The OSP News & Updates, published by the Office of Sponsored Projects, is a bi-weekly subscription-based newsletter that provides OSP and sponsor updates and reminders, quick facts, guidance and training in all aspects of sponsored projects administration. To subscribe, visit https://subscribe.yale.edu/browse?search=OSP.

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1 OSP Training

1.1 Brown Bag Meetings
Reminder: because December is such a busy month we’re skipping the December Brown Bag meeting and we’ll see you again in January. Registration is open for the January Brown Bag.

1.2 IRES PD v15 Sneak Peak
The bad news: unfortunately, at the last minute, this topic was cancelled for the November meeting. The IRES support team had some critical issues that needed to be resolved immediately and was unable to attend the Brown Bag meeting.

The good news: it’s exciting to see that so many of you are interested in seeing the new version of IRES PD and its back on the agenda for January!
1.3 BROWN BAG ZOOM
At last, a meeting without any technical or audio issues for our remote participants! Thank you for persevering through our Zoom growing pains. Our next goal is to provide video feed of the podium speaker in addition to the PowerPoint presentation – wish us luck!

Our Zoom audience has grown and always surpasses the number of in-person attendees. Despite comments that you look forward to networking in-person with colleagues, attendance numbers reflect how convenient it is to attend via Zoom.

1.4 BROWN BAG Survey
Again, thank you to those who completed the Brown Bag survey! Every month we review your comments and questions, and the plan is to answer your questions either in future OSP News and Updates or at Brown Bag meetings. We’ve compiled of list of your suggested topics and both past and future meeting agendas are developed based on your requests.

The goal of the Brown Bag meetings is to make these meetings relevant for those involved with the administration of sponsored projects. At any time, if you have a question, comment, or suggestion for a future BB topic, please let us know by contacting osp.trainings@yale.edu.

2 INDUSTRY SUPPORTED CLINICAL TRIALS AND INFORMED CONSENT DOCUMENTS

The Clinical Trial Agreements team in the Office of Sponsored Projects (OSP) is responsible for confirming that clinical trial consent forms (ICFs) are consistent with the clinical trial agreement and the budget, when ICFs describe the following:

- Payments to research participants for participation in the clinical trial (i.e., stipends),
- Reimbursements to research participants (e.g., for travel costs),
- Costs of research procedures, and
- Who may cover the potential costs associated with diagnosing and treating research-related injuries.

Typically, ICFs include specific sections on study participants’ expected costs and payments, as well as provisions addressing the potential coverage of research-related injuries (e.g., “Economic Considerations” or “In Case of Injury” sections). Some ICFs may include these provisions under different headings.
OSP and the Human Research Protection Program (HRPP) have developed a process that allows investigators to submit new clinical trial protocols in IRES IRB system without first seeking OSP’s review of the ICFs. The HRPP staff requests a member of the OSP Clinical Trial Agreements team to complete the consistency review using IRES IRB. If any inconsistencies are identified, the HRPP and/or Yale IRB will communicate the request for revisions directly to the Principal Investigator (PI) and the PI Proxy.

Requested revisions must be incorporated into the ICFs before the study receives final approval. The clinical trial sponsor should approve the final version of the ICF prior to the submission to the IRB. If the sponsor or the PI proposes additional revisions, OSP may have to conduct additional assessment of the consistency, per HRPP request.

Although the IRB is responsible for reviewing and approving the overall content of ICFs, OSP and HRPP work closely together to ensure that the proposed language is consistent with the clinical trial agreement and budget and is written in language understandable to a study participant.

If you have questions about the consistency review performed by OSP, please contact Jeri Barney at jeri.barney@yale.edu. Questions about the HRPP and IRB processes can be directed to Monika Lau at monika.lau@yale.edu or hrpp@yale.edu.

### 3 NEW ONLINE FORM – REQUEST FOR DUA

Data Use Agreements (DUAs) are contracts that generally facilitate the transfer of data for faculty to use in scholarly activities that is subject to some restriction on its use. DUAs serve to outline the terms and conditions of the transfer.

A new webform is available online to expedite your requests for Data Use Agreements (DUA). Completing this form will ensure OSP has all the information necessary to fulfill your request.

If you need a DUA, please complete and submit the [Request for Data Use Agreement form](#).
4 WORKDAY REPORTS

4.1 AWARD BUDGET AND AUTHORIZED AMOUNT VARIANCE – YALE REPORT
This new report provides a comparison of the cumulative budget through the current budget period against the authorized funding for the sponsored awards in a department.

4.2 ACCELERATED/DECELERATED SPENDING ON AWARDS – YALE
This report has been updated to include the Award Principal Investigator

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1 Thank you to all who have contributed to this newsletter. Please direct questions or suggestions regarding newsletter content to Tracy Coston at osp.communications@yale.edu or tracy.coston@yale.edu. To unsubscribe, visit https://subscribe.yale.edu/browse?search=OSP. For archived issues, visit OSP News & Updates archives.