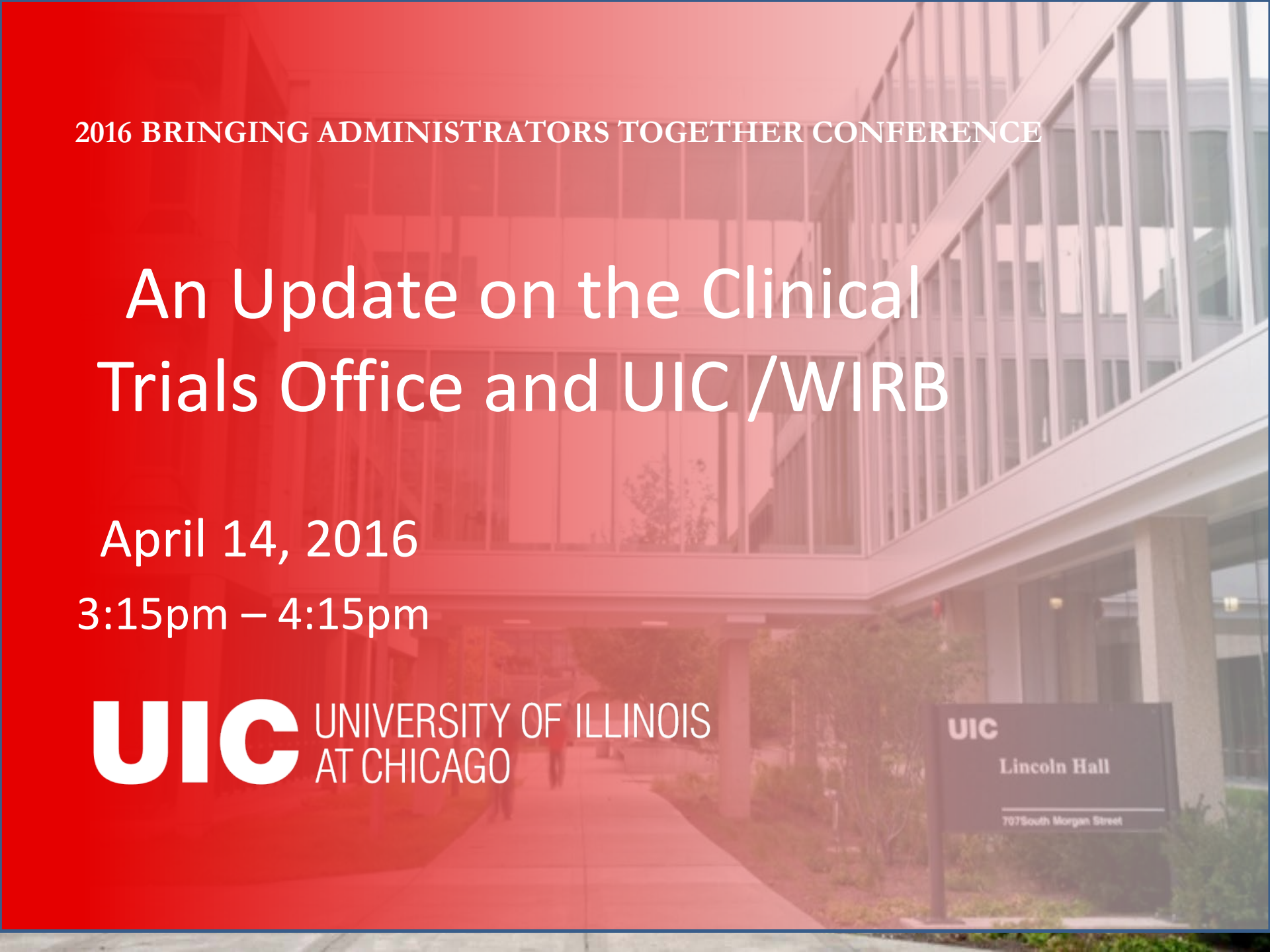
2016 BRINGING ADMINISTRATORS TOGETHER CONFERENCE

An Update on the Clinical Trials Office and UIC /WIRB

April 14, 2016

3:15pm – 4:15pm

UIC UNIVERSITY OF ILLINOIS AT CHICAGO



Workshop Presenter(s)

- Name: Diane Downs, MSN, RN
  Title: Associate Director, Clinical Trials Office, Office of the Vice Chancellor For Research
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- Name: Cynthia Tom-Klebba, MA, CIP
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Please …

- Turn off cell phones.
- Avoid side conversations.
- Please save your questions for the end.
- Sign the attendance roster.
- Complete the evaluation at the end of the workshop.

