Annual Meeting of the Ohio Physiological Society at the University of Toledo

Dr. Lance Stechschulte
Postdoctoral Fellow
Department of Physiology and Pharmacology
Officer, Ohio Physiological Society

Dr. Terry D. Hinds, Jr.
Assistant Professor
Department of Physiology and Pharmacology
President, Ohio Physiological Society

The American Physiological Society (APS) is a member of the Federation of American Societies for Experimental Biology (FASEB), a coalition of 26 independent scientific societies devoted to fostering education, scientific research, and dissemination of information in the physiological sciences. The Society was founded in 1887 with 28 members and now has over 10,500 members. The National headquarters of the Society is based in Bethesda, Maryland, on the FASEB campus. The Ohio Chapter of the APS, the Ohio Physiological Society (OPS), was established in 1986, and one of the highlight events of this organization is an annual meeting. On October 17, 2015, the 30th annual meeting was hosted by the OPS President, Dr. Terry D. Hinds, Jr., and the Department of Physiology and Pharmacology at the University of Toledo College of Medicine and Life Sciences.

Fifty-seven members of OPS, including faculty members, postdoctoral fellows, graduate trainees and undergraduate students from 10 of Ohio’s universities and Colleges attended the meeting and exchanged their scientific interests rooted in Physiology. Besides funding from the OPS and the APS, the meeting was supported by Dr. Christopher Cooper, the Dean of the University of Toledo College of Medicine and Life Sciences, and other corporate sponsors.

The conference began with opening remarks from the OPS President, followed by research presentations from graduate students. The first talk was by Natalie Sirianni (University of Toledo) titled "Angiotensin II induces adipogenesis in human mesenchymal stem cells: Contributions of the HO-1-SIRT1 pathway". The second talk was given by Pavani Beesetty (Wright State University) titled "TRPM7 channel activity in transgenic mice lacking TRPM7 kinase activity". Then, Harshal Waghulde (University of Toledo) gave a talk titled "Development of a novel Gper-1 Knock out rat model using a modified CRISPR/Cas9 technology". Following this was a presentation from Alisa Blazek (The Ohio State University) titled "Walking Exercise regulates Gene Expression to Maintain Cartilage Health and alters Genes Associated with Osteoarthritis". The last talk of the session was from Xi Cheng (University of Toledo) titled "CRISPR/Cas9-based genome modification of a Novel Rat Long Non-coding RNA within a homologous GWAS associated locus for QT-intervals." The topics were diverse, and the scientific impact was reflected through the active discussions that followed each presentation. Ending the morning session was an interactive event entitled 'Networking Bingo’, an activity that enhanced interactions between meeting attendees from different Institutions.

The second scientific session opened with presentations from faculty members. The first given by Dr.
Kathleen Broomall (Miami University) titled "Chronotherapy to Normalize Fasting Blood Glucose May Attenuate Metabolic Syndrome with Hyperglycemia”. The second talk was given by Dr. Edwin Sanchez (University of Toledo) titled "Nuclear Receptor Chaperones: Fulcrums of Molecular and Metabolic Equilibria”. Both presentations received excellent questions, a testament to the enthusiasm of the attendees.

Dr. Don DeFranco from the University of Pittsburgh gave a Keynote presentation titled “Integration of genomic and non-genomic signals in embryonic stem cells”. He discussed his laboratory’s work on the risk of glucocorticoids administered to pregnant women at risk of premature delivery. His group showed that glucocorticoids increase the development of neurons at the expense of the progenitors, thus leading to a thinner cortex and decreased neurodevelopment.

After the keynote speaker, nine students presented during the Data Blitz session, which were 90 seconds in length designed to stimulate interest in the poster session. The meeting then moved into the poster room, where a total of 20 posters were displayed, presented and judged for their overall scientific caliber. The energy of the room had continued for several hours before the meeting reconvened at the Radisson Hotel for dinner and announcements of awards. Praveen Kumar Alla (Wright State Univ.) earned the prestigious Dr. Lauf travel award with an outstanding poster presentation. Two additional prizes, funded by the Office of the Dean of the University of Toledo College of Medicine and Life Sciences were given for best oral presentation and outstanding science. Alisa Blazek (The Ohio State University) was awarded the Dean Cooper best oral presentation award while Harshal Waghulde (University of Toledo) was awarded the Dean Cooper outstanding science award.

