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FOR MEDICAL SCIENCES

RESIN

(Research Support Information Network)

Presented by: Office of the Vice Chancellor for Research

Date: November 1, 2016

Agenda

- **Updates & Timely Information from Research Support:**
  - Office of the VCR
    - RSC
    - IRB
    - IACUC
    - HIPAA
  - TRI
    - BioVentures
  - COI & Export Control
    - ORSP
    - ORC
    - DLAM
    - OGSP
  - ORRA
    - Cost/Grants Accounting

Export Control & Conflict of Interest Philip R Principe, JD, Director, COI

- **Philip R Principe, JD**
  - **Director, Export Control & Conflict of Interest**
    - Contact: 501-686-6168
    - PPrincipe@uams.edu
- **Westley Ashley, JD**
  - **Assistant Director, Conflict of Interest**
    - Same main COI number: 501-686-6447
    - WLAshley@uams.edu

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CT.Gov-Final Rule and NIH Policy

Tracy Gatlin, CT.gov Administrator

- **ClinicalTrials.Gov Final Rule**
  - Effective/Compliance Dates
    - Effective Date: January 18, 2017
    - Compliance Date: April 18, 2017
  - NIH Policy
    - All trials funded in whole or part by NIH funds are expected to register and report results regardless of phase, type of intervention or whether subject to FDAAA.
      - Effective Date: January 18, 2017

CT.Gov-Final Rule and NIH Policy Tracy Gatlin, CT.gov Administrator

- Key Reporting Requirements

Reporting Requirement	ICMJE Policy (Effective 2005)	FDAAA Final Rule (Issued in 2016)	Final NIH Policy (Issued in 2016)
Scope	Registration	Registration & Results Reporting	Registration & Results Reporting
Phase	All	Not Phase 1	All
Intervention Type	All	Drug, biologic, & device products regulated by the FDA	All-including behavioral interventions
Funding Source	Any	Any	NIH
Enforcement	Refusal to publish	Criminal proceedings and civil penalties (up to $10,000/day); loss of HHS funding	Loss of NIH funding

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- **Which Requirements Apply (Final Rule vs Statute)?**
  - Registration information determined by Study Start Date
    - Study Start Date on or after January 18, 2017: FINAL RULE
    - Study Start Date before January 18, 2017: STATUTE (FDAAA)
  - Results information determined by Primary Completion Date
    - Primary Completion Date on or after January 18, 2017: FINAL RULE
    - Primary Completion Date before January 18, 2017: STATUTE (FDAAA)

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- **Practical Implications:**
  - Study Start Date (registration) and Primary Completion Date (results) determines which requirements apply
  - Independent of when the trial is first released to ClinicalTrials.Gov
    - Ex: Study Start Date is March 2017; trial first registered December 2016
      - Dec. 2016-follow requirements at the time of registration (STATUTE)
      - January-April 2017-update study record to meet the requirements of the FINAL RULE.

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- **Practical Implications** (Cont.)
  - Ex.: Study Start Date is June 2014; Primary Completion Date is July 2017
    - Registration information follows the STATUTE
    - Results information follows the FINAL RULE

CT.Gov-Final Rule and NIH Policy

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- **Key Revisions**
  - Approved and Unapproved drug or device products
  - Expanded Access
  - Changes requiring update of some items within 15 or 30 days of a change (ex. Recruitment status, Primary Completion Date-30 days)
  - Elaboration of definitions
  - New “required” elements and options
  - Protocol and Statistical Analysis Plan (if a separate document) submission, including amendments.
  - All Cause Mortality table

CT.Gov-Final Rule and NIH Policy

Tracy Gatlin, CT.gov Administrator

- **When must corrections be made?**
  - Within 15 days for clinical trial registration information.
  - Within 25 days for clinical trial results information.

CT.Gov-Final Rule and NIH Policy

Tracy Gatlin, CT.gov Administrator

- **Compliance**
  - FDAAA and NIH holds all parties accountable
    - Investigators
    - Institutions
  - Penalties for Noncompliance include:
    - Refusal to publish (ICMJE)
    - Monetary penalties
      - $10,000/day
    - Criminal proceedings
    - Withholding of funds
      - Investigator
      - Institution

CT.Gov-Final Rule and NIH Policy

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ADDITIONAL RESOURCES

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- **NIH Resources**
  - NIH Policy on the Dissemination of Clinical Trial Information
    - http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html
    - Questions? clinicaltrials.disseminationpolicy@mail.nih.gov

