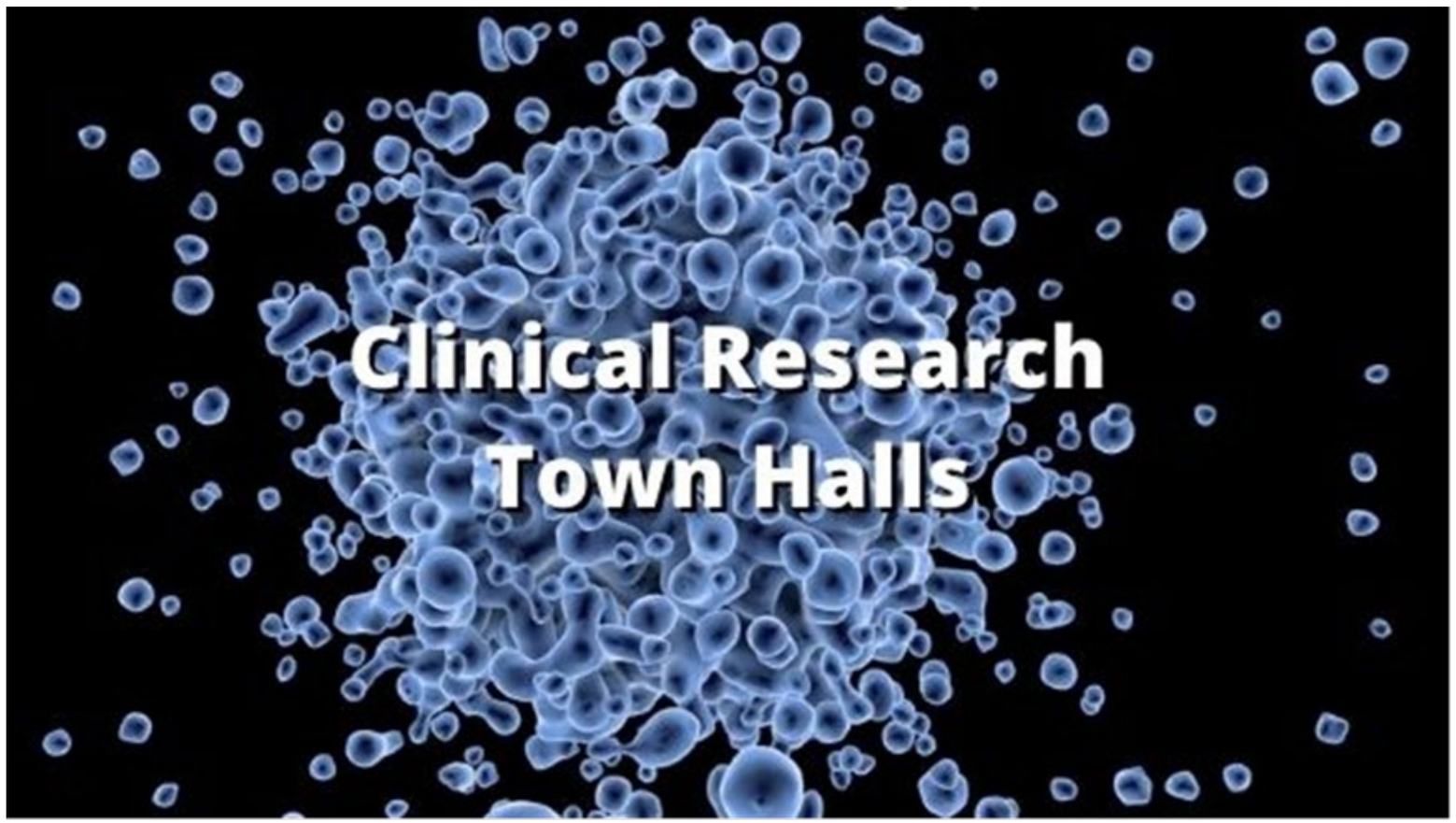
University of CINCINNATI | OFFICE OF RESEARCH

Special OCR Town Hall Lunch & Learn Sessions



Lunch & Learn Special Session:
Clinical Research Town Hall Discussion

Thursday, December 16th, 2021

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December 2021 Studies of the Month
#1

ADHD Study

ADHD Study for Children and Adolescents

What
The purpose of this study is to evaluate the long-term efficacy of an investigational drug for children and adolescents with ADHD for whom stimulant medications are unsuitable, intolerable, or ineffective.

Who
Children and adolescence 6-17 years of age who experience ADHD symptoms or have been diagnosed with ADHD.

Pay
Participants may receive compensation for transportation and/or time for study visits. All study visits, tests, procedures and medications will be provided at no cost to participants.

Details
For more information, visit www.ADHDleaguestudy.com or contact Emily Baltes-Thompson at 513-558-3952 or baltesec@ucmail.uc.edu.

UC Health.

16-20 IRB# 2019-1098

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December 2021 Studies of the Month #2

Schizophrenia Study

Study for Individuals with Schizophrenia

What

Sodium benzoate is a common food additive which is being investigated as a potential treatment for schizophrenia. This outpatient study will look at the safety of sodium benzoate, and at how well it works in improving symptoms of schizophrenia when added to existing medication. Sodium benzoate is investigational because it has not been approved by the U.S. Food and Drug Administration (FDA) for this use.

Who

Men and women 18-45 years old who have been diagnosed with schizophrenia for at least 2 years, are currently receiving outpatient treatment, and have not been hospitalized for schizophrenia symptoms over the last 3 months.

Pay

Participants will receive payment for time and travel up to $600.

Details

For more information, contact Karen Tugrul, RN at 513-558-6831 or tugrulkc@ucmail.uc.edu.

UC Health.

UC 13-18 IRB# 2017-02471

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We are excited to announce the launch of the UC Office of Clinical Research site on Bearcats Landing!

Visit Bearcats Landing by entering [my.uc.edu](my.uc.edu) into your web browser *(UC login required)*.

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The First First Friday of the New Year!!!

