# Departmental Administrators Meeting
# Tuesday, October 22, 2013

Flynn Auditorium – Law School
9:00 – 11:00 AM

Presented by OCGA and OSP

# Agenda

- Introductions
- FY 2013 Recap of Sponsored Projects at Vanderbilt
- Federal Government Shutdown
- OMB Super-Circular
- Federal Drawdown – Request for Funds
  - NSF drawdown system change
  - HHS subaccounts
- Grant Closeout
- Progress Report Changes/Project Updates
  - NIH
  - NSF
  - Department of Education
- NIH Publication – Open Access
- Award Acceptance
  - IACUC & IRB Approval Verification Process
  - Conflict of Interest (FCOI) Process
- COEUS Updates

# Introductions

# Sponsored FY13 Proposal Activity

| | | 2012 Proposal Count | 2013 Proposal Count |
|---|---|---|---|
| Medical Center | Competing | 2,228 | 2,395 |
| | Non-Competing | 816 | 881 |
| | Total: | 3,044 | 3,276 |
| University | Competing | 923 | 835 |
| | Non-Competing | 232 | 250 |
| | Total: | 1,155 | 1,085 |
| Total: | | 4,199 | 4,361 |

# Sponsored FY13 Proposal Activity

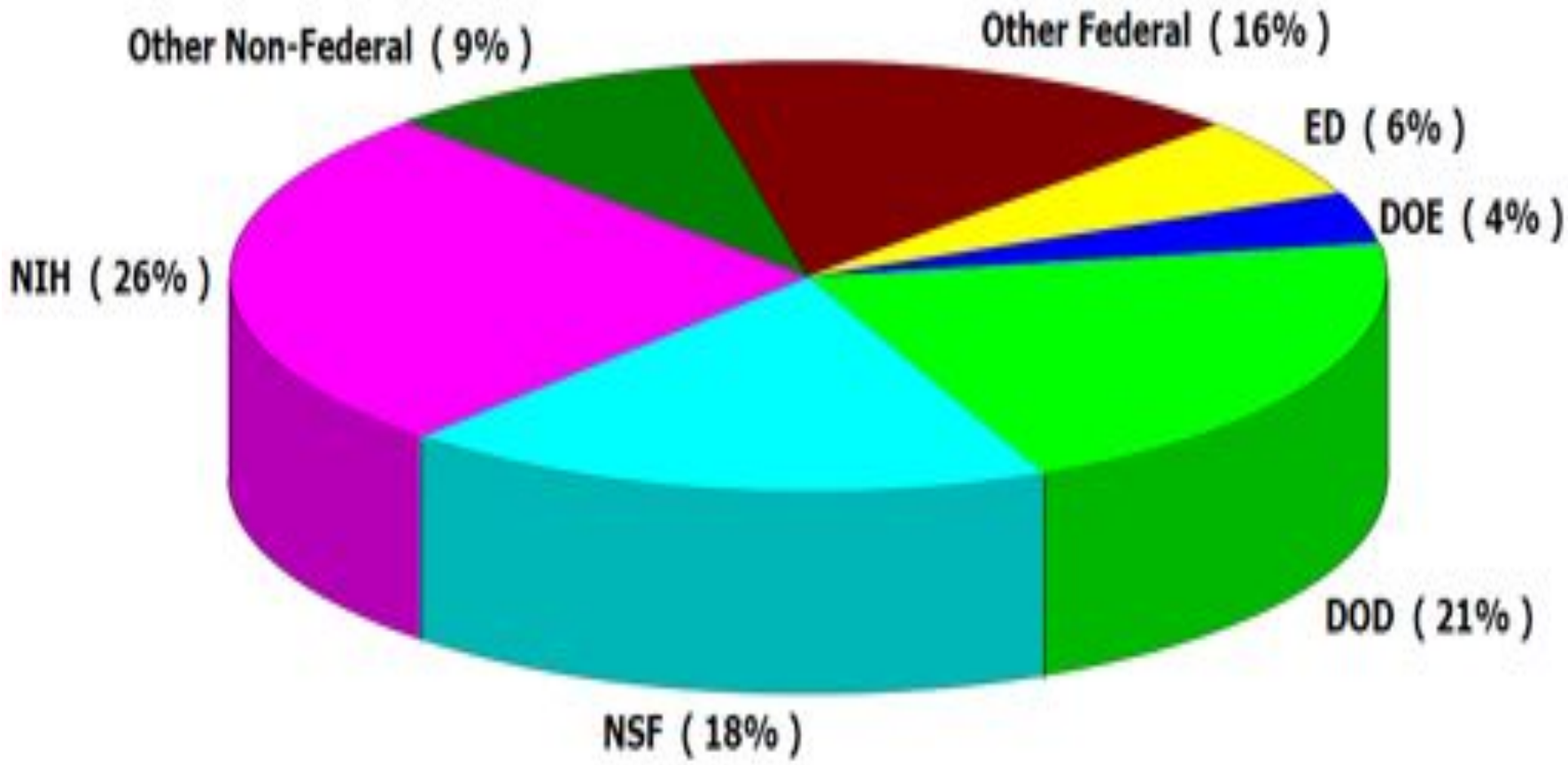
| | | 2012 Proposal Count | 2013 Proposal Count |
|---|---|---|---|
| Medical Center | Federal | 1,921 | 2,020 |
| | Non-Federal | 1,123 | 1,256 |
| | Total: | 3044 | 3276 |
| University | Federal | 931 | 864 |
| | Non-Federal | 224 | 221 |
| | Total: | 1155 | 1085 |
| Total: | | 4,199 | 4,361 |

