

2014 BRINGING ADMINISTRATORS TOGETHER CONFERENCE

# Introducing the Clinical Trials Office: A Concierge Approach to Research Administration

4/1/14 Breakout Session 1

**UIC** UNIVERSITY OF ILLINOIS  
AT CHICAGO

**UIC**

Lincoln Hall

707 South Morgan Street

# Workshop Presenter

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# Please ...

- Please feel free to ask questions during the presentation.
- 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) at UIC *aka* Clinical Trials Research Administration Office
- Discuss the interrelationship between the CTO, the Office of Research Services (focus for this workshop--- contract component) and the Office for the Protection of Research Subjects (IRB)
- Compare and contrast the differences between the Medicare Clinical Trial Policy and the device regulations
- Describe the purpose of a coverage analysis

# Our Model: Clinical Trials Research Administration Office

- Initiate a centralized unit to assist with the research administrative components
- Website will contain all information pertaining to the conduct of clinical trials (clinical trials resource center)
- An opportunity to conduct a clearer and more comprehensive review of projects, which facilitates communication between the entities
- Standardize the contractual and fiscal processes for clinical research
- Goal is to work towards a one-stop method (drop off and pick up project one location)---user friendly approach

# Benefits of Integration

- Enhance regulatory knowledge and support
- Check and balance to meet federal, state and institutional requirements
- Provide training opportunities
- Cost effective
- Accountability
- Faster turn around times with project reviews
- Growth of research operation

# The Services of the CTO at UIC

Point of contact for the conduct of clinical trials

- Centralized process for coverage analysis...
  - Harmonizes the research related documents (protocol, informed consent, budget and contract)
- Centralized process to contact Medicare
- Centralized process to obtain prior approval from Medicare for device trials
- Protocol Registration System (PRS) administration for [clinicaltrials.gov](http://clinicaltrials.gov)
- Centralized process to develop research budgets (strategic budget guidance)

# ClinicalTrials.gov

## PUBLIC LAW 110–85—SEPT. 27, 2007

Section 801: ClinicalTrials.gov offers up-to-date information for locating federally and privately supported clinical trials for a wide range of diseases and conditions.

“Applicable clinical trials” generally include interventional studies (with one or more arms) of FDA-regulated drugs, biological products, or devices that meet one of the following conditions:

- The trial has one or more sites in the United States
  - The trial is conducted under an FDA investigational new drug application or investigational device exemption
  - The trial involves a drug, biologic, or device that is manufactured in the United States or its territories and is exported for research
  - Pediatric post market surveillance of device studies
- CIVIL MONEY PENALTIES—for non compliance
  - International Committee of Medical Journal Editors (ICMJE ): requires/recommends registration of clinical trials in public trials registries.



# *ClinicalTrials.gov*

## *Protocol Registration System*

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### **Login**

Welcome to the [ClinicalTrials.gov](http://ClinicalTrials.gov) Protocol Registration System (PRS).

OMB N  
EXPIRA  
[Burden](#)

**Organization:**

**Username:**

**Password:**

[Forgot passw](#)

Login

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[PRS account registration information](#)

# Clinical Trial Steps or Phases

- **Phase I:** Drug or treatment tested in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
- **Phase II:** The drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
- **Phase III:** The drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
- **Phase IV:** Studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.

Taken from <http://www.nlm.nih.gov/services/ctphases.html>, March 18, 2014

# Who pays for the conduct of a clinical trial?

- 100% Industry Sponsor (i.e. Amgen, Johnson & Johnson, etc.)
- Federally funded, i.e. NIH
- Healthcare Insurance (Medicare and/or private, i.e. Blue Cross Blue Shield)
- The subject
- The department/ institution
- Some combination

# What is the difference between Medicare & Medicaid & Private/Commercial Insurance?

- Medicare- federally funded
- Medicaid- funded by federal and state
- Private/Commercial insurance- not funded by the government... but....many follow Medicare rules on coverage

# False Claim Act (FCA)

Effective tool in combating fraud against the federal government

- History: Enacted in 1863 by Congress concerned suppliers of goods to the Union Army during the Civil War were defrauding the government
- § 3729 et seq., may result in fines of up to 3x's the programs loss + \$11,000 per claim filed
- 1986-2013: Federal government recovered >\$35 billion (majority of largest settlements are from health care related cases)

