposal mechanism for receiving and reviewing proposals submitted to core programs in the Division of Environmental Biology (DEB), the Division of Integrative Organismal Systems (IOS), the Division of Molecular and Cellular Biosciences (MCB), and to the programs in the Research Resources Cluster of the Division of Biological Infrastructure (DBI).”

Full proposals deadlines to MCB of November 20, 2017 ([NSF 17-589](#)) and to DBI of December 8, 2017 ([NSF 16-506](#)) will still apply. IOS and DEB will have no call for preliminary proposals in January 2018.

All four divisions will release new solicitations to replace several archived solicitations in the middle of calendar year 2018, inviting proposals to be funded with FY 2019 funds. **There will be no deadlines for submissions to any of the new solicitations.**

For full detail, see [Dear Colleague Letter, NSF 18-011](#).

Upcoming Professional Development Opportunities for Researchers

Information and registration links for these events are online at <https://u.tamu.edu/RDSPD> (topical list) or <https://u.tamu.edu/RDS-UE> (chronological list).

[Writing Successful Proposals – All Faculty](#)

October 18, 1:00-4:00, 3147 ILSB

Registration Deadline: 10:00 a.m. October 18

[Arts & Humanities Fellows Program Proposal Writer's Workshop](#)

November 1, 1:00-4:00, 3147 ILSB

Registration Deadline: 10:00 a.m. November 1

Deadlines Approaching for International Seed Grant Program

October 23: Letters of Intent due for the Texas A&M University-CONACYT: Collaborative Research Grant Program

October 30: Proposals due to Texas A&M-FAPESP Research Program

See additional information on these two programs below.

Texas A&M University-CONACYT: Collaborative Research Grant Program

Letters of Intent due: October 23, 2017

Invitation for full proposal: After November 1, 2017

Full proposals due: January 12, 2018, 6:00 p.m.

Award Notifications: After May 2018

Award Period (TENT): September 1, 2018-August 31, 2019

Transfer of funds (TENT): September 2018 (All compliance documents must be in place for funding to occur.)

Website: <https://u.tamu.edu/CONACYT>

Texas A&M University and the Consejo Nacional de Ciencia y Tecnologia (CONACYT) began the Collaborative Research Grant Program in 2001. This competitive, peer-reviewed program advances inter-institutional cooperation in science, technology, and scholarly activities through the complementary efforts of scientists and scholars from Texas A&M and Mexican institutions. Principal investigators (PIs) may apply for a Type I Award providing up to \$24,000 in joint funding or a Type II Award providing up to \$50,000 in joint funding. PIs may not submit proposals to both award programs.

Texas A&M-FAPESP Research Program – NEW!

Proposals due: October 30, 2017

Website: <https://u.tamu.edu/FAPESP2017>

The Division and São Paulo Research Foundation (FAPESP) have established the Texas A&M-FAPESP Research Program to implement scientific and technological cooperation through the funding of joint research projects between Texas A&M researchers and researchers from the State of São Paulo, Brazil. Funding for the Texas A&M principal investigator is US \$10,000 per proposal per award. FAPESP will provide an equivalent amount of funding for their PIs.

Deadline Approaching for Internal Seed Grant Program

October 30: Deadline for Proposals

PESCA Grant Program

Award Notifications: Dec. 18, 2017
Estimated date of grant funding: May 1, 2018 (Pending receipt of any required compliance approvals.)
Website: <https://vpr.tamu.edu/researchdevelopment/funding/internal/PESCA>

The Division funds the PESCA Grant Program to support significant research and scholarly projects that have the potential to lead to the awarding of external funding by agencies and endowments such as national endowments, major federal research funding agencies, institutes, foundations and councils. The maximum award amount is \$10,000 for single-authored proposals; \$18,000 for co-authored proposals; and \$25,000 for proposals with three or more authors.

NIH's Next Generation Researchers Policy Now Posted

NIH announced their newest plans to implement their Next Generation Researchers Initiative on Aug. 31, 2017. The goal is to "increase the number of NIH-funded early-stage investigators and assure, as best [NIH] can, that funded early-stage investigators have a reasonable chance to secure stable funding during the earliest stages of their independent research careers." [NOT-OD-17-101](#) describes the new initiative and defines a new class of investigator, the Early-Established Investigator. Early-Stage Investigators still are recognized in the policy, but New Investigators will no longer receive NIH-wide special consideration in review and awarding of grants.

Early Stage Investigators (ESI) are still recognized and are individuals within 10 years of completing their terminal research degree or of completing post-graduate medical training and who have not previously been awarded a substantial NIH independent research grant.

Early-Established Investigator (EEI) is a PI/PD within ten years of receiving their first substantial, independent NIH R01 equivalent research grant *as an ESI*.

NOT-OD-17-101 supersedes prior year notices on new and early stage investigators and describes how NIH and its ICs

- Will prioritize funding for meritorious R01 or equivalent applications from ESI PD/PIs
- May prioritize funding for meritorious R01 or equivalent applications from EEI PD/PIs who are have lost or at risk of losing all NIH research support or who are supported by only one active award.

The goal for FY 2017 (just ended Sep 30) is to fund ~200 more ESI awards than in FY 2016. According to the FAQs, individual "ICs may continue to fund certain non-ESI New Investigators according to their own programmatic and strategic interests."

For complete information and discussion, see

- [NOT-OD-17-101](#)
- [Open Mike blog](#)
- Next Generation Researchers Initiative [web page](#)
- [Frequently Asked Questions](#)

National Academies of Sciences, Engineering, and Medicine

In honor of the centennial of World War I, an open competition for scholars under the age of 30 to research and write a scholarly paper on a major aspect of how scientists and engineers in the United States were engaged in the World War I effort has begun. The focus is on institutional changes and the research enterprise in America. In effect, scholars should look at how the war experience shaped long-term relationships among scientists and engineers and U.S. policymakers regarding national security and public welfare. Research grants in the amount of \$5,000.00 will be available to five scholars who submit the most compelling proposals by December 1, 2017. Proposals will be judged by a NAS review committee, and the authors of the best proposals will be invited to submit fully developed research papers. A winning paper will be selected by the review committee, and the paper's author will be awarded a \$10,000.00 prize.

