UAMS

UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES

RESIN Research Support Information Network (RESIN)

Presented by: Office of the Vice Chancellor for Research

Date: December 5, 2017

Agenda

- **Updates & Timely Information from Research Support:**
  - Office of the VCR
    - RSC
    - IRB
  - IACUC
    - Biosafety
    - Finance/Cost Acctg.
  - COM - OSPAN
  - Export Control & COI
    - ORSP
    - ORC
    - DLAM
    - ORRA
  - TRI
    - BioVentures

New Fee-for-service Core Facilities

Stephanie Byrum, PhD, Assist. Prof., Dept. of Biochemistry and Molecular Biology

COBRE Center for Translational Pediatric Research (CTPR)

- **Funded July 11, 2017**
  - Arkansas Children's Research Institute
  - Partnership with UAMS
  - Alan Tackett, PhD (Principal Investigator)

- **Mission:** investigate how pediatric diseases develop from a systems biology and mechanistic approach, with the ultimate goal of identifying the intersections of disease and development, which will produce targets for therapeutic intervention and the development of new treatments

- **Only pediatric center of our kind in the United States and likely the world**
  - Systems Biology-focused
  - State-of-the-art technology
  - Large data analysis

UAMS
UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

New Fee-for-service Core Facilities

Stephanie Byrum, PhD, Assist. Prof., Dept. of Biochemistry and Molecular Biology

Developmental Genomics Core Facility

- Personnel: Dr. Stewart Macleod & Chris Randolph
- Location: 2nd floor of Arkansas Children's Research Institute
- Equipment: Illumina NextSeq500, fragment analyzer
- Whole exome, total and targeted RNA-seq, gene expression, ChIP-seq
- New fee-for-service core facility
  - Available to UAMS and ACRI investigators
  - Available for external uses
- Visit the COBRE website to request service and rates: www.archildrens.org/archildrens-COBRE

UAMS
UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

New Fee-for-service Core Facilities

Stephanie Byrum, PhD, Assist. Prof., Dept. of Biochemistry and Molecular Biology

Developmental Bioinformatics Core Facility

- Directors: Drs. Stephanie Byrum and Galina Glazko
- Bioinformaticians: Drs. Charity Washam, Yasir Rahmatallah, Brian Piccolo, Sree Chintapalli
- Location: 2nd floor of Arkansas Children's Research Institute
- New fee-for-service core facility
  - Available to UAMS and ACRI investigators
  - Available for external uses
  - Only fee-for-service bioinformatics core in Arkansas

New Fee-for-service Core Facilities

Stephanie Byrum, PhD, Assist. Prof.,
Dept. of Biochemistry and Molecular Biology

Developmental Bioinformatics Core Facility

- Proteomic data analysis
  - Label-free quantitative proteomics: iBAQ and spectral counting
  - Tandem Mass Tagging
  - Post-translational modifications
  - Custom workflows (e.g., metaproteomics)
- Genomic data analysis
  - RNA-seq
  - 16S microbiome
  - ChIP-seq
  - Custom workflows (e.g., metagenomics)
- Visit the COBRE website to request service and rates: www.archildrens.org/archildrens-COBRE

UAMS
UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

IACUC Update

Kerrey Roberto, IACUC Administrator

- **Tracy Gatlin**
  - Regulatory Specialist I, ORRA
  - ClinicalTrials.gov Administrator
  - IACUC Assistant

UAMS
UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

IACUC Update

Kerrey Roberto, IACUC Administrator

- **Renewal protocol reminder**
  - AUPs are approved for a maximum of three years
  - You will receive a reminder 4-6 months before expiration
  - Please submit renewal for review **at least two months** before the expiration month
    - Example: Protocol expires in December – Submit renewal by the October deadline (1st Friday)

UAMS
UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

IACUC Update

Kerrey Roberto, IACUC Administrator

- **Tips for preparing an AUP**
  - Use the correct form – available on IACUC website
  - Use available resources! We are here to help you!
    - DLAM
    - TRI – Biostatistics & Research Design
    - IBC
    - Library
    - Pre-review

UAMS
UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

IACUC Update

Kerrey Roberto, IACUC Administrator

- **IACUC Office**
  - Biomed I, B102B
  - 501-686-8542

UAMS
UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

RESEARCH OPERATIONS ASSESSMENT

November 13, 2017

UAMS
UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

EXECUTIVE SUMMARY
INTRODUCTION AND SCOPE

Gather Data (August 29 – October 13)

- Review document submissions to gain an initial understanding of current state (governance and processes) and provide a framework for interview discussions.