# Sponsored Award Activity

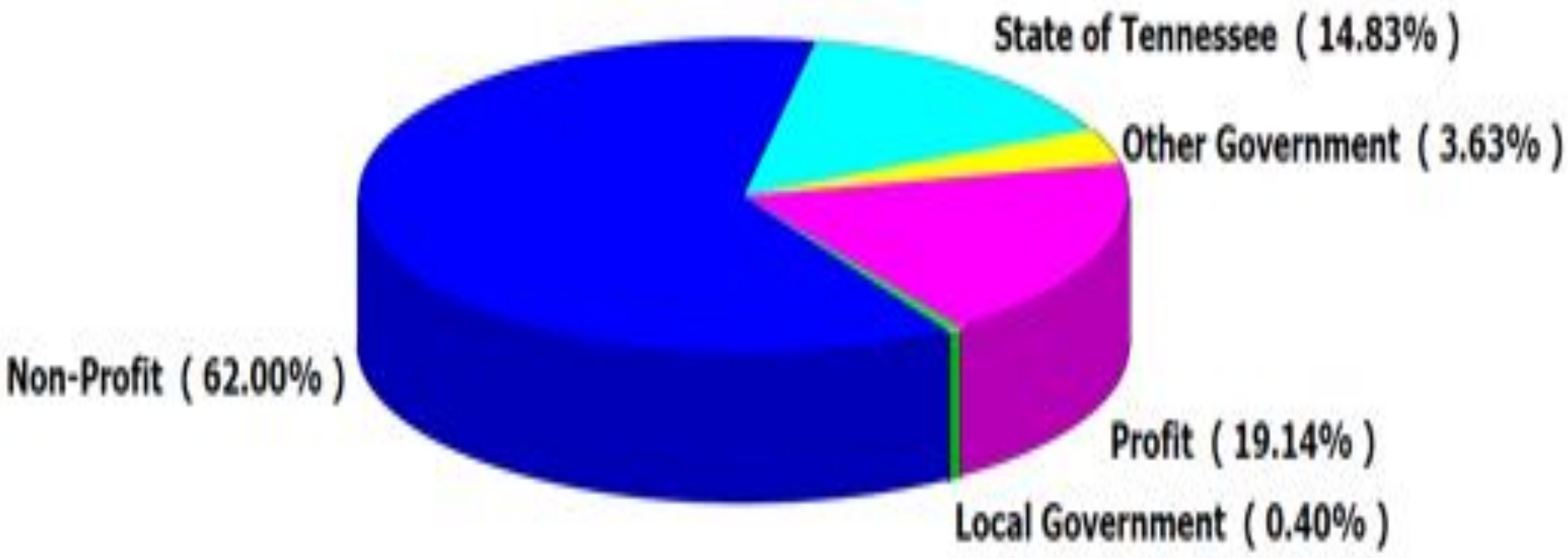
| | Medical Center | University |
|---|---|---|
| 2012 | 431.4 M | 139.3 M |
| 2013 | 471.6 M | 144.5 M |

*Award data as of 9/18/2013. This information may differ from previously reported information as awards are received with retroactive start dates impacting FY data.