Friday, January 7th, 2022, 9:00am, Virtual Presentation

UC Health Colleges: 200 Years of Innovation

Gino J. Pasi

Archivist/Curator

Henry R. Winkler Center for the History of the Health Professions

University of Cincinnati Libraries

Donald C. Harrison Health Sciences Library

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Today's Presentation:

Lunch & Learn Special Session:
Clinical Research Town Hall Discussion

OCR Leadership
And other Special Guest Clinical Research Leadership

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Submitted Questions

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UC Office of Clinical Research

Imaging Services
Monene Kamm
Lois Carpenter 50%

Sr. Director
Maria Stivers

WCH Research Administration
Kristen Tenney, 10%

Marketing & Recruitment

Miranda Gulasy

Manager
Zak Johnson

Compliance, Education & Training

Nate Harris

Budgets

Heather Roberson
Macy Michael

Operations/Project Management

TBD

Contracting

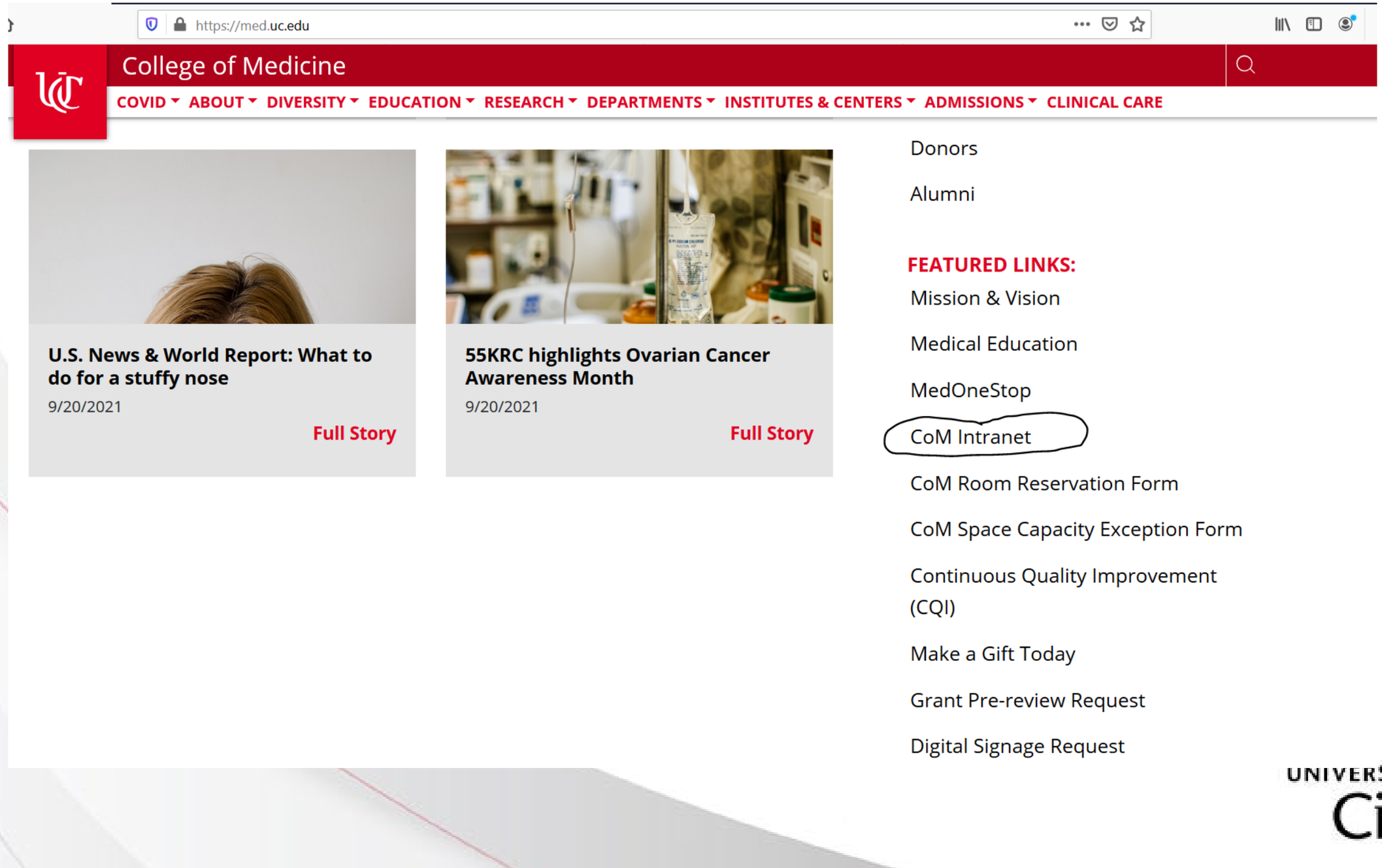
UC Sponsored Research Services

UCH EPIC Analyst
Charlie Fremont

UCH Research Approvals and Access
Sheree Sims

Accessing the Dashboard

- Med.uc.edu
- Scroll down to CoM Intranet



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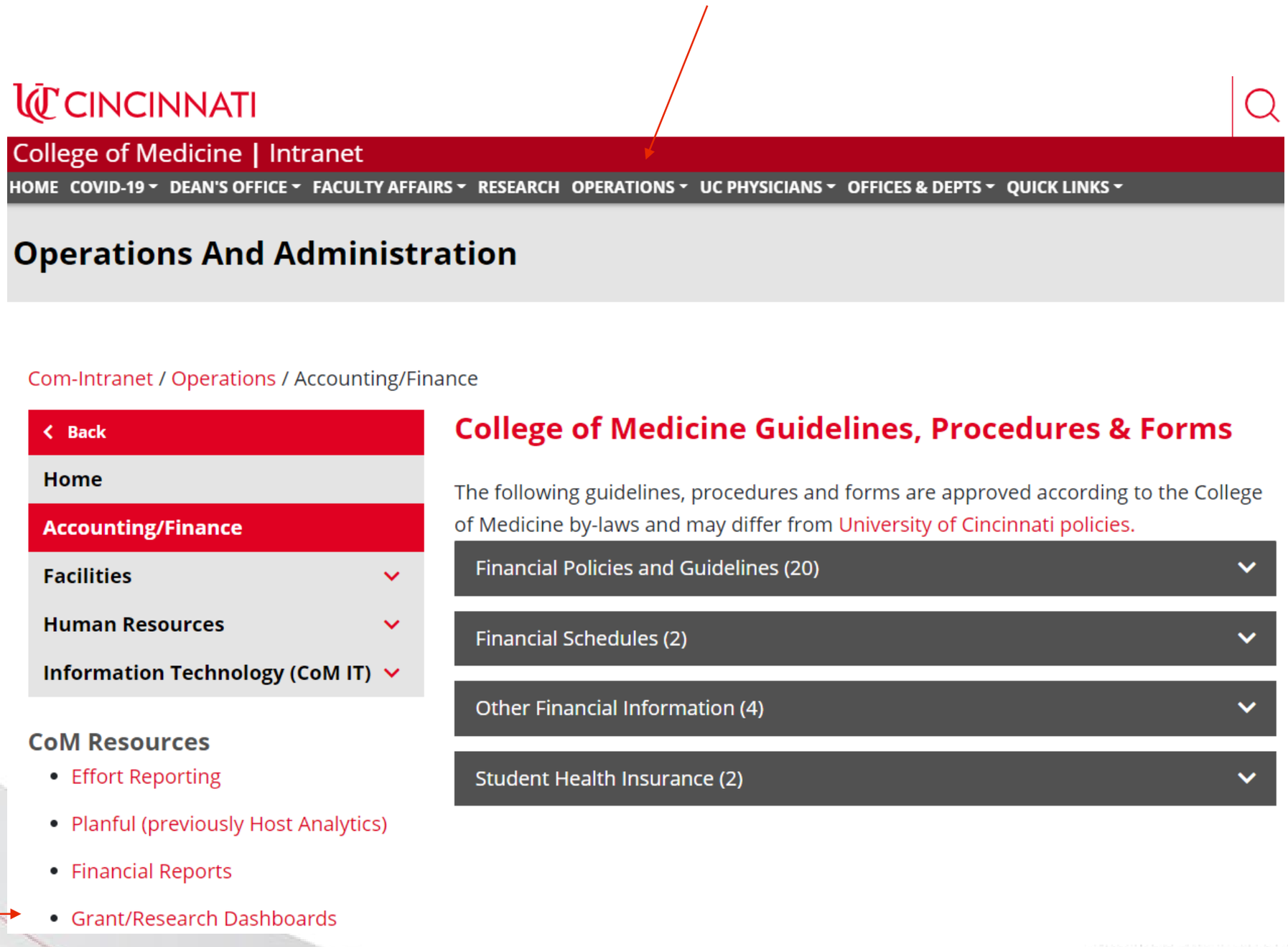
Accessing the Dashboard