# FCA

- Knowingly presents, makes, uses, caused, conspires to defraud the Government, has possession, custody or control of property or money...(can be demonstrated by “reckless disregard” or “deliberate ignorance”)
- Submits a false claim for payment, or uses a false record or statement or causes a third party to submit a false claim for payment or use a false record or statement to obtain payment  
...require no proof of specific intent to defraud

# Ways to trigger the FCA

- Physician submits a bill to Medicare for Medical services he/she did not perform
- Bills submitted with incorrect code(s) to obtain payment
- Bills Medicare for items and services paid for by the Sponsor in a clinical trial “double dipping”
- Report inaccurate time and effort with studies
- Uses research funds for personal purposes, such as family travel

# False Claim Settlements

- 7/2013: Northwestern University \$2.93 M -Cancer Research Grant Fraud Claims (improper submission of claims to NIH for grant expenditures and improper use of NIH funds)
- 8/2013: Emory \$1.5 M (not following Medicare's clinical trial policy- billed for items and services not allowed)
- 12/8/2005: Rush \$1.0 M (not following Medicare's clinical trial policy- billed for items and services not allowed)



# Medicare...Then & Now

1965- Congress passed legislation establishing the Medicare program as Title XVIII and Title XIX of the Social Security Act, established in response to specific medical care needs of the elderly

1973- coverage expanded for certain disabled persons and certain persons with kidney disease

2000- Clinical Trial Policy, prior to this National Coverage Determination Medicare beneficiaries could not participate in clinical trials- as Medicare would not cover the costs of routine care

Then- Two parts: Hospital Insurance (HI *aka* Part A) and Supplementary Medical Insurance (SMI *aka* Part B)

Now- Four parts: Part A (Hospital coverage), Part B (Medical Insurance) Part C *aka* Medicare Advantage Plans (combines A, B and perhaps D into an HMO or PPO with a private insurer) and Part D (Prescription Drug coverage)

# Underlying theme...Medical Necessity

- Medicare's definition of medical necessity stems from the SSA of 1965 (1862[a][1][A])...states **no payment** under Medicare Part A or Part B for any expenses incurred for items or services which, except for certain named exceptions “*are not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body part*”
- Not medically necessary: a particular service is not a benefit under the defined benefit, for this diagnosis, at this time (Article for Medical Necessity –A3369- WPS, 2/1/02)

# Medicare *Fact or Fiction*

- Medicare pays for all “standard of care” in research studies
- Medicare’s goal is to promote research & scientific progress
- Medicare is all about primary prevention
- Federal Agencies, including Center for Medicare & Medicaid Services (CMS ) & the NIH communicate regularly to ensure consistency with all the rules

# National Coverage Determinations (NCD) & Local Coverage Determinations (LCD)

Underlying theme...is the item or service reasonable and necessary; provided for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body party...(and falls under a Medicare benefit category)

- National Coverage Determinations (NCDs): US nationwide determination of whether Medicare will pay for an item or service.
- Local Coverage Determination (LCD)-*aka* local medical review policy (LMRP) is a decision by a fiscal intermediary (FI) or carrier whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with §1862(a)(1)(A) of the Social Security Act (e.g., determination as to whether the service or item is reasonable and necessary).
  - LCDs are developed when there is no NCD or when there is a need to further define a NCD
  - LCDs cannot conflict with NCDs

# Medicare Coverage of Device Clinical Trials

“1995 Device Regulations” Devices and Related Services 60 FR 48417

- Medicare covers the device in device clinical trials if it is a investigational device exemption (IDE) with a Category B designation
- Medicare Coverage: limited to those devices used in FDA and IRB approved studies and is case-by-case:
  - Category B IDE device clinical study
  - Category A IDE device clinical study before billing routine costs of clinical studies involving a Category A device
  - Post-market approval studies or registries of carotid stents
  - Studies for proximal embolic protection devices (EPDs) in carotid artery stenting (CAS) procedures

## Excerpt from Medicare letter approving billing for a particular device study

... “Note that the provider is responsible for insuring that all aspects of the billed services are in full compliance with all pertinent Centers for Medicare and Medicaid Services (CMS) regulations and billing provisions”

# 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” ...

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

## A. THREE requirements:

- The subject or purpose of trial must be an evaluation of an item or service that fall within a Medicare Benefit Category and is not statutorily prohibited
- 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 volunteer. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group

## B. Deemed to be automatically qualified are:

- 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)...until qualifying criteria are developed and certification process established



## C. Desirable Characteristics

- The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
- The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
- The trial does not unjustifiably duplicate existing studies;
- The trial design is appropriate to answer the research question being asked in the trial;
- The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
- The trial is in compliance with Federal regulations relating to the protection of human subjects; and
- All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