Learn more: <https://buff.ly/2jw0f92>

Texas A&M University Controlled Substances Guidance Now Online

The controlled substances guidelines have been posted online at (and attached) (<http://rcb.tamu.edu/controlledsubstances>). Anyone who uses, or plans to use, controlled substances in their research or teaching activities must have their own DEA license. The guidelines cover information for DEA license holders on responsibilities, acquisition, storage, reporting requirements, record-keeping requirements, and appropriate disposal of controlled substances. A training module is located on the website, within the training section of the guidelines (<http://rcb.tamu.edu/more/controlled-substances-training>).

The Animal Welfare Office (845-1828) is the contact for questions about the controlled substances guidelines and the controlled substances program. For questions or assistance with obtaining a DEA license, please contact the Animal Welfare Office.

Multiple Updates from the Human Research Protection Program

Updates provided in an attachment with this newsletter include:

- reminder about the FDA presentation on Oct. 12
- AAHRPP Re-Accreditation Status
- Revised Common Rule Overview
- National Institutes of Health (NIH) Changes
- NIH Certificate of Confidentiality (CoC) Changes
- Guidelines for Good Clinical Practice (GCP) E6 (R2)
- Federalwide Assurance Information

Texas A&M University Export Control Shipping Guidelines

Physical items that are being shipped, mailed, or carried out of the United States need to go through Customs in the destination country. Texas A&M does not have a central international shipping office, but the Export Controls Office can assist with shipment information that will facilitate your research. The director of Export Controls, Mr. Rayland VanNorman can be reached at 979-862-6419 or raylandc@tamu.edu for more information. More details on this guidance are attached to the newsletter.

System Regulation for Unmanned Aircraft Systems Posted

In accordance with the new [System Regulation on Unmanned Aircraft Systems \(UAS\)](#), Texas A&M University has established a Supervising Authority to review and approve unmanned aerial system (UAS)/drone flights that occur on campus. These rules apply to faculty, staff, students, visitors, and contractors on campus property and to university employees operating UAS off-campus as part of their job responsibilities.

There are three ways to fly UAS at Texas A&M University:

1. In accordance with an FAA-issued Public COA.
2. In accordance with FAA Part 107 rules.
3. For educational purposes

For other types of UAS flights (not captured through one of the three categories identified, contact EHS at ehsd@tamu.edu.

To fly UAS in accordance with an FAA-issued Public COA or in accordance with FAA Part 107 rules:

1. Submit your application to the Texas A&M University UAS Supervising Authority through the following link: <https://www.tamus.edu/business/risk-management/uas/uas-application/>. Applications should be submitted a minimum of 15 business days before desired flight.
2. Attach all requested documentation to ensure delays are avoided.
3. Completed on-line applications will be reviewed by the Supervising Authority; any questions will be directed to the individual who completed the application.
4. All University-owned or acquired UAS must be properly registered in accordance with FAA requirements. Use the FAA's Web site to register UAS: <https://registermyuas.faa.gov/>. Additionally, all UAS must be placed on inventory and have an asset number assigned.

Please see the corresponding announcement attached and posted in the September 19, 2017, edition of Texas A&M TODAY.

Sign Up for Notifications about Limited Submission Proposal Opportunities

The list of current Limited Submission Proposal (LSP) opportunities, maintained by the Division of Research, is available at <https://u.tamu.edu/LSP>.

To receive notifications about new LSP opportunities as soon as they are announced, email Ms. Shelly Martin at shelly.martin@tamu.edu.

Bulletin for Principal Investigators

The Division of Research at Texas A&M University issues a brief weekly bulletin for Principal Investigators that highlights research accomplishments and projects, funding opportunities, honors and promotions, workshops, and other items that may be of interest to the PI community. [Click here](#) to subscribe or unsubscribe to the bulletin.

Research Fellows Program

Division of Research

Office of the Vice President for Research

The Vice President for Research (VPR) is searching for two tenured faculty members to serve administrative appointments as Research Fellows. The appointments are expected to represent 25-35% FTE for one to two years. One Fellow will continue to develop programs and services for the post-doctoral research community at Texas A&M, working closely with the Post Doc Associations and the offices in the Colleges of Medicine and Veterinary Medicine and Biomedical Sciences. The second Research Fellow will work to enhance the research infrastructure core facilities at Texas A&M, including the ongoing deployment of the iLab system.

Each Research Fellow will serve as a member of the programmatic leadership team for the Division of Research and will have access to the senior administrative staff, including the VPR. Depending on the particular topic, the Fellow may work independently under the guidance of the VPR or team with another senior member of the Division. As a member of the team, the Research Fellow will have an opportunity to participate in the activities and operations of the Division.

Although the Division is flexible on the start and end dates for the appointment of the Research Fellow, and can also be flexible as to the work schedule and division of time between the fellow's responsibilities in their department and college and the administrative role in the Division of Research, we hope to have the Fellows begin their appointments in January 2018 or before.

For full consideration, interested parties should send a CV and a single-page cover letter outlining their interests in the positions directly to Interim VPR Karen Butler-Purry at vpr@tamu.edu by October 16, 2017. It is anticipated that the Research Fellows will be selected and announced shortly thereafter.

WATER SECURITY SYMPOSIUM 2017

RESEARCH NETWORKING EVENT

Wednesday, November 8, 2017

1:30-4:30 p.m.