Workshop Objectives

- Describe the function and role of the Clinical Trials Office (CTO)
- Discuss the relationship between the CTO, the Office of Research Services and the Office for the Protection of Research Subjects
- Compare and contrast the differences between the Medicare Clinical Trial Policy and the device regulations

Workshop Objectives (cont)

- Describe and discuss the purpose of Medicare coverage analysis
- Describe the process of the UIC IRB Review and WIRB Criteria for Review
- Discuss the incorporation of the Medicare Coverage Analysis with IRB review of study and informed consent

All Things Medicare

Federal Regulations

Clinical Trial Policy

Consultation

Research Billing

Medicare Coverage Analysis

Normal Routine Care

Expertise With Medicare Context of **CLINICAL TRIALS**

CTO / OVCR Contact Information

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Clinical Trial.gov

Device Clinical Trial

Partnership With Department to Facilitate Research

Medicare Approval

Qualifying Clinical Trial

Match Protocol Consent Budget

Subject Injury Language

NCD LCD

Clinical Trial Agreement Negotiation

False Claim Act

Prohibited

The UIC Model: Clinical Trials Administration Office (CTO)

- Centralized unit to assist UIC researchers with administrative processes
- Website contains information pertaining to the conduct of clinical trials research at UIC http://research.uic.edu/ct
- Enhance compliance with federal, state and institutional requirements –for example, *Medicare Coverage Analysis*
- Create partnerships with UIC research community re: *Conduct of Clinical Trial Research*

Services of UIC CTO

- Review and negotiation of confidentiality Agreements (CDA), Clinical Trial Agreements (CTA) and all modifications/amendments
- Centralized process for conduct of a Medicare Coverage Analysis
- Set the stage for compliant clinical trial billing
- Centralized office to contact Medicare for coverage questions & obtain approval for device trials

Services of UIC CTO (cont)

- Administrators for Clinicaltrials.gov
- Assist with the development of research budgets in collaboration with Hospital (UI Health Administration)

Additional Services of the UIC CTO

Training for UIC research community

- Research Coordinators
- Budget Negotiators
- Investigators
- Clinical Staff
- Business & Support Staff

Milestones of UIC CTO

- Assisted facilitation of a White Paper submission to local CMS Fiscal Intermediary (in an attempt to expand coverage of Stem Cell Transplant for Sickle Cell Disease)

  *** Decision Memo for Stem Cell Transplantation (Multiple Myeloma, Myelofibrosis, and Sickle Cell Disease) (CAG-00444R) ***

- Provided > 40 training sessions
- 93 Medicare coverage analyses to date for Academic Year 2016
- Provide coverage guidance for development of Investigator initiated clinical trials
- Share Point will be available early summer

Medicare and Devices

1995 Device Regulations

Medicare covers the cost of the device and routine care in clinical trials if:

- The device is an IDE with a Category B designation
- May cover routine costs, but not the device with a Category A designation
- Coverage is limited to devices used in FDA and IRB approved studies and is case-by-case

Medicare's National Coverage Determination (NCD) Routine Costs in Clinical Trials (310.1)

Medicare covers "routine costs" of "qualifying clinical trials" IF:

- Item/service is not otherwise excluded from coverage
- Item/service has not been promised free of charge to subject
- Item/service is not being paid for by the Sponsor

- Qualifying Clinical Trial
  - Must satisfy the three necessary requirements AND
  - Be "deemed" by CMS to meet the "seven desirable characteristics"…

  Typically, the investigational item or service is not covered, *but* the administration of the investigational item or service is covered

NCD Routine Costs in Clinical Trials (310.1) (cont)

A. THREE requirements:

- The subject or purpose of the trial must be an evaluation of an item or service that falls within a Medicare benefit category and is not statutorily excluded from coverage
- The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent
- Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group

