

**Coverage
Analysis- Steps
before submission
of a Clinical Trial
to the IRB**

- *Submit IDE material to FI*
- Project Submission
- Study
- Contract
- Draft Budget
- Informed Consent Document

Coverage Analysis (CA)
(Goal 7 to 10 days)

Draft issued to PI – 5 days to review (if concerns, discuss and possibly modify coverage analysis with supporting documentation.

- PI-modify consent form based on CA
- Work on Budget- use CA to assist

Submit Study to IRB

Contract Review

- IRB Approval
- Contract Executed
- Study Initiation

Internal Review

Consent form checked with Coverage Analysis....if IDE study, check for FI's approval if none, cannot bill Medicare for study.

Types of Coverage Analysis (CA)

- A. Expedited: (No Subject Billing), such as: PK Studies, Nursing, Behavioral, Chart Review (No billing Grid, Form)
- B. Light: (Appears) sponsor pays for all items/services related to study and no Third party billing will occur. (Billing Grid and Modified Summary)
- C. Full: Some items are covered by the sponsor; some items may be billed to Third party payors. (Billing Grid and Detailed Summary)