MSC, Room 2406A

Event Convenors

Institute for Sustainable Communities

Dr. Phil Berke, Urban Planning

Dr. Wendy Jepson, Geography

Dr. Garrett Sansom, Public Health

This event will bring together Texas A&M principal investigators (PIs) who are interested in the broad spectrum of water security research topics, including:

- Economic Development
- Climate Change and Water Insecurity
- Human Well-Being and Public Health
- Water Governance
- Water and Sanitation Infrastructure
- Cities and Urban Planning
- Agriculture and Animal Science
- Water-Energy-Food Nexus
- Water in The Humanities
- Bio-Cultural Dimensions of Water Insecurity
- Water Security of Ecosystems

Presentations: PIs are invited, but not required, to present their ongoing water-security related research in a 2-minute flash presentation to highlight current projects, area of expertise, and future research interests.

Register

<http://vpr.tamu.edu/researchdevelopment/registrations/water-security-symposium>

Schedule

1:30 p.m. – Welcome & Introductions

2:00 p.m. – Flash Presentations

3:00 p.m. – Breakout Sessions

4:00 p.m. – Networking and Refreshments

Introductory Presentations

Dr. Phil Berke, Director, Institute for Sustainable Communities

Dr. Wendy Jepson, Water Security Initiative

Dr. Rabi Mohtar, Texas A&M Water-Energy-Food Nexus Initiative

Flash Presentations

Breakout Discussions

These sessions will allow PIs to connect with potential collaborators in the following theme areas: (1) human health, well-being and development; (2) water governance; (3) coupled natural-human systems; (4) method, tools and technologies; (5) water-energy-food nexus.

Networking

with light refreshments



DIVISION OF RESEARCH
TEXAS A&M UNIVERSITY



TEXAS A&M UNIVERSITY
Institute for Sustainable
Communities



[Animals](#) [Biohazards](#) [Humans](#) [Biosafety Occupational Health](#) [Export Controls](#) [iRIS Portal](#)

Controlled Substances Guidelines

GUIDELINES FOR THE PURCHASE, STORAGE, USE, AND DISPOSAL OF CONTROLLED SUBSTANCES IN RESEARCH AND TEACHING AT TEXAS A&M UNIVERSITY

It is the policy of Texas A&M University to comply with state and federal law, including the Memorandum of Understanding (MOU; <http://www.theccb.state.tx.us/reports/PDF/1210.PDF>) between the Texas Department of Public Safety (DPS) and the Texas Higher Education Coordinating Board (THECB) and the Drug Enforcement Administration (DEA; <https://www.deadiversion.usdoj.gov/drugreg/process.htm>) requirements governing the purchase, storage, use, and disposal of Controlled Substances.

Reason for Guidelines

These guidelines establish processes and controls for the purchase, storage, use, and disposal of Controlled Substances used in research and teaching at Texas A&M University.

Definitions

Authorized Agent: a co-investigator, graduate student, post doc or member of laboratory staff authorized by the Registrant to access the secure storage cabinet, dispense, administer, and log Controlled Substances.

Clinical Setting: A setting where a Controlled Substance is used in a medical or veterinary application.

Controlled Substance: The current official schedule (I, II, III, IV and V) of controlled substances can be found in section 1308 of the most recent issue of Title 21 Code of Federal Regulations (CFR) Part 1300 to end (21 CFR §1308) and the final rules which were published in the Federal Register subsequent to the issuance of the CFR.

Non-Clinical Settings: A setting where a Controlled Substance is used in research, teaching or testing, which is not a clinical usage of the Controlled Substance.

Registrant: An individual who is named as the Registrant on a DEA registration (<https://apps.deadiversion.usdoj.gov/webforms/jsp/regapps/common/newAppLogin.jsp>).

Effective September 1, 2016, the State of Texas no longer requires a state Controlled Substances registration or license.

Responsibilities and Processes

These guidelines do not apply to Clinical Setting activities performed at or through a Texas A&M University participating pharmacy or clinic, which are governed by federal and state accrediting and regulatory agencies and are subject to review and audit by those agencies.

Investigators and teaching faculty who use Controlled Substances in the University's Non-Clinical Settings must obtain and keep current United States Drug Enforcement Administration (DEA) registration, unless exempted by law. Registrants are responsible for procuring, maintaining security, keeping records, and disposing of Controlled Substances in accordance with federal regulations. The Registrant may not allow the permit to lapse until all Controlled Substances are spent, disposed of, or transferred to another registered person.

All faculty, staff, and students are responsible for full compliance with state and federal law and DEA regulations governing the purchase, storage, use and disposal of Controlled Substances. Registrants have ultimate responsibility for ensuring proper acquisition, use, maintenance, security, accountability and disposal of Controlled Substances.

The Division of Research (DOR) Controlled Substance Program provides guidance to employees with licensing and registration, procurement, use, recordkeeping, storage, security and disposal of Controlled Substances used in research.

Training

When checking the Controlled Substance box during grant submission, the appropriate individuals responsible for Controlled Substance compliance will be notified. Following notification, the individual

requesting permission will be contacted to ensure that he/she has a DEA registration number and directed to appropriate educational material.

Training Slides (PDF)

During periodic inspections carried out by various compliance elements, both internal and external (IACUC, IRB, USDA, DEA, etc.), registrants will be informed/trained as to the appropriate procurement, use, recordkeeping, storage, security and disposal of Controlled Substances used in research.

Purchasing Controlled Substances

Registrants who purchase and receive Schedule I and II Controlled Substances must retain DEA 222 forms, purchase orders and packing receipts for two years from the date of receipt and have them available for inspection.

Registrants who purchase and receive Schedule III-V Controlled Substances must retain purchase orders and packing receipts for two years from the date of receipt and have them available for inspection.

Storage of Controlled Substances

Storage of Controlled Substances must comply with federal requirements. Registrants are responsible for establishing and maintaining effective controls and procedures to prevent unauthorized access, theft or diversion of Controlled Substances.

Registrants are directly responsible for:

- Establishing adequate security to prevent unauthorized access to Controlled Substances.
- Establishing adequate security to prevent the diversion of Controlled Substances.
- Storing Controlled Substances listed in Schedules I-V in a secured location and in a securely locked, substantially constructed cabinet, or security cabinet (i.e., not easily broken into or moved; see 21 CFR § 1301.71-1301.76).

