RESIN Research Support Information Network (RESIN)

Presented by: Office of the Vice Chancellor for Research

Date: November 6, 2018
Agenda

- Updates & Timely Information from Research Support:
  - Office of the VCR
  - RSC
  - IRB
  - IACUC
  - HIPAA
  - Tissue Bank
  - BioVentures
  - COI
  - ORSP
  - ORRA
  - DLAM
  - TRI
  - Core Facilities
  - Biomedical Informatics

11/6/2018
New Seminar Series for early career researchers

Modeled after the CATS program at University of Utah

Emphasizes the Matrix Mentoring Model

- Self-mentorship in the context of guidance from senior professional development mentors, scientific content experts, staff contributions, and opportunities for peer mentorship.
Covers Core Principles:

- Scientific Career Development
  - IDPs; mentoring; RCR, etc.

- Grant Writing and Management
  - Writing specific aims; NIH peer review; post award compliance; etc.

- Leadership
  - Conflict resolution; collaboration; negotiation; etc.
First Friday ever *other* month

(Dec 7, Feb 1, April 5, and June 6 for 2018/19)

12:00 p.m. to 1:30 p.m. - ED II, 8121

(Lunch provided for the first 40 attendees)

Inaugural Seminar – Dec. 7, 2018

- Program/Series Introduction
- Researcher Toolkit
- Your thoughts on your training needs
For more information:

TRI.UAMS.edu > Training > Research Fundamentals

Contact Nia Indelicato

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Phone: (501) 526-0363

Mitel phone - 46312
New CITI Module on the RCR

Access module by clicking “Add a Course” and then scroll down to bottom where you’ll see Revised Common Rule.

IRB Blog posts

Recent posts include:

- Changes to exempt status research
- Changes to informed consent language
- Resources to learn more about the RCR
Revised Common Rule Training Opportunities
Jennifer Holland, JD, IRB Director

- Webinar of Presentation recorded on October 30th
  - Webinar dates:
    - Friday, November 9th
    - Two Times: 7:30 - 9:00 a.m. & 12:00 - 1:30 p.m.
    - Same Location: Cancer Institute, 10th Floor Room 1017 (Strauss McCaskill Center)
Revised Common Rule
Training Opportunities
Jennifer Holland, JD, IRB Director

- Additional Webinar Dates:
  - November 13th, 12:00 – 1:30 p.m.
    - RAHN Building (COPH), G226
  - November 30th, 12:00-1:30 p.m.
    - RAHN Building (COPH), G226
Upcoming Local Presentation – Save the Date

- Informed Consent under the RCR
- Tentative for **Wednesday, December 12th** at **1:30 p.m.** in the Walton Auditorium.

  *If OHRP does not issue guidance for the new consent form elements by then, this presentation will likely be postponed.*
New Employee – Tiffany Brown

Background

- Clinical Trials Finance Administrator
- Neurodiagnostic Technologist
- Clinical Research Coordinator

No IRB meeting on Christmas or New Year’s Day

- Last meeting 2018 - December 18th. First meeting 2019 - January 8th
Mission

- To deliver a diverse, high quality human biospecimen repository with appropriate patient protections, best practice collection methodologies, clinical data capture mechanisms and integrated information technology.

- To provide this resource to UAMS research programs to enhance diagnostic, preventative, and therapeutic research.

- To build a self-sustaining, scalable program that focuses and expands resources to meet the needs of researchers.
Why TBAPS?

- IRB approved protocol for broad patient consent and tissue collection by TBAPS-trained staff
- Collection of solid tissue (fresh, snap-frozen, and paraffin-embedded) and fluid (blood, urine) specimens
- SOP development for tissue acquisition
- Project specific tissue procurement and storage
- Specimen tracking using secure, web-based data management software (caTissue Suite)
HIPAA: In 2013, as required by the passage of the Genetic Information Nondiscrimination Act, the Privacy Rule was modified to establish that genetic information is health information protected by the Privacy Rule to the extent that such information is individually identifiable…

NIH, under the NIH Genomic Data Sharing (GDS) policy, expects that researchers generating large-scale human genomic data use specimens or cell lines for which consent was obtained for future research purposes and broad sharing.

UAMS: Policy MS.4.01 Approved by Hospital Medical Board states “The Medical Staff Rules and Regulations require that all tissues removed during an operation shall be promptly sent to the Hospital Pathologist. Exceptions listed below should, in no way, preclude submission of the material, if desired, but submission is not required. Any tissue, other than these exceptions, which is considered for research purposes, must be cleared through the Hospital Pathology Department prior to submission to another lab.”

UAMS MEDICAL CENTER POLICIES & PROCEDURES
Number: MS.4.01
Policy Title: Pathology Services – Surgical Specimens
Source: Department of Pathology
Approved By: Hospital Medical Board
Date Approved: April 13, 1982
Review/Revise Date: 10/99, 9/02, 3/05, 12/08, 11/14, 12/15
Replaces Policy:

PURPOSE
To insure that all surgical specimens are collected, prepared, and processed in the correct manner.