Conduct Interviews (September 25 – October 11)

- Obtain a perspective from the research community and key stakeholders, further assess the infrastructure and processes to conduct a gap analysis.

Present Current State (October 23)

- Outline our observations, gap analysis, and highlight any functional areas in need of additional review.

Present Future State Model (Week of November 13)

- Draft a proposed operating model based on validated information from documents and interviews, incorporating industry best practice.

Develop Final Recommendations (Week of December 11*)

- Submit a final report which outlines the proposed research infrastructure, nature and level of resources required, and recommendations with a high level implementation strategy.

EXECUTIVE SUMMARY
REPORT ORIENTATION

- **This report is organized into three key areas of clinical research operations:**

Governance and Executive Leadership

Clinical Research Professionals

Business Operations Professionals

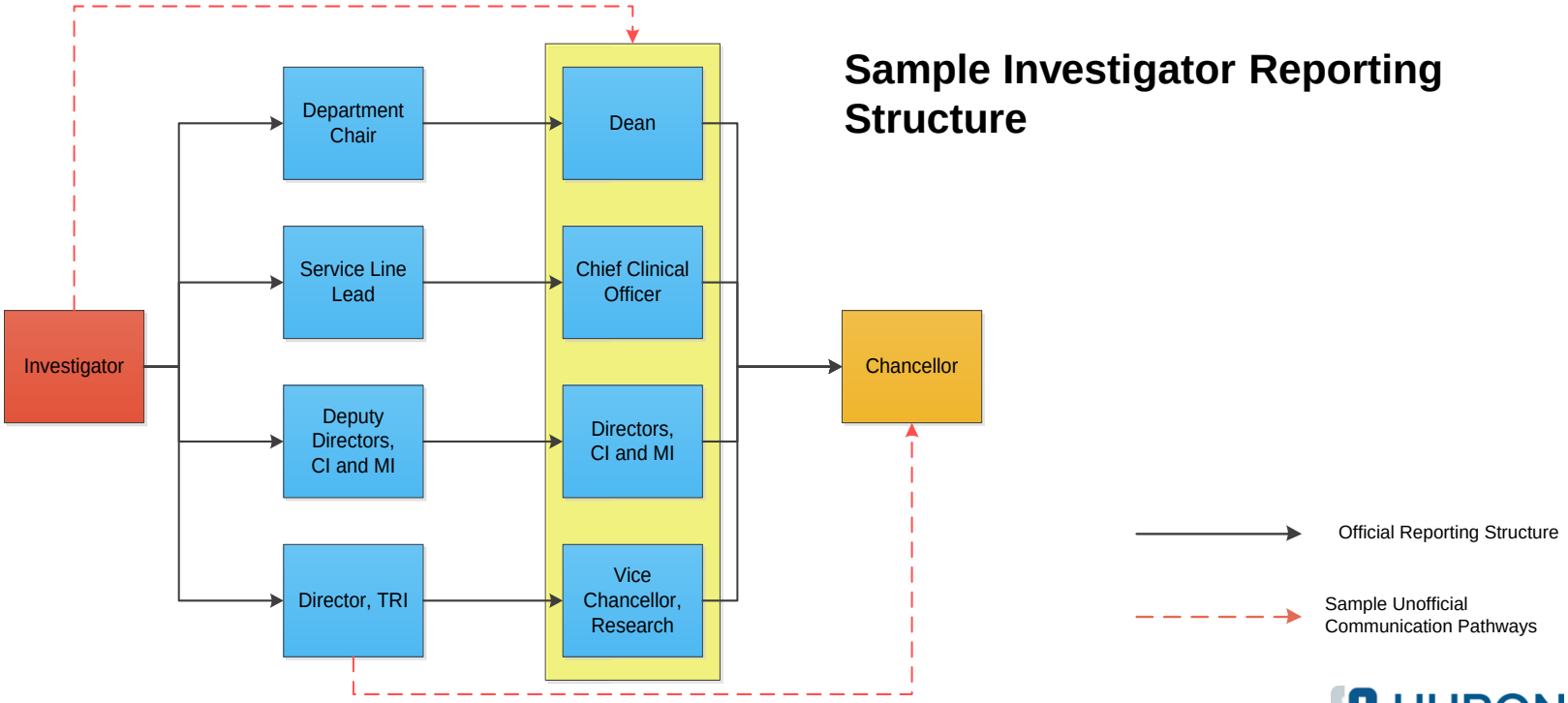
2

Proposed Governance

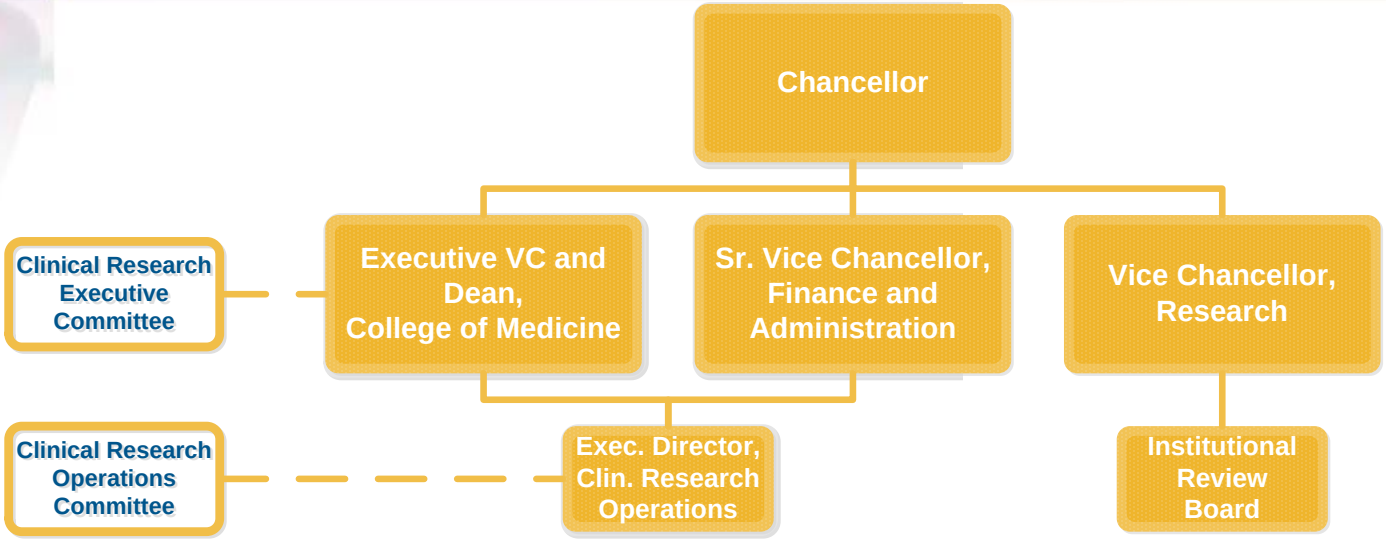
GOVERNANCE
CURRENT STATE

- **There are not clearly defined, unified executive and physician leaders representing UAMS-wide clinical research.**
  - Clinical research staff and management report to multiple leadership positions.
  - It is unclear who has the authority to make decisions involving clinical research because there are multiple pathways through which decisions are made.