Reporting Theft, Unauthorized Use, or Significant Loss of Controlled Substances

The Registrant must notify the local DEA office orally within one business day after the discovery of theft or significant loss of any Controlled Substances as prescribed by 21 C.F.R. 1301.76. A written report to the DEA, using DEA Form 106 (https://www.deadiversion.usdoj.gov/21cfr_reports/theft/), must be submitted within 15 days after the discovery. The Animal Welfare Office should be notified along with the DEA when the DEA is initially notified and when the written report is sent to the DEA.

Theft or significant losses must be reported whether or not the Controlled Substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

Inventory Records of Controlled Substances

The Registrant is responsible for maintaining appropriate records and inventories of all Controlled Substances where licensed activity is conducted at the University for the period of time as specified in the System Policy 61.99: Records Retention, as part of the registration requirements (21 CFR § 1304.04 and 1304.11). Complete and accurate Controlled Substance records must provide a complete audit trail, from purchase, receipt or acquisition to their dispensing or disposal and must be readily available for review by DOR compliance personnel or other authorized regulatory agencies. Registrants should use the Controlled Substances Record or an equivalent form consistent with 21 CFR § 1304 (https://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_04.htm).

Records pertaining to Controlled Substances in Schedule I and II must be maintained separately from all other records of the Registrant. Records for Schedule III, IV, and V controlled substances must be maintained either separately from all other records of the Registrant or in such form that the information required is readily retrievable from the ordinary business records (21 CFR § 1304.04).

Use of Controlled Substances

The Registrant must maintain a record of the acquisition, administration, and disposal for each Controlled Substance included on his or her inventory.

Only the Registrant and Authorized Agents may access the secure storage cabinets for Controlled Substances. The Registrant must ensure that a current list of Authorized Agents is on file.

Controlled Substances may not be sold, furnished, or transferred except as permitted by state and federal laws and regulations.

Disposal of Controlled Substances

The Registrant is responsible for the return or disposal of Controlled Substances in accordance with federal and state requirements. The Environmental Health and Safety Office can provide assistance and guidance in this area.

The Registrant must document the disposal of Controlled Substances (https://www.dea diversion.usdoj.gov/21cfr_reports/surrend/), and a copy of DEA Form 41 (https://www.dea diversion.usdoj.gov/21cfr_reports/surrend/41_form.pdf) must be maintained with the Registrant's records to provide accountability for the disposal of these Controlled Substances.

When a Registrant leaves the university or rescinds their license, arrangements for disposal and/or transfer of all his/her Controlled Substances must be made prior to departure or license termination.

Failure to Comply

Failure to comply with federal and state requirements may result in personal, civil, and /or criminal liability. In addition, noncompliance may result in University disciplinary action and/or suspension or termination of research.

Related Statutes, Policies, or Requirements

21 U.S.C. 801, et. seq.

21 C.F.R. 1300, et. seq.

Texas Health and Safety Code Chapter 481 Texas Controlled Substances Act

Memorandum of Understanding (MOU) between the Texas Department of Public Safety (DPS) and the Texas Higher Education Coordinating Board (THECB)

<http://www.theccb.state.tx.us/reports/PDF/1210.PDF>

System Policy 61.99: Records Retention

Forms

DEA Form 41

DEA Form 160

Contact Office

Animal Welfare Office


[Home](#) / [Other Programs](#) / [Controlled Substances Guidelines](#)

[Division of Research](#) | [Privacy & Security](#) | [Contact Us](#) | [Site Map](#)

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Texas A&M University
Controlled Substances Guidelines
Training Module
September 2017



DIVISION OF RESEARCH

Applicability

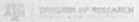
- Guidelines for the purchase, storage, use, and disposal of controlled substances used in research and teaching activities at Texas A&M University.



RESEARCH COMPLIANCE & BIOSAFETY

Licensing and Registration Requirements

- Investigators and teaching faculty who use, or plan to use, controlled substances in their research or teaching must register with the federal Drug Enforcement Agency (DEA) and obtain a license.
- The license/registration must be obtained prior to purchasing and using controlled substances.



RESEARCH COMPLIANCE & BIOSAFETY

Obtaining DEA registration

- You may register on-line <https://www.dea diversion.usdoj.gov/>
- You may obtain the DEA forms at any area office of the DEA.
- Registration assistance is available at 1-800-882-9539 or at DEA.Registration.Help@usdoj.gov

DEPARTMENT OF JUSTICE
DIVISION OF RESEARCH RESEARCH COMPLIANCE & BIOSAFETY

Definitions

- **Authorized Agent:** a co-investigator, graduate student, post doc or member of laboratory staff authorized by the registrant to access the secure storage cabinet, dispense, administer, and log controlled substances.
- **Controlled Substance:** A drug or chemical whose manufacture, possession, or use is regulated by a government, such as illicitly used drugs or prescription medications that are designated a controlled drug. The current official schedule of controlled substances (I, II, III, IV and V) can be found at <https://www.dea diversion.usdoj.gov/21cfr/cfr/2108cfrt.htm>

DEPARTMENT OF JUSTICE
DIVISION OF RESEARCH RESEARCH COMPLIANCE & BIOSAFETY

Definitions

- **Clinical Setting:** A setting where a controlled substance is used in a medical or veterinary application.
- **Non-Clinical Settings:** A setting where a controlled substance is used in research, teaching or testing, which is not a clinical usage of the controlled substance.
- **Registrant:** An individual who is registered with the DEA and whose name is on the DEA license.

DEPARTMENT OF JUSTICE
DIVISION OF RESEARCH RESEARCH COMPLIANCE & BIOSAFETY

Responsibilities of the Registrant

- Investigators and teaching faculty who use controlled substances in the University's non-clinical settings must obtain and keep a current DEA license/registration.
- Registrants may not allow the license/registration to lapse until all controlled substances are spent, disposed of, or transferred to another registered person.

