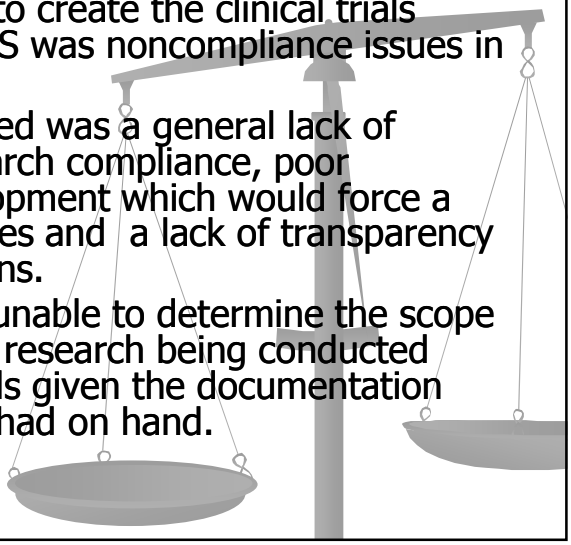
Jackson Health System

Lessons from a newly developed clinical trials office within an established teaching hospital.

Compliance, Compliance, Compliance

- The driving force to create the clinical trials office (CTO) at JHS was noncompliance issues in billing.
- What we discovered was a general lack of education in research compliance, poor compliance development which would force a compliant processes and a lack of transparency between institutions.
- The hospital was unable to determine the scope and impact of the research being conducted within its four walls given the documentation and knowledge it had on hand.



Research & Development

First Lesson:

Although our executive leadership approved the centralized research office upon learning of noncompliance in spirit- In Reality we had no idea all that it would entail!

Second lesson:

Our IRB of record supported the new hospital research process to come into compliance.

Third lesson:

Discover your own institution's specific requirements. For example the JHS procurement process reports up to the county because we are a county hospital. Device procurement and vendors on campus are handled very differently.

Fourth lesson:

Doctors may not dispense medications from their offices while providing services to JHS research participants on JHS premises. Research pharmacy must be utilized for research.

Fifth Lesson:

Transparency is required. The hospital was not represented in research contracts as well as other study related documents leaving the hospital unaware and vulnerable at many points. Three party agreements are best suited to ensure the hospital sees all.

Sixth Lesson:

System interfaces are critical to transparency and accurate billing. These should be thought out in advance with a research component in mind.

Jackson Health System Mission & Vision

Mission

To build the health of the community by providing a single, higher, standard of quality for the Residents of Miami Dade County.

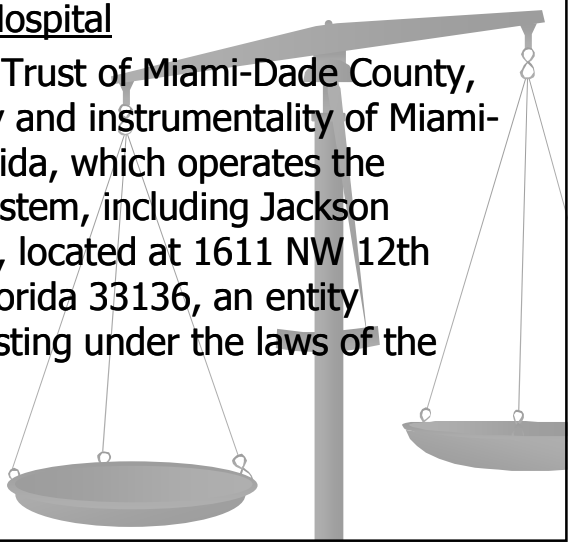
Vision

Our Strategic Vision is to be nationally recognized and internationally recognized as a world class academic health system and to be the provider of choice for quality of care.

Jackson Health System

Legal Name of the Hospital

- The Public Health Trust of Miami-Dade County, Florida, an agency and instrumentality of Miami-Dade County, Florida, which operates the Jackson Health System, including Jackson Memorial Hospital, located at 1611 NW 12th Avenue, Miami, Florida 33136, an entity organized and existing under the laws of the State of Florida.

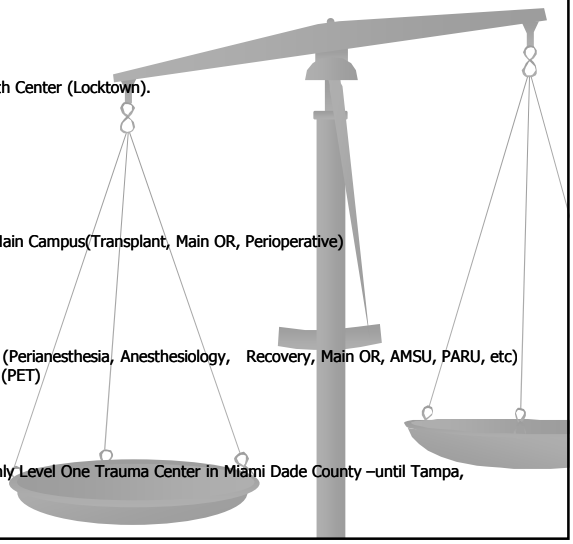


JHS is Different in size & scope

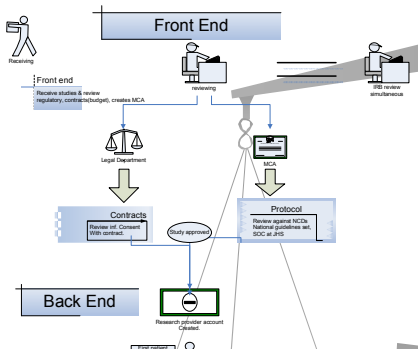
- Fiduciary responsibility to citizens of MDC
- Academic medical center
- 3rd largest health system in the country
- Subject to the Sunshine Law (Public Records Act)
- Employ 12,000 people

Jackson Health System Sites

1. Ambulatory Care Center (ACC)
2. CHI Doris Ison Health Center CHI
3. Martin Luther King Jr (Clinica Campesina)
4. Communicable Disease Control / Infectious Control Community Health of South Dade
5. Corrections Health services
6. Critical Care Hospital Center
7. Dr. Rafael A Penalver clinic
8. Emergency Care Clinic
9. Holtz Children's Hospital Center
10. Jackson Perdue Medical Center
11. Jackson North Community (Mental Health Center (Locktown).
12. **Jackson North Med. Center**
13. Jackson Pediatric Center(PPEC)
14. **Jackson South Comm. Hosp.**
15. JHS Biscayne Imaging Center
16. Jefferson Reaves Sr. , Health Center
17. Juanita Mann Health Center
18. Liberty City Health Center
19. Medical/Surgical Hospital Center JHS Main Campus(Transplant, Main OR, Perioperative)
20. Mental Health Hospital Center
21. Miami Hope Center
22. North Dade Health Center
23. Opa-Locka Women's Health Center
24. Ortho-Rehab-Neuro Hospital
25. Perioperative Services JHS Main Campus (Perianesthesia, Anesthesiology, Recovery, Main OR, AMSU, PARU, etc)
26. Prevention, Education Treatment Center (PET)
27. Radiology Rehab Hospital Center
28. Rosie Lee Wesley Health Center
29. South Dade Homeless Assistance Center
30. Highland Outpatient Clinic Center
31. Jackson's RYDER Trauma Center (The only Level One Trauma Center in Miami Dade County –until Tampa, Florida)