Before the meeting concluded, Dr. Peter Lauf (Wright State University) gave concluding remarks. He was enthusiastic for the young scientists, their mentors, and their research projects. He also thanked the faculty and staff at the University of Toledo for hosting a fruitful and inspiring conference.

Clinical Research Snippets

Anand B. Mutgi, MD
Sadik A. Khuder, PhD

Obesity has become a major public health problem across the world. Obesity is associated with increased morbidity and mortality. Treatment has included lifestyle changes, such as eating fewer calories and being physically active. Increase in water consumption in conjunction with caloric restriction is advocated to reduce weight. However the evidence to support this benefit is limited and is not practiced routinely. This month we review a small but well randomized controlled clinical study that evaluated the benefit of water preloading before main meals and quantified the benefits.
Efficacy of water preloading before main meals as a strategy for weight loss in primary care patients with obesity: RCT (pages 1785-1791).
Helen M. Parretti, Paul Aveyard, Andrew Blannin, Susan J. Clifford, Sarah J. Coleman, Andrea Roalfe and Amanda J. Daley


This was a UK based study with patients recruited from several general practices. Adults with BMI greater than 30 were recruited between 2013–2014. Eighty-four patients were randomized to either drinking 500 mL of water 30 minutes before main meal or control group who were asked to imagine their stomach being full before meals. Both groups received instruction on healthy diet and regular reminders. Surprisingly, after 12 weeks of observation, both groups lost weight (2.4 kg for the water loading group and 1.2 for the control group). The difference was marginally significant (p=0.063) after adjustment for demographic variables. Moreover, participants who were preloaded with water 3 times a day lost as much as 4.3 kg.

This study provides preliminary evidence of water loading before meals as a simple but effective intervention for losing weight. The effect of drinking water may be mediated through fullness of the stomach and suppressing hunger as well as a decreased energy density of stomach contents. Weight loss in the control group suggests that dietary advice in combination with periodic reminders also helps with weight loss (text message reminders). While awaiting a larger study this simple intervention and frequent reminder through text messages is an effective means of weight reduction.

Changes to the “Common Rule” for Human Subject Research Coming

Roland T. Skeel, MD
Chair, University of Toledo Biomedical IRB

On September 8, 2015, the U.S. Department of Health and Human Services (DHHS) published a “Notice of Proposed Rule Making” (NPRM) that would be the most extensive changes of rules for the protection of human subjects in research since 1981. The NPRM is seeking comment on these proposals which the Office for Human Research Protections (OHRP) has promulgated to “better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.”

Four big issues that the UT Biomedical IRB and the UT Department for Human Research Protection (DHRP) supports are: 1) Making consent forms less lengthy and more transparent and relevant; 2) requiring permission from the subject (patient) for study of biospecimens, even when the investigator is not given information that could identify the donor; 3) eliminating continuing review for many expedited studies and those where study interventions have been completed; 4) liberalizing the determination of what studies are exempt or outside the scope of the regulations.

What follows are selected sections from the NPRM 2015 Summary published by the DHHS.

"The following list encompasses the most significant changes to the Common Rule proposed in the NPRM:

1. Improve informed consent by increasing transparency and by imposing stricter new requirements regarding the information that must be given to prospective subjects, and the manner in which it is given to them, to better assure that subjects are appropriately informed before they decide to enroll in a research study.
2. Generally require informed consent for the use of stored biospecimens in secondary research (for example, part of a blood sample that is left over after being drawn for clinical purposes), even if the investigator is not being given information that would enable him or her to identify whose biospecimen it is. That consent would generally be obtained by means of broad consent (i.e., consent for future, unspecified research studies) to the storage and eventual research use of biospecimens.
3. Exclude from coverage under the Common Rule certain categories of activities that should be deemed not to be research, are inherently low risk, or where protections similar to those usually provided by IRB review are separately mandated.
4. Add additional categories of exempt research to accommodate changes in the scientific landscape and to better calibrate the level of review to the level of risk involved in the research. A new process would allow studies to be determined to be exempt without requiring any administrative or IRB
review. Certain exempt and all non-exempt research would be required to provide privacy safeguards for biospecimens and identifiable private information. New categories include:

