SRA INTERNATIONAL
ANNUAL MEETING
CHICAGO 2024
OCTOBER 26-30

WHAT'S WITH ALL THE RULES IN CLINICAL RESEARCH

SESSION: W208
OCTOBER 30, 2024

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DISCLOSURES & ACKNOWLEDGMENTS

- I HAVE NO FINANCIAL OR OTHER CONFLICTS TO DISCLOSE.
- THIS INFORMATION IS PROVIDED FROM MY EXPERIENCES AND NOT TO BE INFERRED AS THE OFFICIAL STANCE OF MY ORGANIZATION.
- I AM INDEBTED TO COLLEAGUES ALONG THE WAY THAT HAVE ASSISTED WITH THIS PRESENTATION
  - TOLISE DAILEY
  - KEVIN TITUS

OBJECTIVES

IDENTIFY THE GOOD CLINICAL PRACTICE (GCP) GUIDELINES AND HOW THEY IMPACT RESEARCH

UNDERSTAND SIGNIFICANT REGULATIONS THAT GOVERN CLINICAL RESEARCH

INVESTIGATE VARIOUS WAYS TO MEET THESE VARIOUS REGULATIONS AND GUIDELINES

TODAY'S AGENDA

REASONS FOR RULES AND REGULATIONS

COMMON REGULATIONS AND GUIDELINES

BUDGET CONSIDERATIONS

REASONS FOR RULES & GUIDELINES

PROTECTION OF HUMAN SUBJECTS

SAFETY OF PUBLIC AND DATA INTEGRITY

TRANSPARENCY AND TRUST

APPROPRIATE FINANCIAL STEWARDSHIP

TYPES OF RULES AND GUIDELINES

PROTECTION OF HUMAN SUBJECTS

STUDY CONDUCT AND DATA INTEGRITY

FINANCIAL ACCOUNTABILITY

PROTECTON OF HUMAN SUBJECTS

PROTECTION OF HUMAN SUBJECTS

COMMON RULE (45 CFR 46), FDA (21 CFR 50 and 56)

- INSTITUTIONAL REQUIREMENS FOR HUMAN SUBJECTS RESEARCH
- CONSENT ELEMENTS
- IRB REVIEW
- VULNERABLE POPULATIONS

BUDGET DEVELOPMENT

- STAFFING: REGULATORY REPORTING AND CONSENT PROCESS
- RECRUITMENT CONSIDERATIONS

PROTECTION OF HUMAN SUBJECTS

FDA REGULATIONS

- FDA 21 CFR 50 and 56 – IRB AND INVESTIGATOR RESPONSIBILITIES
- FDA 21 CFR 312 (DRUGS) or 812 (DEVICES)
- FDA 21 CFR 11 – ELECTRONIC RECORDS/ELECTRONIC SIGNATURES

BUDGET DEVELOPMENT

- STAFFING: REGULATORY REPORTING, CONSENT PROCESS
- INVESTIGATOR-INITIATED STUDIES: INCREASED STAFFING AND REPORTING
- DON'T FORGET: MONITOR VISITS, ADVERSE EVENT/UNANTICIPATED PROBLEM REPORTING ETC.

PROTECTION OF HUMAN SUBJECTS

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

- USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI)
- COVERED ENTITIES, BUSINESS ASSOCIATES

BUDGET DEVELOPMENT

- STAFFING: CONSENT AND AUTHORIZATION PROCESS
- PROTOCOL DEVELOPMENT: AUTHORIZATION, SCREENING, DATA COLLECTION
- APPROPRIATE SHARING OF DATA AND SAMPLES

PROTECTION OF HUMAN SUBJECTS

DATA SAFETY MONITORING BOARD (DSMB)

- FEDERAL STUDIES: ALL PHASE III STUDIES, SOME PHASE I AND II STUDIES
- INDUSTRY STUDIES: FDA MAY REQURE
- INSTITUTIONAL/LOCAL REQUIREMENTS

BUDGET DEVELOPMENT

- FEES FOR DSMB REVIEWERS
- STAFFING TO MONITOR DSMB PROCESS AND REGULATORY REPORTING
- INVESTIGATOR-INITIATED STUDIES: INCREASED WORKLOAD

PROTECTION OF HUMAN SUBJECTS

CONFLICT OF INTEREST (COI)

- NIH REQUIREMENTS
- FDA REQUIREMENTS
- SPONSOR REQUIREMENTS
- LOCAL COI REQUIREMENTS

BUDGET DEVELOPMENT

- INVESTIGATOR/CONSULTANT CONSIDERATIONS
- EXTRA MONITORING
- SPECIAL ATTENTION: INVESTIGATOR-INITIATED RESEARCH

STUDY CONDUCT AND DATA INTEGRITY

STUDY CONDUCT AND OPERATIONS

GOOD CLINICAL PRACTICE (GCP) ICH E6 (R2)

- "HOW-TO MANUAL" OF CLINICAL RESEARCH
- DOCUMENTATION REQUIREMENTS
- PROTOCOL INFORMATION
- ESSENTIAL DOCUMENTS

BUDGET DEVELOPMENT

- ADEQUATE TRAINING
- ESSENTIAL DOCUMENT MAINTENANCE
- MONITORING ACTIVITIES

STUDY CONDUCT AND DATA INTEGRITY

DATA INTEGRITY AND SECURITY (21 CFR 11)

