

The Intersection Between Medicare Coverage Analysis, IRB Review and the Consent Form

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Agenda

- Review of regulations (CTP, FDA/HHS) and their relationships
- Description of Cedars-Sinai's MCA process
- Overview of integration between the MCA, IRB review, management of research-related injury and consent form development
- Advantages, Challenges & Questions

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CMS Clinical Trial Policy

Qualifying Clinical Trial Requirements:

- The purpose of the trial must be 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.

Deemed Trials:

- 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, CMS, DOD, and VA;
- Trials conducted under an investigational new drug application (IND)
- IND exempt trials

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CMS Clinical Trial Policy

Routine costs of a clinical trial include items/services:

1. typically provided absent a clinical trial (e.g., conventional care);
2. required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
3. needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications

Items/services not covered in a clinical trial include:

1. investigational item or service, itself unless otherwise covered outside of the clinical trial;
2. provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
3. customarily provided by the research sponsors free-of-charge for any enrollee in the trial

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CMS Coverage for Device Trials

- Devices that may be covered under Medicare:
 - Devices approved by FDA through PMA or 510K
 - IRB-approved Non-Significant Risk devices
 - CMS approved Category B IDE - device and routine costs may be covered
 - CMS approved Category A IDE - routine costs may be covered; device is not covered
- Sponsor is responsible for submitting IDE coverage request to CMS
- Approved IDE studies listed on CMS website:
<https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html>

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IRB Responsibility and Research Billing

Regulation/Policy	Guidance
OHRP IRB Guidebook (1993)	Risks to research subjects posed by participation in research should be justified by the anticipated benefits to the subjects or society. This requirement is clearly stated in all codes of research ethics, and is central to the federal regulations. Risk is defined as "The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study."
45 CFR 46.116(b)(3) & 21 CFR 50.25(b)(3)	When appropriate, ICF must include "Any additional costs to the subject that may result from participation in the research"
45 CFR 46.116(a)(6) & 21 CFR 50.25(a)(6)	For research involving more than minimal risk, ICF must include "an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained"
FDA Guide to Informed Consent – Information Sheet (2011)	If the subjects may incur an additional expense because they are participating in the research, the costs should be explained. IRBs should consider that some insurance and/or other reimbursement mechanisms may not fund care that is delivered in a research context.

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MCA at CSMC

- Office of Research Compliance and Quality Improvement (ORCQI)
 - IRB
 - Research Compliance
 - MCA
- Request for MCA review is through Webridge: electronic submission system for human subject and animal research at CSMC. All new studies, continuation reports, amendments and adverse event reports are submitted and processed electronically.
- MCA performed up front-prior to IRB review
- Minimum documents required:
 - Protocol
 - ICF (if available)
 - Drug studies: IDB
 - Device studies: FDA designation letter; IFU (if available); CMS approval letter for billing

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MCA review required

- New studies:
 - Billable services
 - Protocol mandated item, service or procedure designated as either "standard of care" or "research related" which will create a billing charge to either the patient/patient's insurance or research account.
 - Study sponsor is not paying for all protocol-required procedures (including SOC items/procedures)
- Amendments:
 - Change designation of items/services from research (RES) to standard of care (SOC)*
 - New items/procedures added to SOC *
 - *billable to patient/insurance
 - Increase in frequency of items and procedures under SOC

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Creating MCA Flowchart


1. Using the MCA flowchart template, the study team designates protocol mandated items as SOC or Research Related.
2. Practice Guidelines/references are added for all SOC items.
3. Direct links to references and/or practice guidelines are listed at the bottom of the flowchart.
4. Footnotes are added, as necessary, that are specific for billing clarification purposes, such as windows for protocol mandated items/procedures.

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Responsibilities

Study Team

- Develops initial MCA flowchart using the flowchart template in Webridge.
- Designates study related items/services as SOC or RES.
- Identifies appropriate practice guidelines/references for SOC items.
- Submits and responds to MCA queries in Webridge.
- Ensures that the consent flowchart and the cost language in the summary memo are included in the consent form.



MCA Analyst

- Determines whether the study is a qualifying clinical trial (or a billable device)
- Verifies accuracy of flowchart against protocol.
- Reviews and verifies submitted practice guideline/references and provide additional literature as needed.
- For QCT, identifies research related services that may be billable to the patient (expanded care).
- Creates the summary memo with the consent cost language and a consent flowchart (upon completion of budget flowchart).

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NCD 310.1 Requirement for Coverage

- A trial must be a qualifying clinical trial (QCT)
 - Conventional Care or Standard of Care – billed to patient/insurance:
 - Items or services that are part of regular care and would be done even if the patient did not take part in the research study
 - Research Related, but Billable Items/Services or Expanded Care – allowed to be billed to patient/insurance in a QCT:
 - For Drug Studies: administration of the study drug(s) and clinical monitoring for side effects of study drug
 - Research Related Items/Services – covered by study:
 - Items or services done for research purposes only, including investigational drug

