



*RESEARCH* ADDRESS

COLLABORATIONS ON CAMPUS & INTERCAMPUS

Thomas Flaig, MD

Vice Chancellor for Research

December 8, 2020

# AGENDA

## “Progress through Collaboration”

- Welcome and Introduction: Thomas Flaig, MD
- Central Research Administration
- Metrics of research on CU Anschutz Campus
- Sponsored research funding
- Research response to COVID
- The richness of our research community
- Special projects and future plans
- Questions

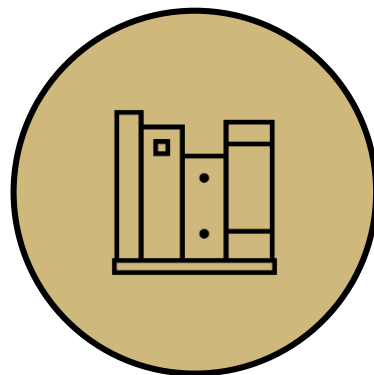


# MY BACKGROUND



- MD from the University of MN
- **2003** – Oncology Fellowship – UCHSC (9th and Colorado)
- **2006** – Joined the faculty in medical oncology
- **2011** – Medical Dir – Cancer Trials Office
- **2015** – Assoc Dir CU Cancer Center
- **2016** – Chief Clinical Research Officer – UCHealth
- **2016** – Assoc Dean for Clinical Research – SOM
- Started in role as Vice Chancellor March 1, 2020
  - Served as Interim VCR (Aug 2019 – Feb 2020)





# CENTRAL RESEARCH ADMINISTRATION



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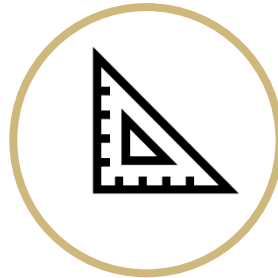


# CENTRAL RESEARCH ADMINISTRATION

*Serves a large and wide-ranging research community*



**5000** faculty  
**1500** PRAs  
**300** post docs



**2 million+**  
square feet of  
research space



**>2000**  
clinical trials



**>5000**  
sponsored  
projects  
in FY 2020



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# OFFICE OF THE VICE CHANCELLOR FOR RESEARCH CENTRAL ADMIN ORGANIZATION



Alison Lakin, PhD  
Associate Vice Chancellor  
Regulatory Compliance



Jori Leszczynski, DVM  
Assistant Vice Chancellor  
Laboratory Animal Research (OLAR)



Amy Gannon *via EVCAF*  
Associate Vice Chancellor, Controller  
Financial services, Bursar and  
Grants and Contracts (OGC)





# CENTRAL RESEARCH ADMINISTRATION

## *Provides key support*

- Provides required institutional structure
  - IBC, IACUC, radiation safety, hazardous waste, safety audits
  - IRB, HIPAA, research privacy, COI, Export Control, FDA applications
  - OLAR, animal husbandry, veterinary services
  - Research Integrity Oversight
- Maintains key accreditations
  - AAALAC, AAHRPP





# ASSOCIATE VICE CHANCELLOR OF BASIC SCIENCES RESEARCH (AVCBSR)

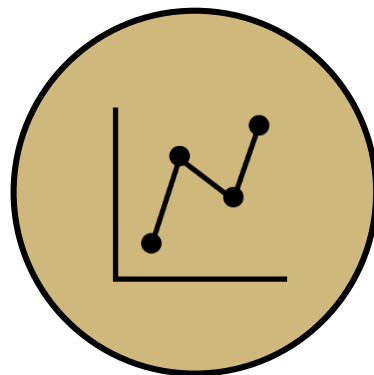


Lori Sussel, PhD

- October 2020
- Recognized researcher (nationally & internationally)
- Professor, Pediatrics and Cell & Developmental Biology
- Director, Diabetes Research Center
- Barbara Davis Diabetes Center
  - Director of Basic and Translational Research
  - Sissel and Findlow Family Chair







# METRICS OF RESEARCH



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# CENTRAL RESEARCH ADMINISTRATION

## *Supporting research*



**3124**

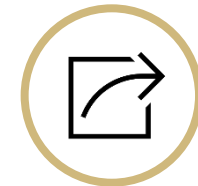
proposals/grants

12+ per  
business day



**1,619**

research contracts  
from other entities



**1,131**

subcontract to  
other entities



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# CLINICAL RESEARCH / IRB SUPPORT

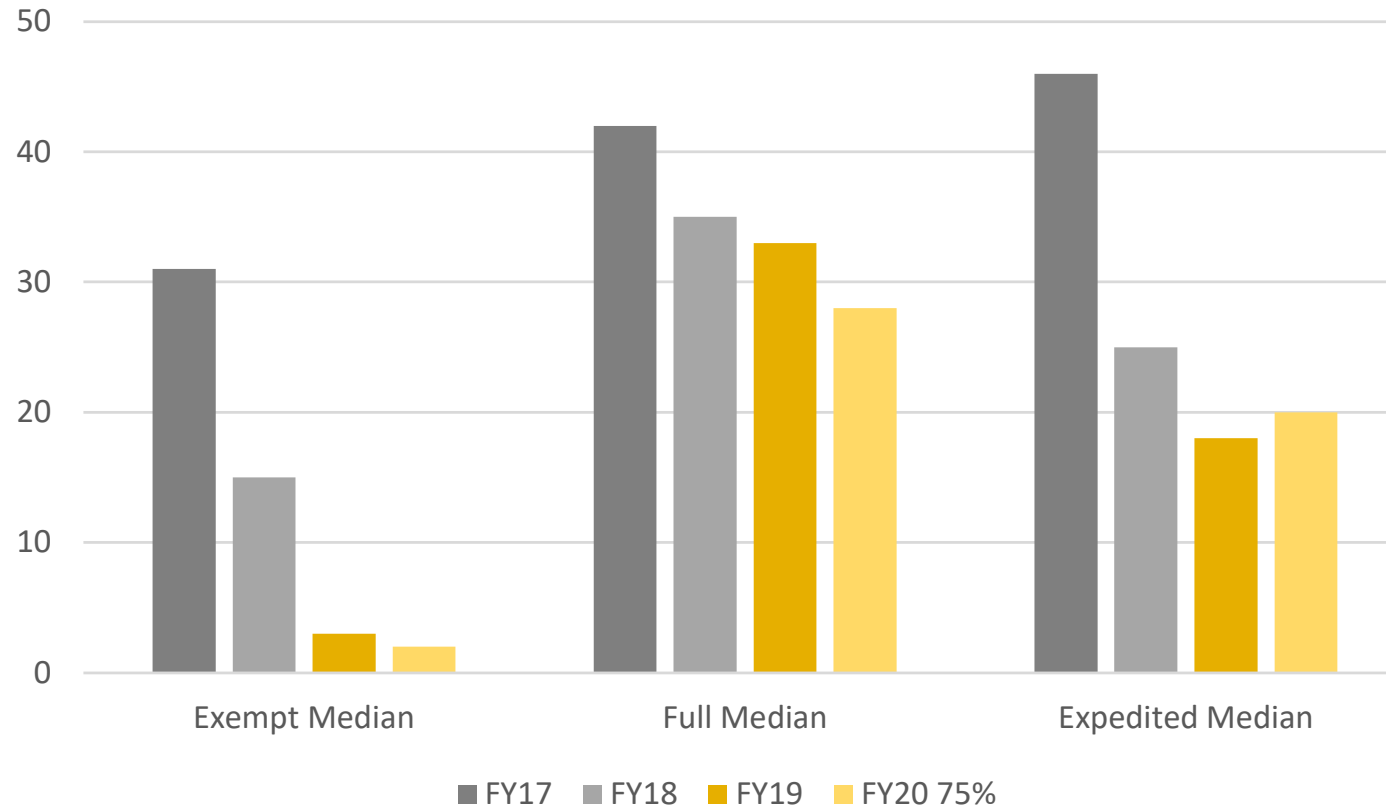
- Zen Desk (help desk) – 17,000+ contacts annually
- Training – 25 courses in research education with 800+ attendees
- IND/IDE active applications with FDA – 94
- 5796 active projects with IRB approval
  - 2241 open clinical trials





# COMIRB TIMELINES

Median Days to Approval



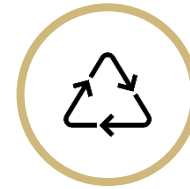


# ENVIRONMENTAL HEALTH AND SAFETY



**550**

lab inspections  
annually



**116**

tons of regulated  
medical waste



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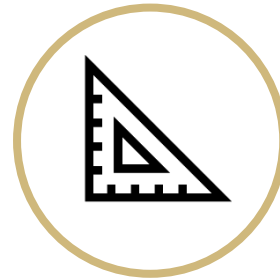




# OLAR



**95** total personnel



Oversees **100,000** sq feet  
Increases to **130,000** with  
current construction



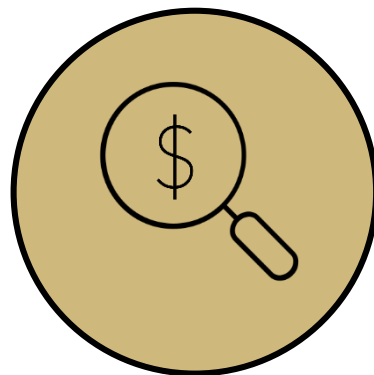
Provides research  
support to over **320**  
Investigators covering  
**530** IACUC protocols



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# SPONSORED RESEARCH FUNDING