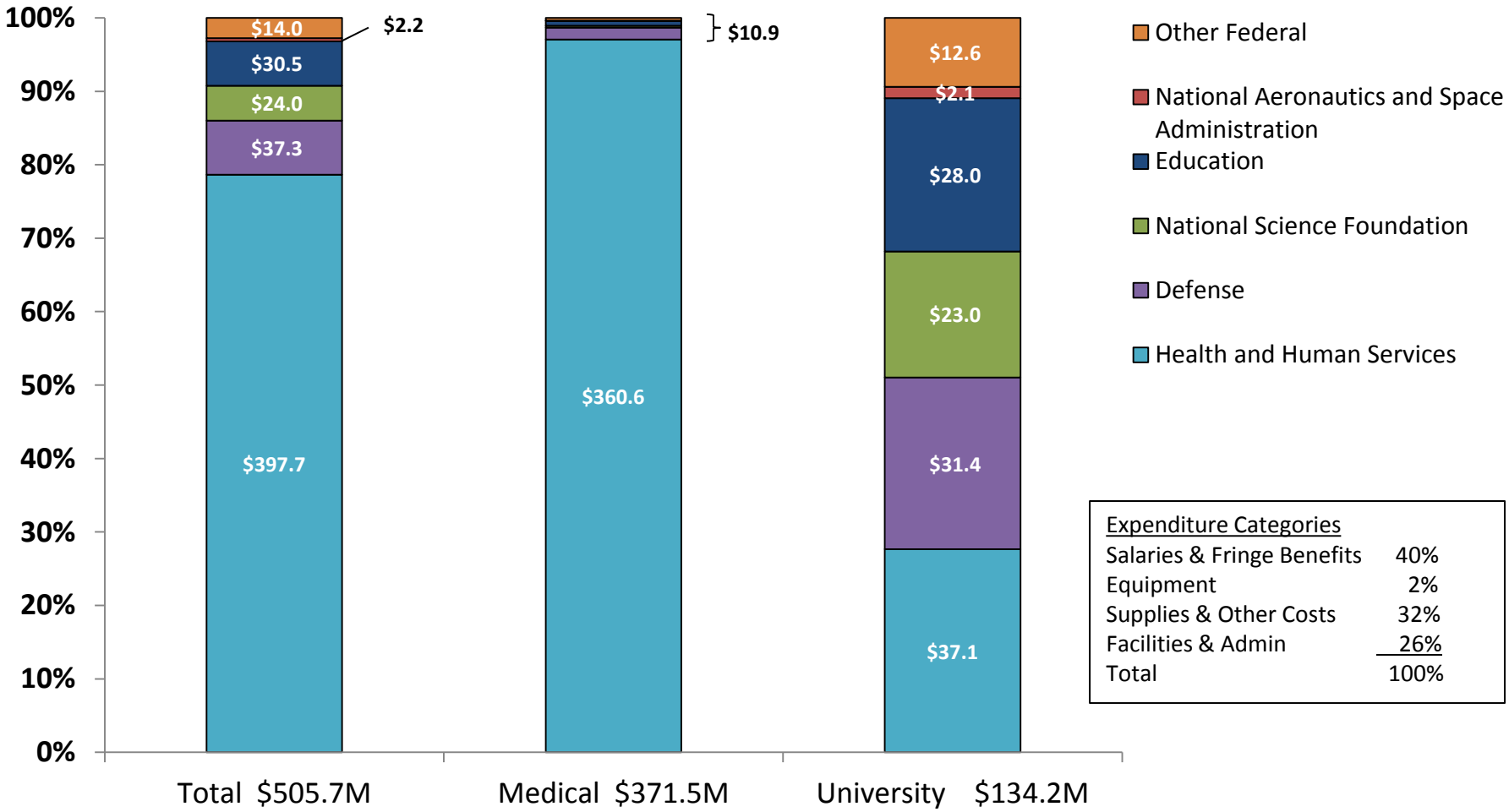
# University Central Sponsored Award Activity FY 13



# University Central Sponsored Award Activity Non-Federal: FY 13



## *Total Federal Expenditures $505.7M*




| Expenditure Categories | |
|---|---|
| Salaries & Fringe Benefits | 40% |
| Equipment | 2% |
| Supplies & Other Costs | 32% |
| Facilities & Admin | 26% |
| Total | 100% |

# Update on Federal Government Shutdown

## *It's finally over……*

*President Obama signed legislation ending the 16-day federal government shutdown on Oct. 17, allowing the government to reopen…..*

*So what impact has this caused on pre-and-post award grant administration…..*

# Update on Federal Government Shutdown

## *It's finally over……Pre-award Admin.*

## NIH updates

- On Friday 10/18/2013, NIH issued an update and guidance on grant application due dates. Please see NOT-OD-14-003 for a listing of new dates and additional guidance including:
  - Rescheduling October Application Due Dates
  - Processing of Applications Submitted During the Shutdown
  - Replacing an Application that was submitted for an October Due Date
  - Rescheduling Peer Review Meetings
  - Opportunity of "Refresh" Applications that are Reassigned to May 2014 Council

# Update on Federal Government Shutdown

*It's finally over……Pre-award admin.*

## NIH updates for October Deadlines

Standard Due Dates:

| Activity Code | Original Due Date | New Due Date |
|---|---|---|
| R01s, U01s (New) | October 5 | November 12 |
| Ks (New) | October 12 | November 12 |
| R03s, R21s, R34s, R36s (New) | October 16 | November 18 |
| R15s (All) | October 25 | November 18 |