DIVISION OF RESEARCH RESEARCH COMPLIANCE & BIOSAFETY

Responsibilities of the Registrant

- All faculty, staff and students are responsible for full compliance with state, and federal law and DEA regulations governing the purchase, storage, use, and disposal of controlled substances.
- Registrants have ultimate responsibility for ensuring proper acquisition, use, maintenance, security, accountability, and disposal of their controlled substances.

DIVISION OF RESEARCH RESEARCH COMPLIANCE & BIOSAFETY

Screening and Authorizing Agents

- Registrants are responsible for all security provisions pertaining to the controlled substances in accordance with the requirements of the regulations.
- Authorized agents of the registrant may engage in approved activities under the direction of the registrant.

DIVISION OF RESEARCH RESEARCH COMPLIANCE & BIOSAFETY

Purchasing

- Registrants who purchase and receive Schedule I and II controlled substances must retain DEA 222 forms, purchase orders and packing receipts for two years from the date of receipt and have them available for inspection.
- Registrants who purchase and receive Schedule III-V controlled substances must retain purchase orders and packing receipts for two years from the date of receipt and have them available for inspection.

 DIVISION OF RESEARCH

RESEARCH COMPLIANCE & BIOSAFETY

Inventory Records

- Registrants are responsible for maintaining appropriate records and inventories of all DEA controlled substance activity for a minimum of two years from the initial receipt.
- Records must provide a complete audit trail, from purchase, receipt or acquisition to dispensing or disposal.
- Records must be readily available for review by compliance personnel or other authorized regulatory agencies.

 DIVISION OF RESEARCH

RESEARCH COMPLIANCE & BIOSAFETY

Inventory Records


- Registrants must maintain a real-time record of the acquisition, administration, and disposal for each DEA controlled substance included on his or her inventory.
- The registrant must document the use of each DEA controlled substance.

 DIVISION OF RESEARCH

RESEARCH COMPLIANCE & BIOSAFETY

Inventory Records

- Records pertaining to controlled substances in Schedule I and II **must** be maintained separately from all other records of the registrant.
- Records for Schedule III, IV, and V controlled substances **may** be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records.

 DIVISION OF RESEARCH

RESEARCH COMPLIANCE & BIOSAFETY

Storage of Controlled Substances

- Storage of controlled substances must comply with federal requirements.
- Registrants are responsible for establishing and maintaining effective controls and procedures to prevent unauthorized access, theft or diversion of controlled substances.
- The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized agents. When it is necessary for non-authorized persons to enter the storage areas, the registrant shall ensure adequate observation by an authorized person.

 DIVISION OF RESEARCH

RESEARCH COMPLIANCE & BIOSAFETY

Storage of Controlled Substances

- Registrants are directly responsible for:
 - Establishing adequate security to prevent unauthorized access to controlled substances.
 - Establishing adequate security to prevent the diversion of controlled substances.
 - Storing controlled substances in a secure location and in a securely locked, substantially constructed cabinet, or security cabinet (i.e., not easily broken into or moved).

 DIVISION OF RESEARCH

RESEARCH COMPLIANCE & BIOSAFETY

Disposal of Controlled Substances

- The registrant is responsible for the return or disposal of controlled substances in accordance with federal requirements.
- Texas A&M University Environmental Health and Safety Office will provide assistance and guidance in this area.
 - Environmental Health and Safety will work with a reverse distributor on an individual basis to assist registrants with disposal of controlled substances.
 - Contact Jeffery Truss (jctruss@tamu.edu) or EHS (ehsd.tamu.edu) for assistance.

 DIVISION OF RESEARCH

RESEARCH COMPLIANCE & BIOSAFETY

Destruction and Disposal Records

- Registrants must document the disposal of controlled substances and a copy of DEA Form 41 must be maintained with the registrant's records to provide accountability for the disposal of these controlled substances.
- When a registrant leaves the University or rescinds their license, arrangements for disposal and/or transfer of all their controlled substances must be made prior to departure or license termination.

 DIVISION OF RESEARCH

RESEARCH COMPLIANCE & BIOSAFETY

Reporting Significant Loss

- The registrant must notify the local DEA field office (Houston) in writing within **one business day** after the discovery of theft or significant loss of any DEA controlled substances. A written report to the DEA, using DEA Form 106, must be submitted within 15 days after the discovery.
- The University Police Department and Animal Welfare Office should be notified along with the DEA.
- Theft or significant losses must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

 DIVISION OF RESEARCH

RESEARCH COMPLIANCE & BIOSAFETY

Failure to Comply

- Compliance with all federal regulations is the sole responsibility of the Registrant as the DEA license holder and may result in personal, civil, and/or criminal liability.
- Failure to comply may also result in University disciplinary action and/or suspension or termination of research.

 DIVISION OF RESEARCH

RESEARCH COMPLIANCE & BIOSAFETY

Links to DEA forms

- DEA Registration <https://www.deadiversion.usdoj.gov/>
- DEA Form 41 (Disposal of Controlled Substances) https://www.deadiversion.usdoj.gov/21cfr_reports/surrend/41_form.pdf
- DEA Form 106 (Reporting a Significant Loss) https://www.deadiversion.usdoj.gov/21cfr_reports/theft/

 DIVISION OF RESEARCH

RESEARCH COMPLIANCE & BIOSAFETY

Texas A&M University's Controlled Substance Program

- Texas A&M University's Controlled Substance Program is housed in the Division of Research's Animal Welfare Office.
- The Controlled Substance Program provides guidance to investigators and research staff on obtaining a DEA registration/license.
- The Controlled Substance Program provides registrants with information pertaining to procurement, record keeping, storage, security, and disposal of controlled substances used in research.