- Link on CoM Intranet – Accounting/Finance



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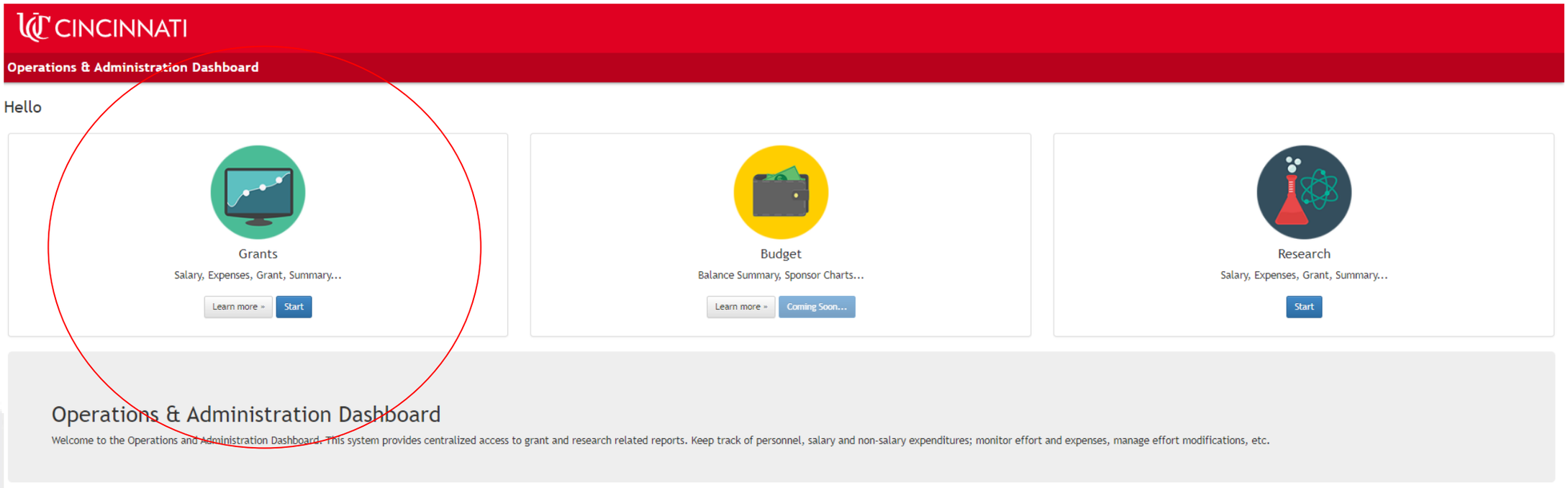
Accessing the Dashboard

- Will need to log in with UC ID/password



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Selecting a Department

- Initial view is summary by Department; select the department in the list or from the drop-down menu

CINCINNATI

Operations & Administration Dashboard

College ▾ Departments ▾

COM College of M

COM Pharmacology & Systems Physiology
Dermatology
Emergency Medicine
Environmental Health
Family Medicine & Community Medicine
Internal Medicine

Departm

Department	New Projects		Active Projects	Current Project Cumulative Budget		Current Project Expense	
	Month	Current FY		Direct	Indirect	Direct	In
Admin & Dean's Areas, Arts Finance & Administration, COM Faculty Affairs	0	2	4	$1,283,798.00	$17,927.56	$444,054.53	$6
Anesthesiology	0	2	13	$13,052,214.00	$4,823,598.20	$4,349,386.93	$2
Biomedical Informatics	0	1	2	$89,386.00	$33,655.10	$41,679.20	$1
Cancer & Cell Biology	0	7	33	$13,897,966.18	$4,810,813.50	$4,951,573.20	$2
COM Dean Academic Affairs	0	0	1	$637,875.00	$0.00	$692,600.00	$0
COM Dean Office of Research	0	4	8	$6,443,677.00	$772,145.34	$808,817.46	$2
COM Pharmacology & Systems Physiology	1	12	48	$19,948,535.46	$6,362,625.44	$7,354,550.01	$3
Dermatology	0	0	12	$987,940.78	$133,310.70	$377,915.95	$4
Emergency Medicine	2	14	35	$17,498,401.29	$3,780,217.48	$3,637,418.42	$7
Environmental Health	2	42	108	$26,710,027.76	$7,725,820.86	$9,481,172.54	$4