Sample Investigator Reporting Structure



GOVERNANCE
PROPOSED MODEL



+ **The proposed governance model provides a defined institution-wide clinical research leadership structure and an identified governing body.**
  - The Executive Director role has clear authority and accountability for clinical research administration across UAMS, in contrast to multiple reporting pathways that currently exist.
  - Governance and Steering Committees provide opportunities for faculty and stakeholder input.
+ **A matrix reporting structure provides the necessary leadership skills to ensure financial viability, sound business practices, and quality and compliant clinical research conduct.**
  - Physician and administrative leaders are identified and oversee clinical research across UAMS.
  - The independence and objectivity of compliance functions are maintained.

3

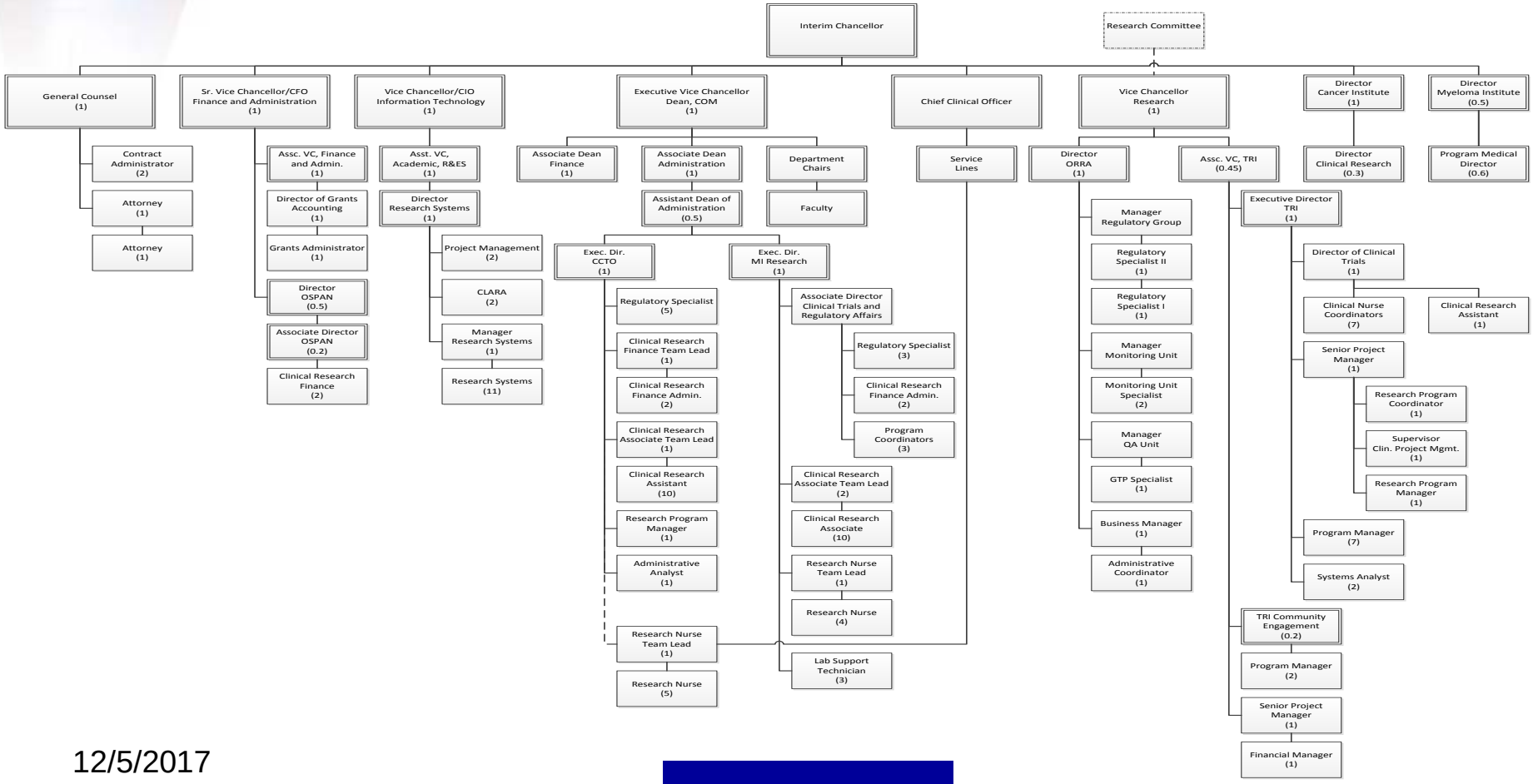
Proposed Operating Model

DRAFT

HURON

ORGANIZATIONAL STRUCTURE
CURRENT STATE

- **UAMS does not have an institution-wide clinical research organizational chart. Huron created this organizational chart based on information provided by UAMS.**