 DIVISION OF RESEARCH

RESEARCH COMPLIANCE & BIOSAFETY

Contact Information

- Animal Welfare Office
 - 979-845-1828
 - animalcompliance@tamu.edu

- Tennille Lamon, DVM, MS, CPIA
Director, Animal Welfare Office

DAVIDSON OF RESEARCH RESEARCH COMPLIANCE & BIOSAFETY

Human Research Protection Program

Updates - 10.3.2017

FDA Educational Presentation – October 12, 2017 @1:00

Ms. Alanna Bias, Supervisory Consumer Safety Officer-Investigator, from the **Food and Drug Administration (FDA)** to speak on campus on October 12. The event will be held at the **Thomas G. Hildebrand, DVM '56 Equine Complex from 1:00-3:00 p.m.**

Boxed lunches will be available at 12:30 p.m. with the presentation beginning at 1:00 p.m. The session will also be available via audio connection.

The presentation will cover the following information:

- When is an **IND** (Investigational New Drug Application) required in human research?
- When does human research with new investigational **devices** require an **IDE** (Investigational Device Exemption)?
- When does human research with nutritional **supplements** or conventional **foods** require an IND?
- **Documentation** requirements for human research involving test articles.

The event requires an RSVP. There is no cost to attend. For more information about the event or to RSVP (note if you will need login information for the audio feed), please contact Texas A&M's Office of Research Compliance and Biosafety Outreach at outreachrcb@tamu.edu or **979-458-1467**.

AAHRPP Re-Accreditation Status

Step 1 clarifications are complete.

Step 2 documents are due by October 10th.

The site visit is expected during the first quarter of 2018.

<http://www.aahrpp.org/>

Revised Common Rule Overview – Effective and Compliance Date January 19, 2018

There has been no information on the delay of the compliance data as requested by these groups, AAMC, AAU, APLU, COGR, and many others.

The revised rule is applicable to new research that will be approved on or after compliance date. Research approved prior to this date will remain under the current Common Rule unless switched to the revised Common Rule requirements.

Ongoing previously approved research must comply with the new requirements before it can be switched. This determination is to be made on a **study-by-study basis**. It has been recommended by industry experts to make this determination at the time of continuing review. The switch must be documented in the records.

Highlights of the Final Rule

New and Revised Definitions:

- The final rule provided new and revised definitions, including: “clinical trial,” “human subject,” “intervention,” “private information,” “identifiable private information,” “identifiable biospecimen,” “minimal risk,” “research,” and “written or in writing” (to include electronic formats). (§____.102).
- **Clinical Trial.** Clinical trial was not defined in the previous version of the Common Rule. A clinical trial is “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.” (§____.102(b)).
- **Human Subject.** (§____.102(e)).
- The definition of “human subject” was expanded to cover the collection of biospecimens. The new definition includes “a living individual about whom an investigator, whether professional or student conducting research: (i) *obtains information or biospecimens* through intervention or interaction with the individual, *and uses, studies, or analyzes the information or biospecimens*; or (ii) *Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.*”

Activities deemed not to be research. Four new activities are deemed to not be “research”:

- Scholarly and journalistic activities (e.g. oral history, journalism, biography, literary criticism, legal research, and historical scholarship);
- Public health surveillance activities;
- Collection and analysis of information, biospecimens, or records for criminal justice or criminal investigative purposes; and
- Certain activities in support of intelligence, homeland, security, defense, or other national security missions. (§____.102(l)).

Broad Consent will be allowed for prospective consent of unspecified future research from the subject for storage, maintenance and secondary research use of identifiable private information and identifiable specimens. When broad consent is in place, other mechanisms for access identifiable data and specimens may not be applicable (de-identification, waivers of consent, study specific consent).

New Exempt Categories 7 and 8 apply to broad consent. Broad consent is a useful option for entities that provide medical or behavioral treatments that have appropriate tracking mechanisms.

Consents documents for Clinical Trials must be posted online.

Limited IRB Review is a new term that requires a board member to verify that appropriate confidentiality measures are in place. The current Common Rule allows an institution to delegate exemption determinations to individuals outside of the board (qualified staff); however, the Revised Common rule requires limited IRB review of exempt research be carried out by a board member. Limited IRB review is required for certain parts of Exempt Category 2 (educational, survey, interview research); parts of Exempt Category 3 (benign behavioral interventions); Secondary research on specimens or data; where identifiers are collected in each of these exempt categories;

Continuing Review is no longer a requirement for certain research that is no more than minimal risk and qualifies for expedited review. We are waiting for the OHRP update to the Expedited Review categories. An IRB may choose to require continuing review of such research as long as the rationale is documented. It is unclear at this time the extent of what qualifies as appropriate rationale for ongoing continuing review of minimal risk research. However, investigators are still required to submit all modifications and report all new information such as unanticipated problems, noncompliance, complaints, etc., on minimal risk research that qualifies for expedited review. Leading industry experts suggest that there needs to be some type of periodic 'check-in'. The FDA has not aligned it's regulations with this revision.

Use of a Single IRB for Cooperative Research effective January 19, 2020.

- A single IRB must approve cooperative (projects that involve more than one institution) studies for research conducted in the United States, except where:
- More than a single IRB review is required by law (including tribal law); or
- Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate. (§ _____.114)).
- The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of such Federal department or agency.

Additional things to consider include:

How will an institution/IRB manage research under 2 versions of the Common Rule simultaneously? We recently received information from the iMedRIS group that may help: iRIS can be updated to manage the flow of information required for this task.

Revised Common Rule: <https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf>

National Institutes of Health (NIH) Changes

The NIH has adopted from the Revised Common Rule the **definition of Clinical Trial** and will be effective January 25, 2018.

Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health related outcomes.

This definition has a broader scope to include evaluations of health related biomedical or behavioral interventional studies, pilot/feasibility studies, exploratory/developmental studies and large-scale efficacy studies. Other requirements come along with this change in definition.

Good Clinical Practice Training was required as January 1, 2017 of all investigators involved in the design, conduct, oversight, or management of clinical trials. This will now include a wider group of investigators including those doing behavioral studies. CITI offers a GCP course for social and behavioral researchers that will meet the NIH training requirements.