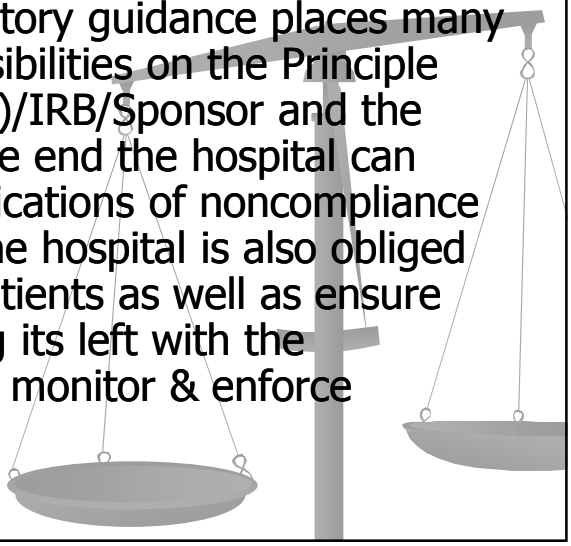


Workflow of a Centralized Clinical Trials Office



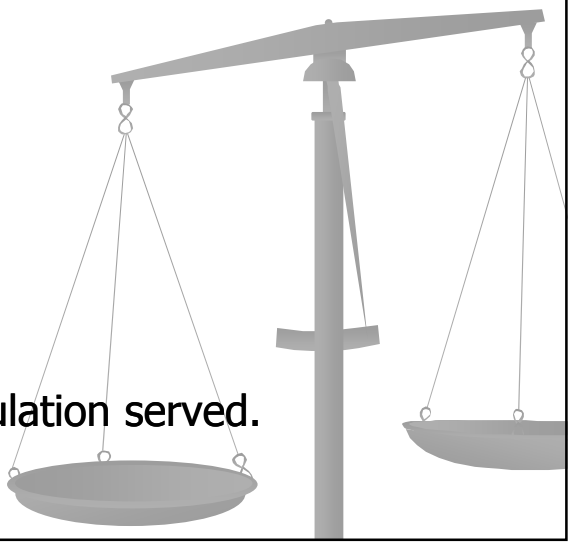
Collective Knowledge

- Although regulatory guidance places many primary responsibilities on the Principle Investigator (PI)/IRB/Sponsor and the University, in the end the hospital can suffer the ramifications of noncompliance issues. Since the hospital is also obliged to protect its patients as well as ensure compliant billing its left with the responsibility to monitor & enforce compliance.



Regulatory

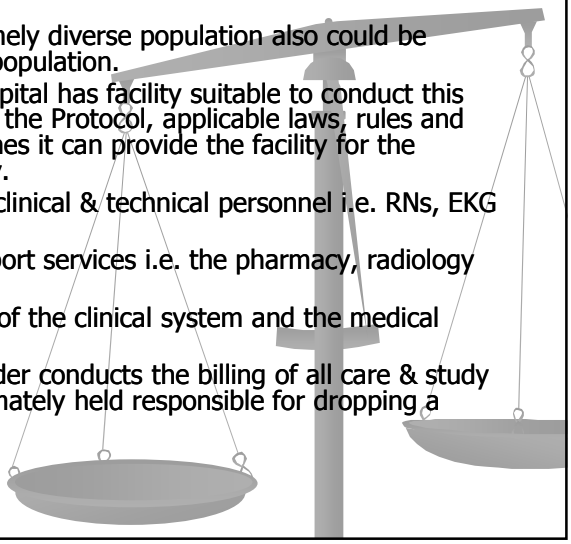
- FDA
- CFR
- OIG
- JCAHO
- CMS Guidelines
- Contract Law
- HIPAA
- Vulnerable population served.



The Assorted Hospital Functions in Research

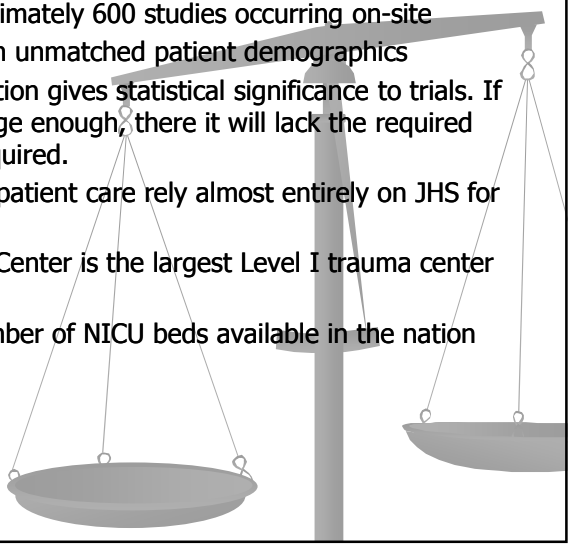
Hospital's Role in a Study:

- Hospital serves an extremely diverse population also could be considered a vulnerable population.
- Contract description: Hospital has facility suitable to conduct this Study in accordance with the Protocol, applicable laws, rules and regulations, and determines it can provide the facility for the performance of the Study.
- The hospital employs all clinical & technical personnel i.e. RNs, EKG techs.
- Hospital provides all support services i.e. the pharmacy, radiology etc.
- Hospital is the custodian of the clinical system and the medical record.
- The hospital as the provider conducts the billing of all care & study for the facility and is ultimately held responsible for dropping a 'clean bill.'



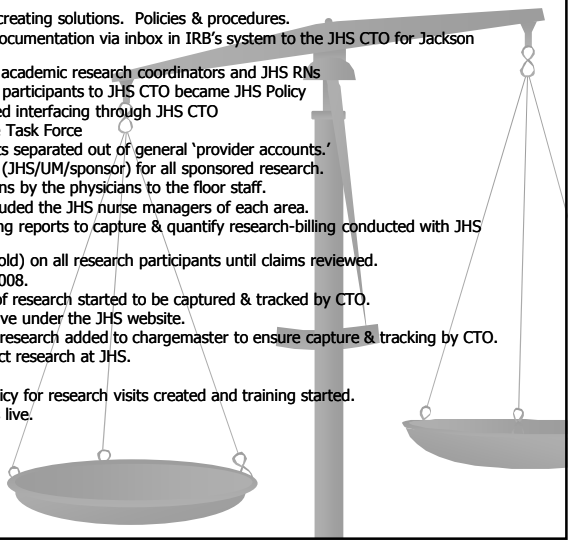
JHS: Partner in Research not just a Study Site
What are your assets?

