

Automation of NIH ADRC Required Tables



2023 Spring ADRC Meeting

May 1, 2023

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NIH Required Tables

Background

- Originally developed by the Administrator Group
 - A1 Federal Funded Grants Supported by Resources of the ADRC
 - A2 Non-Federal Funding Supported by Resources of the ADRC
 - A3 Funding for Therapeutic Trials
 - A4 Training Awards
 - A5 ADRC Collaborations
- A way to concisely report Center's activity to NIH

Current Tables

A1 Federal Funded Grants Supported by Resources of the ADRC

A2 Non-Federal Funding Supported by Resources of the ADRC

A3 Funding for Therapeutic Trials

A4 Training Awards

A5 ADRC Collaborations

A6 Underrepresented Group-Related Grants

A7 Biomarkers

E1 Underrepresented Group Events and Activities

E2 Summary Table of Underrepresented Group (URG)-Related Activities

G1 Summary Table of REC Trainees and Scholars

G2 Summary Table of REC Events

NIH Required Tables

- Each Center has their own way of collecting the data for the tables
- Table creation can be very time-consuming
- NIH takes Center data and prepares reports—tedious process

What if
there was a
better way?

Goal: Make grant and project
reporting to NIH more streamlined
and efficient

Imagine a world where....

Grant Number
U24AG057437
K99AG070109
1R01AG075012-01A1
R01HD093694
R24AG063724
R01AG052954
R33AG068483/ R61AG068483
T32AG078114
UL1TR002366
R01CA172764
R01AG069781
K01AG058785
R01AG072895



Table 1. Federal Funded Grants Supported by Resources of the University of Kansas - ADRC, Year 03				
Principal Investigator/ Project Director	Grant Title/Number	Source & Total Amount	Project Period	Role of ADRC
Aisen, Paul	Alzheimer's Clinical Trials Consortium (ACTC) (U24) U24AG057437	NIH \$838,832	2/2/2017-6/30/2023	Study coordination
Andrews, Shea	Elucidating the Causal Associations Underlying Alzheimer's Disease K99AG070109	NIA \$251,797	02/01/2021-07/01/2022	Consultation
Bailey, Heather	The role of prior knowledge and event segmentation in age- and Alzheimer's-related changes in event memory 1R01AG075012-01A1	NIH \$1,952,529	09/15/2022 - 05/31/2027	Recruitment
Boyne, Pierce Billinger, Sandra (Co-PI)	High-Intensity Interval Training to Recover Walking Post-Stroke: HIT-STROKE Trial R01HD093694	NIH \$805,484	4/3/2018-2/28/2023	Consultation
Bums, Jeffrey	Aligning PCPs and Patients with Alzheimer's Research Efforts: MyAlliance for Cognitive Health R24AG063724	NIH/NIA \$4,146,697	6/1/2020-3/31/2023	Study design/development, recruitment
Bums, Jeffrey	Prescribing Smart Aging: Integrating Health Systems with Community-Based Lifestyle Interventions R01AG052954	NIH/NIA \$2,865,176	9/15/2017-3/31/2023	Subjects, study design/development
Bums, Jeffrey	Remote Monitoring and Virtual Collaborative Care for Hypertension Control to Prevent Cognitive Decline R33AG068483/ R61AG068483	NIH/NIA \$11,354,079	08/01/2020 - 07/31/2025	Study design/development, recruitment
Bums, Jeffrey	Multidisciplinary Research Training Program in Alzheimer's Disease and Related Disorders T32AG078114	NIH/NIA \$1,459,964	8/1/2022-7/31/2027	Training, education
Castro, Mario	Frontiers Clinical and Translational Science Institute at the University of Kansas UL1TR002366	NIH/ NCATS \$18,338,759	7/29/2022-6/30/2027	Administrative support
Cheng, Nikki	Progression of DCIS to Invasive Breast Cancer Through CCR2 Chemokine Signaling R01CA172764	NCI \$4,604,235	9/1/2020-5/30/2025	Consultation, metabolic analyses
Crawford, Peter Thyfault, John (MPI)	Ketogenic Oscillations and Neurometabolic Healthspan R01AG069781	NIH/NIA \$1,579,218	09/30/2020-05/31/2025	Consultation, study design
Crawford, Peter	Administrative Supplement to Ketogenic Oscillations and Neurometabolic Health Span R01AG069781-01S1	NIA \$385,204	09/30/2020 - 05/31/2025	Consultation, brain tissue
Devos, Hannes	Neurophysiological Changes in Pre-Clinical Alzheimer's Disease K01AG058785	NIA/NIH \$637,636	2/1/2019-1/31/2024	Pilot funding, consultation, study design, human subjects
Ding, Wen-Xing	Mechanisms of Impaired Lysosomal Biogenesis and Autophagy in Alcohol-Associated Alzheimer's Disease R01AG072895	NIA \$1,918,175	9/30/2020-5/31/2025	Consultation, study design