# Update on Federal Government Shutdown

## *It's finally over……Pre-award admin.*

## NSF updates

On Friday 10/18/2013, NSF issued a memo that can be found at: http://www.nsf.gov/bfa/dias/policy/postshutdown/guidance_oct18.pdf. This memo outlines NSF plans on resumption of operations. Most notably:

- Impact on Existing Deadlines
  - NSF will provide revised due dates for funding opportunities with deadlines or target dates occurring between 10/1 and 10/25.
  - It is important to note that not all divisions have finalized their plans and may not adjust their target dates depending on the deadline. Please refer to the specific NSF division for more information.

# Update on Federal Government Shutdown

*It's finally over……*

## Other Federal Agencies

- Dept of Ed
- NASA
- DOE

These agencies have not adjusted any deadline dates regarding grant submissions and accepted proposals during the shutdown.

# Update on Federal Government Shutdown

*It's finally over……Pre-award admin*

## Submission of Progress Reports

**Submit as planned for any upcoming deadlines and for progress reports where the deadline has passed, please submit as soon as possible.**

# Update on Federal Government Shutdown

*It's finally over……*

## Post Award Administration

- Receiving funds during and after shutdown

# OMB Super-Circular

# Federal Drawdown

- NSF system changes to ACM$
- HHS Subaccounts
  - NIH Policy Notice NOT-OD-13-120
    - *Starting October 2013 . . .*
    - *Starting October 2014 . . .*

# Grant Closeout

- NSF ACM$ Announcements
- HHS Notice
  - NIH Policy Notice NOT-OD-13-120

# Progress Reporting Updates and Reminders

- NSF
  - NSF has transitioned to Research.gov for submission of all project reporting http://www.research.gov/
- NIH
  - NIH has transitioned the majority of progress reporting to the RPPR format (snap and fellowships)
  - NIH will begin piloting non-snap progress reports for FDP Institutions using the RPPR format
- Dep. of Education
  - Continue to use G5 system

Reminder: A Coeus Continuation application and PEER log is required if a progress report triggers the next funding increment

# NIH Publications-Open Access Policy

- Policy was effective **April 7, 2008**

- **Non-compliance** could result in loss of or delay of funding
  - For non-competing continuation grant awards with a start date of **July 1, 2013** or beyond:
    - NIH will delay processing of an award if publications arising from it are not in compliance
    - Investigators will need to use My NCBI to enter papers onto progress reports. Papers can be associated electronically using the RPPR, or included in the PHS 2590 using the My NCBI generated PDF report

# VICTR RESOURCES TO ASSIST WITH NIH PUBLIC ACCESS COMPLIANCE (NIH PAC)

MY RESEARCH | GOVERNANCE DASHBOARD | MY PROFILE | QUICK LINKS | LOGOUT | CONTACT US | SEARCH STARBRITE

VANDERBILT UNIVERSITY | StarBRITE

Planning & Implementation | Recruitment | Research on Practice and Policy | Funding | Data Management | Education | BioVU & SD | Basic Science

- ROCKET
- Investigator Support
- Study start-up
- Price Checker
- Charge Intention
- ÜBER Project Tracker
- Studios
- Customized Action Plan
- IMPACTT
- Study Templates
- Tools for Grant Writing
- Tools for Manuscript Writing
- ClinicalTrials.gov

## Tools for Manuscript Writing

### Note to Authors: NIH Public Access Policy

**Changes to Public Access Policy Compliance Efforts Apply to All Awards with Anticipated Start Dates on or after July 1, 2013 (NOT-OD-13-042)**

For non-competing continuation grant awards with a start date of July 1, 2013 or beyond:

1. NIH will delay processing of an award if publications arising from it are not in compliance with the NIH public access policy.
2. Investigators will need to use My NCBI to enter papers onto progress reports. Papers can be associated electronically using the RPPR, or included in the PHS 2590 using the My NCBI generated PDF report.