- Currently JHS has approximately 600 studies occurring on-site
- JHS has a population with unmatched patient demographics
- Magnitude of JHS population gives statistical significance to trials. If the sample size is not large enough, there it will lack the required statistical significance required.
- Studies/trials requiring inpatient care rely almost entirely on JHS for that component.
- Jackson's Ryder Trauma Center is the largest Level I trauma center in the Southeast
- JHS has the greatest number of NICU beds available in the nation

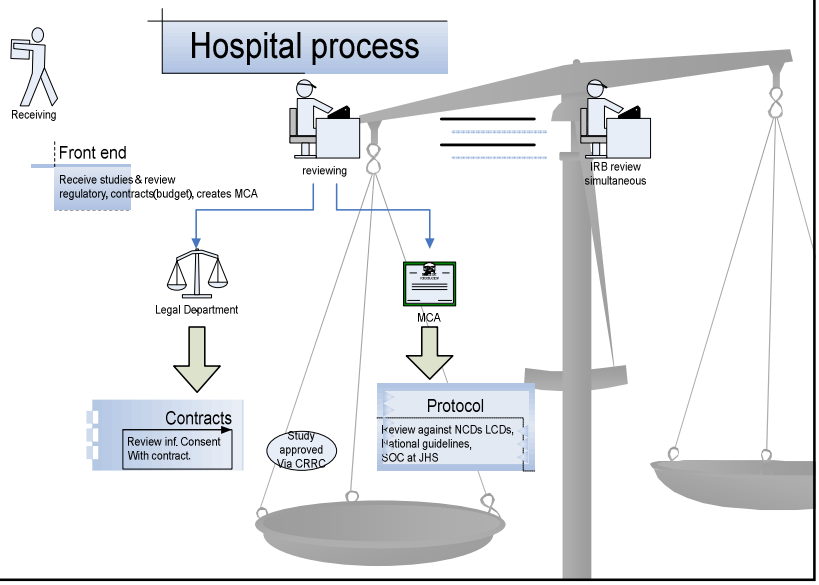


Development of a compliant process over time

- January 2007 CTO Office established.
- Ongoing process of identifying areas and creating solutions. Policies & procedures.
- **July 2007 IRB** created access to study documentation via inbox in IRB's system to the JHS CTO for Jackson involved studies.
- August 2007 Cerner training instituted for academic research coordinators and JHS RNs
- December 2007 identification of research participants to JHS CTO became JHS Policy
- December 2007 Research Pharmacy started interfacing through JHS CTO
- February 2008 Started Research Revenue Task Force
- February 2008 *Research* provider accounts separated out of general 'provider accounts.'
- March 2008 JHS required 3-party contract (JHS/UM/sponsor) for all sponsored research.
- January 2008 JHS CTO required orientations by the physicians to the floor staff.
- March 2008 JHS CRRC determinations included the JHS nurse managers of each area.
- October 2008 developed the research billing reports to capture & quantify research-billing conducted with JHS patients.
- November 2008 started the bill hold (Q-hold) on all research participants until claims reviewed.
- JHS CTO hired staff through out 2007 & 2008.
- August 2009 Medical records component of research started to be captured & tracked by CTO.
- August 2009 Clinical Trials Website went live under the JHS website.
- September 2009 Pathology component of research added to chargemaster to ensure capture & tracking by CTO.
- October 2009 fees are increased to conduct research at JHS.
- Velos Research software of Feb 2008
- March 2010 Research Encounter ticket policy for research visits created and training started.
- April 2010 Research Encounter ticket goes live.

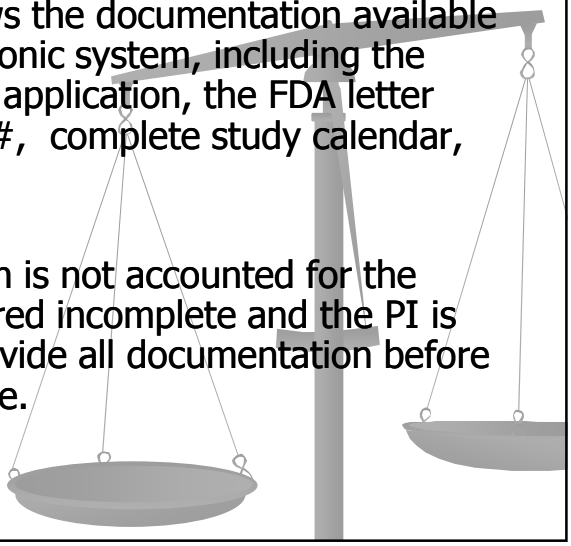


FRONT END



1.JHS CTO Process Documentation Complete

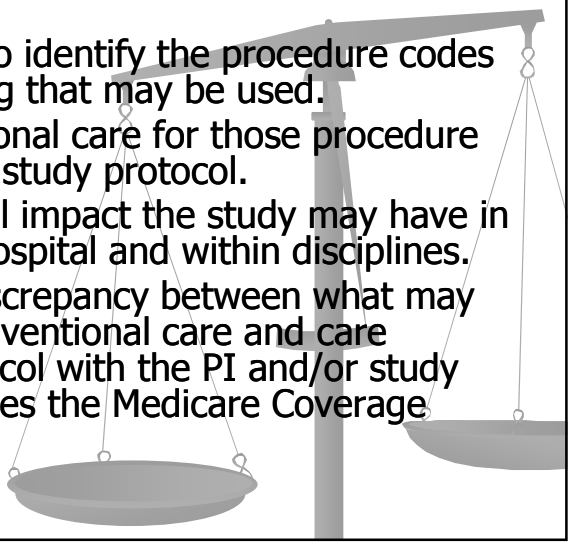
- CTO staff reviews the documentation available in the IRB electronic system, including the signed JHS CTO application, the FDA letter identifying IND #, complete study calendar, etc.
- If documentation is not accounted for the study is considered incomplete and the PI is prompted to provide all documentation before review is possible.



2. JHS CTO Process - study review pre-CRRC

The JHS CTO

- Reviews a study to identify the procedure codes and specific coding that may be used.
- Explores conventional care for those procedure codes against the study protocol.
- Identifies potential impact the study may have in certain areas of hospital and within disciplines.
- Reconciles any discrepancy between what may be considered conventional care and care described in protocol with the PI and/or study coordinator. Creates the Medicare Coverage Analysis (MCA).