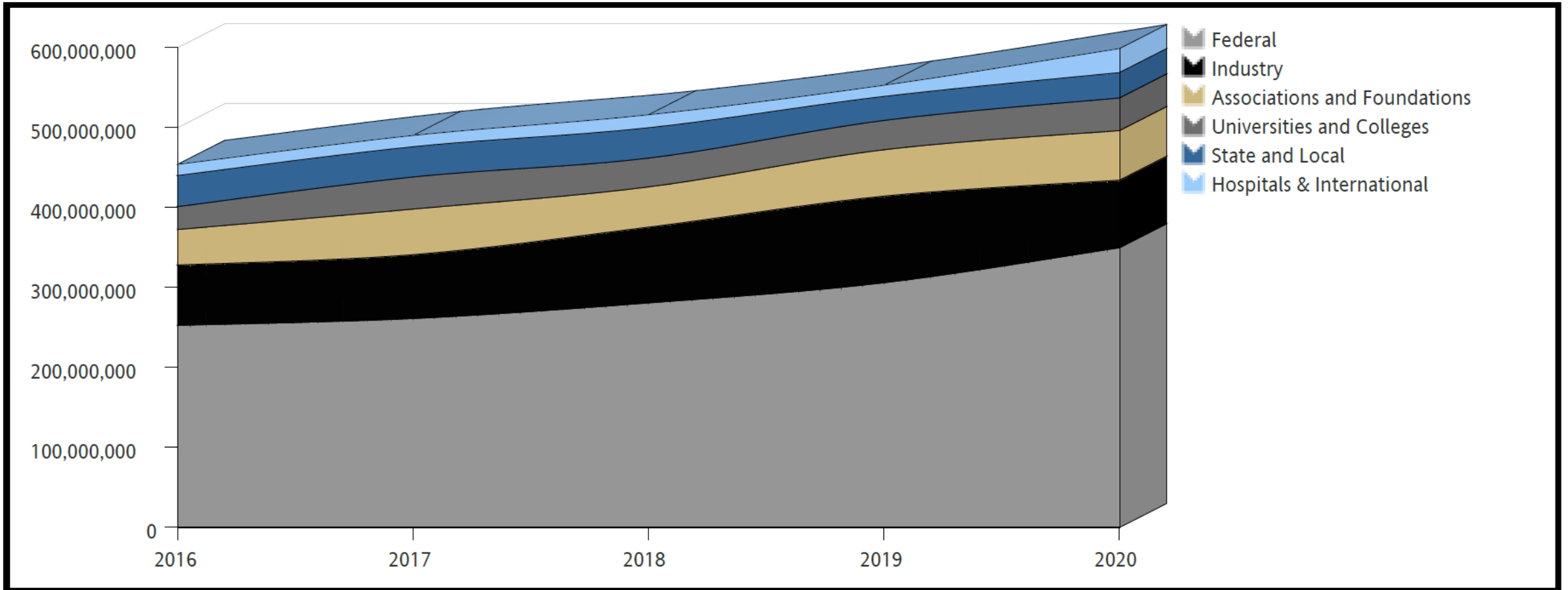
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# CAMPUS AWARDS BY SPONSOR TYPE



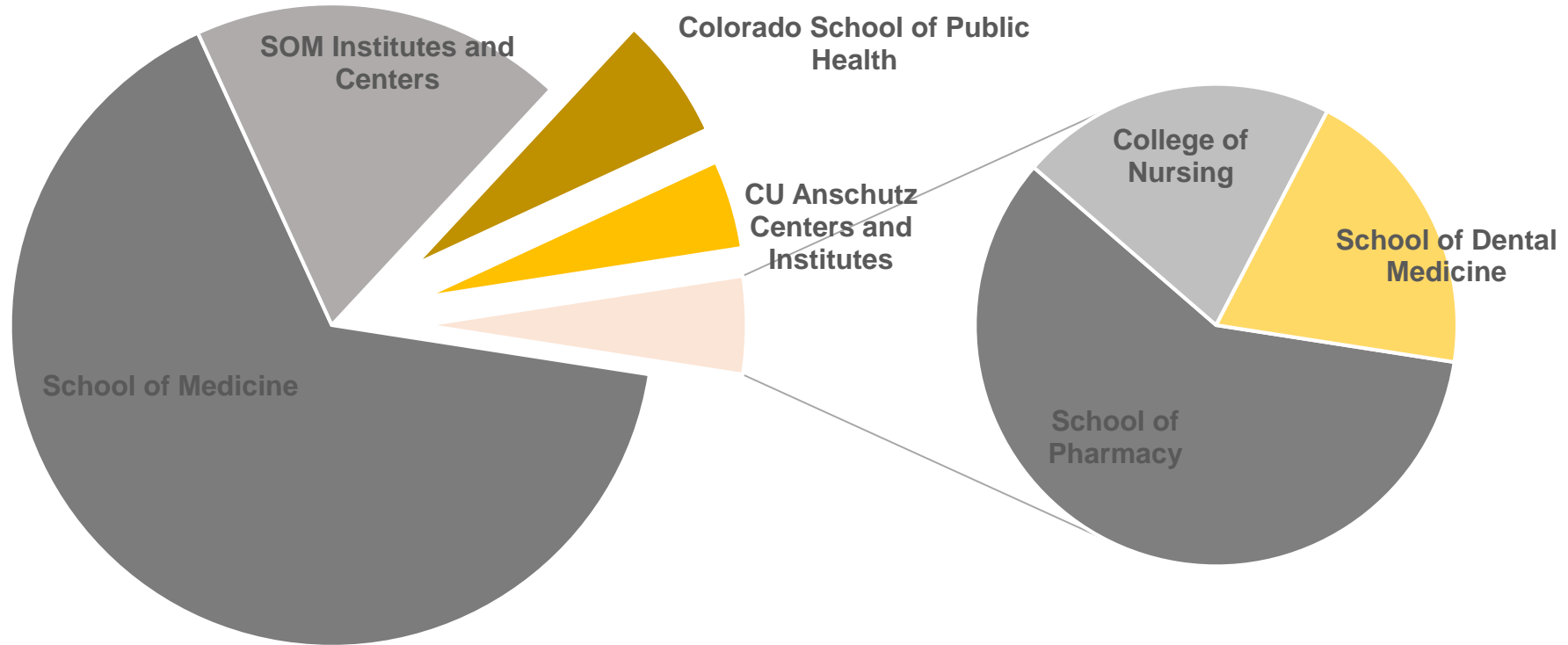
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# CAMPUS FUNDING CONTRIBUTIONS



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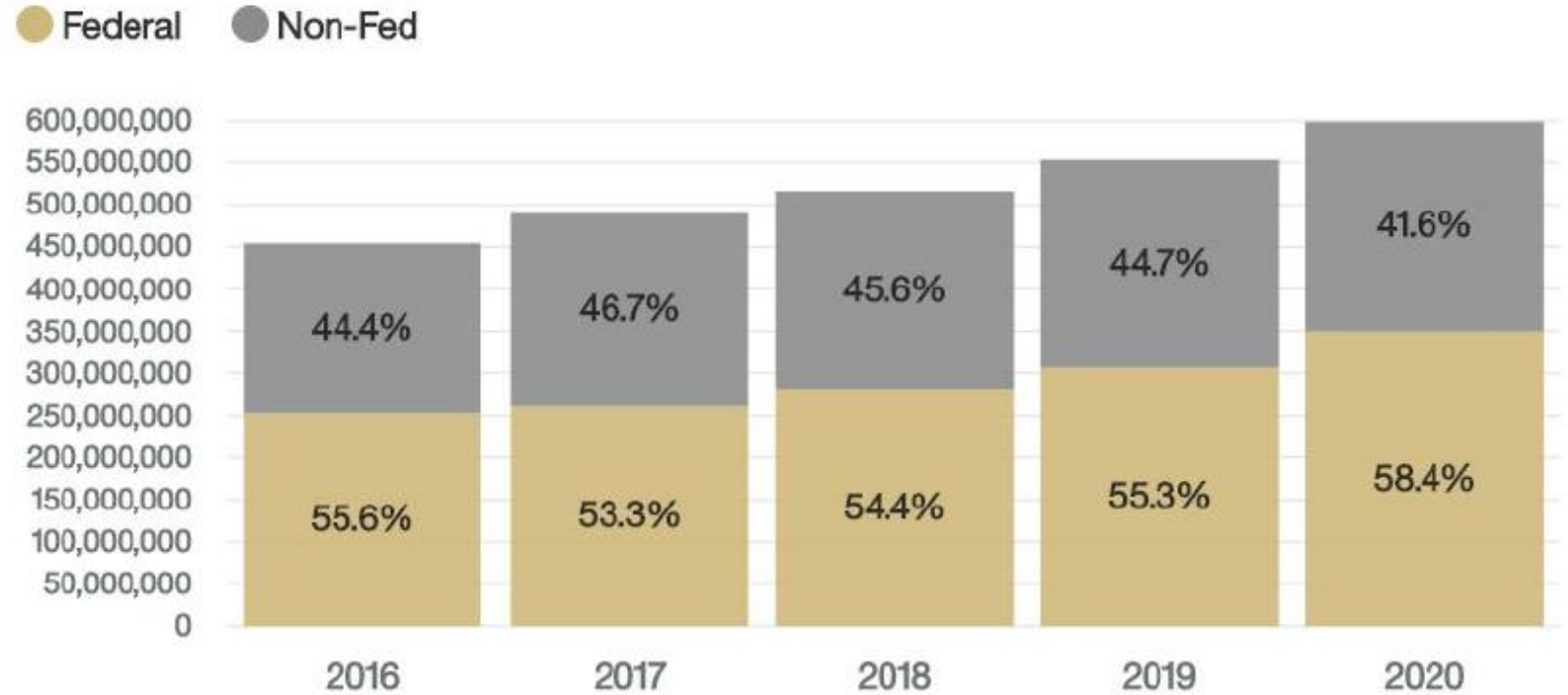
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# PROPORTION OF FEDERAL FUNDING