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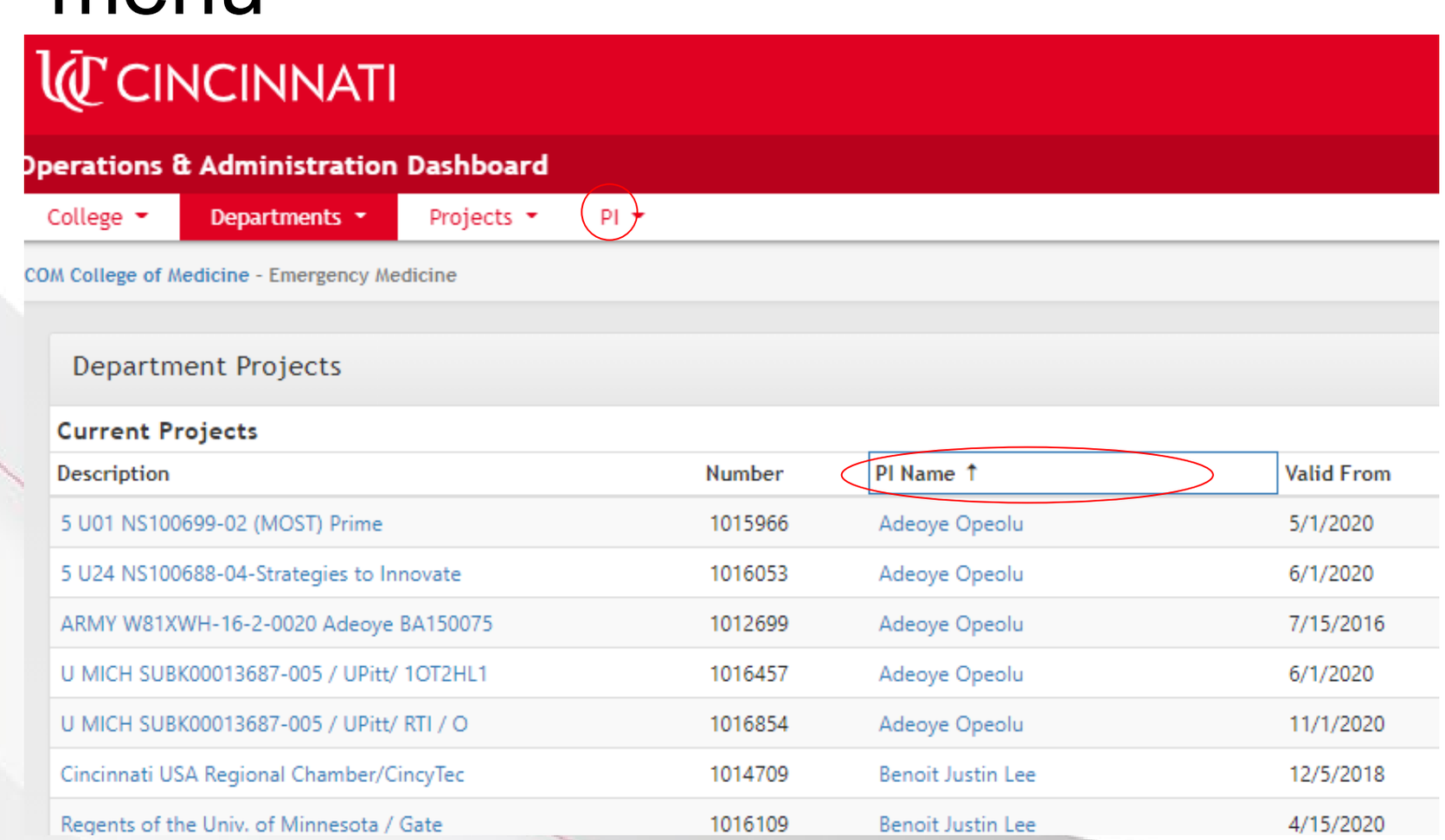
Grant Listing

- You can change the sort of the list by clicking the column title
- You can narrow the list down to a certain PI by clicking a PI name or selecting from the drop-down menu



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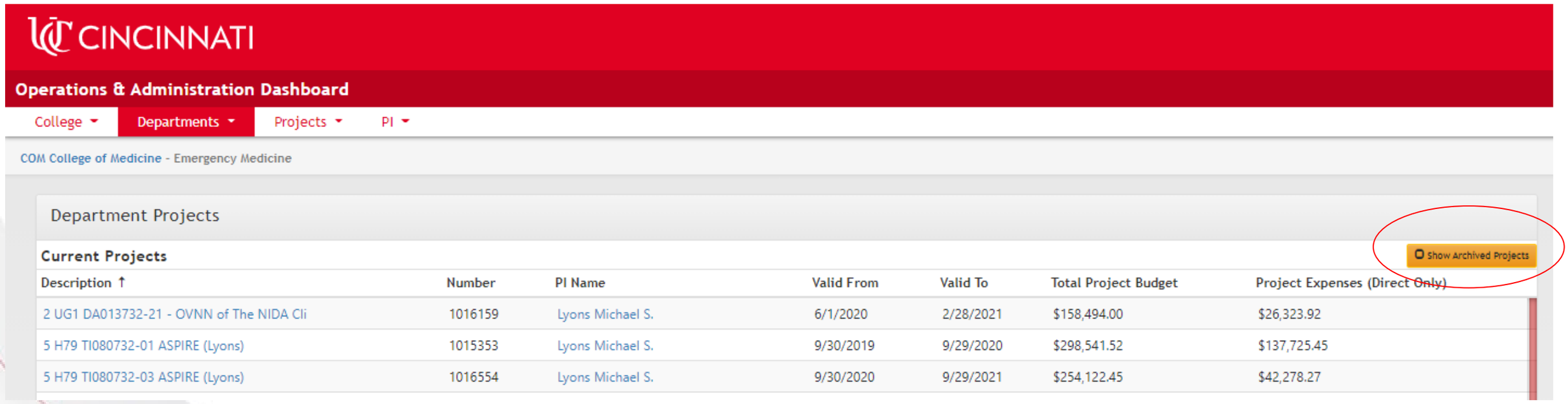
Active vs Archive List

- Check box to toggle between inactive (archived) and active (current) grant list