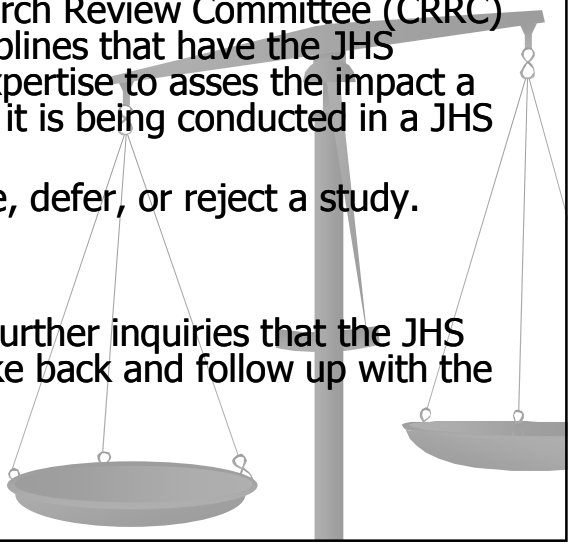


3. JHS CTO Process - Presented to CRRC

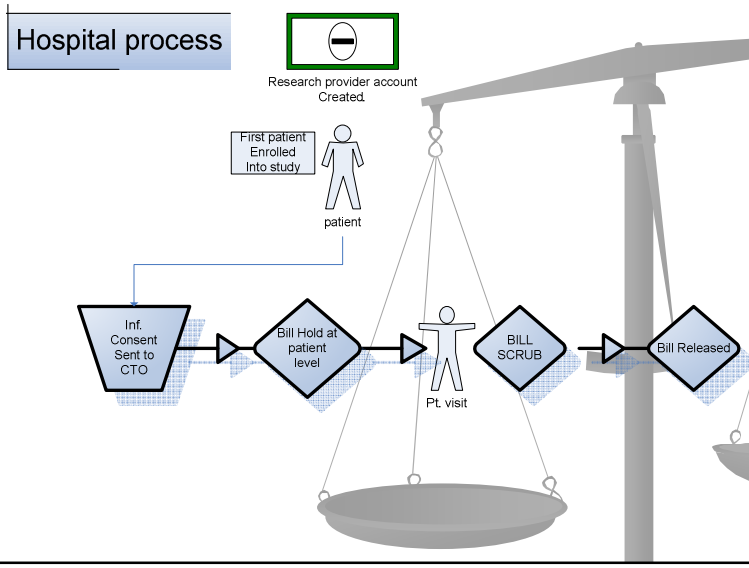
- The Clinical Research Review Committee (CRRC) is a group of disciplines that have the JHS experience and expertise to asses the impact a study will have as it is being conducted in a JHS facility.
- CRRC can approve, defer, or reject a study.

<u>Post CRRC:</u>

- CRRC may make further inquiries that the JHS CTO staff then take back and follow up with the PI.

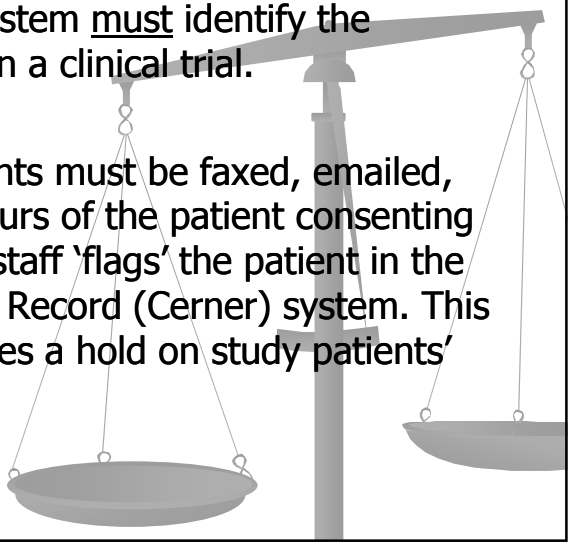


BACK END



Study Approved
Patient enrollment Starts

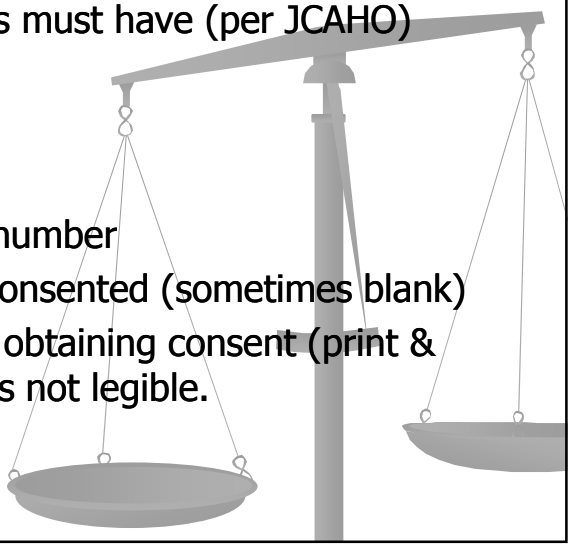
- Jackson Health System must identify the patients enrolled in a clinical trial.
- JHS Policy: Consents must be faxed, emailed, dropped off 24 hours of the patient consenting to the trial. CTO staff 'flags' the patient in the Electronic Medical Record (Cerner) system. This automatically places a hold on study patients' claims.



Required on Patient Consent

The patient consents must have (per JCAHO)

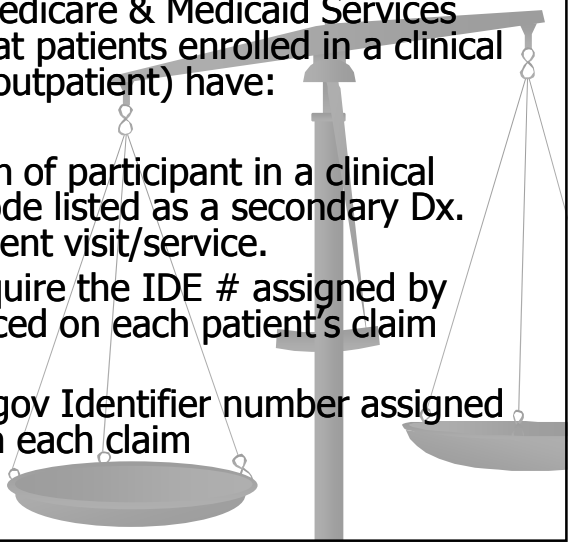
1. PI's name
2. Eprost #
3. Patient name
4. Medical Record number
5. Date patient is consented (sometimes blank)
6. Name of person obtaining consent (print & sign). Sometimes not legible.



Why is the timeliness of patient consents so important?

- The Centers for Medicare & Medicaid Services (CMS) requires that patients enrolled in a clinical trial (inpatient or outpatient) have:

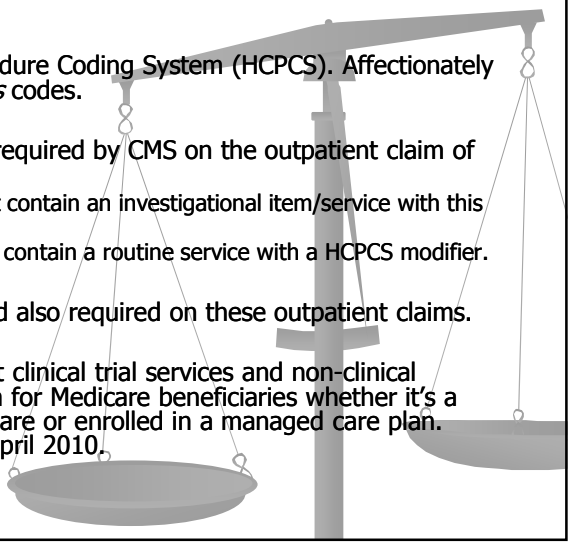
1. V70.7(Examination of participant in a clinical trial) Diagnosis Code listed as a secondary Dx. Code on each patient visit/service.
2. Device studies require the IDE # assigned by the FDA to be placed on each patient's claim submitted.
3. The ClinicalTrials.gov Identifier number assigned is also required on each claim