POLICY
Surgical specimens shall be processed for pathology evaluation only according to approved guidelines established by the College of American Pathologists, The Joint Commission, and the Hospital Medical Board.
Process

1. Contact Project Manager (Rémelle Eggerson) or Director


3. Patients consented by TBAPS-trained staff prior to procedure
Process (cont.)

4. Specimens acquired from the pathology grossing room and processed by TBAPS staff using standardized protocols

5. Specimens stored in vapor-phase isothermal liquid-N$_2$ tanks that are monitored 24/7; or de-identified and distributed fresh to approved labs$^1$

6. Specimen information and de-identified$^2$ clinical information entered into caTissue database with IT oversight and backup

$^1$Projects requiring fresh tissue may have additional, project-specific requirements and require consultation

$^2$Optional identifiable personal health information available with IRB approval and signed Attestation for Medical Records Retrieval
Tissue Biorepository and Procurement Service (TBAPS)
Steve Post, PhD, Director, UAMS Tissue Bank

Contact

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Draft Guidance documents describe the FDA’s current thinking on an issue

- In general, Draft Guidance documents do not establish legally enforceable responsibilities
- FDA is proposing to amend its regulations
- Accompanied by a comment period (usually 60 days)
History of ClinicalTrials.gov

- 1997: FDAMA passed; Section 113 required NIH to create a registry for clinical trials
- 2000: NIH releases CT.gov Web Site
- 2007: FDAAA passed; required
  - More types of trials to be registered
  - Additional trial information (e.g. summary, AEs)
  - Allowed penalties for non-compliance (civil monetary penalties up to $10,000 per day)
September 2016

- Final Rule for FDAAA 801 issued
- Clarifies which information is to be submitted, when it is to be submitted, and whether compliance has been achieved

September 2016

- NIH required clinical trials funded in whole or part by NIH must be registered (effective January 2017)
Poor Compliance with Registration

  - 20% of industry trials and 50% of NIH-funded trials did not comply with reporting requirements

- BMJ (2018) EUCTR
  - Commercial sponsor: 68% reported results as required
  - Non-commercial sponsor: 11% reported results within 12 months
Draft Guidance

- FDA has not enforced the civil penalties section of FDAAA
- September 2018: FDA released a draft guidance which provides a mechanism for enforcement
- Emphasize that this is a DRAFT guidance
- Comment period extends through November 20, 2018
Draft Guidance for CT.gov

- Requires the “responsible party” to submit the registration and results information for “applicable clinical trials”
- Non-compliance will be identified during BIMO inspections and from complaints received by the agency
- FDA will send a “Pre-Notice Letter” requiring correction within 30 days
Draft Guidance for CT.gov (cont.)

- If non-compliance is not remedied within 30 days after receiving the notice, the FDA will seek civil penalties

- (Many bureaucratic notices and actions happen here including an opportunity to contest the charges)
Civil Monetary Penalties

May be requested for:
- Failure to submit registration and results
- Submitting false or misleading information
- Failure to submit required certification to FDA
- Knowingly submitting a false certification

Maximum penalty: $10,000 for all violations adjudicated in a single proceeding

If not corrected within 30 days, up to $10,000 per day until the violation is corrected
You may access the DRAFT guidance at: https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM607698.pdf

Send electronic comments to: https://www.regulations.gov

Submit written comments to: Dockets Management Staff (HFA-305), FDA, 5630 Fishers Lane, Rockville, MD 20852
ORSP, OSPAN, SciCom & GMCPA

- Chili Lunch
  - Friday, November 9
    - 10:30 am – to 2:30 pm
    - Biomed Atrium

- To Benefit 3 Head Start Classrooms

- Cost
  - $5.00/bowl of chili and cornbread
  - $1.00/dessert
Bake Sale
- Tuesday, November 20, 2018
- 10:00 am to 2:30 pm
- Biomed Research Center 1 Atrium
Showcase for Medical Discoveries – Opioids   Linda Williams, M.S., Research Liaison, Office of Research

Opioids Research Showcase

- Wednesday, Nov. 14, 2018
- 4:30 – 6:00 p.m.
- 12 posters
- 10th floor Winthrop P. Rockefeller Cancer Institute

Showcase of Medical Discoveries

Opioids

The 22nd Showcase of Medical Discoveries with a wine and cheese reception will feature UAMS investigators discussing their research. This showcase is open to all interested faculty, students, staff and invited guests. The series’ ongoing goals include fostering communication and collaboration between investigators and increasing awareness of exciting research.
Next RESIN

- **December 4, 2018 @ 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](http://www.uams.edu/research/RESIN_Achive.asp)