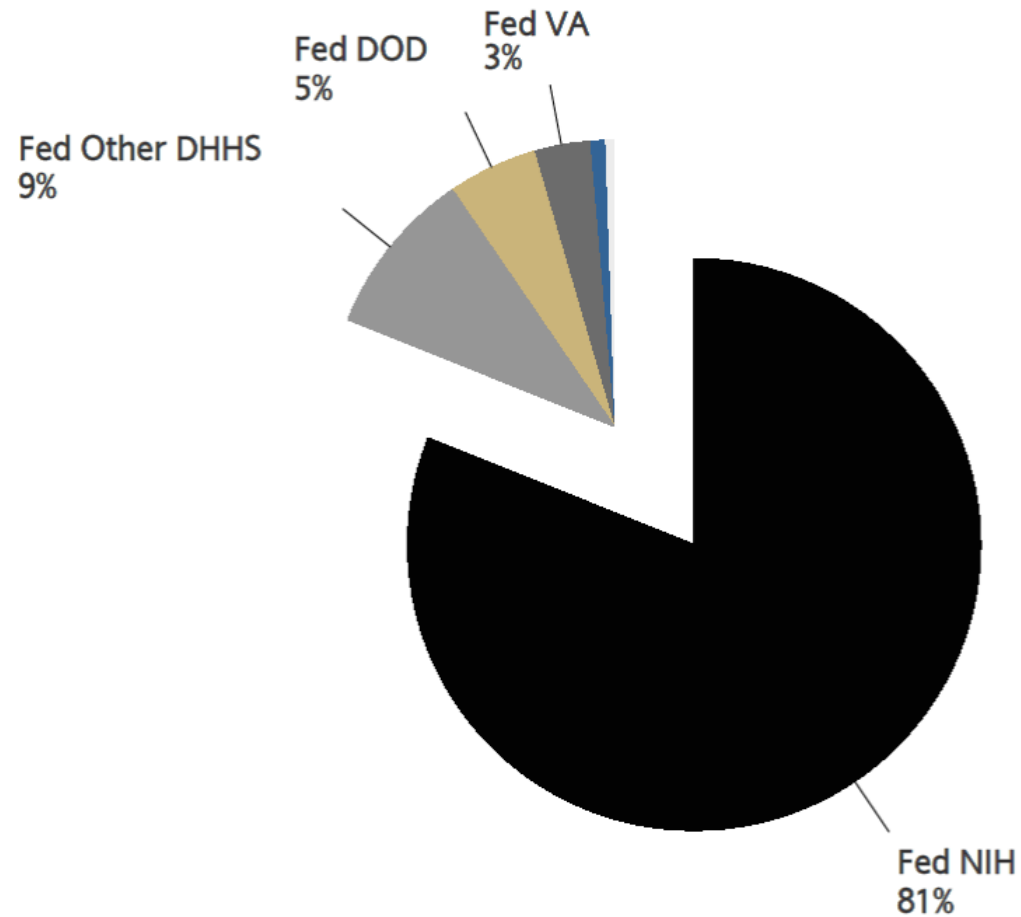
Federal  
VS  
Non-Federal  
(Awards)







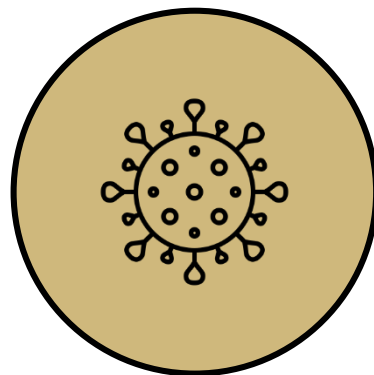
# 2016-2020 FEDERAL SPONSORS



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# RESEARCH RESPONSE TO COVID



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# COVID-19 TIMELINE

- **March 16** – moved to critical access only due to COVID-19
- **April 24** – announced laboratory research reconstitution plan
- **May 15** – developed clinical research prioritization framework
- **May 18** – moved to phase 2 of research reconstitution
- **June 5** – lab-based researchers at 50% of baseline levels
- **June 19** – lab-based personnel over 50% - shifts utilized
- **July 2** – community research framework finalized
  
- **November 20** – CU Anschutz elevated to COVID Level Red





# OUR COLLECTIVE RESPONSE

## Gratitude to the entire research community

- Prioritizing our safety and maintaining our mission
- Adaptation and flexibility
- A communal spirit of purpose and teamwork
- Ongoing vigilance and focus



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# ENVIRONMENTAL HEALTH AND SAFETY

## **EHS** *is*

**DIRECTOR**  
ETHAN CARTER

**DIVISION MANAGERS**

CODY COBURN  
Occupational Health

MARCIA FINUCANE  
Biological Safety

JERMAN LOPEZ  
Hazardous Materials

ALISON MCGRATH  
Research Safety &  
Industrial Hygiene

RIAD SAFADI  
Radiation Safety

+ 25 FULL-TIME STAFF

- During COVID, the team has added additional responsibilities
  - Established and managed the COVID health screening check points which have screened **370,000** people since May 11
  - Developed new biosafety guidelines in response to the pandemic
  - Added Infection Prevention Specialist
    - Conducted contact tracing for 1622 individuals
  - Added a COVID testing site to better serve the CU Anschutz University Community



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# REGULATORY COMPLIANCE RESPONSE

- June of 2020
  - First COVID focused clinical trial opened in 10 days from submission
- 30 emergency INDs for COVID-19 treatments
- Coordinated clinical trial prioritization with campus partners





# 2020 CCTSI COVID-19 RELATED RESEARCH PROGRAM AWARDS



- **J. David Beckham, MD**
  - A prospective, observational cohort trial for the treatment of hospitalized COVID19 patients with high-titer anti-SARS-CoV2 convalescent serum



- **Anna Maw, MD**
  - Rapid implementation of lung ultrasound in the management of hospitalized adults with COVID-19



- **Brian Montague, DO**
  - Prospective Identification of SARS-CoV2 Infection in Healthcare Workers



- **David Prawel, PhD**
  - Additive Manufacturing of Certified PPE: A Path Towards Mass Production



- **Ron Sokol, MD**
  - Assistant Vice Chancellor for Clinical and Translational Science
  - Director, Colorado Clinical and Translational Sciences Institute
  - **CCTSI Town Hall**  
Dec 15, 2020 12:00 PM





# VIDEO

Researchers at the CU Anschutz Medical Campus have been working countless hours responding to the COVID-19 pandemic.

Here are a few insights on current research efforts.



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[Click here](#)



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# COVID BIOBANK

- CU Anschutz COVID biobank launched in March of 2020
- Pandemic posed special challenges:
  - Logistical challenges of patient access, PPE considerations, pandemic dynamics
- Biobank to serve as an institutional resource for collection and distribution of COVID patient samples
- Collecting both prospective and retrospective samples
- Realtime sample processing for prospective samples (PBMC isolation, etc)