Outpatient Claims

<u>Outpatient Claims Only:</u>

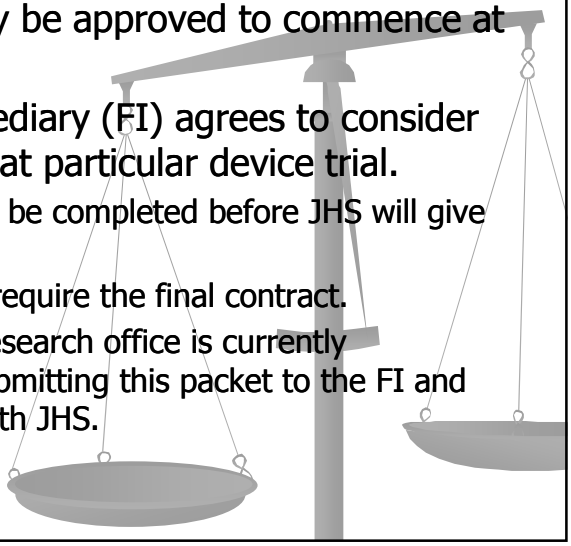
1. Healthcare Common Procedure Coding System (HCPCS). Affectionately know by coders as *hicspics* codes.
2. Modifiers: Q0 and Q1 are required by CMS on the outpatient claim of patients enrolled in a trial.
   - Q0 Identifies all lines that contain an investigational item/service with this HCPCS modifier.
   - Q1 identifies all lines that contain a routine service with a HCPCS modifier.
3. Condition Code 30 is a field also required on these outpatient claims.
4. JHS may not bill outpatient clinical trial services and non-clinical services on the same claim for Medicare beneficiaries whether it's a patient with straight Medicare or enrolled in a managed care plan. Created encounter ticket April 2010.



Device Trials
Six steps

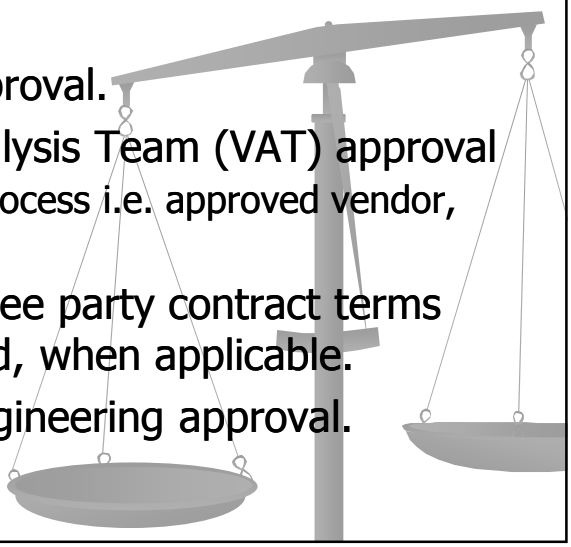
- A Device Trial may be approved to commence at JHS if:

1. The Fiscal Intermediary (FI) agrees to consider claims billed on that particular device trial.
   - This process must be completed before JHS will give final approval.
   - This packet does require the final contract.
   - The university's research office is currently responsible for submitting this packet to the FI and communicating with JHS.



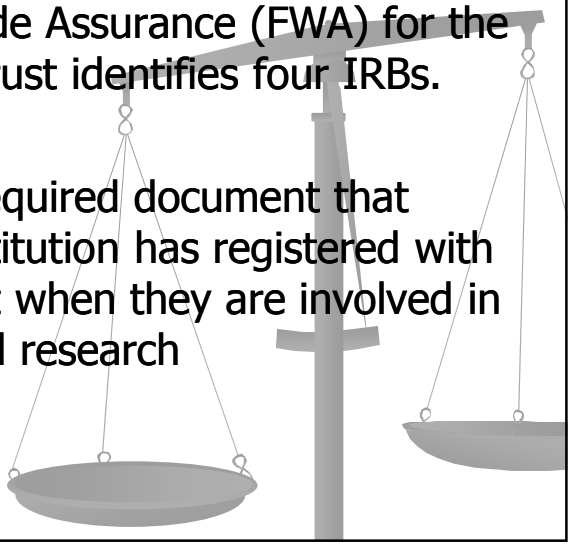
Device Trials
cont'd

2. IRB approval.
3. JHS CRRC Approval.
4. JHS Value Analysis Team (VAT) approval (Procurement process i.e. approved vendor, etc.).
5. Acceptable three party contract terms are established, when applicable.
6. Biomedical engineering approval.



Federal Wide Assurance

- The Federal Wide Assurance (FWA) for the Public Health Trust identifies four IRBs.
- The FWA is a required document that ensures the institution has registered with the government when they are involved in federally funded research

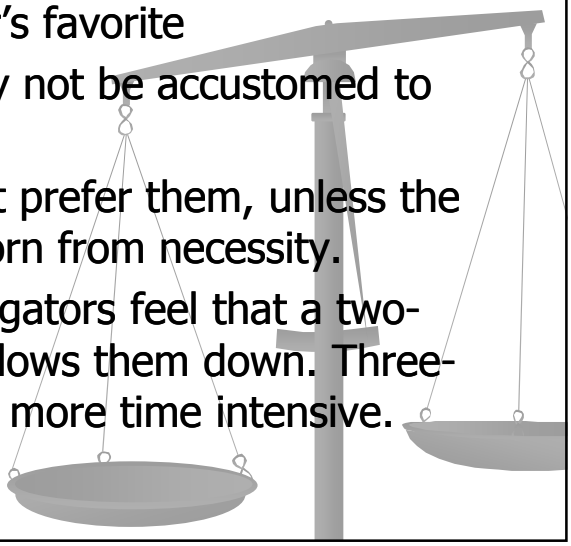


Hospital contracts in research with University and Sponsor

Negotiating three party contracts

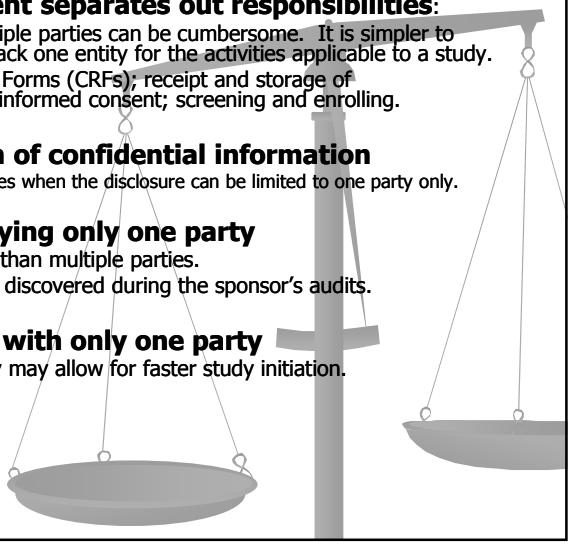
Three party contracts

- Not the sponsor's favorite
- Universities may not be accustomed to them
- Hospitals do not prefer them, unless the preference is born from necessity.
- Principal Investigators feel that a two-party contract slows them down. Three-party is seen as more time intensive.