- certain research involving benign interventions with adult subjects;
- research involving educational tests, surveys, interviews or observations of public behavior when sensitive information may be collected, provided that data security and information privacy protections policies are followed;
- secondary research use of identifiable private information originally collected as part of a non-research activity, where notice of such possible use was given;
- storing or maintaining biospecimens and identifiable private information for future, unspecified secondary research studies, or conducting such studies, when a broad consent template to be promulgated by the Secretary of HHS is used, information and biospecimen privacy safeguards are followed, and limited IRB approval of the consent process used is obtained.

5. Change the conditions and requirements for waiver or alteration of consent such that waiver of consent for research involving biospecimens (regardless of identifiability) will occur only in very rare circumstances.

6. Mandate that U.S. institutions engaged in cooperative research rely on a single IRB for that portion of the research that takes place within the United States, with certain exceptions. To encourage the use of IRBs that are otherwise not affiliated with or operated by an assurance-holding institution (“unaffiliated IRBs”), this NPRM also includes a proposal that would hold such IRBs directly responsible for compliance with the Common Rule.

7. Eliminate the continuing review requirement for studies that undergo expedited review and for studies that have completed study interventions and are merely analyzing data or involve only observational follow-up in conjunction with standard clinical care.

8. Extend the scope of the policy to cover all clinical trials, regardless of funding source, conducted at a U.S. institution that receives federal funding for non-exempt human subjects research.

In sum, the proposed modifications described above are designed to continue to uphold the ethical principles upon which the Common Rule is based, as applied to the current social, cultural, and technological environment.”


To learn more about the NPRM, the following six OHRP training videos can be accessed at [http://www.hhs.gov/ohrp/education/training/index.html](http://www.hhs.gov/ohrp/education/training/index.html)

1. Overview of the NPRM
2. Exclusions & Exemptions Under the NPRM
3. IRB Review & Operations Under the NPRM
4. Informed Consent Under the NPRM
5. Research with Biospecimens Under the NPRM
6. Secondary Research Use of Data

### New Clinical Trials

A Multicenter, Treatment-Blind Phase 3B study to Evaluate Whether 6-week Up-Titration in Tecfidera® Dose is Effective in Reducing the Incidence of Gastrointestinal Adverse Events in Patients with Multiple Sclerosis (109MS416).
Dr. Boyd Koffman - Neurology

Measuring the Improvements through the use of Dysis™ Colposcope and the Dysismap™ in Detecting Dysplasia of the Cervix.
Dr. Lance Talmadge - OB/GYN

### IRB Corner

The Biomedical IRB office processed 57 protocol related actions between the June and July IRB meetings. There are currently 50 requests for information awaiting a response from the Principal Investigator.

<p>| September - October IRB Actions |  |</p>
<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prep, New Exempt NHSR</td>
<td>1</td>
</tr>
<tr>
<td>Expedited - New, Continuing, Amend.</td>
<td>28</td>
</tr>
<tr>
<td>Convened - New, Continuing, Amend.</td>
<td>6</td>
</tr>
<tr>
<td>IRB Administrative Actions</td>
<td>10</td>
</tr>
<tr>
<td>Internal Safety Reports</td>
<td>6</td>
</tr>
<tr>
<td>Authorized for CIRB Review</td>
<td>6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>57</strong></td>
</tr>
</tbody>
</table>

**Items pending PI response:**
- July: 13
- August: 19
- September: 18
- **Total**: 50

---

**Contact Us**

Health Science Campus • Center for Creative Education Bldg.

2920 Transverse Drive, Floor 3 • Toledo, OH 43614

Phone: 419.383.6919 • ClinicalResearch@utoledo.edu