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- **ClinicalTrials.Gov Resources:**
  - Final Rule Information: https://prsinfo.clinicaltrials.gov
  - Changes from Current Practice described in the Final Rule (PDF):
    - http://prsinfo.clinicaltrials.gov/FinalRuleChanges-16Sept2016.pdf

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- **Contact Information:**

Tracy L. Gatlin

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Institutional Commitment for Grants—Rules of Engagement

Lawrence Cornett, Ph.D., Vice Chancellor for Research

- **Issue:** Applicants often will request "institutional commitment" with the knowledge and/or belief that this will improve chances for funding
- What do we mean by "institutional commitment"? (usually $$, space, time)
- Suggested process for requesting institutional commitment

Institutional Commitment for Grants—Rules of Engagement

Lawrence Cornett, Ph.D., Vice Chancellor for Research

- **Types of Grants that "*Require*"* Institutional Commitment**

--NIH Program Project/Center Grants (P Series)

--NIH Cooperative Agreement Grants (U series)

--NIH Shared Instrumentation Grants (S10)

--NSF EPSCoR Infrastructure Grants (Asset mechanism)

*Require doesn't mean absolutely need

Institutional Commitment for Grants—Rules of Engagement

Lawrence Cornett, Ph.D., Vice Chancellor for Research

- **Types of Grants that Usually Don't Need Institutional Commitment**

  --NIH Research Grants (R mechanism)

  --NIH Training Grants (F series)

  --NIH Career Development Grants* (K series)

  --NSF Program Announcements

  --Foundation Grants

*NIH K series grants require significant time commitment from applicant

Institutional Commitment for Grants—Rules of Engagement

Lawrence Cornett, Ph.D., Vice Chancellor for Research

- **Institutional commitment can come from multiple sources**
- So, when asking for institutional commitment, start with your division director/chair and work upwards in the “org chart”
- Chances for success increase if project aligns with institutional priorities
- Be reasonable (e.g., $$ ask should not exceed IDCs from the grant)

Institutional Commitment for Grants—Rules of Engagement

Lawrence Cornett, Ph.D., Vice Chancellor for Research

Plain Language Informed Consents

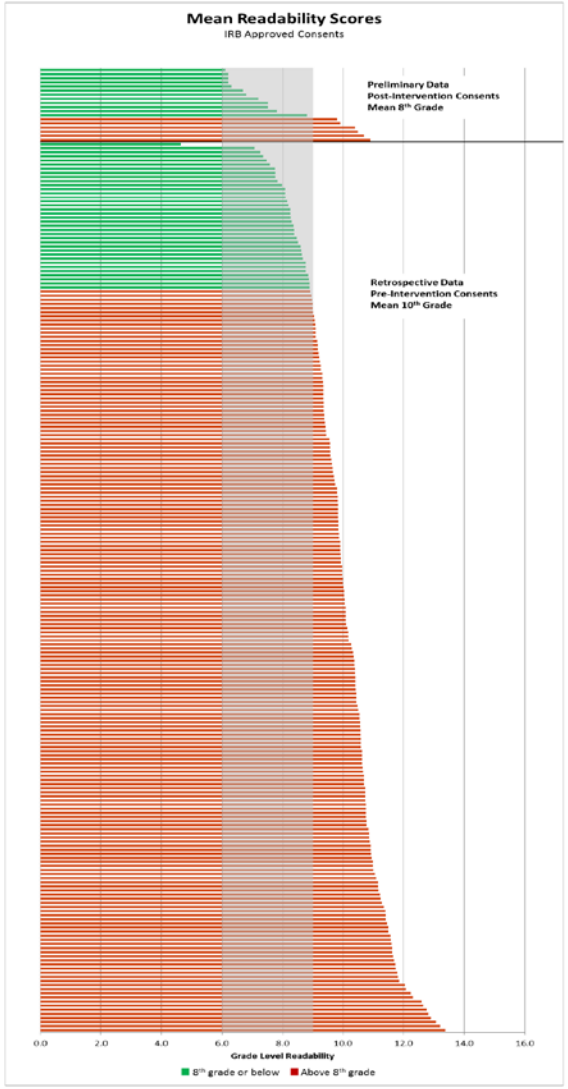
Kristie Hadden, PhD, UAMS Center for Health Literacy/TRI

"Moving the needle on improving informed consents at UAMS"