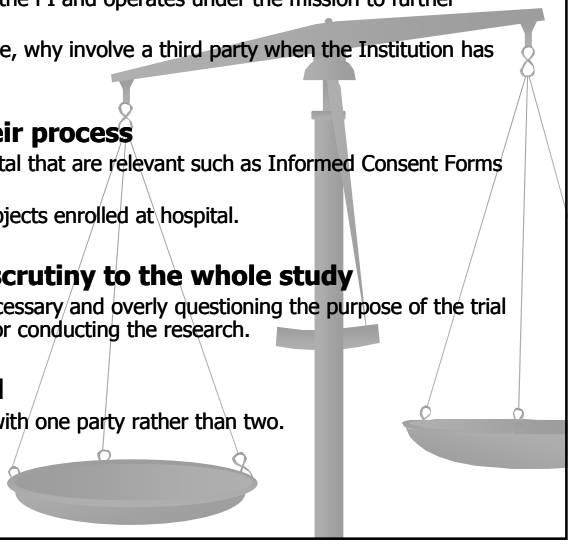
Reasons why the sponsors may disfavor a three party contracts

- **A three party Agreement separates out responsibilities**:
  Tracking responsibilities of multiple parties can be cumbersome. It is simpler to recognize it's own duties and track one entity for the activities applicable to a study.
  e.g. Submission of Case Report Forms (CRFs); receipt and storage of medications/devices; obtaining informed consent; screening and enrolling.
- **Limiting dissemination of confidential information**
  Why disclose a protocol to two parties when the disclosure can be limited to one party only.
- **Reporting to and notifying only one party**
  It is simpler to notify one party than multiple parties.
  e.g. reporting risks of the study discovered during the sponsor's audits.
- **Contract Negotiations with only one party**
  Negotiating with only one entity may allow for faster study initiation.



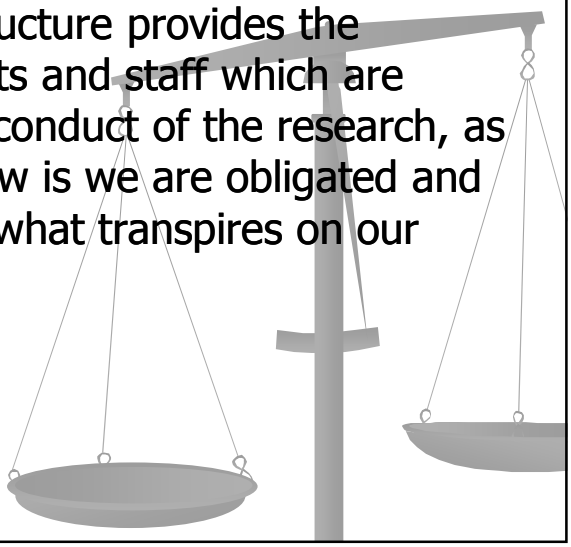
Why would universities resist including a third party in the contract

- **Ownership - It is my business**
  The institution retains/employs the PI and operates under the mission to further research.
  From the university's perspective, why involve a third party when the Institution has the research expertise.
- **Additional steps to their process**
  Forwarding documents to hospital that are relevant such as Informed Consent Forms (ICF).
  Reporting adverse event for subjects enrolled at hospital.
- **Unwanted additional scrutiny to the whole study**
  Perhaps it is perceived as unnecessary and overly questioning the purpose of the trial and sponsor-provided budget for conducting the research.
- **Moving things forward**
  Again, it is easier to negotiate with one party rather than two.



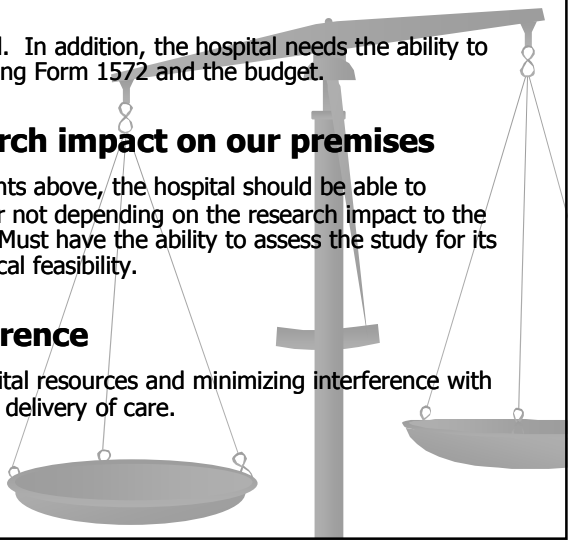
If three party contracts are so disfavored, why insist on them?

- The hospital structure provides the facilities, patients and staff which are involved in the conduct of the research, as a result, our view is we are obligated and responsible for what transpires on our premises.



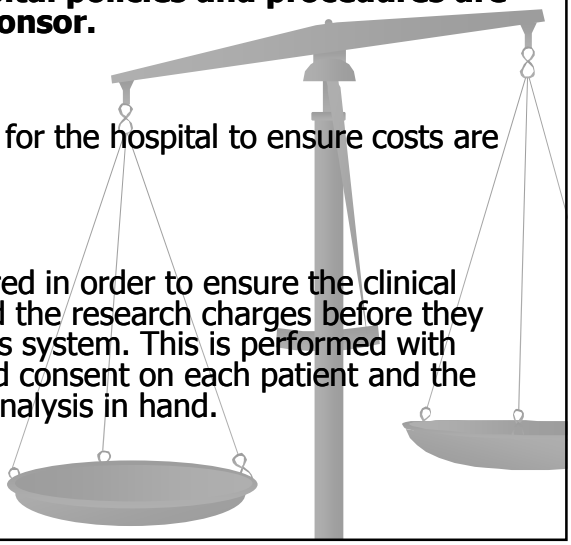
JHS requires three party contracts for the following reasons:

- **Transparency**
  It all starts with the protocol. In addition, the hospital needs the ability to review all documents including Form 1572 and the budget.
- **Control over research impact on our premises**
  After reviewing the documents above, the hospital should be able to determine its involvement or not depending on the research impact to the patient, staff and facilities. Must have the ability to assess the study for its scientific importance and fiscal feasibility.
- **Minimizing Interference**
  Assessing utilization of hospital resources and minimizing interference with business operations and the delivery of care.



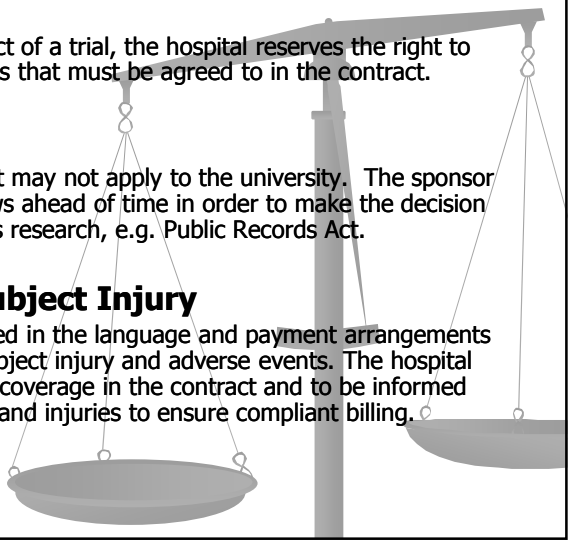
JHS requires three party contracts for the following reasons, cont'd.:

- **Ensuring that hospital policies and procedures are followed by the sponsor.**
- **Cost effectiveness**
  Providing the budget for the hospital to ensure costs are covered.
- **Billing compliance**
  The bill-hold is required in order to ensure the clinical floors have separated the research charges before they drop into the Siemens system. This is performed with the required informed consent on each patient and the Medicare Coverage Analysis in hand.