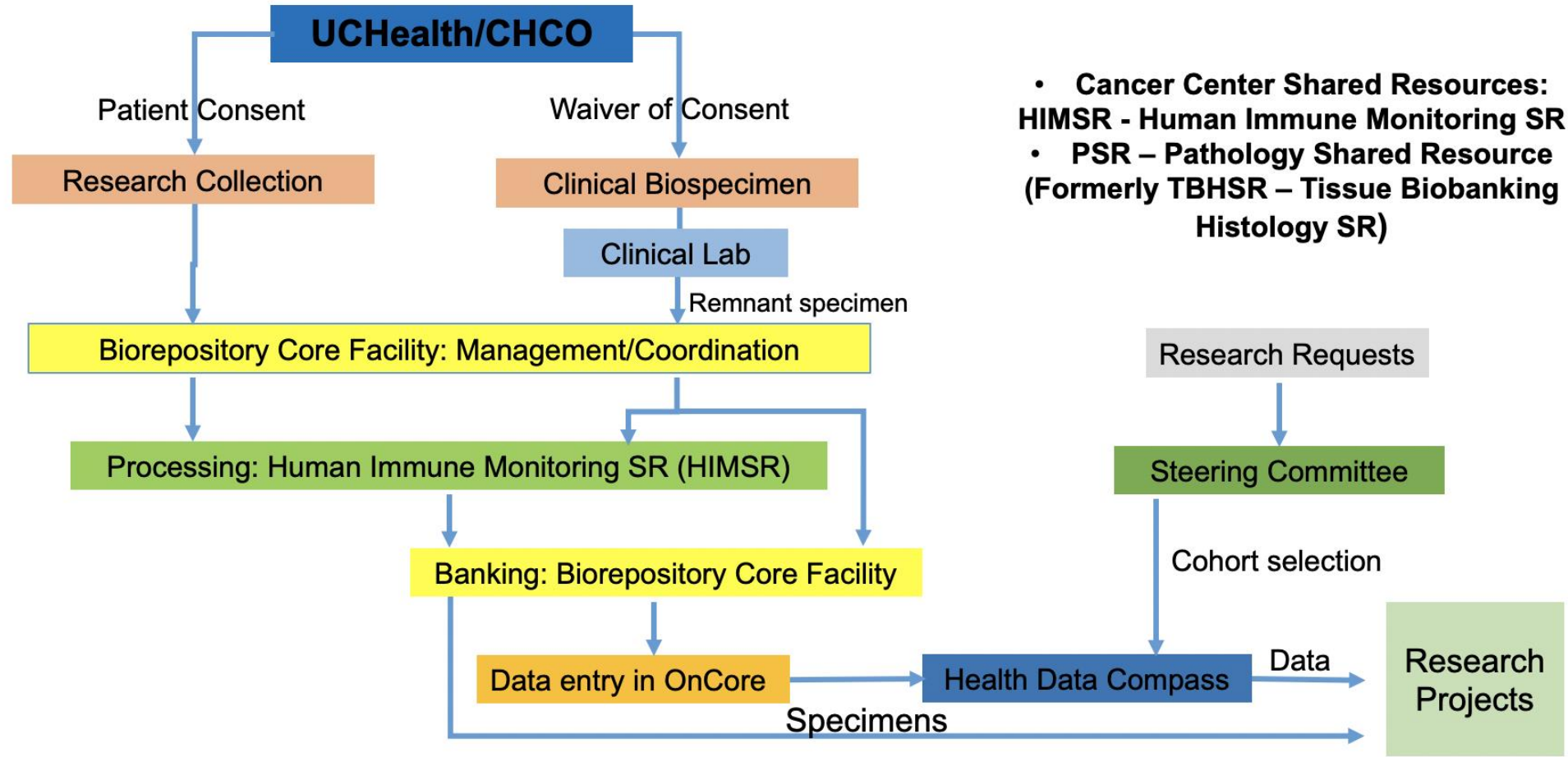


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# COVID BIOBANK LOGISTICS







# COVID BIOBANK TISSUE ALLOCATION COMMITTEE

## Founding members



Eva Grayck, Chair



Peter Gottlieb



Bryan Haugen  
(Past chair)



Adrie Van Bokhoven

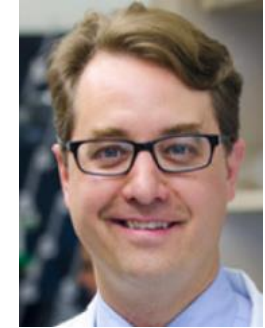


Martin Voskuil

## Non-voting (ex officio) members



Alison Lakin



Tom Flaig



Marcia Finucane



Matthew Steinbeiss



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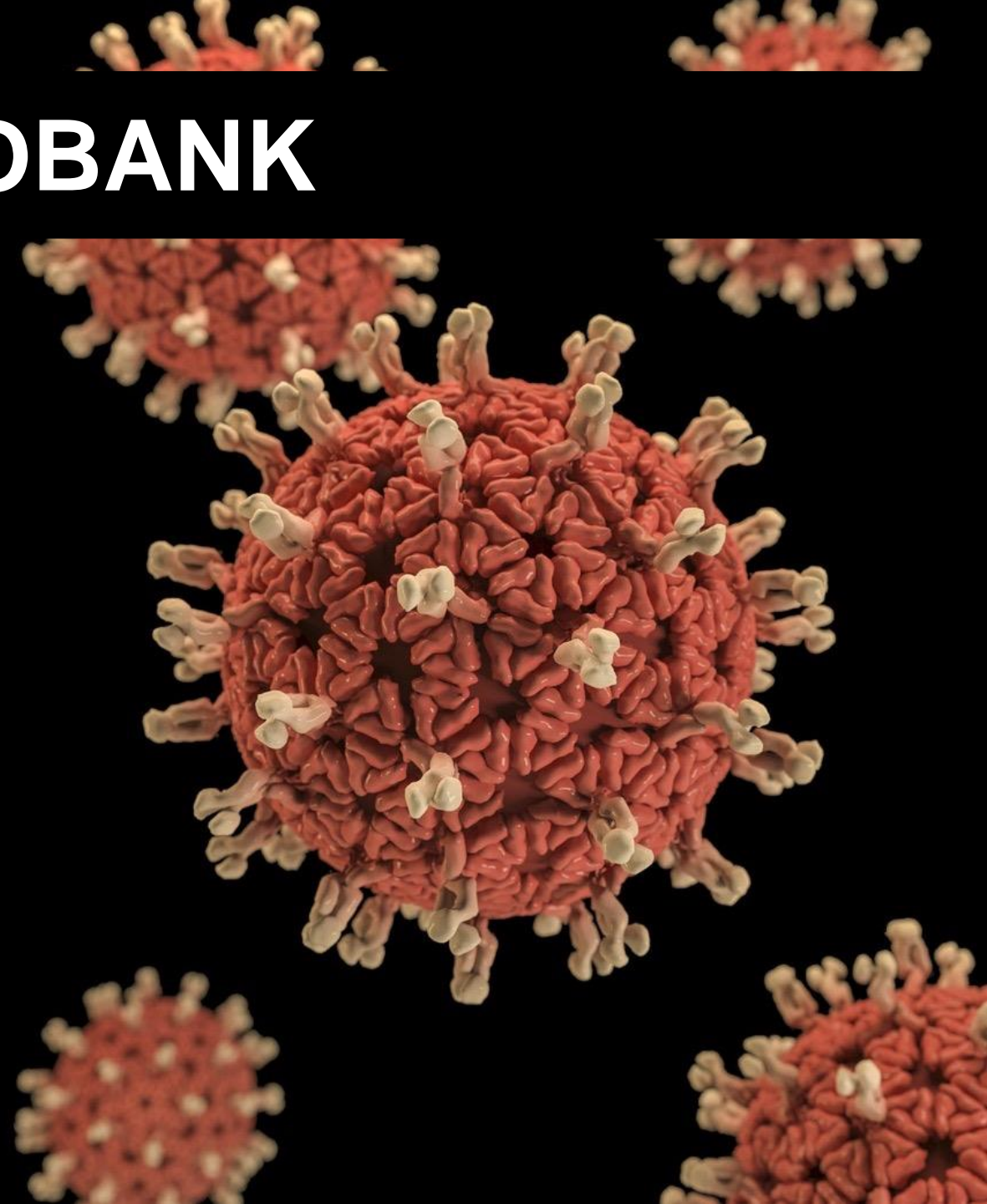
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# COVID BIOBANK

- Approximately 150 participants in the prospective cohort
- > 3000 in the retrospective cohort
- Nasal Swab (RNA/DNA) (>2,500)
- RNA (Nasal Swabs) COVID+ (>2,500)
- DNA Germline (>1,000)
- Whole Blood (DNA, PBMC, BC) (>3,500)
- Plasma (>2,500)
- Serum (>1,500)
- Urine (~600)
- **3500 unique samples distributed from the biobank**





# BIOBANK: THANK YOU... A PARTIAL LIST

- Biorepository Core Facility
- Cancer Center Shared Resources:
- Human Immune Monitoring Shared Resource (HIMSR)
- Pathology Shared Resource (PSR), (Formerly TBHSR – Tissue Biobanking Histology SR)
- Department of Pathology
- UCHHealth Clinical Laboratory
- CHCO Clinical Laboratory
- CReST (CCSTI)- Clinical Research Support Team
- Regulatory Affairs
- CHCO - Allergy and Immunology Team
- CHCO - Pediatric Intensive Care Unit
- University Hospital COVID intensive units/floors
- UCH Emergency Department Biorepository
- CCPM
- Study Participants







# WEBSITE & REDCAP SURVEY LINKS

COVID-19 Biobank Website:

[research.cuanschutz.edu/covid19biobank](https://research.cuanschutz.edu/covid19biobank)

REDCap Link to request samples:

<https://redcap.ucdenver.edu/surveys/?s=ALDKDYDPT7>

Contact:

[Matthew.Steinbeiss@CUAnschutz.edu](mailto:Matthew.Steinbeiss@CUAnschutz.edu)



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# COVIDome.org

A multidimensional dataset to accelerate translational research in COVID19 through collaborative analysis