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Data Status

- Data updated monthly; header always shows most recent update

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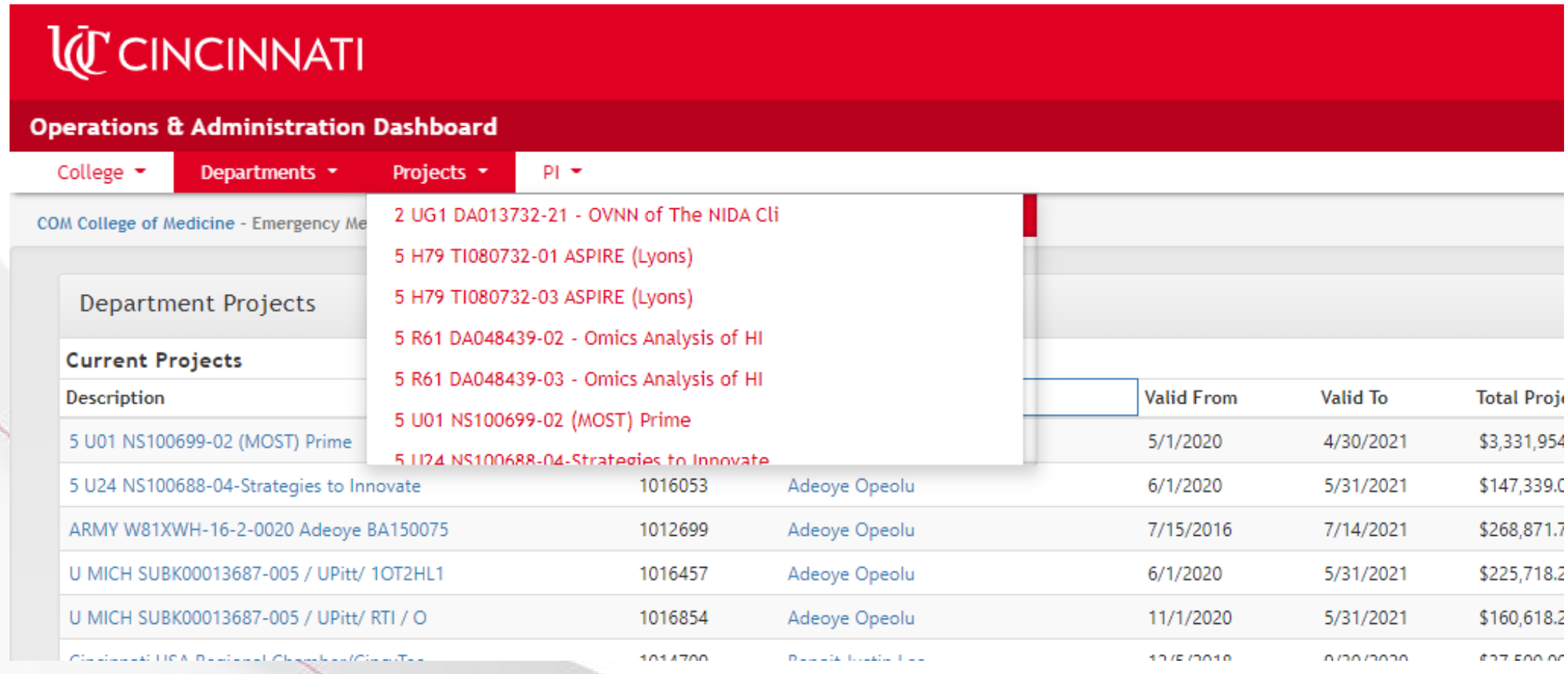
Selecting a Grant

- You can select a certain Grant by clicking a Grant Description or selecting from the drop-down menu



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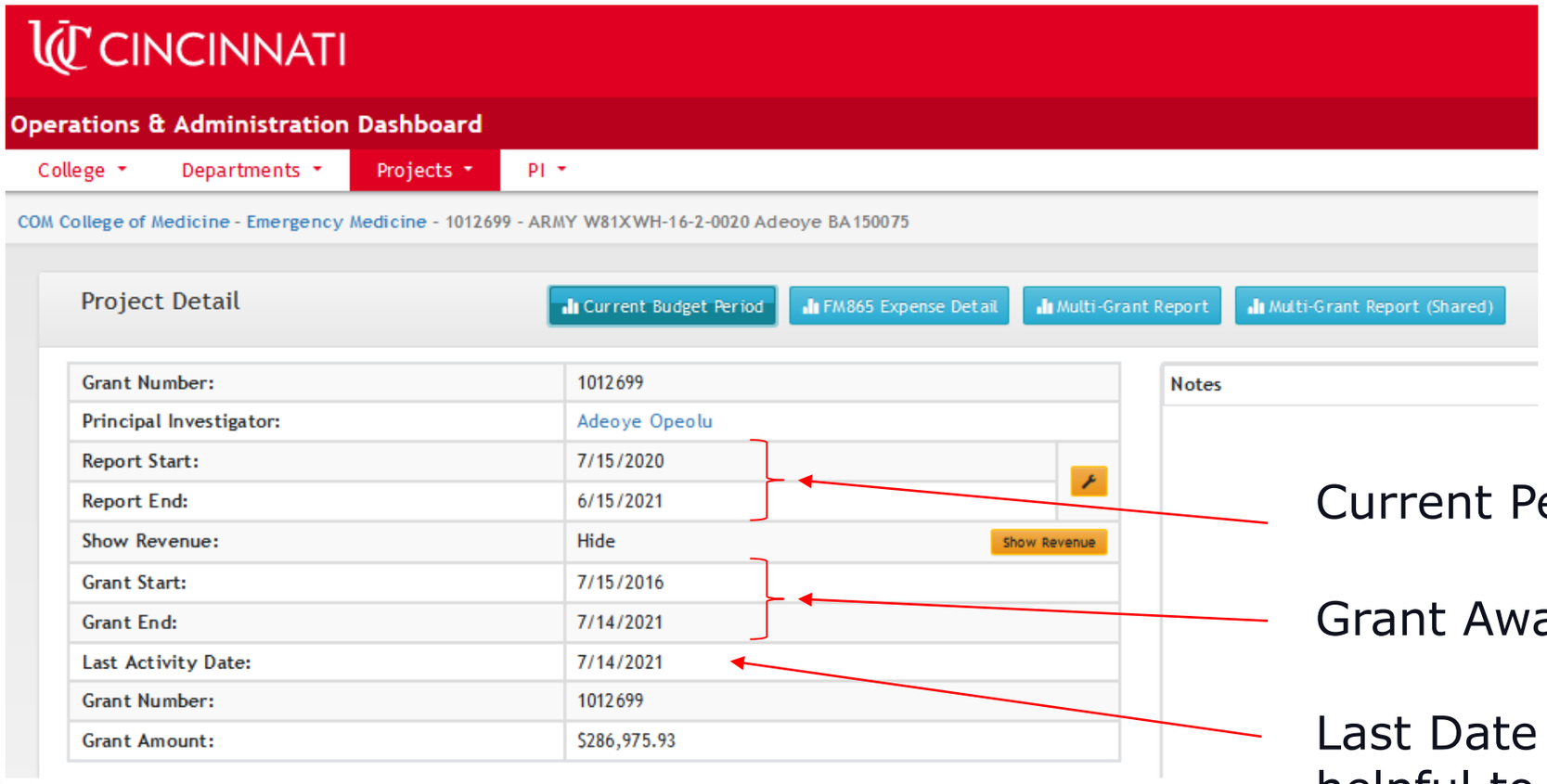
Project Details



Current Period

Grant Award Period

Last Date of transaction – helpful to know if there is activity beyond the Current Period