Registration and reporting on Clinicaltrials.gov is applicable to all NIH funded clinical trials instead of a subset of applicable clinical trials. The lead investigator will be responsible for registration no later than 21 days after enrolling the first subject, updating the information on the website at least once every 12 months and providing a summary of the results no later than one year after completion of the study.

Use of a Single IRB is required effective January 25, 2018 for multi-site studies where each site will conduct the same protocol supported by NIH funds through grants, cooperative agreements, sub-awards or contracts. Unless our operational system becomes multi-site research compatible we may have to use mechanisms such as Smart IRB or enter into other reliance agreements. The primary institution may request direct cost funding for the additional costs associated with single IRB review of multisite research. Delayed-onset determinations are still applicable when appropriate.

NIH Compliance - <https://grants.nih.gov/policy/clinical-trials/reporting/steps.htm>

NIH Human Subjects - <https://humansubjects.nih.gov/>

NIH Certificate of Confidentiality (CoC)

NIH released information of September 7, 2017 that a CoC will automatically be issued when a study involves identifiable sensitive information effective **October 1, 2017** for all research that was commenced or ongoing on or after **December 13, 2016**. The term “identifiable, sensitive information” means information about an individual that is gathered or used during the course of biomedical, behavioral, clinical, or other research, where the following may occur:

- An individual is identified; or
- For which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

This includes categories of exempt research, research with bio-specimens for which there is even a small risk of identifying the subject, research generating genomic data from bio-specimens and any other type of NIH supported research for which there is even a small risk of identifying the subject.

When the CoC is issued the Investigator’s shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or bio-specimen that contains identifiable, sensitive information about the individual unless consent is obtained.
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or bio-specimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Disclosure is permitted only when:

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Necessary for the medical treatment of the individual to whom the information, document, or bio-specimen pertains and made with the consent of such individual;
- Made with the consent of the individual to whom the information, document, or bio-specimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

The institution is to inform any third party that receives the identifiable sensitive information that they must also abide by these conditions.

CoC Regulation: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>

***For studies that are already in progress that have continuing subjects or are continuing to enroll new subjects, the investigators will be required to update the consent document to include language about the CoC. Suggested consent language is published on the NIH website: <https://humansubjects.nih.gov/coc/suggested-consent-language>**

Guidelines for Good Clinical Practice (GCP) E6 (R2) - Released in November of 2016.

GCP guidelines affect FDA regulated research and clinical trials. The fundamental differences between the R1 and R2 version of the guidelines are in respect to sponsor/investigator responsibilities and risk-based monitoring. Significant changes are to the following areas:

Investigator Responsibilities

The investigator should assure that there is a suitable monitoring plan in place to supervise the all study personnel engaged in the study.

Adequate Resources

The duty of the principal investigator (PI) is to oversee the “individual or party to whom the investigator delegates study tasks conducted at the trial site” even if it is outsourced to a third-party organisation. The PI to “ensure this party is qualified to perform those study tasks and should implement procedures to ensure the integrity of the study tasks performed and any data generated”.

Records and Reports

The investigator must maintain records of the documents for critical processes and clear documented evidence of the PI’s oversight and involvement in the trial; ensure the protocol, and applicable regulations are followed; ensure the integrity of all data;

Sponsor

This section has experienced the largest modification, with a total of 16 new items added to the R2 version. The revised part offers a very detailed view of the sponsor’s responsibilities, including quality management, CRO, trial management, data handling, record keeping and noncompliance.

Quality Management

The sponsor is required to implement a system to manage quality throughout the design, conduct, recording, evaluation, reporting and archiving of clinical trials”, and that the sponsor “should focus on trial activities essential to ensuring human subject protection and the

reliability of trial results. The sponsor must also employ a risk-based approach to monitor the clinical trial.

Contract Research Organization - CRO

The sponsor must “ensure oversight of any trial-related duties”, and “should document approval of any subcontracting of trial-related duties and functions by a CRO”.

Trial Management, Data Handling and Record Keeping

The sponsor is to have written procedures in place for all electronic systems that address “validation and functionality testing, data collection and handling, system maintenance, system security measures, change control, data backup, recovery, contingency planning and decommissioning”.

Noncompliance

When noncompliance occurs, the sponsor should perform a root cause analysis and implement a corrective and preventive action plan. Grave violations of the rules or protocol must be reported immediately to the regulatory authorities.

https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2_Addendum_Step2.pdf

Federalwide Assurance Information

This paragraph was copied from the revised Final Rule Response to Comment Section:

*“We also considered the alternative of maintaining the pre-2018 standard of allowing institutions to voluntarily extend their FWAs to nonfederally funded research. We concluded that this alternative would not further the expressed goal of increasing the application of consistent protections to clinical trials, regardless of the source of support, because the extension of the FWA would be optional. **We therefore plan to implement the proposed nonregulatory change to the assurance mechanism to eliminate the voluntary extension of the FWA to nonfederally funded research’.**”*

<https://www.federalregister.gov/d/2017-01058/p-130>

Questions may be emailed to the HRPP Director, Aliese Seawright, at the following address: a.seawright@tamu.edu.



TEXAS A&M UNIVERSITY EXPORT CONTROL SHIPPING GUIDELINES FOR PRINCIPAL INVESTIGATORS

October 2017 *

Fundamental Research Exclusion

Much of your research may be excluded from United States (U.S.) export controls, if it meets the definition of “Fundamental Research” under the Fundamental Research Exclusion¹. However, this exclusion *does not* extend to physical items (including but not limited to chemicals and biologicals) being shipped, mailed or carried (exported) out of the U.S. Everything that crosses the U.S. border is an export: even if it’s temporary, even if it wasn’t sold, even if it will be used for Fundamental Research.

What You Should Know Before You Export a Physical Item

Texas A&M University (TAMU) does not have a centrally controlled international shipping department. However, the Export Controls Office (ECO) (<https://vpr.tamu.edu/resources/export-controls>) is here to support you if you need to export an item or items, to facilitate your research. If you have questions or concerns, please contact the ECO at exportcontrols@tamu.edu or telephone 979-862-6419. Alternatively, you can contact the TAMU Export Control Director, Rayland C. VanNorman at Raylandc@tamu.edu.