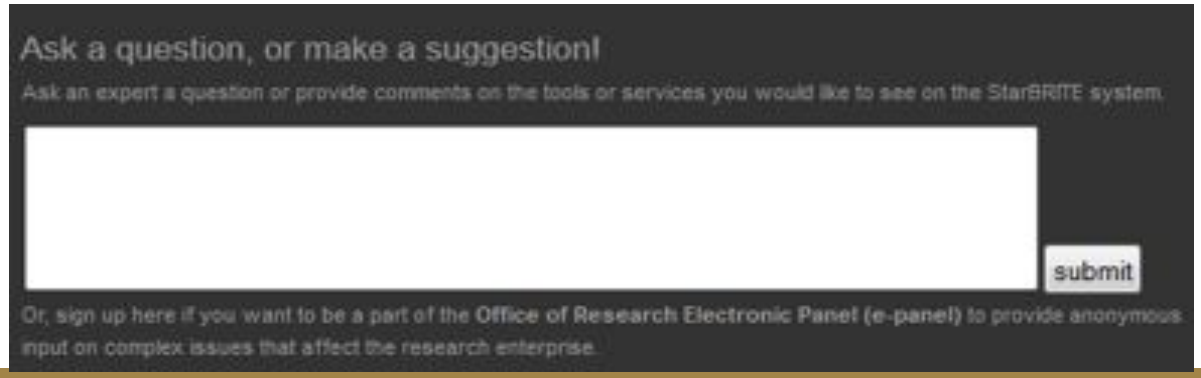
Please see NOT-OD-12-160 for more details.

**For more information:**

- NIH Public Access website
- NIH Public Access Policy Details
- Submission Methods
- NIH Manuscript System
- Using MyNCBI My Bibliography to Monitor Compliance
- My NCBI – New Features for My Bibliography for eRA Commons Users
- Eskind Biomedical Library NIH resources
- Vanderbilt's Amendment to Publication Agreement (vunet id and password required)
- Submitting an Article to PubMed Central (Video)
- Approving Submission of an Article to PubMed Central (Video)
- Changes to the NIH Public Access Policy and the Implications (PPT - January 2013)

# VICTR RESOURCES TO ASSIST WITH NIH PUBLIC ACCESS COMPLIANCE (NIH PAC)

- My NIH Public Access Dashboard in StarBRITE
- Voluntary registration for weekly Notifications of noncompliant pubs
- Regularly scheduled 'clinics' (4th Thursday, 11-12, CRC Conf. Room, no reg. required)
- Research Support Services hotline: 615-322-7343
- Ask a question through StarBRITE



# NIH Publication Compliance Dashboard

https://starbrite.vanderbilt.edu/pubaccess/

Add any grant to your dashboard

My Grants

Export | Filters: | Submit via NIHMS | Monitor Grant | Watch a grant

| PubMed Id | PI Name | PMCID | Title | First Author Name | *NIHMS Person |
|---|---|---|---|---|---|

KL2 RR024977 (50 1 293 ) The Vanderbilt Institute for Clinical and Translational Research (VICTR) KL2 — Remove Grant

KL2 TR000446 (50 0 283 ) The Vanderbilt Institute for Clinical and Translational Research (VICTR) KL2 — Remove Grant

| | | | | | |
|---|---|---|---|---|---|
| 23256400 | Bernard,Gordo... | [2012] Potential subjects' responses to an ethics questionnaire in a phase I study of ... | FINDER, STUART G | | |
| 22739144 | Bernard,Gordo... | [2012] Optimizing drug outcomes through pharmacogenetics: a case for preemptive ... | SCHILDCROUT, J S | | |
| 22991200 | Bernard,Gordo... | [2012] Regulation of late endosomal/lysosomal maturation and trafficking by cortact... | KIRKBRIDE, KELLY... | | |
| 22044651 | Bernard,Gordo... | [2012] Sleep in children and adolescents with Angelman syndrome: association with ... | GOLDMAN, S E | | |
| 23604678 | Bernard,Gordo... | [2013] BET1L and TNRC6B associate with uterine fibroid risk among European Americ... | EDWARDS, TODD L | Velez E... | |
| 22880117 | Bernard,Gordo... | [2012] Subthalamic nucleus deep brain stimulation impacts language in early Parkinso... | PHILLIPS, LARA | | |
| 22577785 | Bernard,Gordo... | [2012] National survey of children's hospitals on legacy-making activities. | FOSTER, TERRAH L | | |
| 23245707 | Bernard,Gordo... | [2012] Ethical and legal issues in pain research in cognitively impaired older adults. | MONROE, TODD B | Monroe... | |
| 22567136 | Bernard,Gordo... | [2012] CNR1 genotype influences HDL-cholest | | | |
| 22718199 | Bernard,Gordo... | [2012] Fine-mapping classical HLA variation as | | | |
| 22722360 | Bernard,Gordo... | [2012] Clinical and translational research studi | | Byrne... | |
| 22688329 | Bernard,Gordo... | [2012] Fall in C-peptide during first 2 years fro | | | |
| 22610117 | Bernard,Gordo... | [2012] Extremely low-coverage sequencing an | | Price, Al... | |
| 22626819 | Bernard,Gordo... | [2012] Obesity and oxidative stress predict Al | | | |
| 22590586 | Bernard,Gordo... | [2012] Loss of the urothelial differentiation marker FOXA1 is associated with high gra... | DEGRAFF, DAVID J | | |

*NIHMS Person: NIHMS person is the person who currently is responsible for any actions needed to complete the processing of a manuscript

Expandable to monitor status of each publication

Email individual publication information to someone

# Award Acceptance

- As part of OSP's review of any final restricted budget (new or continuation/adding new funding), we have been charged with ensuring proper IRB and IACUC review has occurred.
- This will not hold up receiving a center number, however, if IRB and or IACUC has not been approved, the center will remain in DRAFT, meaning no drawdown or invoicing will take place.