Joaquin M. Espinosa, PhD

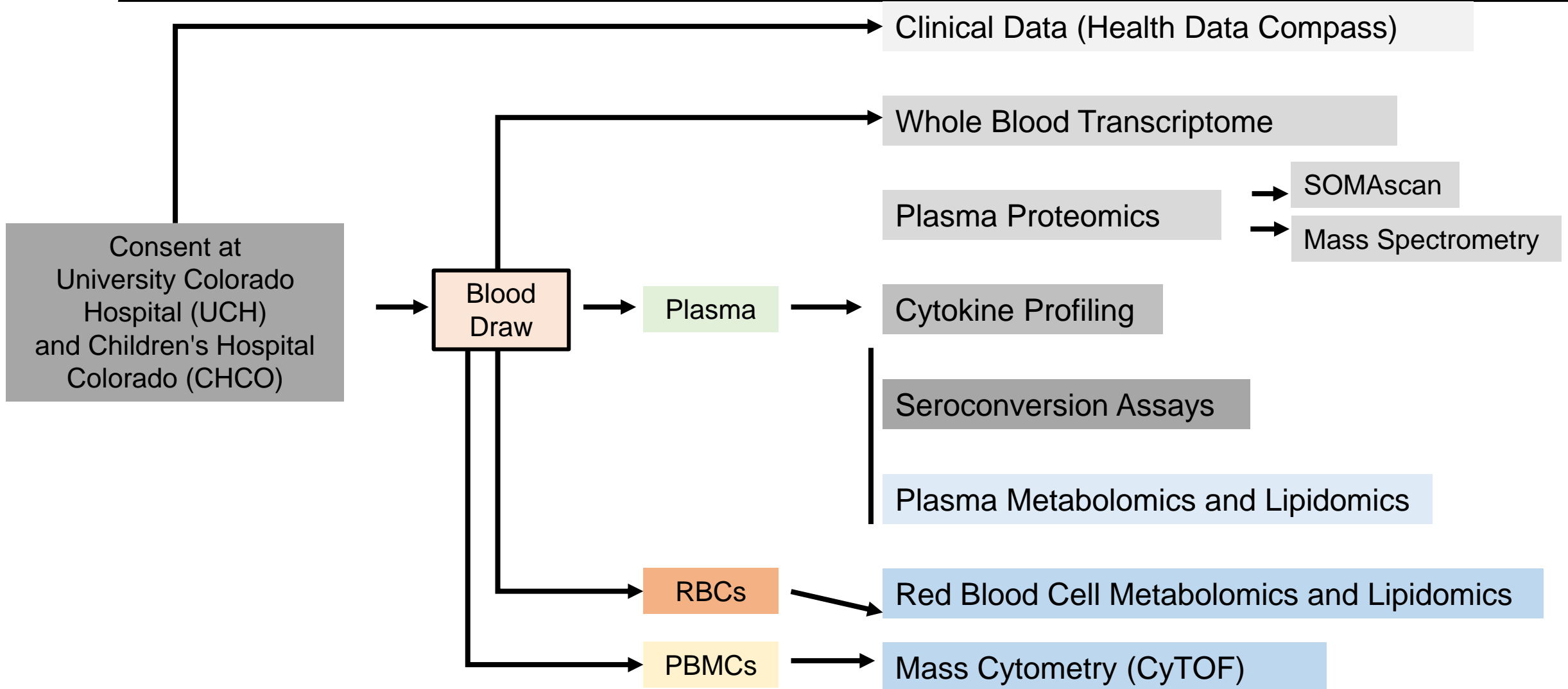


LINDA CRNIC INSTITUTE  
for **DOWN SYNDROME**





# DATASETS GENERATED





# DEFINING BIOSIGNATURES OF SEROCONVERSION

Seroconversion indices



The Spearman  
Factory

MS Proteomics  
SOMAscan Proteomics  
MSD Cytokines  
CyTOF

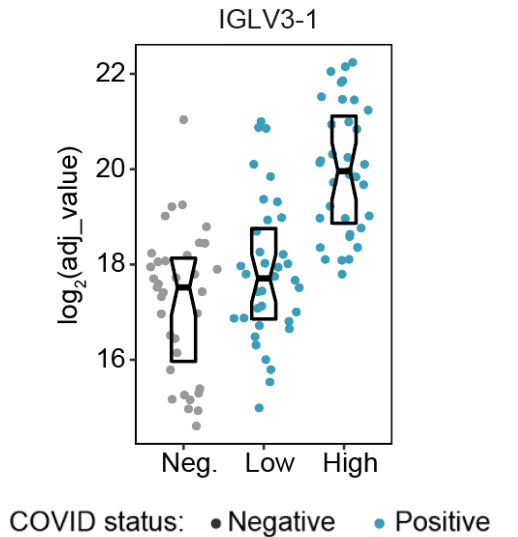
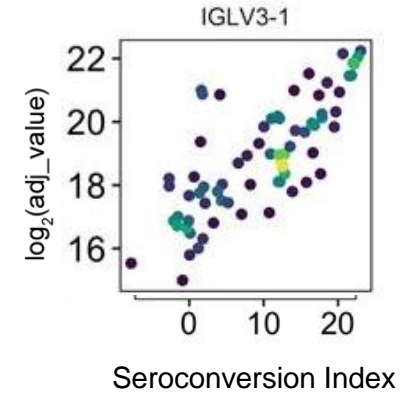
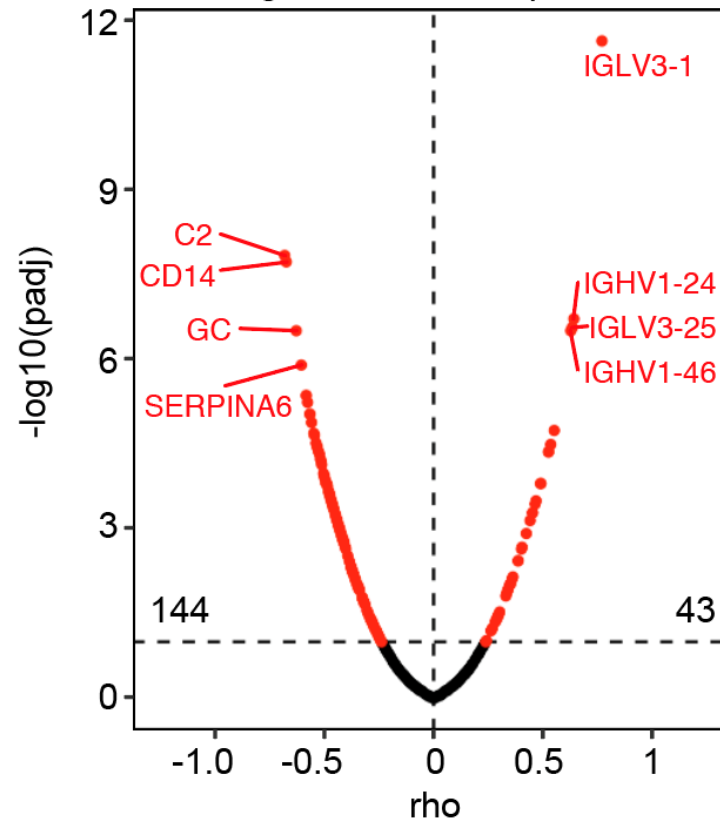


Proteins and cell types  
associated with  
seroconversion

Seroconversion vs. MS proteomics

Correlation with seroconversion:

negative positive





# COVIDOME EXPLORER

COVIDome Explorer

Cohort | Transcriptome | Proteome | Cytokines | Metabolome | Immune Map

- Overview
- Effect of COVID-19 status
- Effect of Seroconversion

## Dataset Options

### Platform

MSD

### Statistical Test

- Kolmogorov-Smirnov Test
- Student's t-test
- Wilcoxon test

### Adjustment Method

- none
- Bonferroni
- Benjamini-Hochberg (FDR)

### Sex

Male  Female

### Age Group

All  21 & Over

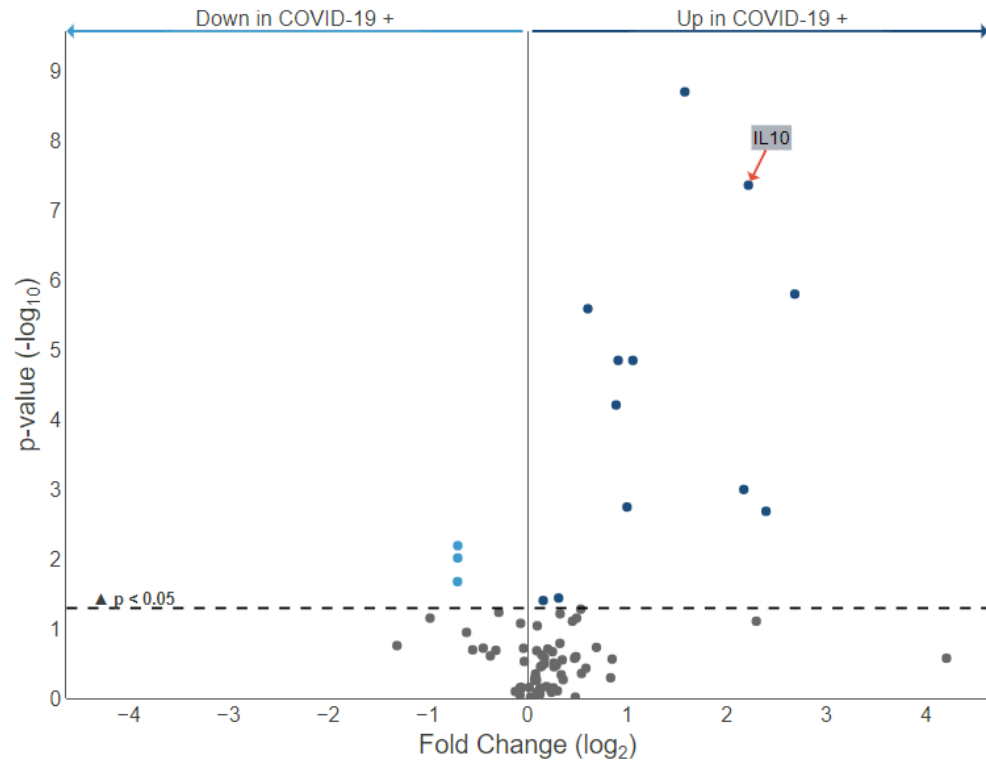
### Highlight Cytokine (optional)