All U.S. origin items will be controlled for export to a U.S. Embargoed or Sanctioned country². Depending on the circumstances, an Export License Exception may apply. Please contact the ECO if you are planning a research trip to one of the countries listed.

Every U.S. export is an import to another country. All shipments will need to go through Customs in the destination country. Some items may be prohibited or require prior authorization. Some items may incur duty or VAT (Value Added Tax) costs.

Things to Consider Doing:

- Use an experienced freight forwarding company to assist you with all the U.S customs, export and shipping requirements, as well as proper packaging to ensure safe delivery of your item. For example, TAMU has a successful history with Lognet Worldwide Inc. (<http://lognetworldwide.com>) as an International Logistics partner. The TAMU contact at Lognet is Mr. Van Clark Van_Clark@lognetworldwide.com (please note there is a “_” between Van and Clark) or office telephone +1-281-449-5067.

¹ 15 C.F.R. § 734.8c, 22 C.F.R. § 120.11

² <https://www.bis.doc.gov/index.php/policy-guidance/country-guidance/sanctioned-destinations>
https://www.pmdotc.state.gov/embargoed_countries/

A freight forwarder/broker can help with documentation. Remember the shipper of record (“Principal Party of Interest” or PPI) is responsible for what the documentation says. The forwarder may not have the familiarity with the item to determine the correct Export Control Classification Number (ECCN) or tariff code, and value. Errors can lead to delays, expense and/or legal issues.

- Alternatively, work with the vendor or manufacturer of the item to be exported and request that they ship the item(s) internationally, on your behalf. They should be very familiar with the U.S. export control requirements, as these requirements relate to their product(s).

If business needs dictate that you cannot use either of the above options, please contact the TAMU ECO for support. To avoid unnecessary delays in your research, please contact the ECO as soon as you reasonably believe that you may have an export concern. Depending on the complexity of the item(s) and if perhaps an Export License is needed, the process could take six weeks or longer to complete.

Why the U.S Government Regulates Exports and What is Subject to These Regulations

The U.S. government controls certain items from export for various reasons, such as: national security, nuclear non-proliferation, regional stability, etc. For some examples of the types of items that may be export controlled, please see Attachment A. This list ***is not*** an exhaustive list. Items not listed may still be export controlled. Please contact the ECO if you think you might have an export controlled item.

TAMU Hazardous Material Shipping

<https://ehsd.tamu.edu/Pages/HazMatShipping.aspx>

TAMU Export Control Manual

<https://vpr.tamu.edu/resources/export-controls/export-control-manual/view>

Texas A&M University
Export Control Office
154C Joe H. Reynolds Medical Sciences Building
206 Olsen Boulevard
2407 TAMU | College Station, TX 77843-2407
Main: 979.862.6419
exportcontrols@tamu.edu

ATTACHMENT A

The following list illustrates, by example, the types of dual use (and potentially higher risk/controlled) equipment commonly found in research laboratories and for which Principal Investigators should identify/request classification:³

- Measuring and sensing devices
- Gas movement and filtering devices
- Precision tooling, positioning and balancing instruments
- Optical and photonic components (including sensors, infrared and focal plane array detectors)
- Oscilloscopes; spectrometers; fermenters
- Nuclear/radioactive transport or shielding equipment
- Class 3 and 4 lasers, and related precision beam equipment
- Semiconductor substrate and etching development equipment and processes
- Fiber optic cable development equipment
- Marine submersible equipment (including hydrophones, signal receiving/emitting devices, pingers, acoustical releases, submersible video and television apparatus, etc.)
- Unmanned aerial vehicles (drones)
- Inertial navigation systems and related instruments
- Remotely operated vehicles (ROVs)

While vendors often self-identify ITAR items, Principal Investigators should nonetheless remain aware that, in the event that the vendor does not self-identify, the following types of items are often ITAR controlled. In general, these types of items would be used by the following research disciplines: marine, geological, geographic, and atmospheric research.

- Night vision goggles, infrared cameras
- Gravimeters
- Equipment on loan from federal sponsors
- Sonobuoys and deep oceanic position signaling devices
- Military-band communications systems or GPS
- DOD funded military electronics
- Submersible vessels and related remotely operated accessories
- Inertial navigation units, modem chips, and components
- Radar applications
- Wind tunnel apparatus

³ This list is not intended to be comprehensive of all possible dual use instruments.

Texas A&M System Announces Unmanned Aircraft Systems Regulations

September 19, 2017



By Texas A&M University Environmental Health and Safety

In accordance with the new [System Regulation on Unmanned Aircraft Systems \(UAS\)](#), Texas A&M University has established a Supervising Authority to review and approve unmanned aerial system (UAS)/drone flights that occur on campus. These rules apply to faculty, staff, students, visitors, and contractors on campus property and to university employees operating UAS off-campus as part of their job responsibilities.

There are three ways to fly UAS at Texas A&M University:

1. In accordance with an FAA-issued Public COA.
2. In accordance with FAA Part 107 rules.
3. For educational purposes

For other types of UAS flights (not captured through one of the three categories identified, contact EHS at ehsd@tamu.edu.

To fly UAS in accordance with an FAA-issued Public COA or in accordance with FAA Part 107 rules:

1. Submit your application to the Texas A&M University UAS Supervising Authority through the following link: <https://www.tamus.edu/business/risk-management/uas/uas-application/>. Applications should be submitted a minimum of 15 business days before desired flight.
2. Attach all requested documentation to ensure delays are avoided.
3. Completed on-line applications will be reviewed by the Supervising Authority; any questions will be directed to the individual who completed the application.
4. All University-owned or acquired UAS must be properly registered in accordance with FAA requirements. Use the FAA's Web site to register UAS: <https://registermyuas.faa.gov/>. Additionally, all UAS must be placed on inventory and have an asset number assigned.