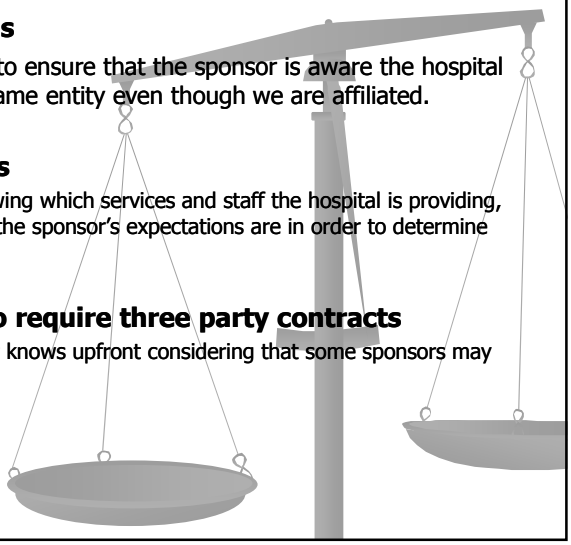
JHS requires three party contracts for the following reasons, cont'd.:

- **Right to terminate**
  Being involved in the conduct of a trial, the hospital reserves the right to terminate studies for reasons that must be agreed to in the contract.
- **Applicable laws**
  Some laws apply to JHS that may not apply to the university. The sponsor should be aware of such laws ahead of time in order to make the decision whether to involve JHS in its research, e.g. Public Records Act.
- **Adverse Events/Subject Injury**
  The hospital must be involved in the language and payment arrangements in the contract regarding subject injury and adverse events. The hospital has the right to require this coverage in the contract and to be informed promptly of adverse events and injuries to ensure compliant billing.



JHS requires three party contracts for the following reasons, cont'd.:

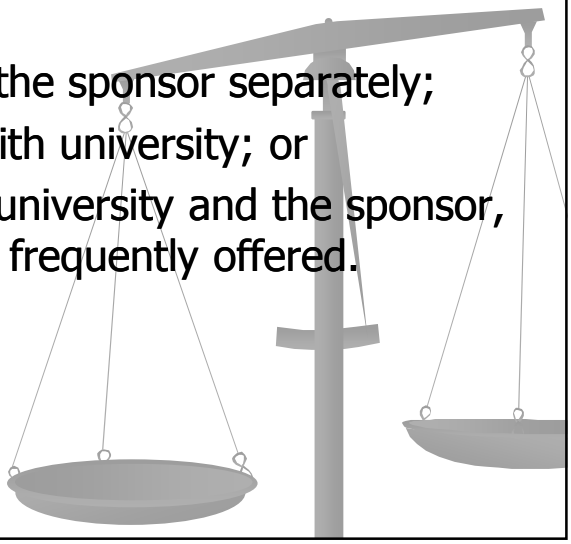
- **Clear definition of roles**
  Avoiding confusion, we like to ensure that the sponsor is aware the hospital and university are not the same entity even though we are affiliated.
- **Sponsor's expectations**
  In addition to the Sponsor knowing which services and staff the hospital is providing, the hospital should know what the sponsor's expectations are in order to determine whether it can meet them.
- **Our current policy is to require three party contracts**
  It is very important the sponsor knows upfront considering that some sponsors may not prefer this arrangement.



Could we do it differently?

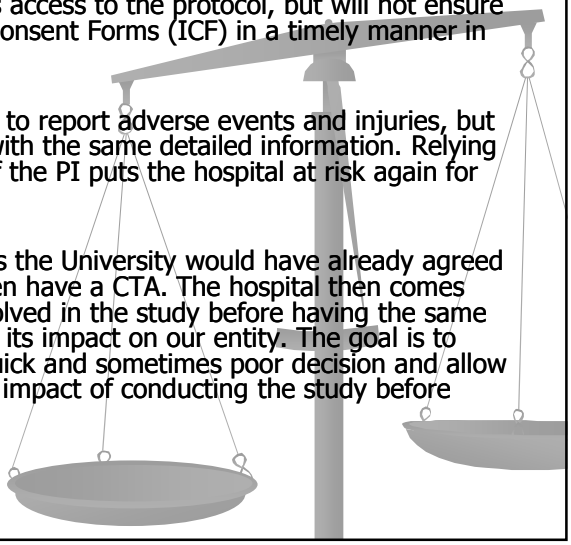
Options:

1. Contract with the sponsor separately;
2. Subcontract with university; or
3. Contract with university and the sponsor, the option not frequently offered.



Option #1: Contract with the sponsor

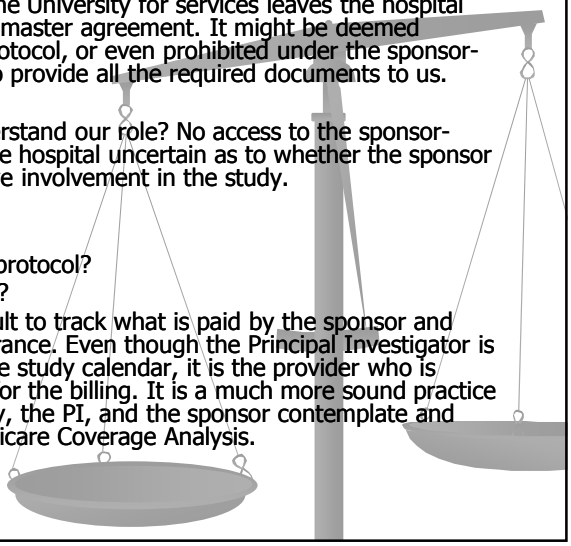
- This option would give us access to the protocol, but will not ensure the receipt of Informed Consent Forms (ICF) in a timely manner in order to bill properly.
- The sponsor may be able to report adverse events and injuries, but not as quickly as the PI with the same detailed information. Relying on the sponsor instead of the PI puts the hospital at risk again for improper billing.
- This option usually means the University would have already agreed to the study and may even have a CTA. The hospital then comes under pressure to be involved in the study before having the same time and ability to assess its impact on our entity. The goal is to avoid the urgency of a quick and sometimes poor decision and allow the hospital to weigh the impact of conducting the study before agreeing to participate.



Option #2
Subcontracting with University

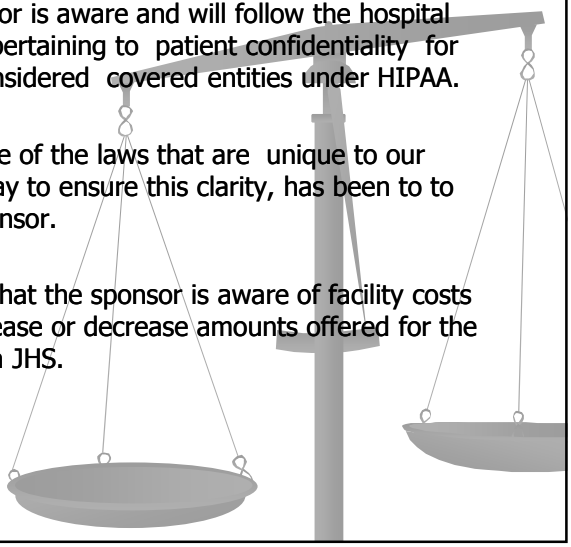
- Subcontracting solely with the University for services leaves the hospital unaware of language in the master agreement. It might be deemed unnecessary to share the protocol, or even prohibited under the sponsor-university contract (CDA), to provide all the required documents to us.
- Does the sponsor truly understand our role? No access to the sponsor-university contract leaves the hospital uncertain as to whether the sponsor truly understands our passive involvement in the study.
- Questions unanswered:
- What is required under the protocol?
- Will our services be covered?

