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
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
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)
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
• 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
Supporting research

- Proposals/grants: 3,124 (12+ per business day)
- Research contracts: 1,619
- Subcontract to other entities: 1,131
• 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
ENVIRONMENTAL HEALTH AND SAFETY

550
lab inspections annually

116
tons of regulated medical waste
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
SPONSORED RESEARCH FUNDING
CAMPUS AWARDS BY SPONSOR TYPE

- Federal
- Industry
- Associations and Foundations
- Universities and Colleges
- State and Local
- Hospitals & International

Year: 2016 to 2020

awards range from 100,000,000 to 600,000,000
CAMPUS FUNDING CONTRIBUTIONS

- School of Medicine
- SOM Institutes and Centers
- Colorado School of Public Health
- CU Anschutz Centers and Institutes
- College of Nursing
- School of Dental Medicine
- School of Pharmacy

University Research
UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

RESEARCH ADDRESS
COLLABORATIONS ON CAMPUS & INTER-CAMPUS
PROPORTION OF FEDERAL FUNDING

Federal vs Non-Federal (Awards)

- 2016: Federal 55.6%, Non-Fed 44.4%
- 2017: Federal 53.3%, Non-Fed 46.7%
- 2018: Federal 54.4%, Non-Fed 45.6%
- 2019: Federal 55.3%, Non-Fed 44.7%
- 2020: Federal 58.4%, Non-Fed 41.6%
2016-2020 FEDERAL SPONSORS

- Fed NIH: 81%
- Fed Other DHHS: 9%
- Fed DOD: 5%
- Fed VA: 3%
RESEARCH RESPONSE TO COVID
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
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
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 1,622 individuals
- Added a COVID testing site to better serve the CU Anschutz University Community
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
• **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
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.

Click here
• 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)
COVID BIOBANK LOGISTICS

UCHealth/CHCO

Patient Consent
Research Collection

Waiver of Consent
Clinical Biospecimen

Clinical Lab
Remnant specimen

Biorepository Core Facility: Management/Coordination

Processing: Human Immune Monitoring SR (HIMSR)

Banking: Biorepository Core Facility
Data entry in OnCore

Health Data Compass
Specimens

Research Projects

- Cancer Center Shared Resources: HIMSR - Human Immune Monitoring SR
- PSR – Pathology Shared Resource (Formerly TBHSR – Tissue Biobanking Histology SR)

Steering Committee
Cohort selection

Research Requests

Coordinated by

University Research
UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS
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
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
COVID-19 Biobank Website:
research.cuanschutz.edu/covid19biobank

REDCap Link to request samples:
https://redcap.ucdenver.edu/surveys/?s=ALDKDYDPT7

Contact:
Matthew.Steinbeiss@CUAnschutz.edu
A multidimensional dataset to accelerate translational research in COVID19 through collaborative analysis

Joaquin M. Espinosa, PhD

COVIDome.org
Consent at University Colorado Hospital (UCH) and Children's Hospital Colorado (CHCO)

DATASETS GENERATED

Clinical Data (Health Data Compass)
Whole Blood Transcriptome
Plasma Proteomics
SOMAscan
Mass Spectrometry

Blood Draw

Plasma
Cytokine Profiling
Seroconversion Assays
Plasma Metabolomics and Lipidomics

RBCs
Red Blood Cell Metabolomics and Lipidomics

PBMCs
Mass Cytometry (CyTOF)
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

log(adj_value)

- C2
- CD14
- GC
- SERPINA6
- IGLV3-1
- IGHV1-24
- IGLV3-25
- IGHV1-46

Seroconversion Index

COVID status: ● Negative ● Positive
THE RICHNESS OF OUR RESEARCH COMMUNITY

Progress through collaboration
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.

**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

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

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*Impact: First therapeutic regimen shown to directly target leukemia stem cells in AML patients*
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)
• 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
• **Sponsored by the AHA**
• **Larry Allen and Dan Matlock**  
  - ACCORDS and the School of Medicine
• Accrued 300 patients from across 3 regions of UCHealth

**THE EPIC-HF TRIAL**

**Presented at the AHA conf NOV 2020**

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GDMT = guideline-directed medical therapy
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

RNA Reads
Identification, characterization, and quantitation of expressed transcripts

Quantitated Transcripts
Co-expression network methodology and trans-omics analyses

Genetic Networks
Incorporation of directionality to facilitate drug target identification

Functional Hypotheses
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

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

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

*Rates are per 100,000 people and are age-adjusted; 2017 numbers are provisional
Source: Colorado Dept. of Health and Environment • Get the data • Created with Datawrapper
SPECIAL PROJECTS AND FUTURE PLANS
Research Bulletin launched in May
  • 13K+ recipients

Vice Chancellor Communiques

University Research website revamp

www.research.cuanschutz.edu
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 Echalier
Associate Director

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

www.research.cuanschutz.edu/ctop
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
• 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
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 NEW COLLABORATIONS ($50K)
Novel Extracellular Vesicle-Based Nanoparticles for Drug Delivery
Dmitri Simberg and Jingshi Shen

Associative Threat Learning: Measuring Mechanisms for Treating Threat-based Psychopathologies
Joel Stoddard and Matt Jones

Biophysical Cues Governing Growth Plate Organization: A Computational & Experimental Approach
Stephanie Bryant and Karin Payne
• On time and on track
  • Designed for collaboration
• Investigational drug pharmacy with the School of Pharmacy
• CCTSI space: Clinical Translational Research Centers
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!