ORA Meeting

• TPE Overview and Discussion
• A Federal Update and Perspective

January 26, 2017
Agenda

• TPE Overview and Discussion

• A Federal Update and Perspective...
This calculator is to be used for all Duke faculty that have reported a total professional effort (TPE) distribution of a less than 50% commitment to Duke University. It is critical that we clarify these situations in external proposals, to provide sponsors with a more complete perspective on our faculty members' commitment to the project than would be clear from the Duke effort percent alone.

Please complete the highlighted fields above, using the faculty member's last name; current TPE distribution between Duke, the PDC and the VA; and the % of their Duke effort committed to the project. The resulting statement listed below should be included in the budget justification for each faculty member with <50% TPE at Duke.

Dr. holds both university and non-university appointments. The commitment of 2.4 calendar months of university appointment to this project represents 8%, or 0.96 calendar months of total professional effort.
A Federal Update and Perspective
Updates and Ongoing Advocacy Efforts
Federal Update - Context

• Previous Discussion (MSPAI & Symposium)
  – Continued national recognition of the impact of the regulatory environment on faculty burden
  – Recognition by federal officials at OMB, NIH, DoD, NSF;
    • Difficult to address except on a case-by-case basis
  – Very positive movement in some areas of regulations: terminal leave, MIRA awards, Common Rule, SubAcct Transition, 120 Days, sIRB Delay, Procurement Delay, Research Policy Board, DS-2 Delay, etc.

• Update
  • Trump 1/20/17: Trump Freezes Pending and Non-Issued Obama-Era Regulations
  • 1/23/17: Tells business leaders - "We think we can cut regulations by 75%"
Very Positive Momentum

  – Interagency Working Group on Research Regulations
  – Micro-purchase Threshold (bids for small purchases)
  – Review & Harmonize across agencies Financial Conflict of Interest Policies
  – Simplified Budget Proposal & Greater Use of Just-in-time
  – Review and Simplify Progress Reports
  – Reduce Sub-recipient Monitoring Burden for Peers with Single Audit
  – Research Policy Board
Very Positive Momentum

- **Common Rule (Protection of Human Subjects):** The final rule differs in important ways from the proposed rule:
  - The final rule **does not adopt** the proposal to require that research involving non-identified biospecimens be subject to the Common Rule, and it **does not require that consent** be obtained in order to conduct such research.
  - The final rule **does not expand** the policy to cover clinical trials that are not federally funded.
  - The final rule **does not adopt** the proposal for more stringent criteria for obtaining a waiver of the consent requirements for identifiable biospecimens.”
  - Among the elements included: requirement to use a sIRB multi-site studies. However, it has been modified to **add substantial increased flexibility** in now allowing broad groups of studies (instead of just specific studies) to be removed from this requirement.
Discussions Underway Requesting Clarification

• NIH Fixed Price – Prior approval requirement (Recent Clarification from NIH IAW OMB regulations)
  – Requirement to **obtain NIH prior approval to enter into fixed price subawards** (either at award or after)
  – COGR is requesting guidance on transition, on what information is needed and when, and on **applicability to capitation awards**
  – UG, Section 200.401 states IHEs, "capitation awards, which are awards based on case counts or number of beneficiaries according to the terms and conditions of the Federal award" are not subject to the cost principles. **Applicability to multi-site clinical trials?**
Discussions Underway

• sIRB (Single IRB for Multi-site Trials)
  – Issue: NIH issued a policy statement that multi-site IRBs would have to be managed under a single IRB effective May 25, 2017 (recently delayed to Sept 25th)
  – Status:
    • Concerns regarding lack of guidance from NIH about implementation requirements, costing, determination and selection process, direct charging, infrastructure award availability

• Uniform Guidance Updates:
  – OMB had planned Federal Register announcement in fall 2016 focused on FAQs and clarification on Procurement threshold; additionally still waiting on Procurement delay to 7/1/18
# Impact of the Regulatory “Freeze”

<table>
<thead>
<tr>
<th>Regulations Affecting Research Institutions Published Since January 2016</th>
<th>Issued</th>
<th>Effective Date</th>
<th>Implications of Regulatory Freeze</th>
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<tbody>
<tr>
<td>NIH Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research</td>
<td>June 2016</td>
<td>September 25, 2017</td>
<td>The regulatory freeze has no impact on this NIH policy and it would be subject to legislative efforts to overturn regulations.</td>
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<tr>
<td>HHS Clinical Trials Registration and Results Information Submission</td>
<td>September 16, 2016</td>
<td>January 18, 2017</td>
<td>With an effective date that precedes the regulatory freeze, this rule remain in effect. It could potentially be overturned by Congress.</td>
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<tr>
<td>NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information</td>
<td>January 19, 2017</td>
<td>January 19, 2018</td>
<td>The regulatory freeze has no impact on this NIH policy and it would be subject to legislative efforts to overturn regulations.</td>
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For regulations that have been published in the Federal Register but not taken effect, agencies have been asked to temporarily postpone effective date for 60 days from the date of the memorandum. Whether this is applicable to regulations with an effective date of 60 days from the date of the memorandum. The Common Rule is therefore subject to review by a department or agency appointed or designated by the President after noon on January 20, 2017 or other designee. It is not clear where this will lead. COGR has been raised with respect to the Common Rule, most recently letter to the new administration and meeting with OIRA and agencies and it was included in a list of regulations that the House Freed Caucus recommends Trump target for removal/elimination in 100 days in office. Whether the removal of proposed changes identified in biospecimens and resulting reduction in proposed to make this less of a target for elimination is unknown. The rule be overturned by legislation that would allow Congress to over regulations issued in the last half of 2016 and to include multiple regulations in one joint resolution of disapproval or via the Congressional Review Act. COGR may seek to reiterate remaining concerns.
Questions