12/5/2017

DRAFT

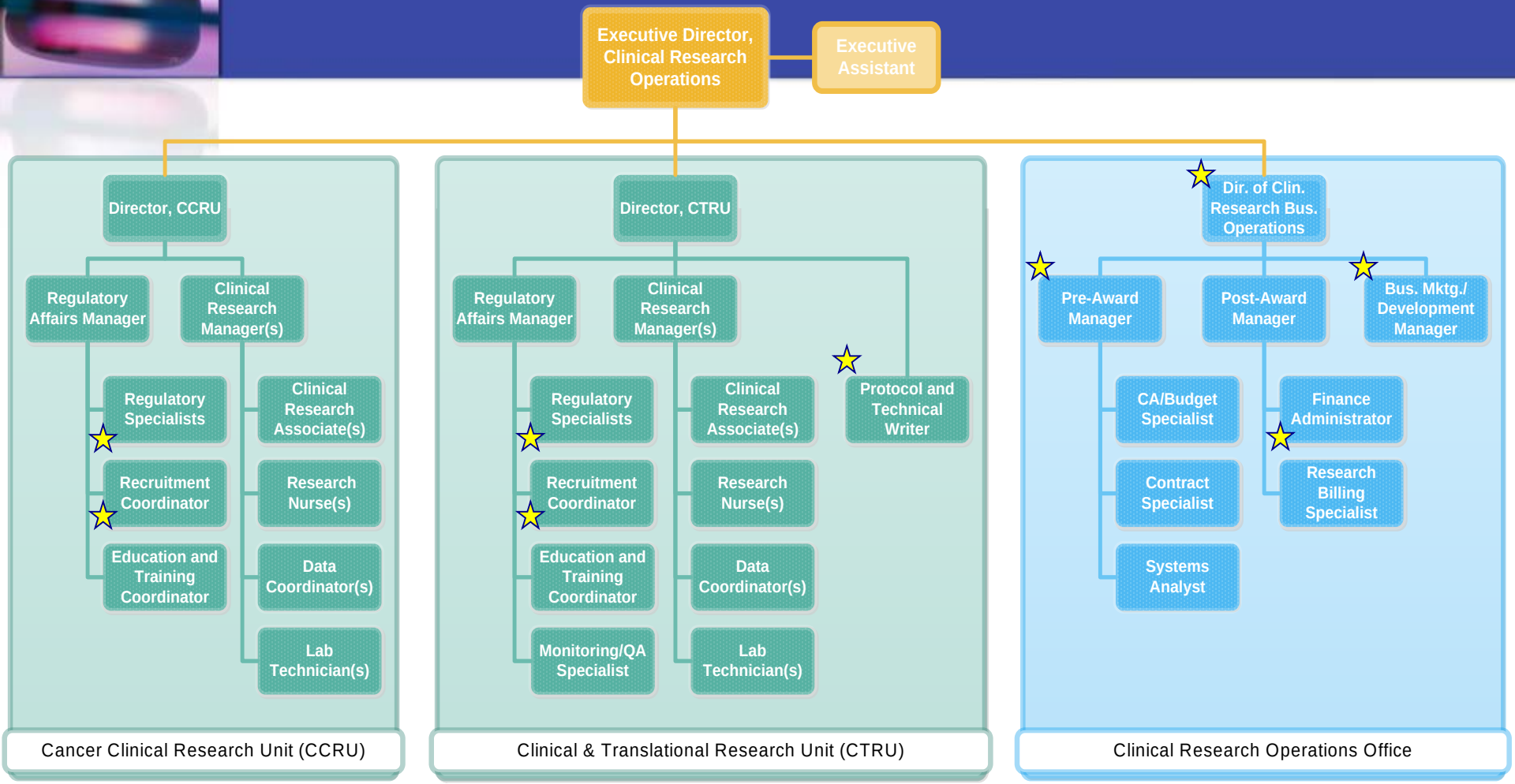
HURON

ORGANIZATIONAL STRUCTURE
PROPOSED FUTURE STATE CONSIDERATIONS

+ **Clinical research professionals remain aligned to departments and disease teams.**
  - The Cancer Institute retains a specific Cancer Clinical Research Unit (“CCRU”) with dedicated oncology clinical research staff, supporting application for National Cancer Institute (“NCI”) designation.
  - A centralized Clinical and Translational Research Unit (“CTRU”) is available for other investigators, retaining programmatic research support of the Translational Research Institute (“TRI”) supporting resubmission of the Clinical and Translational Science Award (“CTSA”).
  - Aligning the CCRU and CTRU (collectively referred to throughout this report as “Clinical Research Units” or “CRUs”) under the Executive Director promotes a culture of investigator-focused customer service.

+ **Administrative burden is shifted from study teams to administrative professionals, providing scalability and mitigating compliance risk associated with inconsistency.**
  - Administrative personnel will be aligned to portfolios and will function as embedded members of the study teams.
  - Aligning administrative personnel across the institution under dedicated managers reduces business process inconsistency and provides internal controls over operational compliance and financial activities.
  - Business operations management will be held to KPIs and metrics that promote accountability to investigators and study teams. For example, KPIs may include that sponsor invoices are generated within thirty (30) days of data entry.

ORGANIZATIONAL STRUCTURE
PROPOSED FUTURE STATE



★ New titles

The Organizational Structure is supported by a Roles and Responsibilities Matrix, provided as an attachment to this report.

DRAFT

RATIONALE AND SUCCESS FACTORS

GOVERNANCE, ORGANIZATION, AND PEOPLE

Rationale

- Establishing an Executive Director and decision-making committees provides for a **unified clinical research leadership**, strengthening **communication and consistency.**
