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# OT2 NIH Funding Mechanism

Post-Award Management Best Practices  
and Key Considerations

# Introductions

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# OT2 Funding

In NIH funding, "**OT2**" stands for a research project awarded under the Other Transactions (OT) activity code, which is an award mechanism that offers flexibility and is used for specific, circumscribed research projects that NIH staff actively manage, unlike traditional grants, cooperative agreements, or contracts.

OT Grants are executed by the NIH Common Fund  
<https://commonfund.nih.gov/about>



Due to the flexibility allowed in the Other Transaction mechanism, the NIH has much more involvement in the day-to-day operations of the project. For example, weekly meetings with the NIH and the PI, increased and unusual reporting requirements, heavy monitoring of expenses funds, etc.



# OT2 Key Characteristics

## Key Characteristics of NIH OT2

### **Distinct from Grants and Cooperative Agreements:**

- OT2 awards are distinct from traditional NIH grants and cooperative agreements, falling under the "Other Transactions" funding category.

### **Focus on Specific Projects/Initiatives:**

- The awards are used for specific, circumscribed research projects or initiatives.

### **Active Management:**

- Projects are actively managed by NIH staff.

# OT2 Key Characteristics

## Key Characteristics of NIH OT2

### **Project-Specific Focus:**

- The OT mechanism is utilized to support discrete, specified, and limited research projects.

### **Examples of OT2 Funding:**

- OT2 funding is used for various NIH initiatives, including the All of Us Research Program engagement partners, the NIH Bridge to Artificial Intelligence (Bridge2AI) Program, AIM-AHEAD and integrating clinical research into primary care settings.

# Importance of OT Grants

**NIH "Other Transaction" (OT)** projects are important because they allow for flexible and adaptable funding mechanisms, enabling collaboration with non-traditional partners, and supporting research that may not fit within the constraints of traditional grant or contract models, fostering innovative, high-impact medical research.

# Key Challenges

## Compliance, Contracts and Reporting

- Extensive Quarterly Reporting
- Mid year NCE to align with NIH OT funding schedule.
  - We had to ensure all 15 sites had budget to continue SOW and reallocating funding between subwardees
- Realigning 5 modules to 3 pillars from year 1 to year 2. Cindy
- Consortium Improvement Plan from year 1 to year 2 required a total rewrite of budget, SOW, and milestones Cindy
- Bilateral agreement required

# Key Challenges

## Financial Management

Managing 15 subwardees, 15 PIs and numerous grant budget managers

Program Income Heather

Conference Planning Cindy

Face to Face meeting travel coordination Cindy

Because this is an OT project, the let us submit by invitation for supplemental funding Maddy



# Case Study

## DUA – Multi-Institutional and multi-international challenges

- Due to the complexity of this project and the cooperation of multiple sites in providing data and sharing with one another, USF had to handwrite a DUA which included all data sharing sites and required each of them to sign off on the same language.
- One site in the EU was not able to sign due to the difference in US and GDPR law.
- One milestone of the project requires the de-identified data become accessible to the public. Now, USF is working on a modified FDP DUA template so that anyone can apply to receive access to the data.



# Case Study

## Single IRB /REB for Canadian partners

- International barriers to sharing data
- Lengthy negotiations with each institution and Canadian partners
  - Consent Forms need additional legal language native to the institutions Multiple modifications each institution has particular concerns
  - IRB struggles that our inst is not producing tools here at USF that others will use to develop from our data set
  - New issues to IRB federated learning data systems, remote data collection vs. electronic data collection
  - IRB struggles with the fact that app/tools are constantly changing



# Case Study

## When the NIH assigns PIs and Institutions to the Project

- Initial proposal had 5 subawards. The NIH then combined our project with another proposal's subawards.
- Challenges when institution is not meeting milestones Cindy



# Case Study

## When the NIH assigns PIs and Institutions to the Project

- Due to differences in work style and a significant change in scope for the subaward, this led to a degradation of the working relationship with one subaward. It was decided to remove them from the project.
- After notification of termination, the subaward sent an invoice for \$98K. We then had to independently verify each expense on the invoice. We noticed that effort for the PI was significantly higher than expected. The OT2 does not allow for change in effort. We asked the subaward to revise the invoice to match what the NIH approved.