IL10

Apply filters and generate plot

MSD Plots | MSD Fold Change Data

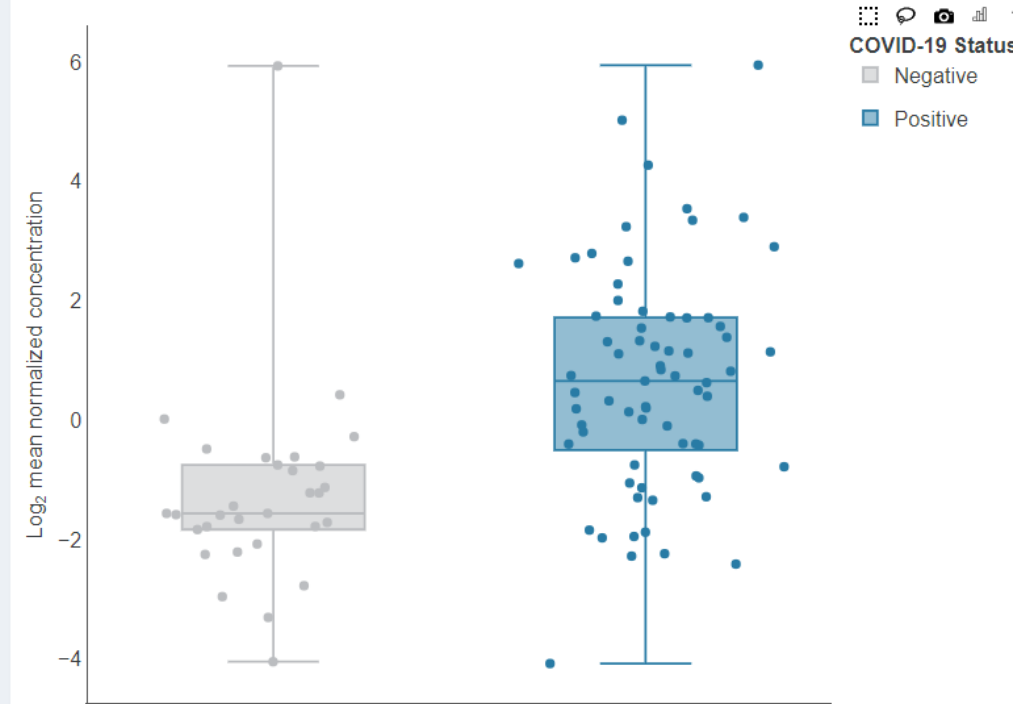
## Effect of COVID-19 Status on all cytokines



## Effect of COVID-19 Status on IL10 in plasma

\*p-value = 4.32e-08

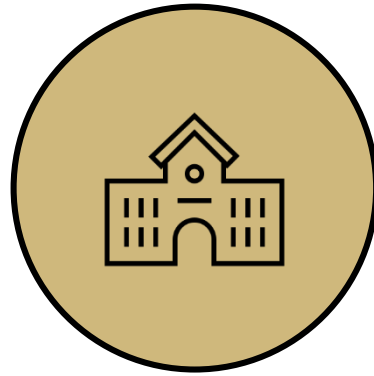
Show as Log<sub>2</sub> Transformed?



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# THE RICHNESS OF OUR RESEARCH COMMUNITY

*Progress through collaboration*



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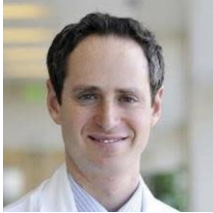
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# TARGETING LEUKEMIA STEM CELLS



Craig Jordan  
Medicine



Dan Pollyea  
Medicine



James DeGregori  
Biochemistry



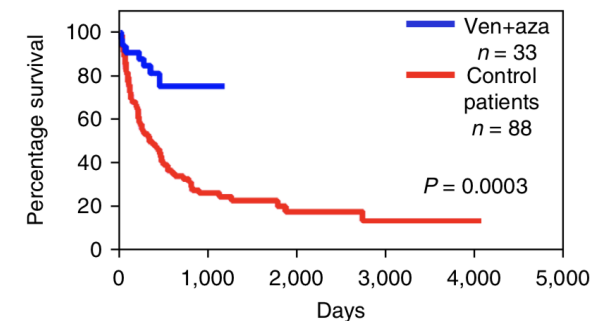
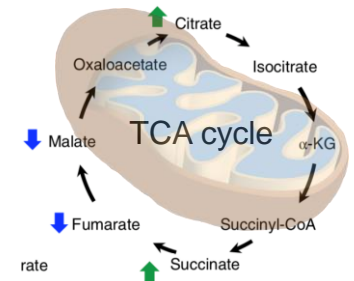
Angelo D'Alessandro  
Biochemistry

**Impact:** First therapeutic regimen shown to directly target leukemia stem cells in AML patients

- Collaboration across Departments within the cancer center
- Venetoclax FDA approved in Nov 2018
- Patients in Colorado had access to improved care 3-4 yr before everyone else

*Cancer Cell, 2018 & Nature Med, 2018*

Fast bench-to-bedside science at CU contributed to development of and mechanistic insight into a new therapy combination that results in deep and durable remission



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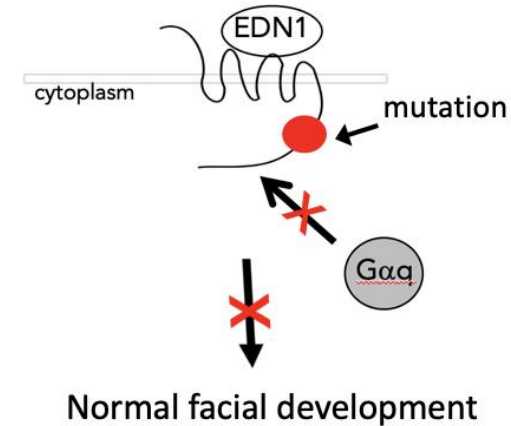
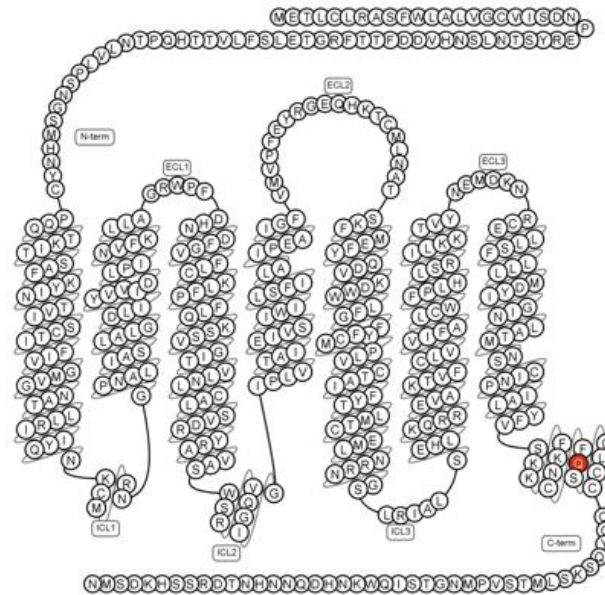


# ORO-OTO-CARDIAC SYNDROME

School of Dental Medicine: David Clouthier, Ph.D.

*In collaboration with Children's Hospital of Philadelphia, Medical College of Georgia and George Washington University*

Defining a novel birth defect syndrome was discovered along with elucidation of the functional mechanism of the mutation.



*Published in the American Journal of Medical Genetics (2020)*







# COLORADO HEALTHY START PROJECT

- Lead by Dana Dabelea, MD, PhD
  - Colorado School of Public Health
  - **LEAD Center: Lifecourse Epidemiology of Adiposity and Diabetes**
- Established a longitudinal cohort of ethnically diverse pregnant women and their offspring
  - >1400 enrolled
- Findings:
  - Maternal obesity and gestational weight gain are related to infant adiposity
  - Healthy diet and physical activity are protective
- Collaborations with CoSPH, SOM, CU Boulder

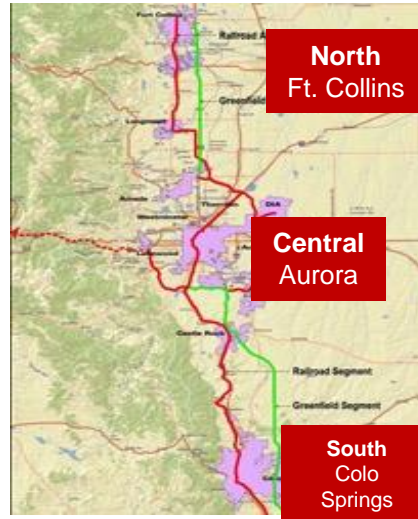
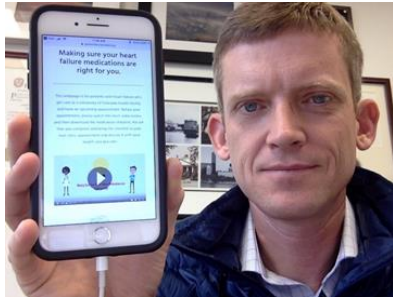


Birth – 9% adiposity



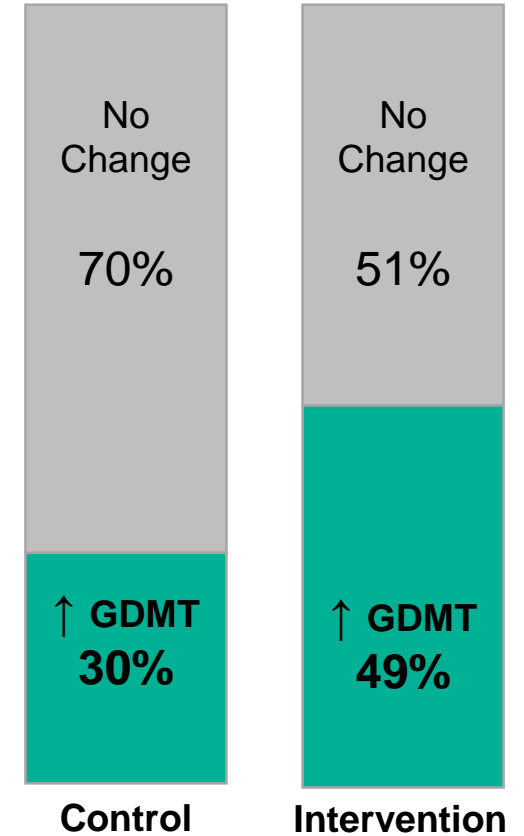


# THE EPIC-HF TRIAL



- *Sponsored by the AHA*
- *Larry Allen and Dan Matlock*
  - *ACCORDS and the School of Medicine*
- **Accrued 300 patients from across 3 regions of UCHealth**