  It is can be extremely difficult to track what is paid by the sponsor and what is covered by the insurance. Even though the Principal Investigator is ultimately responsible for the study calendar, it is the provider who is ultimately held responsible for the billing. It is a much more sound practice if the hospital, the University, the PI, and the sponsor contemplate and ultimately agree on the Medicare Coverage Analysis.



What else could be missed?

- Assurance that the sponsor is aware and will follow the hospital policies especially those pertaining to patient confidentiality for sponsors who are not considered covered entities under HIPAA.
- Making the sponsor aware of the laws that are unique to our organization. The only way to ensure this clarity, has been to to speak directly to the sponsor.
- Hospital costs: Assuring that the sponsor is aware of facility costs for services and any increase or decrease amounts offered for the services performed within JHS.



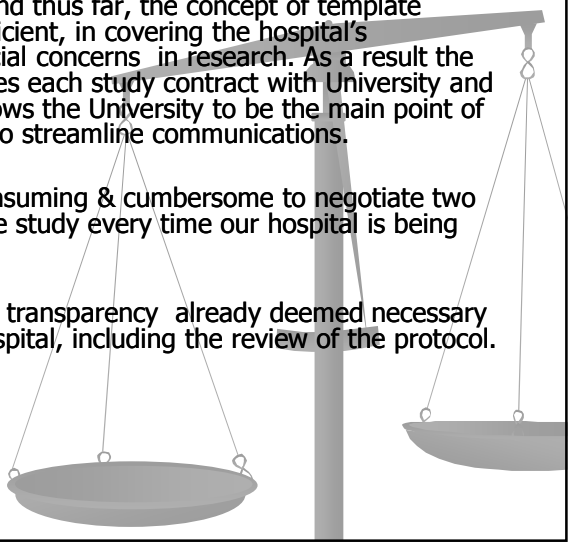
Option #3

Two contracts:

one between hospital/sponsor &

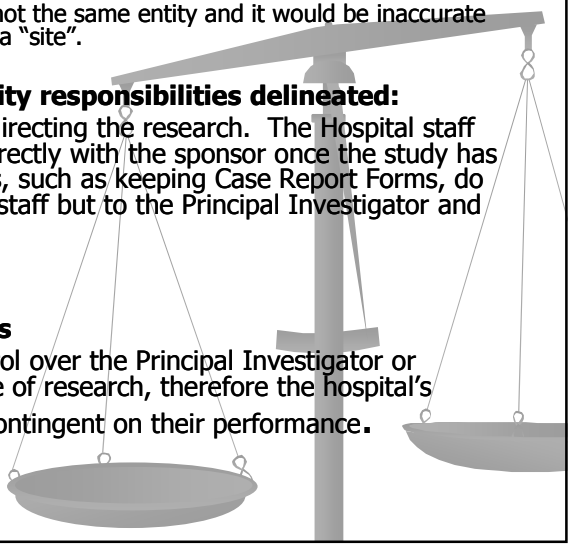
one between hospital/ university

- Every study is different and thus far, the concept of template language has been insufficient, in covering the hospital's compliance/clinical/financial concerns in research. As a result the hospital actively negotiates each study contract with University and sponsor. The hospital allows the University to be the main point of contact on most studies to streamline communications.
- It would be very time consuming & cumbersome to negotiate two separate contracts on one study every time our hospital is being selected for research.
- This process risks the full transparency already deemed necessary for compliance by the hospital, including the review of the protocol.



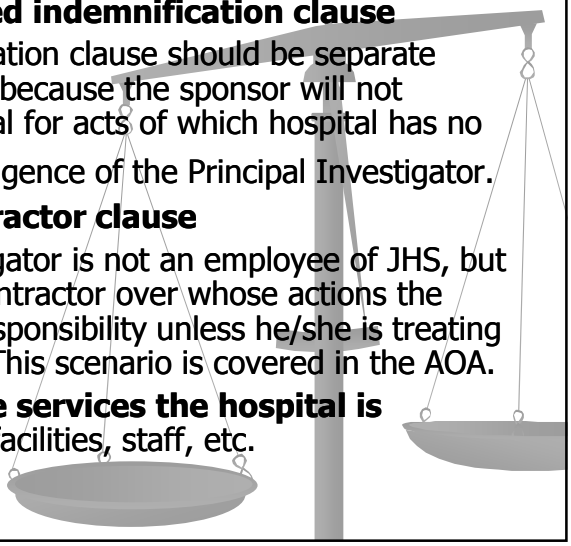
Three party contracts best serve our needs and this is how we protect the hospital

- **Collective names**
  University and hospital are not the same entity and it would be inaccurate to refer to them collectively a "site".
- **Hospital /PI / University responsibilities delineated:**
  The hospital staff is not directing the research. The Hospital staff does not communicate directly with the sponsor once the study has started. Certain activities, such as keeping Case Report Forms, do not apply to the hospital staff but to the Principal Investigator and his/her staff.
- **Payment contingencies**
  The hospital has no control over the Principal Investigator or university for the purpose of research, therefore the hospital's payment should not be contingent on their performance.



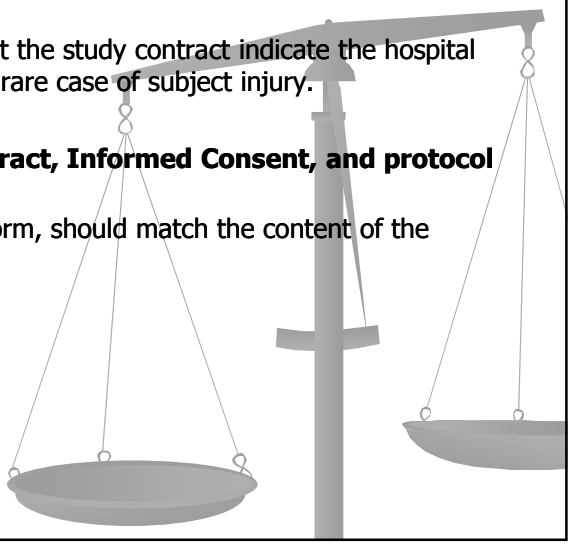
Protecting hospital continues:

- **Avoiding condensed indemnification clause**
  Hospital's indemnification clause should be separate from the university's because the sponsor will not indemnify the hospital for acts of which hospital has no control, such as negligence of the Principal Investigator.
- **Independent contractor clause**
  The Principal Investigator is not an employee of JHS, but is an independent contractor over whose actions the hospital bears no responsibility unless he/she is treating an indigent patient. This scenario is covered in the AOA.
- **Clearly identify the services the hospital is providing**, such as facilities, staff, etc.



Protecting hospital continues:

- **Subject injury**
  It is important to JHS that the study contract indicate the hospital will be reimbursed in the rare case of subject injury.
- **Assuring that the contract, Informed Consent, and protocol are in harmony**
  The Informed Consent Form, should match the content of the contract.



Conclusion

- Even though three party contracts are harder to negotiate, unacceptable to some sponsor and disfavored, we believe that it best serves our needs and allow us to fully protect and serve the best interest of our organization.