Or

National Clinical Trial Number (NCT #)
NCT04048759
NCT03887455
NCT02079909
NCT02431468
NCT03305809
NCT03325556
NCT03367403
NCT03681925
NCT03721705
NCT04001517
NCT04262206
NCT04165109
NCT04585880
NCT02145702



Principal Investigator/ Project Director	Grant Title	Source	Project Period	Enrollment
Burns, Jeffrey	Anti-Amyloid Treatment in JNJ-54861911 Alzheimer's Disease (The A4 Study)	ADCS/ NIH /Lilly	6/2/2014-12/31/2026	20 participants
Burns, Jeffrey	Longitudinal Evaluation of Amyloid Risk and Neurodegeneration--the LEARN Study: A companion observational study to Anti-Amyloid Treatment in Asymptomatic Alzheimer's Disease (A4) Trial	ADCS/AA/NIH	6/12/2015-12/31/2022	15 participants
Burns, Jeffrey	Alzheimer's Prevention Registry GeneMatch Program	Banner Alzheimer's Institute	1/1/2017-12/31/2027	329 participants
Burns, Jeffrey	A randomized, double-blind, placebo-controlled, two-cohort, parallel group study to evaluate the efficacy of CAD106 and CNP520 in participants at risk for the onset of clinical symptoms of Alzheimer's disease	Novartis	5/25/2017-12/31/2027	13 participants
Burns, Jeffrey	Randomized Controlled Pilot Trial of Dapagliflozin in Alzheimer's Disease	AstraZeneca LP	5/1/2018-12/31/2022	48 participants
Burns, Jeffrey	A randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of CNP520 in participants at risk for the onset of clinical symptoms of Alzheimer's Disease (AD) (Generation 2)	Novartis Pharmaceuticals Corp	1/16/2018-12/31/2030	3 participants
Burns, Jeffrey	A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy, and Safety Study of Gantenerumab in Patients with Prodromal to Mild Alzheimer's Disease (Graduate II)	Genentech Inc	11/20/2018-12/31/2030	0 participants
Burns, Jeffrey	An Extension Study of ABBV-9E12 in Early Alzheimer's Disease	AbbVie	5/30/2019-12/31/2022	6 participants
Burns, Jeffrey	Anti-Amyloid Treatment in Asymptomatic Alzheimer's Disease (A4) Open-Label Extension Study	ADCS/ NIH /Lilly	5/15/2019-5/31/2024	20 participants
Burns, Jeffrey	Alzheimer's Disease Neuroimaging Initiative-3 (ADNI3)	ATRI/NIH	9/28/2017-12/31/2027	24 participants
Burns, Jeffrey	Assessment of Safety, Tolerability and Efficacy of LY3002813 Alone and in Combination with LY3202828 in Early Symptomatic Alzheimer's Disease (Trailblazer)	Eli Lilly	5/22/2018 - 6/30/2022	5 participants
Burns, Jeffrey	A Phase 1b, Multi-center, Randomized, Double-Blind, Placebo-Controlled Safety and Biomarker Study of pepinemab Anti-SEMA4D Antibody in early Alzheimer's Disease (AD) (Signal-AD)	IQVIA	10/23/2020 - 12/31/2023	1 participant
Burns, Jeffrey	Phase 3b Open-Label, Multicenter, Safety Study of BILB037 (aducanumab) in Subjects With Alzheimer's Disease Who Had Previously Participated in the Aducanumab Studies 221AD103, 221AD301, 221AD302, and 221AD205 (Embark)	Biogen	8/28/2020 - 2/28/2025	4 participants
Burns, Jeffrey	Donanemab Follow-On Study: Safety, Tolerability, And Efficacy in Symptomatic Alzheimer's with Validation of Remote Neuropsychological Assessments (Trailblazer-Ext)	Eli Lilly	5/11/2021 - 11/30/2023	3 participants

We've done something similar...