# Qualifying Clinical Trial

- A + B (which is assumed to have C)= QCT

Clinical Trials that meet the qualifying criteria will receive Medicare coverage of routine costs

“Should CMS find that a trial's principal investigator misrepresented that the trial met the necessary qualifying criteria in order to gain Medicare coverage of routine costs, Medicare coverage of the routine costs would be denied under §1862(a)(1)(E) of the Act... Where appropriate, the billing providers would be held liable for the costs and fraud investigations of the billing providers and the trial's principal investigator may be pursued”

# Coverage Analysis: A method to work with Medicare in the context of clinical trials

The CA provides a thorough review of :

- Study, the informed consent, the contract and the budget
- Provides a template to develop and negotiate a stronger budget (who is paying for what – Sponsor, Medicare, Subject, or your Department)
- Provides a template for subjects financial liability in the consent (21 CFR 50.25) and also addresses subject injury
- Serves as a guide for the IRB to review the cost section of the informed consent
- NCDs and LCDs
- Tool for audits
- Consistent methodology for research billing

# What documents are needed for a coverage analysis?

- Billing Analysis Form
- Billing Grid
- Study
- Draft ICF
- Draft Budget
- Draft CTA
- Supporting Documents

# Schedule of Events

Billing Plan Section E

IRB # 2013-0766

Protocol: Study of the Safety and Effectiveness of New Device

PI: Jane Doe, MD

Draft date: 11/6/13

Items and Services	Baseline	Operative	3-6 weeks	6 months	12 months
Informed consent	X				
Inclusion/exclusion criteria	X				
Demographics/indication	X				
Medical history	X				
Physical exam	X				X
Complete Blood Count (CBC)	X			X	X
Complete Metabolic Panel (CMP)	X			X	X
Urinalysis	X				X
Pregnancy test	X				
CT or MRI (chest, abd, pelvis)	X		X		X
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

# Billing Plan/Grid

Billing Plan Section E

IRB # 2013-0766

Protocol: Study of the Safety and Effectiveness of New Device

PI: Jane Doe, MD

Draft date: 11/6/13

Items and Services	Baseline	Operative	3-6 weeks	6 months	12 months
Informed consent	R				
Inclusion/exclusion criteria	S				
Demographics/indication	S				
Medical history	S				
Physical exam	PS				S
Complete Blood Count (CBC)	PS			N	S
Complete Metabolic Panel (CMP)	PS			N	S
Urinalysis	PS				S
Pregnancy test	PS				
CT or MRI (chest, abd, pelvis)	PS		N		PS
Surgical information		S			
Device	S		S	S	S
SF-36	S		S	S	S
Concomitant Medications	S	S	S	S	S
Adverse events	S	S	S	S	S