**GDMT = guideline-directed medical therapy**

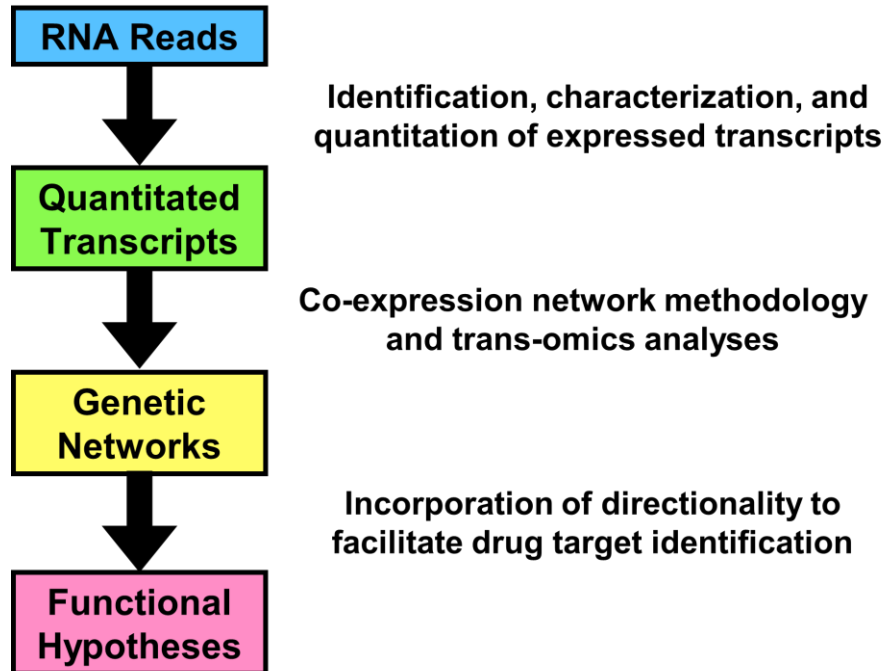


*Presented at the AHA conf NOV 2020*





# NIDA P30 CORE CENTER OF EXCELLENCE IN OMICS, SYSTEMS GENETICS, AND THE ADDICTOME



- Laura Saba, PhD School of Pharmacy
  - In collaboration with University of TN
  - Focused on addiction and drug abuse
  - High end computational resources
  - Bioinformatics/biostatistics collaborations

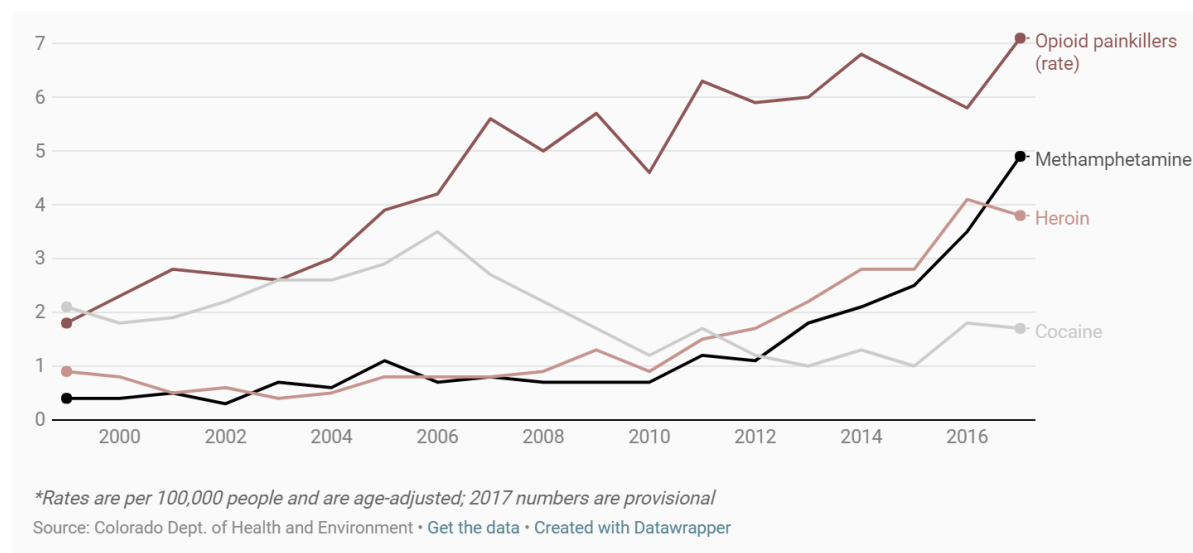




# COLORADO MEDICATION ASSISTED TREATMENT PROGRAM FOR OPIOID USE DISORDER

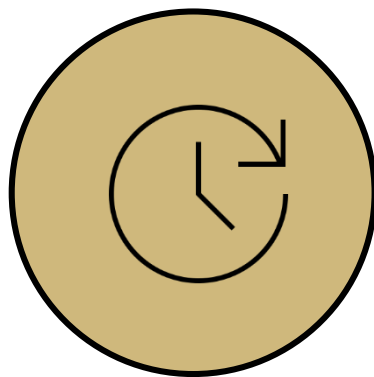
- Collaboration between the College of Nursing and School of Pharmacy
- Serving 20 rural counties in Colorado
- Working with local providers implementing medication-assisted treatment (MAT)
- Impacted over 600 patients in first 14 months

Tanya Sorrell PhD, PMHFNP  
Rosario Medina, PhD FNP-BC CNS  
Paul Cook, PhD  
Mary Weber PhD PMHFNP  
Claudia Amura, PhD, MPH  
Robert Valuck, PhD RPh  
...And many others



Sorrell TR, et al. *J Subst Abuse Treat.* 2020 Jul;114:





# SPECIAL PROJECTS AND FUTURE PLANS



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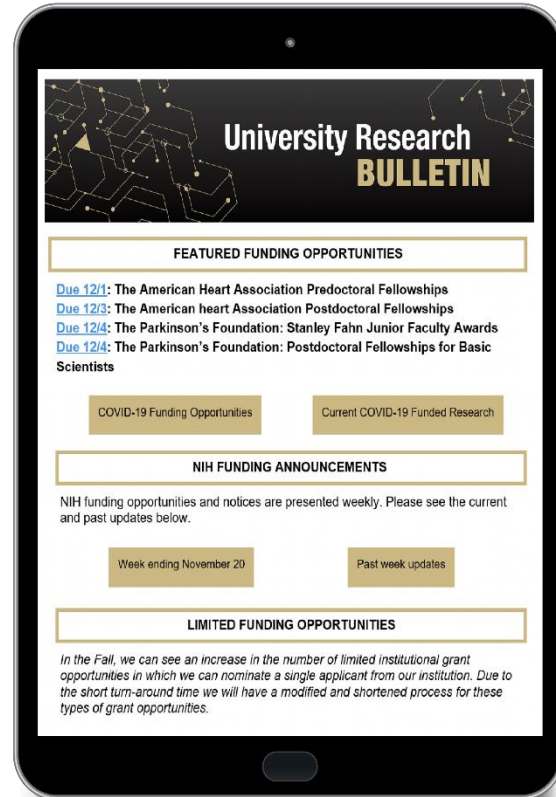
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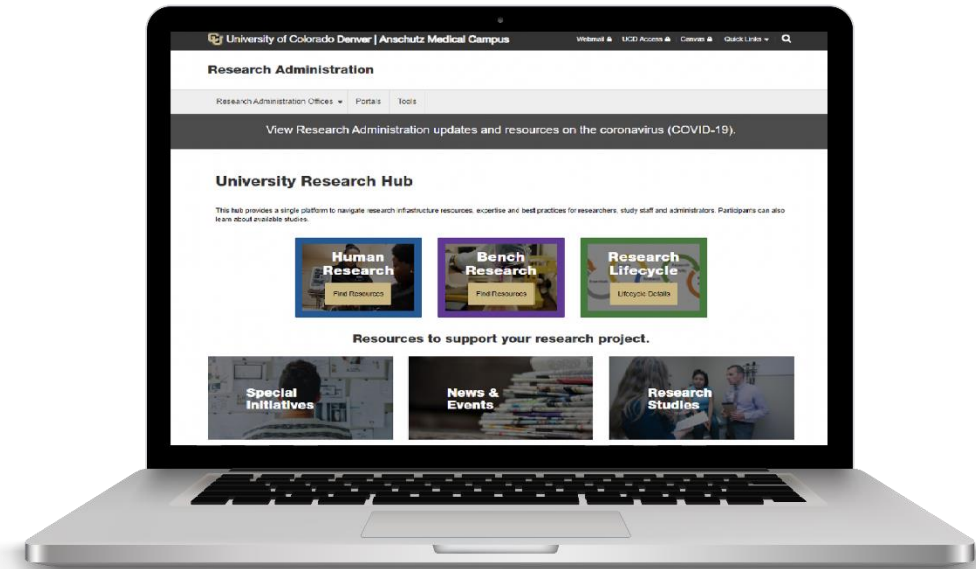


# RESEARCH COMMUNICATIONS

- Research Bulletin launched in May
  - **13K+** recipients
- Vice Chancellor Communique
- University Research website revamp



[www.research.cuanschutz.edu](http://www.research.cuanschutz.edu)



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# CELL THERAPY OPERATIONS PROGRAM (CTOP)

Our mission is to partner with Anschutz Medical Campus investigators and stakeholders to develop innovative Cellular Therapies and facilitate the regulatory and operational conduct of clinical trials.