B. Deemed to be automatically qualified:

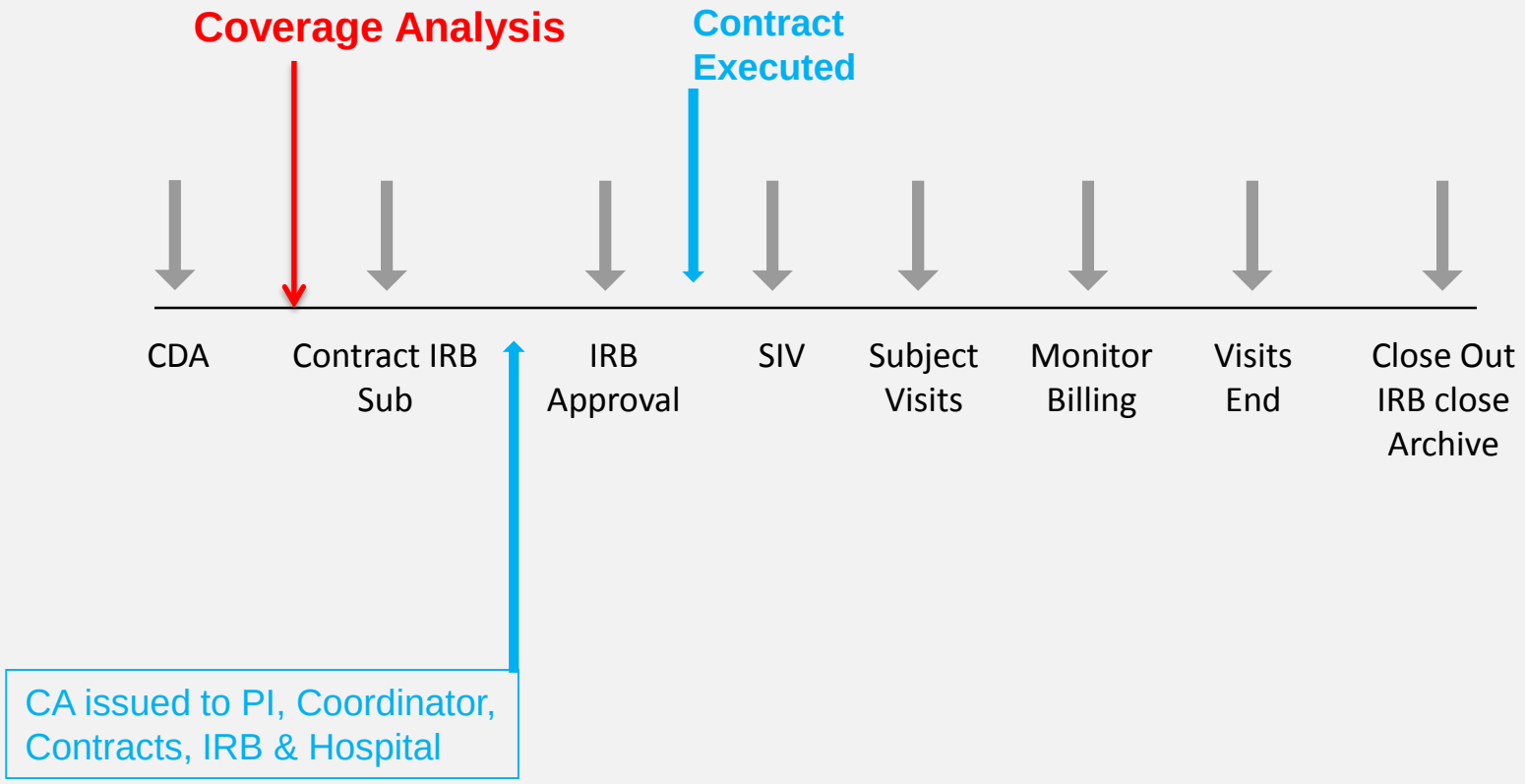
- Trials funded by NIH, CDC, AHRQ, CMS, DOD and VA
- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, DOD and VA
- Trials conducted under an investigational new drug application ("IND") reviewed by the FDA; and
- Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place

Medicare Coverage Analysis (CA): A method to work with the NCD in the context of clinical trials

The CA provides:

- A comprehensive review of the protocol, draft informed consent, draft contract and draft budget
- A template to develop and negotiate a stronger budget (who is paying for what)– *Sponsor*, *Medicare/commercial insurance*, *Subject*, or the *Department*
- Provides a template for subjects financial liability in the consent and also addresses subject injury (§46.116 & 21 CFR 50.25)
- Serves as a guide for the IRB to review the cost section of the informed consent and the subject injury section
- A review of NCDs and LCDs
- A consistent methodology for research billing
- A tool for audits

Clinical Trial Timeline



Coverage Analysis

PI:	**Coverage Analysis issued by:**
Department:	Use with billing grid:
Protocol Title	PAF#
Sponsor:	IRB#
Summary of Study:	Documents Reviewed:
FDA Assigned IND Number:	**NCT Number:**

Administration of the Investigational drug	N	310.1	
Hepatitis B Screening	PS at screening	190.33	Covered To detect viral hepatitis infection when there are abnormal liver function test results, with or without signs or symptoms of hepatitis. Prior to and subsequent to liver transplantation.
CT or MRI (chest, abd, pelvis)	PS at screening, N thereafter		RECIST guideline version 1.1; NCCN Version 1.2016 Invasive Breast Cancer, PI to document medical necessity
PT or INR/ APTT	CL	NCD 190.16/190.17	Medicare has specific guidelines for coverages see attachment

