Clinical Trials Office and Biospecimen Repository

Clinical trials are experimental studies to test how well a potential new medical treatment will work. As such, clinical trials represent the cutting edge of medicine – the place where new research findings are tested to improve the treatment of diseases that affect our animals and best friends. Directed by Dr. Cheryl London and a team of veterinarians and technical staff, the mission of the Veterinary Medicine Clinical Trials Office (CTO) at The Ohio State University is to provide assistance in the design, execution, and evaluation of veterinary clinical trials using client-owned animals, with the overriding goal of advancing the diagnosis and treatment of disease in veterinary patients while enhancing the health of humans. The CTO provides guidance to researchers to help them create the best possible clinical trial. This guidance includes:

- Helping to identify criteria for patient enrollment,
- Ensuring the best tools and statistics are used to measure the treatment’s effectiveness,
- Assessing the risk for potential adverse events,
- Confirming compliance with hospital and sponsor guidelines.

In addition, the CTO has established a broad regional network of specialists, veterinarians, and breed clubs to assist with patient enrollment.

The Tissue Bank (Biospecimen Repository) is closely linked with the CTO. The Tissue Bank obtains consent from owners to collect samples of tumors and normal tissue from dogs and cats, and to store these tissues under controlled conditions. These tissues can then be used by researchers to further understand how diseases such as cancer develop and also to develop new treatments that can be used in both animals and people. These partnerships between owners, veterinarians, and researchers ensures the advancement of medical treatment options for our patients.

A list of current clinical trials can be found at [http://vet.osu.edu/research/recruiting-clinical-trials](http://vet.osu.edu/research/recruiting-clinical-trials)
Dr. Thomas Rosol named to committee for the National Academy of Sciences

Dr. Rosol has been appointed to the 14-person Committee on Federal Regulations and Reporting Requirements: A New Framework for Research Universities in the 21st Century chaired by Larry Faulkner (president emeritus, University of Texas Austin) on behalf of the National Research Council of the National Academy of Sciences. The committee was charged by Congress to conduct a study of Federal regulations and reporting requirements with specific attention to those directed at research universities.

As the only veterinarian among this pool of internationally recognized researchers, Dr. Rosol adds an important voice and perspective to this committee that will provide recommendations that are hoped will positively impact investigators across the nation, including those in our college studying the mechanisms and treatment of human and animal diseases.

The Committee had its first meeting on February 12-13 in Washington D.C. and will meet 5 more times over the next year. The Committee has been convened under the auspices of the Committee on Science, Technology, and Law (CSTL) and the Board of Higher Education and Workforce (BHEW) to conduct a study of Federal regulations and reporting requirements with specific attention to those directed at research universities. Specifically, the committee will:

(1) Identify the Federal regulations with significant impact, and the reporting requirements with which research universities must comply,
(2) Work with congressional committees with jurisdictional responsibility for regulatory oversight and research funding,
(3) Demonstrate methodologies for estimating the personnel time and costs of compliance to research universities, and
(4) Recommend steps needed to implement the framework.

Think of a single problem confronting the world today. Disease, poverty, global warming … If the problem is going to be solved, it is science that is going to solve it. Scientists tend to be unappreciated in the world at large, but you can hardly overstate the importance of the work they do. - Bill Bryson
**Discovery Themes Initiative – Infectious Disease Focus Area**

The Infectious Disease focus area proposal for the Discovery Themes Initiative (DTI), led by Dr. Mike Oglesbee, was approved to move forward after being reviewed as the highest ranking application in the Emerging and Re-Emerging Disease area in response to the DTI second RFP. In addition to long-term goals of building external partnerships, the proposal outlines near-term goals to hire numerous research-intensive faculty that will build upon infectious disease strengths at OSU, filling key gaps in the areas of:

- Antibiotic discovery and optimization
- Treatment and prevention of emerging viruses
- Immunity to intracellular pathogens
- Local microbial communities
- Pathogen emergence
- Social networks and health policy

**New Faculty Hires**

Through the DTI, the Office of Academic Affairs (OAA) will provide half of the salary and start-up costs for new faculty positions, with the balance being covered by colleges. The first 14 tenure-track faculty hires have been approved, and hiring authorizations given for eight. Three positions will be in VBS - two as partnerships with Microbial Infection & Immunity (MMI):

- Drug discovery – viruses: 100% VBS position; VBS as tenure initiating unit (TIU)
- Adaptive immunity to viruses: 70% VBS/30% MMI; VBS as TIU
- Novel vaccine strategies: 70% MMI/30% VBS; MMI as TIU

**Cathie Smith, Program Manager of the Infectious Disease DTI**

Cathie’s position is funded by OAA and reports directly to the Associate Vice President for the Industry Liaison Office (ILO). She has extensive experience in managing complex, inter-institutional initiatives in the health sciences space that include partnerships between industry, academia and National Laboratories. As the dedicated Program Manager of the Infectious Disease DTI, Cathie will ensure strategic alignment of the program with overarching goals of the DTI, will help define programmatic activities to support the direction of the program, and will manage activities of both internal and external partners.

With her office in Goss Laboratory, she has access to the DTI faculty lead and, at the same time, is embedded in a department that is very active in infectious disease research with demonstrated success in IP commercialization and productive relationships with industry. She will also spend some of her time in Bricker Hall, remaining networked with colleagues in ILO who have additional industry connections and with program managers of other DTI focus areas.

