Change is an unending constant; we continue to live in interesting times. Regulatory and budget items feature prominently in the sphere of influence encompassing clinical research. We aim to keep our faculty current.

WUSTL has announced price increases for IRB review of industry-sponsored protocols, Clinical Research Unit, Siteman Cancer Center, Center for Clinical Imaging Research, and others. FDA and NIH have added regulatory requirements. An essay from the Wall Street Journal featured in this Newsletter offers an interesting perspective.

As this goes to press mid-June, we are in federal budget season. The House Appropriations Committee released the draft FY16 Labor/HHS funding bill. Prominent features include a $1.1B (3.6%) NIH budget boost to $31.2B. Much of the increase goes to Alzheimer’s disease research, an antibiotic resistance initiative, and President Obama’s Precision Medicine Initiative. The draft bill also reduces the NIH salary cap by 8%, from the current $183,300 to about $168,600. This increases the burden on universities and others receiving federal funding, to make up any difference between salaries and support from grants. Perhaps of greatest potential impact is the HHS proposal to abolish the Agency for Healthcare Research and Quality (AHRQ), which supports studies of evidence-based medicine. But this is only a draft, with considerable political manicuring and change to come. Stay tuned.

DID YOU KNOW that DoCTR provides funding for clinical research statistical consultation through ICTS, Biostatistics, or other university-based statistical services? A statistical analysis plan is critical to the development of rigorous clinical research and should be included in the early design phases of a research study. The application process is the same as for a grant proposal application. Contact Jon Bucher @ 28649 for further assistance.
NIH news in brief

NEW DEFINITION OF “CLINICAL TRIAL” FROM NIH: Clinical research as defined by NIH currently is research involving human subjects or derivatives from human subjects, epidemiological and behavioral research, and outcomes research and health services research. In this context, clinical trials are a subset of clinical research that has additional protections and oversight requirements. The revised definition states: “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 those interventions on health-related biomedical or behavioral outcomes.” Full release can be found at http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials. In addition, an NIH FAQ about the new definition will be available on the DoCTR website by the end of July.

BIOSKETCH REQUIREMENTS FOR DUE DATES ON OR AFTER MAY 25, 2015: Most of you have already started the painful process of the modified biosketch format. With your extra time and just for fun, there is more help at http://grants.nih.gov/grants/funding/424/index.htm#biosketch


NIH INCLUSION REPORTING UPDATED! Life is better. Inclusion data can now be entered directly into eRA Commons. The Inclusion Management System gives grantees the ability to update inclusion data throughout the submission process as well as the award period. Template forms are available on the DoCTR website under DoCTR Resources.
See more at: http://nexus.od.nih.gov/all/2014/10/30/new-system-for-reporting-inclusion-data-is-live/utm_source=nexus&utm_medium=email&utm_content=nihupdate&utm_campaign=oct14#sthash.ENCjs1DO.dpuf

FDA regulatory burden increases

IT’S AS BAD AS YOU THINK: The number of regulatory requirements imposed by the US Food and Drug Administration (FDA) increased by 15% between the years 2000 and 2012. http://www.raps.org/Regulatory-Focus/News/2014/10/30/20656/Its-Not-Just-You-FDA-Regulatory-Requirements-Really-Are-Increasing/
FDA—New draft IND guidance for sponsor-investigators


News from Washington University

From HRPO:

HRPO has launched a new website. The new format is visually more appealing and more user-friendly. [http://hrpo.wustl.edu](http://hrpo.wustl.edu). Part of the new design includes a page with HRPO self-reported quarterly metrics on review times, number of studies reviewed, and total study volume. [http://hrpo.wustl.edu/about/metrics/](http://hrpo.wustl.edu/about/metrics/)

NEW FEE SCHEDULE EFFECTIVE 7/2015

Revised IRB fees effective 7/2015 include new fees for industry-funded multisite studies conducted outside of the WUSM affiliates. This would apply if WUSM IRB is acting as the IRB for a non-WUSM site involved in the study through a WUSM investigator. Full fee schedule available at: [http://hrpo.wustl.edu/research-toolkit/fees/](http://hrpo.wustl.edu/research-toolkit/fees/)

myIRB LOG-IN CHANGES

Many of you may have noticed that there is another—new—interface when you log in to myIRB. HRPO is upgrading their ID Management System to improve access safeguards, while permitting users with more than one affiliation [such as student and employee] to apply any of their credentials to log in. The last stage of the upgrade is planned for summer 2015.

RADIATION RISK LANGUAGE FLOW CHART

HRPO has developed a flow chart to assist researchers who are drafting consents that include radiation risk language. The flow chart includes new language for 1) when a study involves both therapeutic and diagnostic radiation and 2) when there are diagnostic procedures that involve radiation but the exact number or type of scan(s) is unknown. The flow chart will be available in myIRB soon, and will be available on the DoCTR website under Resources by the end of July.

CENTER FOR CLINICAL IMAGING RESEARCH RELEASES NEW FEE SCHEDULE

Both the CCIR FY2015 & 2016 Fee Tables can be found at [https://www.mir.wustl.edu/research/research-support-facilities/center-for-clinical-imaging-and-research-ccir/for-pis-coordinators/study-costs](https://www.mir.wustl.edu/research/research-support-facilities/center-for-clinical-imaging-and-research-ccir/for-pis-coordinators/study-costs).
News from Washington University cont.

SITEMAN CANCER CENTER FEES UPDATED
FY16 Fee Schedules for Flow Cytometry Core and the Clinical Trials Office have been released. Both can be found on through their website at http://www.siteman.wustl.edu/contentpage.aspx?id=229 and on the DoCTR website by the end of July.

ICTS/CARS/CRU START STUDY MAINTENANCE FEE EFFECTIVE 1/1/15
A new annual $500 fee will apply to all existing and new studies conducted through ICTS CARS and CRU. Billing has already begun. Charges for individual services have not increased at this time. The fee schedule is available at http://icts.wustl.edu/mm/files/CARS%20Annual%20Fee%20ltr%207-10-14%20FINAL%20(2).pdf and will be available on the DoCTR website under DoCTR Resources tab by the end of July.

Editor’s Choice

This recent Wall Street Journal Blog discusses the declining numbers of investigators due to burdens associated specifically with clinical drug trials. A contributor to the blog posted a valuable insight that applies to all investigator-initiated research: “First time Principal Investigators often discover six facts, which they wished they knew before they started: 1) they were trained to be clinicians, not researchers; 2) trials are very time consuming and require exceptional attention to protocol details; patient documentation, and extraneous regulatory requirements, 3) research generates a mountain of paperwork not at all related to clinical care of the patient; 4) because of the time required to conduct clinical trials properly, monetarily they are often not as lucrative as they first appear; 5) if the Principal Investigator is not surrounded by well-paid specialized research staff from the very start, success will just about be impossible; 6) potential sample pools at the new investigator's site are almost always much smaller than first perceived.”

Association of American Medical Colleges, Review Criteria for Research Manuscripts, 2nd edition, has been released.
For those of you who are unfamiliar with the first edition, this free, download-able resource provides essential guidance for the review of scholarly work in the area of medical education. The intent of this guide is to provide a foundation to reviewers such that journals and authors receive clear, constructive feedback based on common review criteria. The free download can be accessed at https://members.aamc.org/eweb/DynamicPage.aspx?webcode=PubHome and searching for “Review Criteria.”
Recent Publications


Gadel S, Friedel C, Kharasch ED. Differences in Methadone Metabolism by CYP2B6 Variants. Drug Metab Dispos. 2015 Jul;43(7):994-1001