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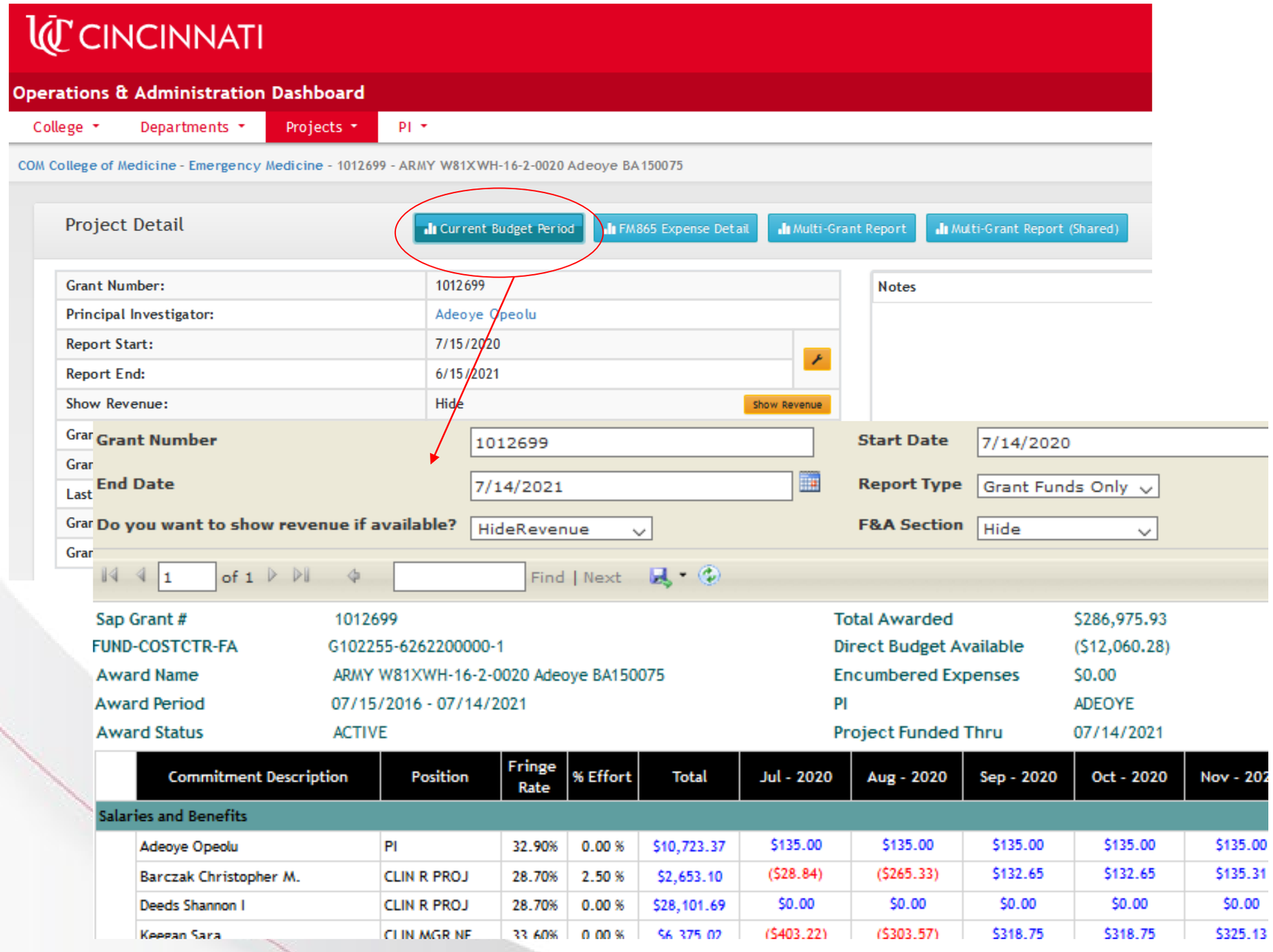
Running Budget Report



Commitment Description	Position	Fringe Rate	% Effort	Total	Jul - 2020	Aug - 2020	Sep - 2020	Oct - 2020	Nov - 202
Salaries and Benefits									
Adeoye Opeolu	PI	32.90%	0.00 %	$10,723.37	$135.00	$135.00	$135.00	$135.00	$135.00
Barczak Christopher M.	CLIN R PROJ	28.70%	2.50 %	$2,653.10	($28.84)	($265.33)	$132.65	$132.65	$135.31
Deeds Shannon I	CLIN R PROJ	28.70%	0.00 %	$28,101.69	$0.00	$0.00	$0.00	$0.00	$0.00
Keegan Sara	CLIN MGR NF	33.60%	0.00 %	$6,375.02	($403.22)	($303.57)	$318.75	$318.75	$325.13

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Cost Share Reporting

Grant Number	1012699	**Start Date**	7/14/2020
End Date	7/14/2021	**Report Type**	All Funds
Do you want to show revenue if available?	HideRevenue	**F&A Section**	Hide

1 of 1 | Find | Next

Sap Grant #	1012699	Total Awarded	$286,975.93
FUND-COSTCTR-FA	G102255-6262200000-1,D700335-6262200000-1,D700231-6262200000-1,D700062-6262200000-1,A100001-6262200000-1	Direct Budget Available	($12,060.28)
Award Name	ARMY W81XWH-16-2-0020 Adeoye BA150075	Encumbered Expenses	$0.00
Award Period	07/15/2016 - 07/14/2021	PI	ADEOYE
Award Status	ACTIVE	Project Funded Thru	07/14/2021

	Commitment Description	Position	Fringe Rate	% Effort	Total	Jul - 2020	Aug - 2020	Sep - 2020	Oct - 2020	Nov - 2020
Salaries and Benefits										
	Adeoye Opeolu	PI	32.90%	0.00 %	$10,723.37	$135.00	$135.00	$135.00	$135.00	$135.00
	Barczak Christopher M.	CLIN R PROJ	28.70%	2.50 %	$2,653.10	($28.84)	($265.33)	$132.65	$132.65	$135.31
	Deeds Shannon I	CLIN R PROJ	28.70%	0.00 %	$28,101.69	$0.00	$0.00	$0.00	$0.00	$0.00
	Keegan Sara	CLIN MGR NE	33.60%	0.00 %	$6,375.02	($403.22)	($303.57)	$318.75	$318.75	$325.13
	Kopec Lauren Christine	SR CR PROJ	28.70%	0.00 %	$6,242.17	$259.49	$331.56	$331.56	$331.56	$338.20

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F&A Reporting

Grant Number	1012699	**Start Date**	7/14/2020
End Date	7/14/2021	**Report Type**	All Funds
Do you want to show revenue if available?	HideRevenue	**F&A Section**	Show