- COVERS ELECTRONIC DATA SENT TO FDA
- CERTIFICATION TO FDA FOR ELECTRONIC SIGNATURES

BUDGET DEVELOPMENT

- SOFTWARE PROGRAMS – COMPLIANT, CERTIFIED?
- IT SUPPORT

STUDY CONDUCT AND DATA INTEGRITY

CLINICAL TRIALS.GOV (FDAAA 801)

- TRANSPARENCY OF DATA RESULTS
- PUBLIC ACCESS TO CLINICAL TRIALS

BUDGET DEVELOPMENT

- STAFF TO MANAGE
- FINANCIAL PENALTIES FOR NON-COMPLIANCE

STUDY CONDUCT AND DATA INTEGRITY

PUBLIC ACCESS TO PUBLICATIONS (Division G, Title II, Section 218 of PL 110-161 - Consolidated Appropriations Act, 2008)

- TRANSPARENCY OF DATA RESULTS
- PUBLIC ACCESS TO CLINICAL TRIALS AND OUTCOMES FUNDED BY PUBLIC FUNDS

BUDGET DEVELOPMENT

- STAFF TO MANAGE
- FINANCIAL PENALTIES FOR NON-COMPLIANCE

FINANCIAL ACCOUNTABILITY

FINANCIAL ACCOUNTABILITY

ANTI-KICKBACK STATUTE (AKS) (42 CFR 1320a-7b(b))

- NO INDUCEMENTS OR REWARDS FOR REFERRALS
- REFERRALS CAN BE FROM ANY SOURCE

BUDGET DEVELOPMENT

- CRIMINAL PENALTIES
- CIVIL PENALTIES (HEAVY FINES AND SANCTIONS(

FINANCIAL ACCOUNTABILITY

STARK LAW (42 USC 1395nn)

- NO MEDICAL REFERRALS CAN BE MADE TO AN ENTITY WHICH THE PHYSICIAN (OR IMMEDIATE FAMILY MEMBER) HAS A FINANCIAL RELATIONSHIP (UNLESS EXCEPTION APPLICABLE)
- HEALTH SERVICES ENTITY CANNOT SUBMIT CLAIMS TO MEDICARE FOR SERVICES RESULTING FROM PROHIBITED REFERAL

BUDGET DEVELOPMENT

- CIVIL PENALITES (HEAVY FINES AND SANCTIONS)
- IDENTIFY SOURCES OF REFERRALS AND ARRANGE FOR OPTIONS, IF NECESSARY

FINANCIAL ACCOUNTABILITY

CLINICAL TRIALS BILLING (NATIONAL COVERAGE DETERMINATION) 310.1)

- ONLY ROUTINE COSTS TYPICALLY ALLOWED
- MEDICARE BENEFIT CATEGORIES
- DRUG ADMINISTRATION COSTS, DEVICES DEPENDING ON DEVICE (CATEGORY A VS CATEGORY B)
- TREATMENT/THERAPEUTIC INTENT

BUDGET DEVELOPMENT

- ALLOWABLE CHARGES ONLY CHARGED TO PARTICIPANT, OTHERWISE TO STUDY
- STAFFING TO COMPLETE MCA AND MONITOR CHANGES
- CONSENT PROCESS
- COORDINATION OF DOCUMENTS, PROTOCOL, BUDGET, INFORMED CONSENT DOCUMENT/TEMPLATE, SCHEDUL OF EVENTS

FINANCIAL ACCOUNTABILITY

FALSE CLAIMS ACT

- "LINCOLN LAW"
- KNOWINGLY OR CONSIPRING TO MAKE A FALSE CLAIM TO THE FEDERAL GOVERNMENT
- *QUI TAM* LAWS – PROVICE WHISTLEBLOWER PROTECTION
- PENALTY ASSESSED CAN BE AWARDED TO WHISTLEBLOWER

BUDGET DEVELOPMENT

- PROCESS IN PLACE TO IDENTIFY CHARGES SUBMITTED TO GOVERNMENT
- SIGNFIICANT PENALTIES

FINANCIAL ACCOUNTABILITY

LABORATORY CERTIFICATION (CLIA AND CAP)

- COLLEGE OF AMERICAN PATHOLOGISTS (CAP)
- TISSUES AND MICROBIOLOGY TESTS
- CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
- TEST KITS AND LAB TESTS

BUDGET DEVELOPMENT

- ENSURE ALL LABS ARE CONDUCTED UNDER CLIA/CAP CONDITIONS
- STAFFING: KEEP ALL DOCUMENTATION ON FILE

STAFF TRAINING

STAFF TRAINING

TRAINING REQUIREMENTS

- HUMAN SUBJECTS PROTECTION, GCP
- RESPONSIBLE CONDUCT OF RESEARCH (RCR)
- SHIPPING AND BIOSPECIMEN HANDLING
- HIPAA
- PROTOCOL-SPECIFIC TRAINING
- INSTITUTIONAL-SPECIFIC TRAINING

BUDGET DEVELOPMENT

- STAFFING
- TRAINING PROGRAMS
- SPONSOR-BASED TRAINING

REVEW AND QUESTIONS

REASONS FOR RULES & GUIDELINES

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CERTIFICATE INFORMATION

QUESTIONS/CONTACT

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