  - A clear organizational structure eliminates ‘fishing’, increases communication among departments, and promotes accountability for consistent service.
  - Roles and responsibilities are clearly defined to enhance oversight, support, and communication within the UAMS clinical research community.
- A hybrid model enhances **workflow management**, provides for **scalability**, and establishes an **investigator-focused customer service orientation** for clinical research.
  - Clinical research professionals are aligned in disease teams, ensuring that study teams develop specialists and that Investigators receive consistent support.
  - Business operations professionals are aligned to portfolios, providing flexibility and scalability of administrative operations while continuing to function as integral members of the study teams.

Success Factors

- **Leadership buy-in** and support of the Executive Director role is necessary to realize the benefits of the hybrid model.
- **Key Performance Indicators** and metrics are necessary to ensure that centralized functions provide quality and timely support to investigators.

RATIONALE AND SUCCESS FACTORS

PROCESS AND TECHNOLOGY

Rationale

+ Applying policies and procedures consistently across the institution **mitigates risk** associated with noncompliance and creates opportunities to **increase clinical research revenue**.
  - Coverage analysis and billing designations will be applied consistently throughout UAMS.
  - Time associated with charge segregation and review activities should decrease, improving traditional revenue cycle management for charges paid by third parties.
  - Improved sponsor invoicing and collections processes will inform the clinical research fee structure and budget negotiations process, increasing trial revenue.

Success Factors

+ Enhanced **communication is vital** to effectively implement a hybrid organizational structure; departments should have a consistent understanding of clinical research policies and procedures.
+ Use **of an institution-wide CTMS is necessary** to provide efficient trial financial management.
+ Process redesign requires **UAMS stakeholder support** for an effective and successful implementation.