CTOP roles include:

- Protocol Development
- Preparation and submission of IND application
- Assistance with Budget development
- Scientific Review Committee submission
- PRMS, IBC and IRB submission
- Pharmacovigilance
- Project Management



Michael Verneris, MD  
Scientific and Medical Director



Ben Echaliier  
Associate Director

## Current team members

Chanel Mansfield – Project Manager  
Cheri Adams – Pharmacovigilance Specialist  
Bob Kowalski – Protocol Development Specialist

[www.research.cuanschutz.edu/ctop](http://www.research.cuanschutz.edu/ctop)



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# AB NEXUS PROGRAM

## Program Administration

### Commitment of Funds

- Memorandum of Understanding executed
  - Anschutz, Boulder, President's Initiative
  - \$3M total commitment over 3 years
- Partnership Specialists hired at each campus

### Administrative Process Improvements

- Master Collaboration Agreement executed
  - Expedited joint proposal review
  - Reduced form requirements
  - No additional F&A on first \$25k of direct costs on intercampus subcontracts



**Cathy Bradley, PhD**

- Assoc Dean School of Public Health
- Deputy Director CU Cancer Center



**Amy Gannon**

Associate Vice  
Chancellor –  
Financial Services  
& Controller

AB Nexus [www.cu.edu/ab-nexus](http://www.cu.edu/ab-nexus)



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# RESEARCH DEVELOPMENT PARTNERSHIP SPECIALIST

- Answer questions about AB Nexus
- Help make connections with research collaborators
  - Organized research meetings between campuses
- Coordinates with counterpart at CU Boulder



**Diane Ladell, MPH**  
Research Development  
Partnership Specialist

[diane.ladell@cuanschutz.edu](mailto:diane.ladell@cuanschutz.edu)



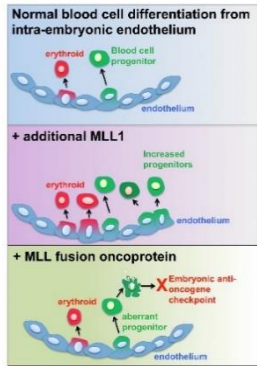
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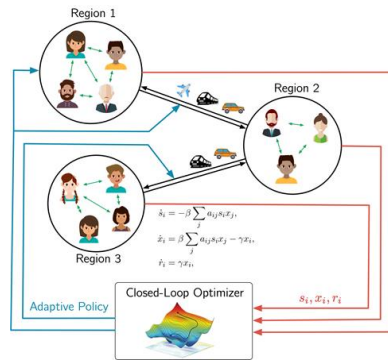
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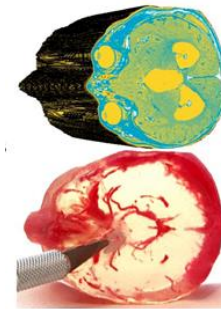
# AWARDED NEW COLLABORATIONS (\$50K)



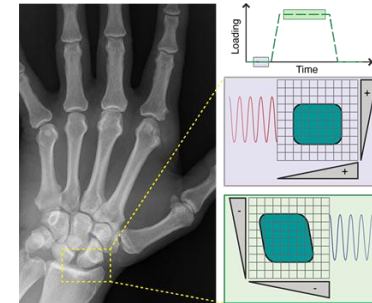
Identification of an embryonic cell-intrinsic cancer checkpoint: studying differential transcriptional effects of the proto-oncogene MLL1 versus MLL-ENL in an embryonic system  
[Patricia Ernst](#) and [Mary Allen](#)



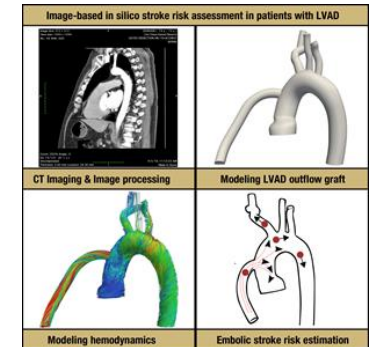
Control-theoretic design of data-driven policies for containing transmission of infectious diseases  
[Emiliano Dall'Anese](#) and [Andrea Buchwald](#)



Patient-specific On-demand Pre-surgical Planning Models via 3D Printing  
[Robert MacCurdy](#) and Nicholas Jacobson, [Jeffrey Stansbury](#), [Simon Kim](#)



Next-Generation Imaging Biomarkers for Rheumatoid Arthritis  
[Corey Neu](#) and [Larry Moreland](#)



Stroke Risk Assessment for Improved Left Ventricle Assist Device Therapy in Heart Failure Patients  
[Debanjan Mukherjee](#) and [Jay Pal](#)

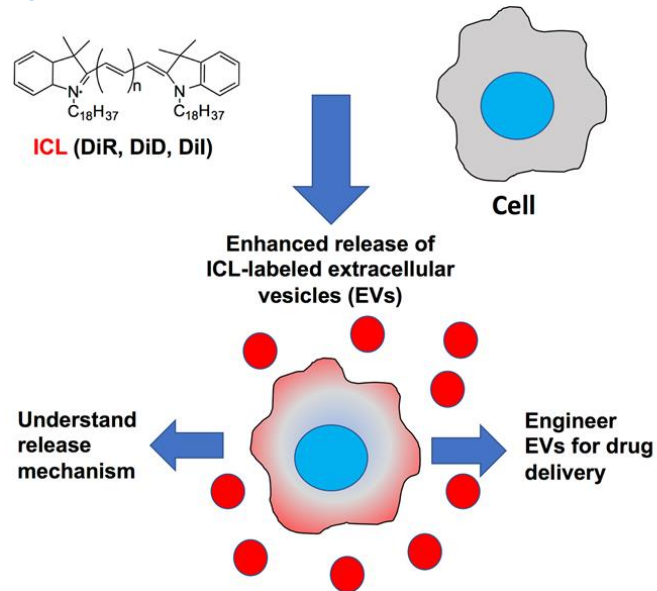




# AWARDED EXISTING COLLABORATIONS (\$125K)

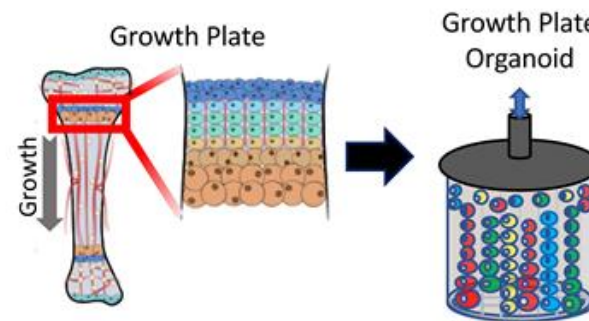
## Novel Extracellular Vesicle-Based Nanoparticles for Drug Delivery

[Dmitri Simberg](#) and [Jingshi Shen](#)



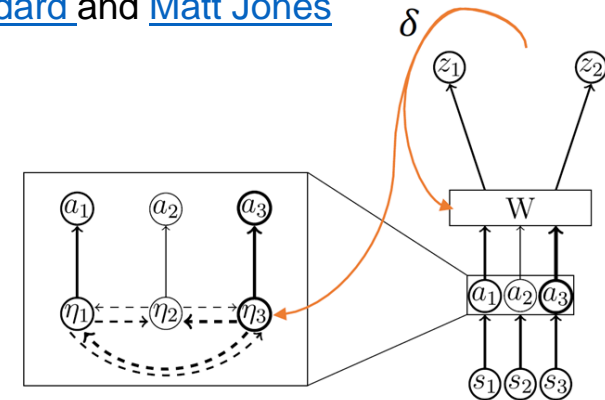
## Biophysical Cues Governing Growth Plate Organization: A Computational & Experimental Approach

[Stephanie Bryant](#) and [Karin Payne](#)



## Associative Threat Learning: Measuring Mechanisms for Treating Threat-based Psychopathologies

[Joel Stoddard](#) and [Matt Jones](#)



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# ANSCHUTZ HEALTH SCIENCES BUILDING

- On time and on track
  - Designed for collaboration
- Investigational drug pharmacy with the School of Pharmacy
- CCTSI space: Clinical Translational Research Centers



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# FUTURE... WHAT'S NEXT

- Progress through Collaboration
  - Promote intra-campus and inter-campus research
  - AB Nexus with CU Boulder – extend further
- New efforts of the AVCBSR
  - Program project/team science work
  - Facilitate support for basic science endeavors
- Promote Diversity, Equity and Inclusion in our research mission





# FUTURE... WHAT'S NEXT

- Communication
  - Consolidate research communication across platforms
- Organization
  - Develop research council from COVID officials' structure
  - Process improvement program for central processes
  - Continue to refine and improve research support services
- Support further development with our hospital partners
- Promote innovation in all types of research





**Thank You!**