1 of 1 | Find | Next

Commitment Description	Position	Fringe Rate	% Effort	Total	Jul - 2020	Aug - 2020	Sep - 2020	Oct - 2020	Nov - 2020	Dec - 2020	Jan - 2021	Feb - 2021	Mar - 2021	Apr - 2021	May - 2021	Jun - 2021	Jul -
Spinner Cristina	Sr Clinical Research Professional - COM	28.70%	0.00 %	$884.36	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
Syori Laura	CLIN RES PRF	28.70%	25.00 %	$0.00	$0.00	$0.00	$0.00	$852.27	$956.25	$956.25	$956.25	$956.25	$956.25	$956.25	$956.25	$956.25	$0
Werff Emily Louise	CR MANAGER	28.70%	2.00 %	$5,307.93	$100.44	$128.33	$128.33	$128.33	$130.90	$130.90	$130.90	$130.90	$130.90	$130.90	$130.90	$130.90	$0
Total Salary				$110,299.75	($156.61)	($2,498.04)	$2,136.22	$2,070.65	$2,020.79	$2,014.91	$1,898.65	$1,617.61	$2,254.33	$1,637.48	$1,607.92	$1,613.78	$0
Fringe Benefits				$37,400.00	($135.40)	($944.34)	$624.34	$605.53	$591.32	$589.39	$551.13	$472.17	$654.66	$477.63	$469.14	$470.34	$0
Student Fringe Benefits				$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
Total Benefits				$37,400.00	($135.40)	($944.34)	$624.34	$605.53	$591.32	$589.39	$551.13	$472.17	$654.66	$477.63	$469.14	$470.34	$0
Total Salaries and Benefits				$147,699.75	($292.01)	($3,442.38)	$2,760.56	$2,676.18	$2,612.11	$2,604.30	$2,449.78	$2,089.78	$2,908.99	$2,115.11	$2,077.06	$2,084.12	$0
Non-Salary																	
Travel Domestic - Concur	530550			$1,775.30	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
Lab Expenses	531900			$21.96	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
Participant Recruitment Services Core	533127			$20,675.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
Other Reserve	706900			$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
Total Non-Salary				$22,472.26	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
Total Direct				$170,172.01	$292.01	$3,442.38	$2,760.56	$2,676.18	$2,612.11	$2,604.30	$2,449.78	$2,089.78	$2,908.99	$2,115.11	$2,077.06	$2,084.12	$0
F & A Expense																	
F & A Expense				$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
F&A Expense - CUFS				$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
Sponsored Awards F&A Expense				$98,699.99	($169.33)	($1,996.57)	$1,601.12	$1,552.17	$1,515.04	$1,510.49	$1,420.89	$1,212.05	$1,687.22	$1,226.74	$1,204.69	$1,208.78	$0
F&A Calculated Adjustment				$1,239.61	($0.04)	($0.01)	$0.00	$0.01	($0.02)	$0.00	($0.02)	$0.02	($0.01)	$0.02	$0.00	$0.01	$0
Total F & A Expense				$99,939.60	($169.37)	($1,996.58)	$1,601.12	$1,552.18	$1,515.02	$1,510.49	$1,420.87	$1,212.07	$1,687.21	$1,226.76	$1,204.69	$1,208.79	$0
Cumulative Total F & A Expense				$99,939.60	$99,770.23	$97,773.65	$99,374.77	$100,926.96	$102,441.98	$103,952.48	$105,373.35	$106,585.42	$108,272.64	$109,499.40	$110,704.09	$111,912.88	$111,
Grant Total monthly with F&A Adjustments				$270,111.61	($461.38)	($5,438.96)	$4,361.68	$4,228.36	$4,127.13	$4,114.79	$3,870.65	$3,301.85	$4,596.20	$3,341.87	$3,281.75	$3,292.91	$0
Cumulative Totals with F&A Adjustments				$270,111.61	$269,650.23	$264,211.27	$268,572.95	$272,801.32	$276,928.45	$281,043.25	$284,913.90	$288,215.75	$292,811.96	$296,153.83	$299,435.58	$302,728.49	$302,

	Jul - 2020	Aug - 2020	Sep - 2020	Oct - 2020	Nov - 2020	Dec - 2020	Jan - 2021	Feb - 2021	Mar - 2021	Apr - 2021	May - 2021	Jun - 2021	Jul - 2021	Total Exp.
Grant Total without F&A Adjustments Grant Actual Totals	($461.34)	($5,438.95)	$4,361.68	$4,228.35	$4,127.15	$4,114.79	$3,870.67	$3,301.83	$4,596.21	$3,341.85	$3,281.75	$3,292.90	$0.00	$32,616.89

	Jul - 2020	Aug - 2020	Sep - 2020	Oct - 2020	Nov - 2020	Dec - 2020	Jan - 2021	Feb - 2021	Mar - 2021	Apr - 2021	May - 2021	Jun - 2021	Jul - 2021
Calculated Rate	57.99%	58.00%	58.00%	58.00%	58.00%	58.00%	58.00%	58.00%	58.00%	58.00%	58.00%	58.00%	58.00%
Budgeted Rate	58.00%	58.00%	58.00%	58.00%	58.00%	58.00%	58.00%	58.00%	58.00%	58.00%	58.00%	58.00%	58.00%

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Revenue Reporting

Project Detail

Current Budget Period | FM865 Expense Detail | Multi-Gr

Grant Number:	1012699
Principal Investigator:	Adeoye Opeolu
Report Start:	7/14/2020
Report End:	7/14/2021
Show Revenue:	Show — Hide Revenue
Grant Start:	7/15/2016
Grant End:	7/14/2021

Useful for Clinical Trials

Grant Number	1012699	Start Date	7/14/2020
End Date	7/14/2021	Report Type	Grant Funds Only
Do you want to show revenue if available?	ShowRevenue	F&A Section	Show

1 of 1 | Find | Next

Sap Grant #	1012699	Total Awarded	$286,975.93
FUND-COSTCTR-FA	G102255-6262200000-1	Direct Budget Available	($12,060.28)
Award Name	ARMY W81XWH-16-2-0020 Adeoye BA150075	Encumbered Expenses	$0.00
Award Period	07/15/2016 - 07/14/2021	PI	ADEOYE
Award Status	ACTIVE	Project Funded Thru	07/14/2021

Commitment Description	Position	Fringe Rate	% Effort	Total	Jul - 2020	Aug - 2020	Sep - 2020	Oct - 2020	Nov - 2020
Total Revenue				$67,986.47	$8,496.95	$461.37	$5,438.96	$4,361.68	$0.00
Salaries and Benefits									
Adeoye Opeolu	PI	32.90%	0.00 %	$10,723.37	$135.00	$135.00	$135.00	$135.00	$135.00
Barczak Christopher M.	CLIN R PROJ	28.70%	2.50 %	$2,653.10	($28.84)	($265.33)	$132.65	$132.65	$135.31