## KEY

**R=Research Efforts**

**PS=may be billable to third party payors if medical necessity is documented**

**S=Paid for/provided by sponsor**

**N=Conventional Care**

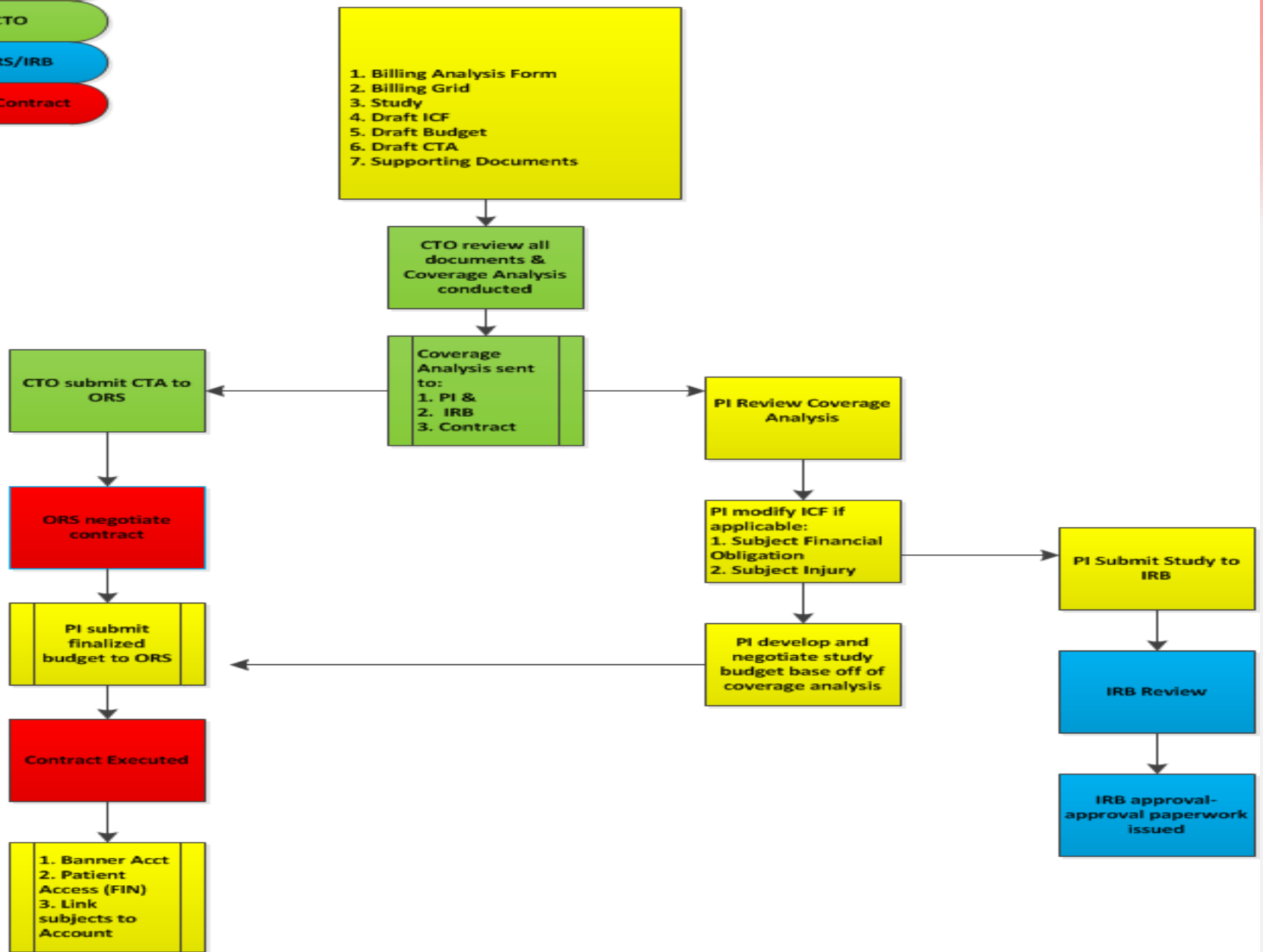
**CL=Central Lab**

# Coverage Analysis

IRB Number#	PAF#
NCT Number: NCT01958021	
Documents reviewed: Protocol, 9/20/13, Informed Consent, Draft Budget, Letter from Novartis with IND number	
FDA Assigned IND number: 117,796	Pending Submission
FDA Assigned IDE number:	N/A
Is study a qualifying clinical trial under Medicare's Clinical Trial Policy?	Yes

CT or MRI (chest, abd, pelvis) Whole body scan)	PS at screening,	L28516	See section 7.2 of study (CT or MRI (chest, abd, pelvis mandated) as is whole body bone scan)
PET Scan (whole body scan)	PS at screening	220.6	
PFT's	PS at screening	LCD L32762 (Novitas Soln)	No LCD in IL. This is not a screening test approved for coverage by Medicare; therefore in order to obtain coverage, the patient has to be symptomatic and the PI has to document medical necessity.
CT or MRI (chest, abd, pelvis) For subjects receiving study medications	N		Recist guideline version 1.1; NCCN v3.2013 Invasive Breast Cancer, PI to document medical necessity
PT or INR/ APTT	CL	NCD 190.16/190.17	Medicare has specific guidelines for indication

- PI
- CTO
- OPRS/IRB
- ORS/Contract





# Workshop Summary

- Introduction to the Clinical Trials Office *aka* Clinical Trials Research Administration Office and its services
- Introduction to a methodology (Coverage analysis process) to harmonize the review of study related documents
- Review of Medicare rules and regulations pertaining to drug and device clinical trials

# For additional information...

- States Requiring Coverage of Clinical Trials Cost <http://www.cancer.gov/clinicaltrials/learningabout/payingfor/laws>
- Centers for Medicare & Medicaid Services, <http://www.cms.gov/Medicare/Medicare.htm>
- Clinical Trials.gov. <http://www.clinicaltrials.gov/>
- International Committee of Medical Journal Editors ICMJE, <http://www.icmje.org/>

Questions / Concerns?  
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