Coverage Analysis Billing Grid

Billing Plan Section E	BILLING GRID				
ORA# 01020304					
Protocol: Study of the Safety and Effectiveness of New Device					
PI: Jane Doe, MD					
Draft date:					
	Baseline	Operative	3-6 weeks	6 months	12 months
Informed consent	E				
Inclusion/exclusion criteria	E				
Demographics/indication	E				
Medical history	E				
Physical exam	S				S
Complete Blood Count (CBC)	S			N	S
Complete Metabolic Panel (CMP)	S			N	S
Urinalysis	S				S
Pregnancy test	S				
X-Ray	S		N		S
Surgical information		E			
ED-5Q	E		E	E	E
SF-36	E		E	E	E
Concomitant Medications	E	E	E	E	E
Adverse events	E	E	E	E	E
Key					
1. **N** = Normal Care (bill to insurance)					
2. **S** = Sponsor paying (bill to research)					
3. **PS** = Patient specific (if not SOC at the time point bill to research; otherwise bill to insurance)					
4. **CL** = Central lab					
5. **E** = Research Effort (time and effort for the conduct of the clinical trial)					

PI: Jane Doe, MD		BUDGET			
	Baseline	Operative	3-6 weeks	6 months	12 months
Informed consent	X				
Inclusion/exclusion criteria	X				
Demographics/indication	X				
Medical history	X				
Physical exam	275				275
Complete Blood Count (CBC)	165			N	165
Complete Metabolic Panel (CMP)	175			N	175
Urinalysis	65				65
Pregnancy test	85				
X-Ray	375		N		375
Surgical information		x			
ED-5Q	x		x	x	x
SF-36	x		x	x	x
Concomitant Medications	x	x	x	x	x
Adverse events	x	x	x	x	x

GOAL

All Documents Match

Draft CA & Draft Billing Grid, IRB Approved Protocol, Consent, Executed Contract with Final Budget

CTO Summary

- Centralized unit to assist UIC researchers with administrative processes
- Website contains information pertaining to the conduct of clinical trials research at UIC
- Enhance compliance with federal, state and institutional requirements –for example, *Medicare Coverage Analysis*
- Create partnerships with UIC research community re: *Conduct of Clinical Trial Research*

UIC IRB Process for Clinical Trials

- Submission Received by OPRS & Assigned for IRB Review
- Review includes identification of subject payment according to the Coverage Analysis
- IRB will request appropriate Subject Injury Option based on Coverage Analysis

WIRB Review Process

- What Qualifies for WIRB Review?
  - Research that meets the National Institute of Health (NIH) definition of a clinical trial, i.e. “A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices)”.

WIRB Review Process

- What qualifies for WIRB? (continued)
  - Research is a Phase II / III / IV clinical trial.
  - Research is designed and research protocol written by the sponsor.
  - The sponsor is a for-profit entity or company.
  - The sponsor holds all INDs / IDEs.
  - The research has not previously been submitted to the UIC IRB for review.
  - The research is greater than minimal risk.

WIRB Review Process

- What doesn't qualify for WIRB?
  - Phase I studies (including I/II, Ib or similar studies)Planned Emergency Research
  - Transplant Research, including Cadaveric Research
  - Embryonic Stem Cell Research
  - Research that involves funds from a federal or non-profit funding agency

WIRB Review Process

- What doesn't qualify? (continued)
  - Research that is investigator-initiated
  - Research that involves the use of recombinant DNA and its derivatives, such as vectors, and infectious agents
  - Research that involves the use of Radioactive drugs or Biologics or radioactive materials*

WIRB Review Process

- Complete the Registration for Protocol Review by Western IRB
- Include:
  - Appendix P and E
  - Sponsor Informed Consent Template
  - Sponsor Research Protocol
  - Copy of Coverage Analysis

WIRB Review Process

- Submissions will be reviewed to ensure:
  - Appropriate Account Number is provided as there are WIRB Review Fees incurred.
  - Verification of UIC HSPP Training (CITI / Initial Investigator Training & HIPAA) for all Research Personnel
  - Completion of Coverage Analysis

WIRB Review Process

- Acknowledgement Letter will be issued when all documents are present in the file.
- Acknowledgement Letter will include the appropriate Subject Injury Option that WIRB will incorporate into the final Consent Document

WIRB Review Process

- WIRB will forward all approved documents to OPRS for verification of language in the Consent Document.
- OPRS will inform WIRB that any hold can be released if the language is consistent with the Coverage Analysis.

WIRB Review Process

- WIRB becomes IRB of Record for the research.
- Refer to the OPRS WIRB Website for additional information on Amendments, Continuing Review, Adverse Events and Final Reports http://research.uic.edu/compliance/irb/investigators-research-staff/review-research-western-institutional-review-board-wirb

IRB / WIRB Summary

- Draft Coverage Analysis must be completed prior to or concurrent with UIC IRB or WIRB Review.
- The UIC IRB will not issue a final Approval notice until the Draft Coverage Analysis and other issues (unrelated to the coverage analysis) have been corrected.

IRB / WIRB Summary

- OPRS will not issue an Acknowledgement Letter for WIRB Review until the Draft Coverage Analysis and other issues (unrelated to the coverage analysis) are corrected.

Questions / Concerns?