5

Next Steps

NEXT STEPS
UPCOMING MEETINGS AND OBJECTIVES

- **Objectives for Governance and Steering Committee Meeting #4 – January 2018:**:
  - Reaffirm Assessment goals and objectives.
  - Reaffirm decision-making and implementation authority.
  - Obtain consensus on Operating Model recommendations.
  - Review and obtain feedback on Future State Recommendations.
  - Review considerations for system evaluation and business process design.
    - Develop and document a prioritized list of requirements, both functional and technical.
    - Align functional requirements with business process changes to further process transformation.
    - Establish evaluation criteria for vendors.

QUESTIONS?

Contact information

- renee@uams.edu
- 501-526-6940

Export Control Update – Int'l Shipment of Items Philip Principe, Dir., Export Control & Conflict of Interest

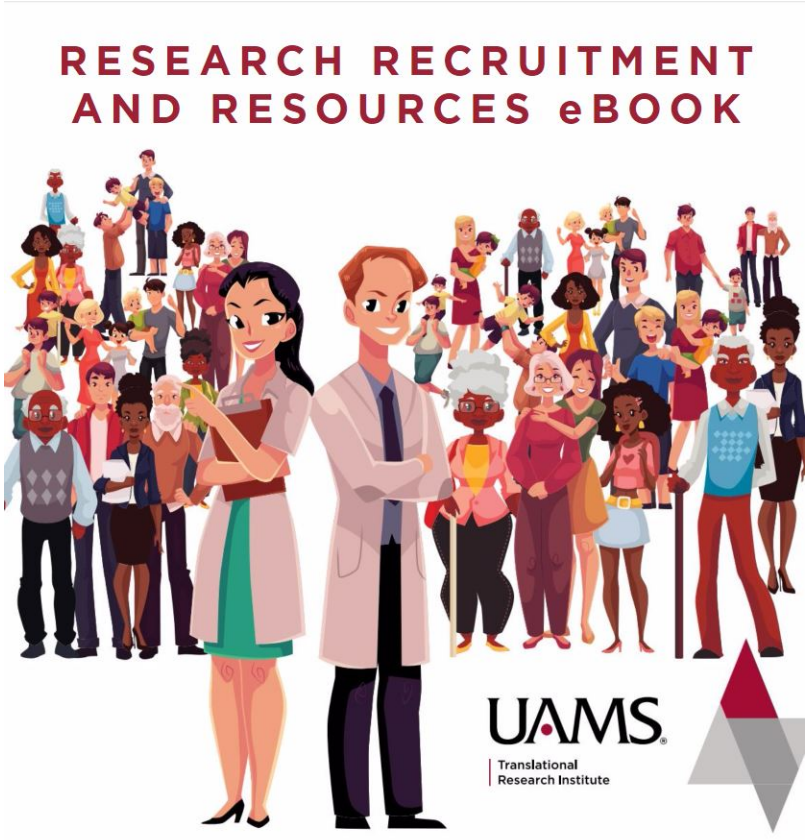
- **International Shipment of Items**
  - Screening of items by Export Control Office required prior to shipment
    - See *Export Management & Compliance Program Guide* available at http://exportcontrol.uams.edu/
  - Obtain Screening via Int'l Shipping Export Control Form
    - http://exportcontrol.uams.edu/international-shipping/

UAMS UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

TRI's eBook for Researchers

David Robinson, TRI Communications Manager
davidr@uams.edu

- **Online resource guide**
- **Participant recruitment**
- **Critical services**
- **Links to more info**
- **Helpful contacts**



UAMS
UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES

TRI's eBook for Researchers

David Robinson, TRI Communications Manager
davidr@uams.edu

eBook Table of Contents

UAMS
UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

Upcoming Events

David Robinson, TRI Communications Manager
davidr@uams.edu

- Dr. Daniel Aires, Univ. Kansas Medical Center, Health Science Entrepreneurship Seminar Series, “Bringing Novel Cancer Therapies from Bench to Bedside in a University Spinout,” **Dec. 12, 4 – 5 p.m.,** IOA, Ford Auditorium

- Dr. Christopher Austin, Director, National Center for Advancing Translational Sciences (NCATS) and U.S. Sen. John Boozman at UAMS and Arkansas Children’s on **Jan. 22**