*There is no more powerful engine driving an organization toward excellence & long-range success than an attractive, worthwhile, achievable vision of the future, widely shared.*

- Burn Nanus
Sue Ringler was recognized for her work as the Volunteer of the Month for Susan G. Komen Columbus. Sue has supported the Race for the Cure for 10 years, joined the education committee & recently became a Komen Ambassador. Komen Ambassador’s volunteer to educate members of the community about Komen Columbus resources. In addition to her effort with Komen Columbus, Sue also helps to deliver Meals on Wheels. For over 30 years, Sue has worked for Dr. Steve Krakowka in VBS as a laboratory link between gnotobiology, immunology, virology and bacteriology. Currently she is also responsible for the departmental IVIS (In Vivo Imaging System) & PCR Core. Kudos Sue! (pictured with rescue dog Ernie).

Presentations

- Pepper V, **Clark ES**, Best C, Onwuka E, James I, Breuer C. A Murine Model of Endocardial Fibroelastosis. American Heart Association’s Ignite Research Reception
- **Wu, L.** Mechanisms Underlying HIV-1 Restriction in Myeloid Cells, University of Rochester Medical Center
- The CL Davis Foundation Newsletter featured **Dr. Rachel Cianciolo** for her comprehensive overview of urinary system pathology at the Australian Society for Veterinary Pathology. Presentations included a guide to the various etiologies of canine glomerulonephridites and validation of novel urinary biomarker assays to detect renal injury.

*When you know better, you do better.*

- Maya Angelou
New grants, awards, and service!

MicroRNA Profiling in Dogs with Chronic Kidney Disease Caused by Glomerular Diseases. Co-Investigators: Mary Nabity, Rachel Cianciolo, Beiyan Zhou; AKC Canine Health Foundation.

HIV-1 Interactions with Host Factors: Mechanisms and Therapy. PI: Li Wu. Co-PIs: Jesse Kwiek, Karin Musier-Forsyth, Kristine Yoder; 2014 Life Sciences Network (LSN) Interdisciplinary Science Proposal Development Fund. This award is specifically allocated to promote the growth of active interdisciplinary faculty research groups that plan to submit a large (> $3M), multi-PI external grant application in the life sciences within one year of this award. Dr. Wu and team will use the LSN Interdisciplinary Science Proposal Development Award to finalize their submission for a program project grant (PPG) to the National Institute of General Medical Sciences (NIGMS).

Investigation of the role of the transcription factor PU.1 in breast cancer bone metastasis. Eason Hildreth, Pelotonia Post-Doctoral Fellowship. Dr. Hildreth is a 2014 PhD graduate mentored by Drs. Thomas Rosol and Ramiro Toribio, currently completing a post-doc in the lab of Dr. Michael Ostrowski in the College of Medicine.


Mike Oglesbee, Special Emphasis Panel (Member), NIH/NIEHS, Pathology Peer Review and Pathology Support for the Divisions of the National Toxicology Program (DNTP) and the Division of Intramural Research (DIR) at the National Institute of Environmental Health Sciences.

A vision is not just a picture of what could be; it is an appeal to our better selves, a call to become something more. – Rosabeth Moss Kanter
True scholarship consists in knowing not what things exist, but what they mean; it is not memory but judgment  
- James Russell Lowell
Wow, more new pubs!


*The opposite of a correct statement is a false statement. But the opposite of a profound truth may well be another profound truth.*

- Niels Bohr
Publication spotlight: Human norovirus contamination of strawberries

Human norovirus is one of the most common causes of foodborne illness in the United States. The virus is often found in fresh produce such as strawberries. However, it has been unclear how contamination of fresh produce with norovirus occurs. Dr. Jianrong Li’s lab found that strawberry plants grown in infected soil can take up the virus via their root system and then store norovirus in both the leaves and the strawberries themselves. These stored viruses are resistant to the surface decontamination that is often used to clean fruit prior to sale. These findings provide important information about how some types of produce may become contaminated with foodborne diseases and should help inform treatment and intervention strategies for protecting food supplies.


Publication spotlight: Developing mucosal vaccines

Mucosal vaccines are designed to be administered at mucosal surface such as the oral or nasal cavity to induce protection against diseases that infect across mucosal surfaces – such as those encountered by the GI tract or airways. Development of strong mucosal immunity is dependent on the presence of IgA, the primary antibody found at mucosal surfaces. The development of safe effective mucosal vaccines has been hampered because adjuvants commonly used to induce strong immune responses at other sites fail to effectively induce IgA when used in mucosal vaccines. Dr. Prosper Boyaka and colleagues have identified one of the key regulatory pathways needed to induce mucosal IgA following sublingual immunization. They also show that neutrophils, a cell typically thought to be the front line of defense against bacterial infections, can inhibit production of IgA. These findings provide new strategies for investigators working to develop safe and effective mucosal vaccines.

Mucosal Immunology  http://www.ncbi.nlm.nih.gov/pubmed/25563500

Have something to contribute to BIOS? An interesting update? Someone we should highlight? A good quote or kudos you’d like to share? Please contact Robyn Luce at luce.73@osu.edu

Keep away from people who try to belittle your ambitions. Small people always do that, but the really great make you feel that you, too, can become great.
– Mark Twain