The screenshot shows an email client window titled "ACTION NEEDED: Complete important surveys by February 24th - Message (HTML)". The interface includes a menu bar with "File", "Message", "Help", "Mimecast", "Acrobat", and "Attachments". Below the menu is a toolbar with icons for "Open", "Quick Print", "Remove Attachment", "Save As", "Save All Attachments", "Upload", "Upload All Attachments", "Select All", "Copy", and "Show Message".

The email content is as follows:

ACTION NEEDED: Complete important surveys by February 24th

Cerise Elliott <nacchelp@uw.edu>
To: Jeff Burns; Ryan Townley; Eric Vidoni; Jaime Perales Puchalt
Cc: Russell Swerdlow; Anne Arthur; Jennifer Freund

Follow up. Start by Monday, February 6, 2023. Due by Monday, February 6, 2023.

ADRC Survey Questions[90].docx
32 KB

Dear University of Kansas ADRC Clinical Core and ORE Core Leaders,

As noted during the October 2022 ADRC meeting, recently enacted Congressional appropriations language (H.R 2617) specifically referred to the ADRCs. To adequately address this language, provided below, we are asking each ADRC to complete 3 surveys related to access to clinical trials and ADRC outreach and care.

Alzheimer's Disease Research Center [ADRC].- The Committee directs NIA to provide Congress a report within 180 days of enactment of this Act detailing the number of individual Alzheimer's patients who have gained access to a clinical trial through the outreach of an ADRC, the number of Alzheimer's disease diagnoses given to patients at an ADRC, and a comprehensive report on patients' and providers' needs that were met through the work of ADRCs that cannot be attained at a physician office.

Please note the survey does not include questions related to the number of diagnoses given to ADRC participants because this information was gathered from the NACC database.

- [Click here](#) to enter clinical trial information for your ADRC between January 1, 2017 to December 31, 2022.
- [Click here](#) to enter ADRC Research Registry information.
- [Click here](#) to enter information that illustrates the work of your ADRC in providing services that cannot be attained at primary care providers offices.

You can find a list of the survey questions in the attached file.

This is a time sensitive request, and your best complete answer is required by **February 24, 2023**.

Note the ADRC Administrator and Director are copied on this email for reference.

Please direct any questions about this survey to elliottce@mail.nih.gov.

Cerise L. Elliott, Ph.D.

Proposal:

Standardized process for ADRC / NIH grant and project reporting

Proof of Concept: A1 Federal Grants Table



Application Programming Interface (API)

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Proof of Concept (continued)

- Would be able to use similar logic for **A3 Therapeutic Trials** table
 - Use NCT#



NIH U.S. National Library of Medicine

ClinicalTrials.gov

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Considerations

- Not all data for **A1 Federal Grants** can be generated from NIH Reporter
 - “Role of the ADRC”
 - Provides annual amount not total amount
- “Enrollment” numbers for **A3 Therapeutic Trials** table are not generated from the NCT#
 - CROMS could be potentially used to generate enrollment numbers

Considerations (continued)

- What other resources are available to generate remaining tables?
 - A2 Non-Federal Funding Supported by Resources of the ADRC
 - A5 ADRC Collaborations
 - A6 Underrepresented Group-Related Grants – [NIH Reporter](#) + [REDCap](#)
 - A7 Biomarkers
 - E1 Underrepresented Group Events and Activities
 - E2 Summary Table of Underrepresented Group (URG)-Related Activities
 - G1 Summary Table of REC Trainees and Scholars – [XTRAIN?](#)
 - G2 Summary Table of REC Events

Next Steps

- Determine what data needs to be captured
 - Consider a “Uniform Data Set” that all Centers would collect
 - Would there be standardized roles for “Role of ADRC”?
- Consider using REDCap to house this data
 - Develop shareable forms and data dictionary
- Determine if data would be shared/stored locally vs. nationally
- Steering Committees to work through, in collaboration with the Administrators, to automate/update these tables
 - Workgroup 1: A2, A5, and A6
 - Biomarker Steering Committee: A7
 - ORE Core Steering Committee: E1 and E2
 - REC Steering Committee: G1 and G2

KU

ALZHEIMER'S DISEASE
RESEARCH CENTER

The University of Kansas Medical Center

KU Alzheimer's Disease Research Center
University of Kansas Medical Center
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