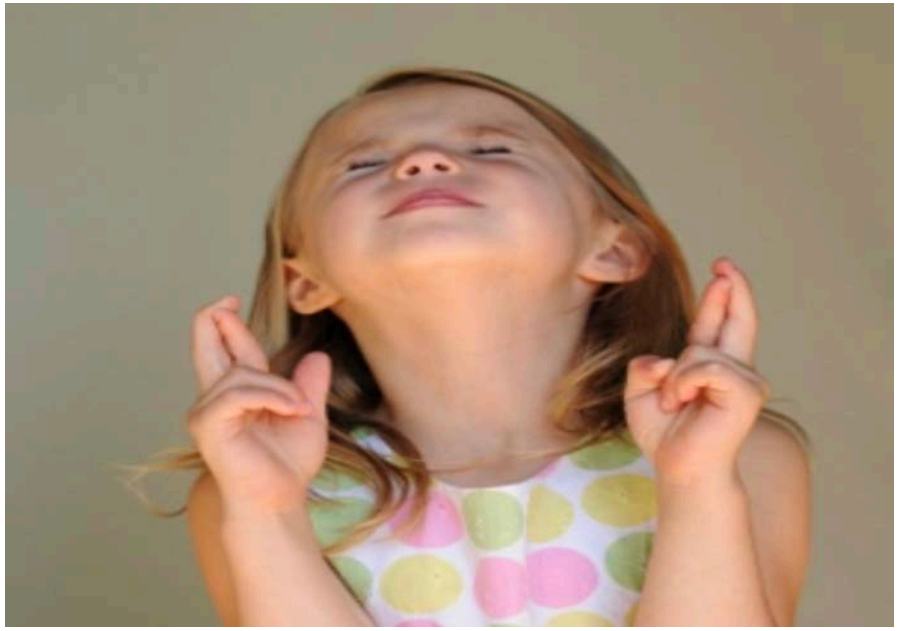
- Dr. Carrie Byington, Texas A&M Dean of Medicine, to present “Transformative Research via Team Science: The Intersection of Epidemiology, Genomics, and Entrepreneurship,” **Jan. 29, 4 p.m.,** Cancer Institute, Walton Auditorium

UAMS
UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

Revised Common Rule

Jennifer Holland, JD, IRB Director

- **Implementation of January 19, 2018 or not???**



Revised Common Rule

Jennifer Holland, JD, IRB Director

- **Consent Form and Process**
  - Concise presentation of *key information of the consent language on the first page(s)
  - Electronic consent – Must give copy

Revised Common Rule

Jennifer Holland, JD, IRB Director

- **Consent Form and Process**
  - Additional language required in some situations
    - Future research with identifiers removed or statement that data will not be shared even if identifiers are removed.
    - Biospecimens might be used for profit and whether the subjects will share in this profit.
    - Will clinically relevant results be shared and in what situations
    - Will biospecimens under go whole genome sequencing

Revised Common Rule

Jennifer Holland, JD, IRB Director

- **Continuing Review Eliminated for Certain Studies**
  - Studies originally reviewed under expedited procedures.
  - Full board studies where the only study activities are limited to data analysis or accessing follow up clinical data

Revised Common Rule

Jennifer Holland, JD, IRB Director

- **Single IRBs**
  - Revised Common Rule is catching up with NIH directives.
  - Prior to NIH rule and Revised Rule, UAMS implemented this process.

Revised Common Rule

Jennifer Holland, JD, IRB Director

- **Coming Soon**
  - IRB Policy Revisions
  - CLARA Revisions
  - Training sessions
  - Consent template revisions
  - Suggested consent clauses
  - OHRP Guidance re interpretation, providing website to post consent forms

Next RESIN

- **Next RESIN**
  - **February 6, 2017 @ 12:00 p.m.**
  - Location - **Walton Auditorium**, Winthrop P. Rockefeller Cancer Institute, 10th floor
  - All RESIN presentations archived on the UAMS Research website
    - http://www.uams.edu/research/RESIN_Achive.asp