# Award Acceptance

Research Involving Animals…..

- The VU-IACUC Office expects any award received where animal work is involved regardless of when it will be performed during the granting period - to have received a full review by the IACUC prior to any draw down of funds.
- If at any point the proposed work changes in a way that results in additional procedures, the PI would be expected to submit an amendment to the approved protocol (if the change involved simply not performing procedures described in the original grant/protocol, then nothing would be required of the PI)

# Award Acceptance

Research Involving Human Subjects…..

- For Human Subject Research, if the HS work is to be preformed at a later time in the project period and the PI does not have all the information to build the protocol application at the time of award, the IRB has an established process called "grant review" formally known as an "umbrella review" that meets federal regulations. This review will suffice for the documentation needed for the sponsor and at final budget time for invoicing and drawing down funding.
- https://www4.vanderbilt.edu/irb/forms/applications-and-consents/

# Award Acceptance

## Research Involving Human Subjects…..

- https://www4.vanderbilt.edu/irb/forms/applications-and-consents/

| | | | |
|---|---|---|---|
| | Determination (Form #1122) | Request | Request |
| | Investigator Held IND (Form #1135) | Investigator Held IND | Investigator Held IND |
| | Device Supplemental Form (Form #1134) | Device Supplemental Form | Device Supplemental Form |
| NEW | Grant Review Application (Form #1106) | Grant Review | Grant Review |
| NEW | Grant Continuing Review | Grant Continuing Review | Grant Continuing Review |
| FOR EXISTING UMBRELLAS | Umbrella Continuing Review (Form #1113) | Umbrella Continuing Review | Umbrella Continuing Review |
| | Specimen and Data Repository Application (Form #1103) | Specimen-and-Data-Repository-Application | Specimen-and-Data-Repository-Application |

# Award Acceptance

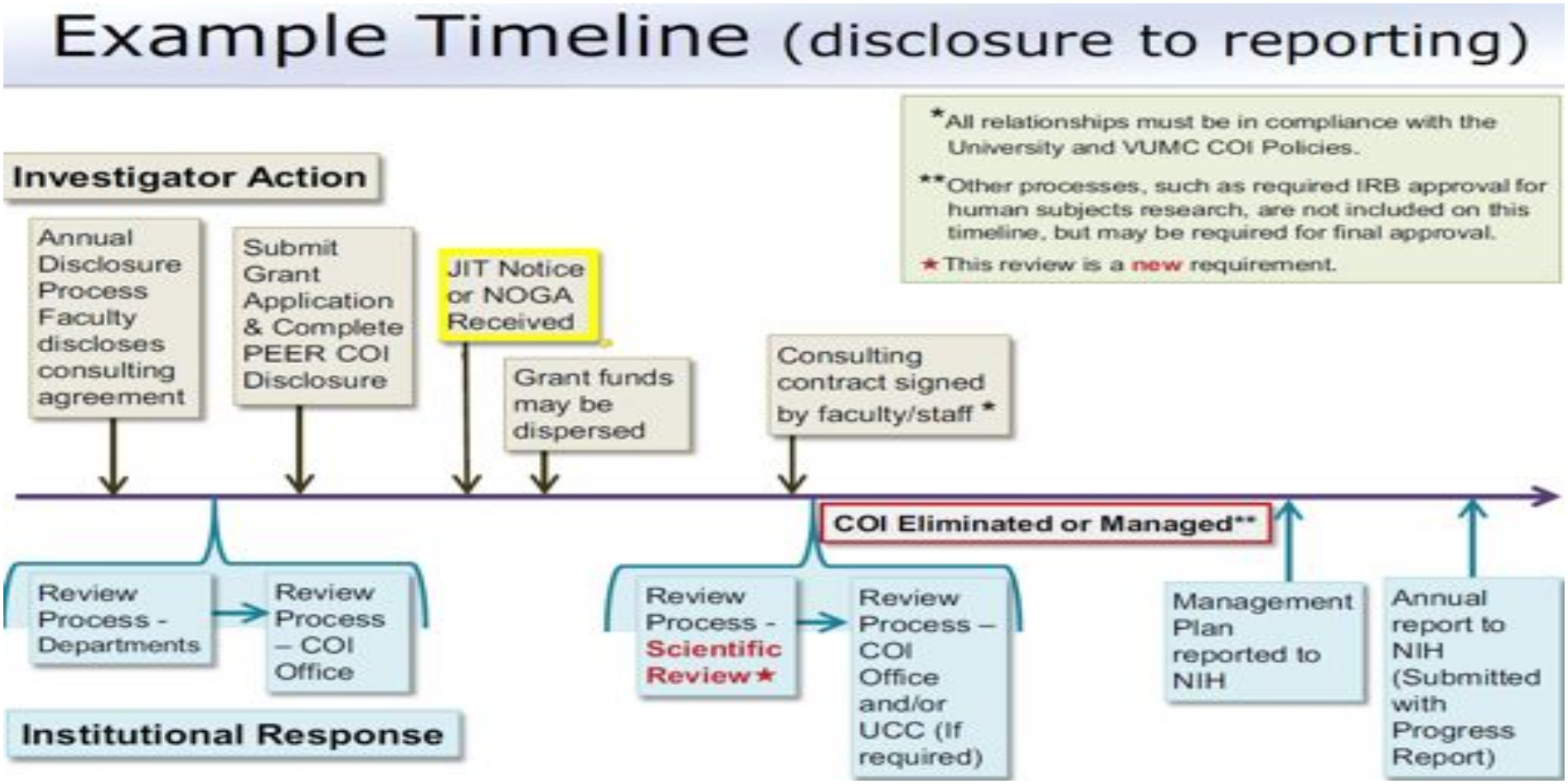
FCOI Process…..