# Case Study

## Carry Forward Automatic or not automatic? That is the question

- The language in the initial bilateral agreement was extremely ambiguous.
- We received conflicting interpretations from the NIH. Eventually, the NIH determined carryforward was not automatic.
- When submitting Year 2 documents, the NIH told us to submit a carryforward request. Then told us to pause our work on the carryforward request. Year 2 was issued as having automatic carryforward.

### *H. Unobligated Balances and Actual Expenditures*

Using the principle of “first-in, first-out,” unobligated funds carried over are expected to be used before newly awarded funds.

### *5. Carryover*

*All funds remaining from the prior years are automatically carried forward and available for use for approved budget categories in the subsequent years. Carryover funds may be used to finish up tasks/milestones from prior years or to offset any future funding.*

# Case Study

## Gift Cards

- Gift Cards distribution consolidated at one location for patient stipends
- Patients with neuro diagnosis required multi visits to complete the protocol
- All the emails! We had to find a solution
- International barriers to gift cards



# Case Study

## OT Budget negotiated yearly

- The budget is negotiated annually. This means a draft budget and justification is collected from all sites for the upcoming year and submitted to the NIH. The NIH then comes back with requested revisions. The sites will then update their budgets and resubmit.
  - We submitted the Year 3 budgets three times. We also met with the NIH to discuss budget issues. After the third submission, we received approval.
- The NIH will sometimes provide extra funds but require them to be used in very specific ways
  - E.g., provided an extra \$250K for a program manager and all investigators' travel to Face-to-Face meeting held by the NIH



# Case Study

## OT Budget negotiated yearly

- New Milestones and SOWs are submitted each year with the budget. These are also submitted with large changes, such as the mid-year NCE the NIH gave us, the Consortium Improvement Plan, etc. New budgets are also required if there are changes to the budgets due to the new milestones and SOW.
- Due to changing milestones, work and additional funds are constantly being taken or added from individual sites. Some subcontracts are on Modification #7 and 8. This requires us to be very familiar with all subaward budgets and creates an extra step of monitoring and tracking.





# Solutions

What we found  
worked for us

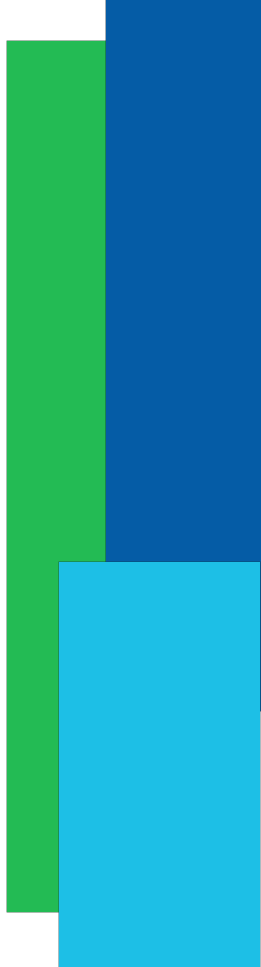
- Quarterly meetings with grant management teams
- Imbedding in the Project Management team
- Tracking subaward modifications and adjustments (monday.com)
- Gift card tracking



# Conclusion

The future of NIH Other Transactions (OT) funding is set to focus on several key areas. One notable initiative is to continue gathering data from over a million participants to accelerate health research and medical breakthroughs.

Overall, while some areas will see continued or increased funding, others may experience reductions or shifts in focus



# Conclusion

**NIH Other Transactions (OT) funding** is crucial for advancing biomedical research and innovation. Unlike traditional grants and contracts, OT funding offers flexibility, allowing the NIH to support high-risk, high-reward projects that may not fit within conventional funding mechanisms.

This flexibility fosters collaboration with a wide range of partners, including private sector entities, and accelerates the development of groundbreaking medical technologies and treatments.



# Conclusion

**Effective post-award management** is equally important. It ensures that projects funded by NIH OT awards are executed efficiently and in compliance with federal regulations

- **Financial Accountability:** Proper tracking of expenditures to avoid overspending and ensure funds are used appropriately WashU
- **Compliance:** Adhering to federal guidelines to prevent legal and financial penalties no nih funding propr
- **Progress Monitoring:** Regularly reviewing project milestones to ensure objectives are met on time
- **Risk Mitigation:** Identifying and addressing potential issues early to avoid project delays or failures irb data governance data release due to HIPAA compliance and DUA access for contract data DA when institution can't meet the DA quota and we hve to shift funding to other intuitions to ensure milestone in DA are met importance in embedded PM

# Questions