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Flowchart Example

FLOWCHART OF PROCEDURES

Procedures	Screening/ Baseline (within 30 days prior to study procedure)	Procedure (Day 0)	Pre- discharge (within 30 hours - 7 days)	30 days ±7 days	3 months ±14 days	6 months ±30 days	12 months ±30 days	Annual up to 5years (±45days)
Demographics & Medical History	S							
Blood test: CMP (Comprehensive metabolic panel)	S		S	S		S	S	S
Transesophageal Echocardiogram (TEE)	S		S	S	R	S	S	S
Transesophageal Echocardiogram (TEE)		RB						
Cardiac CT	S					R		
12 Lead Electrocardiogram (ECG/EKG)	S						S	
STS Risk Score	S							
Informed Consent		R						
Implantation of the Redacted Valve, with transapical delivery system			RB					
Study device: Redacted Valve Replacement System			R					

LEGEND
 R = Research procedure done only for research purposes and covered by the study
 S = Standard of care procedure that is part of regular care and billed to the patient/insurance
 RB = Research procedure that is related to use of the study device or administration and monitoring of study drug, but billed to the patient/insurance
 SS = Standard of care procedure that is part of regular care, but covered by the study

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MCA Documents

- MCA produces two documents:
 - Flowchart:
 - Designates study related items and procedures to either SOC, RES, RES but billable (Expanded care)
 - Determines which items are billable
 - Budget FC: budget development
 - Consent FC: incorporated into the IC document
 - Summary memo:
 - Study sponsor (federal, pharmaceutical etc)
 - Regulatory status of the investigational item or service (approved, off label, PMA, 510 K etc)
 - Determination of whether a study is a QCT
 - Cost language for the financial section of the ICF based on final flowchart

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Harmonization of Documents

MCA Flowchart
*SOC versus RES
MCA Summary Memo
*Cost Language
*Therapeutic Intent

Consent Form
*Flowchart
*Cost Language
*Benefit Language
*Subject Injury Language

Consistent with CTA & Budget Edits by SRFA as needed

All documents are available to the study team, Sponsored Research and Fund Accounting (SRFA) and Research Billing

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Interaction of the MCA, ICF and IRB review

- Consent Flowchart
 - Informs patients which study procedures are SOC or RES
 - Risks for items and procedures designated as RES
 - Provides details of the financial responsibility of the patient
- Summary memo
 - Therapeutic Intent-translates to potential benefit of the study to patient
 - Cost language-incorporated in the financial section of the ICF
- IRB review:
 - Risks determination (designated as RES in flowchart)
 - Financial burden to patient
 - Study related items/procedures designated as SOC
 - IRBAA ensures cost language in the summary memo is consistent in the ICF financial section
 - Benefit to patient-consistent with therapeutic intent

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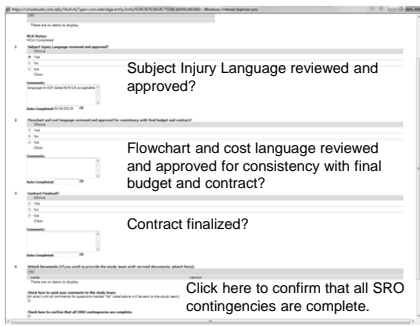
Checks and Balances

- IRB analysts
 - Financial section of the ICF is consistent with the summary memo
 - Risks of RES related procedures are described in the ICF
- SRFA/ISRO
 - Preliminary budget compared to completed MCA flowchart
 - Study team and MCAA informed of discrepancies
 - Cost language checked for accuracy



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Consistency Check by Sponsored Research Office



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Mechanism for Reporting & Management of Research-Related Subject Injury (RRSI)

- Study Team submits Internal AE report in Webridge
- If Study Team assesses AE/SAE as "related" or "probably-related" to the research, they complete RRSI question and provide an explanation
- Research Compliance Staff notifies Research Billing/Patient Financial Services to flag this account for a potential RRSI
- Research Compliance Staff works with study team to gather additional information as needed
- IRB determines whether the event meets definition of a RRSI
- Research Compliance staff determines who covers RRSI based on policy & approved ICF
- Research Compliance staff sends group email to Research Billing/Financial Services, Legal, Risk Management, & Sponsored Research Office, as applicable
- Study Team and sponsor are notified if event is determined to be RRSI

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Reporting RRSIs in the Electronic IRB Adverse Event Report Form

AE035 In your assessment, was the event related to any study drug, device, or procedure?

Assessment of Relationship

- Related
- Probably Related
- Possibly Related
- Unlikely Related
- Not Related
- Clear

AE035a Does the investigator believe that this adverse event meets the definition of "research related subject injury" as defined in the Research Subject Injury Policy?

Yes No Clear

AE035b Please explain why you think this does or does not meet the definition of "research related subject injury".

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TRAINING AND EDUCATION

- Clinical Research Professional Orientation
 - MCA is part of half day course
- MCA updates at IRB Analyst Meetings
- One-on-one training/coaching with new investigators and research staff
- CITI Clinical Trial Billing Compliance Module

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Advantages

- Harmonization of documents
- Negotiation advantage with study sponsors
- Accurately informs research participants of their financial responsibilities
- Informs patients of the risks of study participation
- Limits institutional financial liability
- Enables high-quality clinical research (a CSMC mission) leading to improved patient care

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Challenges

- Finding specific practice guidelines to support assertions of conventional care
- Coordination between budget development, CTA negotiation, and IRB review processes
- Dual role of MCA (budget/billing vs. IRB/consent) can sometimes lead to conflicting approaches
- How to clearly convey to participants information about costs in the informed consent form
- Coordination when relying on external IRB

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Questions?

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