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Running Expense Detail Report

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Operations & Administration Dashboard

College ▾ Departments ▾ Projects ▾ PI ▾

COM College of Medicine - Emergency Medicine - 1012699 - ARMY W81XWH-16-2-0020 Adeoye BA150075

Project Detail

Current Budget Period | FM865 Expense Detail | Multi-Grant Report | Multi-Grant Report (Shared)

Grant Number:	1012699
Principal Investigator:	Adeoye Opeolu
Report Start:	7/15/2020
Report End:	6/15/2021
Show Revenue:	Hide (Show Revenue)
Grant Start:	7/15/2016

Notes

Grant Er
Last Act
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Grant Ag

Budget Month June 2021 **Report Type** Grant Funds Only

Do you want to show revenue if available? HideRevenue

1 of 1 Find | Next

FM865 - COM Emergency Medicine

Grant Number	Fund Number	Cost Center Number	FA	Internal Order Num	Commitment Number	Commitment Description	FIDoc No	Bu Pe
1012699	G102255	6262200000	1	#	536001	Sponsored Awards F&A Expense	104247441	
			1	#	511197	Unrep Unclassified Non-Exempt Part Time <80%	104242725	
			1	#	511040	FT Unrepresented Unclassified Exempt Base Salary	104246170	
			1	#	520102	Exempt Federal Fringe	104246088	

Defaults to current month activity

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A&F Functionality

- Accounting & Finance (A&F) team will have additional functionality, including the ability to:
  - Add notes in the system, which will display on reports.
  - Add encumbrances (projected future expenses) for personnel and non-personnel.

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Next Steps

- Currently educating A&F staff and departments
- Will scale back the use of manual Excel report – goal is to no longer use Excel files by Fall 2021
- Seek feedback from users
- Add enhancements as they are identified by users

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University of CINCINNATI | OFFICE OF RESEARCH

Additional Questions

University of CINCINNATI | OFFICE OF RESEARCH

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Albert Barnes Voorheis Professor and Chair
Department of Neurology and Rehabilitation Medicine
University of Cincinnati Gardner Neuroscience Institute
Senior Associate Dean for Clinical Research
University of Cincinnati College of Medicine
Chief of Research Services, UC Health

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University of CINCINNATI | OFFICE OF RESEARCH

Office of Clinical Research

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Sr. Director
stivermi@ucmail.uc.edu
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Assisting with transition and in communication with UCH and UC teams. Primary contact for questions that cannot be directed to a specific individual or team.

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Main contact for Complion, UCH Greenphire, research in Epic and research operations. Project manager for CTMS SignalPath.

Heather Roberson
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Budget Administrator
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Macy Michael
Clinical Research Budget
Administrator
michaemy@ucmail.uc.edu
937-640-2345

Continues to work on clinical research budgets for many departments. Has access to and monitors the redcap submission form. Responsible for uploading initial budget templates and final budgets to Kuali for ALL clinical trials. Contact for any questions related to clinical trial budgets.

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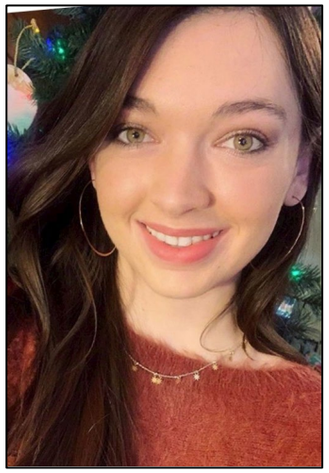
Office of Clinical Research



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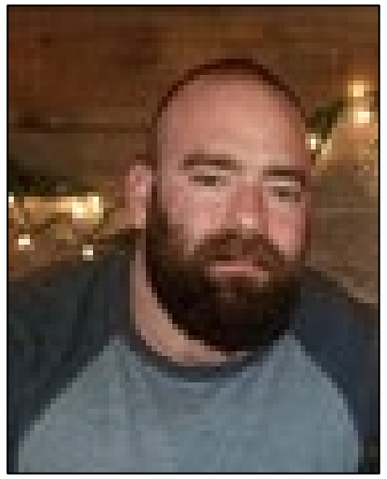

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SRS Accounting

SRS Accounting is responsible for invoicing sponsors, drawing down cash, preparing financial reports, and financial compliance.

Call SRS Accounting if you have an issue with sponsor billing, or with the ordering and distribution of ClinCards for participant payments.

John Ungruhe, Director
ungruhjg@ucmail.uc.edu
513-556-4817

Cindy Lasonczyk, Assistant Director
lasoncca@ucmail.uc.edu
513-556-4818

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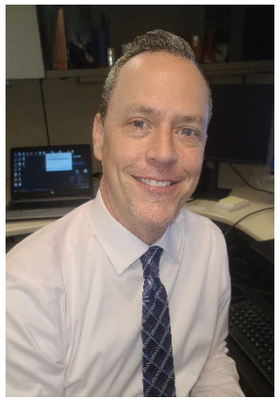
SRS Grants & Contracts

David Gearring, Director
gearridd@ucmail.uc.edu
513-556-5969

SRS Grants & Contracts Division is responsible for reviewing and negotiating the business terms of agreements, ensuring agreements are compliant with University rules, and setting up new awards in the University system

Call a member of the Industry Clinical Trials (ICT) team if you need information or help regarding contract terms or the establishment of your award account.

Heidi Rowles, Contract Specialist
rowleshl@ucmail.uc.edu
513-556-4808



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Senior Legal Assistant
513-558-1726

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Technology Transfer

- CDA/NDA/PIA – confidentiality agreements
- MTA – material transfer agreements
- DUA – data use agreements for de-identified data

Geoffrey Pinski
AVP, Technology Transfer
pinskig@ucmail.uc.edu

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CoM Accounting & Finance Pre-Award Team

- Responsible for the CoM pre-award grant submission process, from intent to submit through gathering documents and routing in Kuali, responding to JIT requests, and working with SRS to set up awards.
- Also responsible for Progress Reports and NCE/Carryforward Requests
- Submissions processed through A&F Pre-Award include federal/state funding and grants that involve effort reporting, return of funds, animal/human subjects, etc.

  -Generally does not include non-governmental clinical trials and investigator initiated trials.

Daniel Brummett
Executive Director

Steve Manning – Asst Director Pre-Award
-Lisa Bilinsky
-Sandra Newman
-Joanna Bordenave
-Noreen Webb-Johnson
-Julie Ison
-Stephanie Wilson