- TRI/IRB/CHL collaboration
  - Established baseline readability of IRB ICs
  - Developed and implementing intervention
    - PL template, New study tools
    - IRB inservices, presentations, etc.
    - Promotion/awareness building
  - Prospectively assessing readability of ICs

Plain Language Informed Consents

Kristie Hadden, PhD, UAMS Center for Health Literacy/TRI



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Plain Language Informed Consents

Kristie Hadden, PhD, UAMS Center for Health Literacy/TRI

Plain Language Template	Readability IRB Approved Consents
Yes	6.1
Yes	6.2
Yes	6.2
Yes	6.2
Yes	6.3
Yes	6.7
Yes	6.8
Yes	7.2
Yes	7.5
Yes	7.5
Yes	7.8
Yes	8.8
No	9.8
No	9.9
No	10.4
No	10.5
No	10.7
No	10.9
Mean Readability	8th Grade

Mean Readability Plain Language Template

6th Grade

Mean Readability NOT Plain Language Template

10th Grade

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Plain Language Informed Consents

Kristie Hadden, PhD, UAMS Center for Health Literacy/TRI

"Moving the needle on improving informed consents at UAMS"

- Preliminary results
  - 100% of informed consents assessed post-intervention that were in the plain language template fell within the recommended readability range
  - 100% of the investigators who did not use the plain language template had informed consents that were above the recommended readability level

NIH GCP Training

Amy Jo Jenkins, Sr. Project Manager
Translational Research Institute

- **Policy on Good Clinical Practice (GCP) Training for NIH Awardees Involved in NIH-Funded Clinical Trials** (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html)
- Released September 16, 2016
- Applies to NIH-funded investigators and site staff who are responsible for the conduct, management and oversight of NIH-funded clinical trials

NIH GCP Training

Amy Jo Jenkins, Sr. Project Manager
Translational Research Institute

- **What are GCPs?**
  - Principles that constitute an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials.
  - Describe the responsibilities of investigators, sponsors, monitors and IRBs in the conduct of clinical trials.
  - Compliance provides assurance that:
    - The rights, safety and well-being of human subjects are protected,
    - Clinical trials are conducted in accordance with approved plans with rigor and integrity
    - Data derived from clinical trials are reliable

NIH GCP Training

Amy Jo Jenkins, Sr. Project Manager
Translational Research Institute

What are NIH Clinical Trials?

- Research studies in which 1+ human subjects are prospectively assigned to 1+ interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
- An *intervention* is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints.
  - drugs, biologics, devices, procedures, delivery systems (e.g., telemedicine, face-to-face interviews), strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits), treatment strategies, prevention strategies, diagnostic strategies

NIH GCP Training

Amy Jo Jenkins, Sr. Project Manager
Translational Research Institute

- **Effective January 1, 2017**
- Consensus agreement of our institutional policy moving forward: TRI, IRB, ORC, Office of the Vice Chancellor for Research
- ***If you are currently conducting an NIH-funded clinical trial, you will need to complete your training prior to the first of the year.***

NIH GCP Training

Amy Jo Jenkins, Sr. Project Manager
Translational Research Institute

- **Two ways:**

1. Complete GCP training using the CITI program.
2. Send record/certificate of current GCP training (i.e., from industry-sponsored trial participation) to Catrice Banks-Johnson (CRBanksjohnson@uams.edu).

- GCP training expires after 3 years.

NIH GCP Training

Amy Jo Jenkins, Sr. Project Manager
Translational Research Institute

- If you have ambitions of conducting an NIH-funded clinical trial, you are highly encouraged to complete the training now!
- Even if you have determined this does not apply to you, you are highly encouraged to complete the training now! *GCP training is likely to be mandated within the next 6-12 months, as many institutions, journals, and other funding sources are trending toward this requirement.*

NIH GCP Training

Amy Jo Jenkins, Sr. Project Manager
Translational Research Institute

- **Note: All investigators and staff participating in industry-sponsored studies have likely already completed GCP training.**
- Check your regulatory binders for documentation!

NIH GCP Training

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Showcase of Medical Discoveries – Basic Subcellular Mechanisms

Linda Williams, Research Liaison, Office of Research

- **Showcase – Basic Subcellular Mechanisms**
  - **November 9, 2016**
  - 4:30 p.m. - 6:00 p.m.
  - 10th floor Winthrop P. Rockefeller Cancer Institute
  - Wine & cheese research reception and 14 poster presentations

Next RESIN

- **Next RESIN**
  - **December 6, 2016 @ 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