- Required for all NSF and PHS applications/awards

- Required for those agencies who have adopted PHS guidelines:
  - Administration for Children and Families (ACF)
  - Alliance for Lupus Research (ALR)
  - American Cancer Society (ACS)
  - American Heart Association (AHA)
  - American Lung Association (ALA)
  - Arthritis Foundation (AF)
  - Juvenile Diabetes Research Foundation (JDRF)
  - Lupus Foundation of America (LFA)
  - Susan G. Komen for the Cure
  - CurePSP

# Award Acceptance

## FCOI Process…..



# Coeus Updates-Using Forms-C Package

- NIH issued an announcement in May regarding the implementation of a new form set to be used for submissions on or after September 25, 2013. Please see NOT-OD-13-074 for details and http://www.vanderbilt.edu/coeus/ for internal proposal preparation guidance.

- Major differences when using Forms-C package:
  - SF424 (R&R) Cover V2-0
  - New detailed budget justification narrative type called S2S budget justification
  - New questionnaires for Planned Enrollment and Cumulative Inclusion human subject data tables

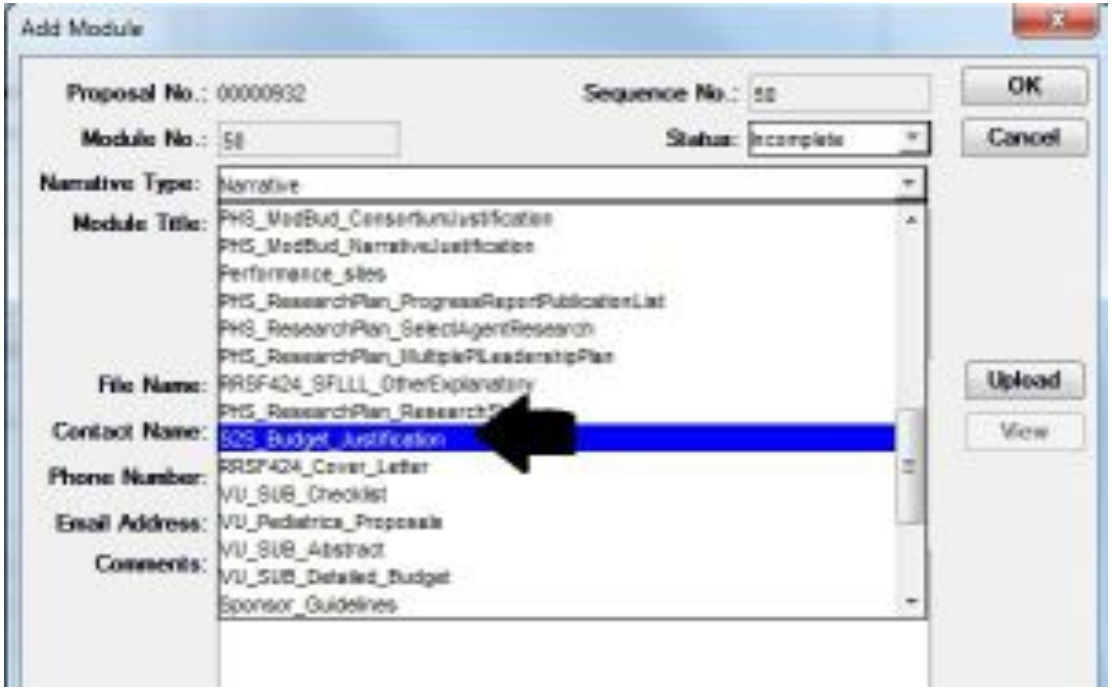
# SF424 (R&R) Cover V2-0

In order to accommodate two new fields added to the SF424 (R&R) Cover V2-0 Form – new fields have been added to the Proposal Tab of COEUS:

- **Previous Grants.gov Tracking ID:** *(under Agency Program Code on bottom left of screen)*
- **Agency Routing Identifier:** *(under Agency Div Code on bottom right of screen)*
- To see how these fields are used, click the "?" beside each field.

# Detailed Budget Justification

If you are proposing a detailed budget, there is a new form type that must be used when uploading the justification narrative. Instead of Detail_Budget_Justification, select S2S_Budget_Justification from the Narrative Type drop-down.



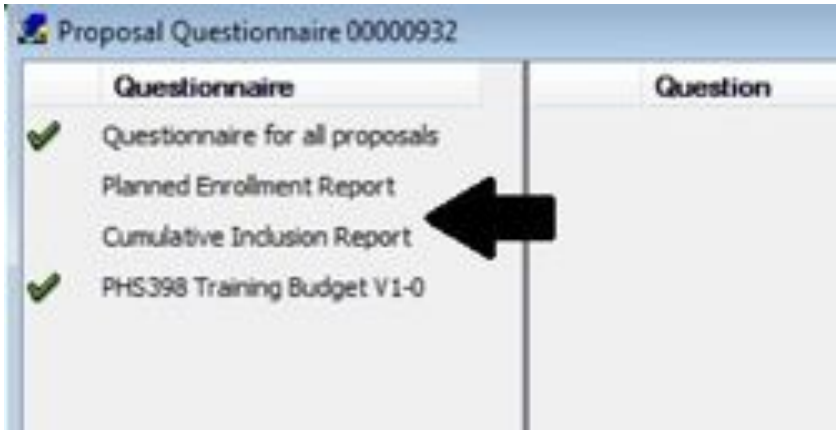
# LIST OF *NEW* GRANTS.GOV FORMS IN FORMS-C PACKAGES

NIH has changed the format for two forms. The new forms are available for download on the COEUS website and should be used for planning purposes and proposal creation.

- Planned Enrollment Report V1-0
  - Used for new, renewal, and re-submission projects that include Human Subjects
- PHS 398 Cumulative Inclusion Enrollment Report V1-0
  - Use for renewal projects that include Human Subjects

## Change to Smart Questionnaire

- Selecting the new forms for Planned Enrollment and/or Cumulative Enrollment will result in **new questionnaires** appearing in COEUS.
- It is recommended that you fill out the form(s) in hardcopy or on your desktop prior to completing the questionnaire(s) in COEUS. Having a completed form available will make it easier to understand the questionnaires in COEUS.



# Sample Enrollment Forms

The old format on the left did not break down ethnicity by race. The new form on the right includes race categories for all ethnic categories

| TARGETED/PLANNED ENROLLMENT: Number of Subjects | | | |
|---|---|---|---|
| Ethnic Category | Sex/Gender | | |
| | Females | Males | Total |
| Hispanic or Latino | 1 | 1 | 2 |
| Not Hispanic or Latino | 4 | 4 | 4 |
| **Ethnic Category: Total of All Subjects *** | 5 | 5 | 10 |
| **Racial Categories** | | | |
| American Indian/Alaska Native | ** | ** | 0 |
| Asian | ** | ** | 0 |
| Native Hawaiian or Other Pacific Islander | ** | ** | 0 |
| Black or African American | 1 | 1 | 2 |
| White | 4 | 4 | 8 |
| **Racial Categories: Total of All Subjects *** | 5 | 5 | 10 |

| Racial Categories | Ethnic Categories | | | | |
|---|---|---|---|---|---|
| | Not Hispanic or Latino | | Hispanic or Latino | | Total |
| | Female | Male | Female | Male | |
| American Indian / Alaska Native | 1 | 7 | 22 | 51 | **81** |
| Asian | 2 | 8 | 33 | 61 | **104** |
| Native Hawaiian or Other Pacific Islander | 3 | 9 | 44 | 71 | **127** |
| Black or African American | 4 | 10 | 55 | 81 | **150** |
| White | 5 | 11 | 66 | 91 | **173** |
| More than One Race | 6 | 12 | 77 | 101 | **196** |
| **Total** | **21** | **57** | **297** | **456** | **831** |

# Questions??

***Thank you for your hard work and dedication!!***