Introductions/ Welcome – Susan Rose, Executive Director
Office for the Protection of Research Subjects

- Coordinators are encouraged to provide feedback and questions on the topics presented.

Update on CTO Changes – Tom Buchanan, KSOM Vice Dean for Research

- CTO has moved to Keck under the leadership of Tom Buchanan and Ted Budge
- ONCORE is intended to make Pre-Award process faster, more user-friendly and transparent. Once ONCORE is live no new studies will be entered in TRUE. ONCORE will help generate budget and info for the MCA coverage analysis. This will help billing to be done correctly.
- Orders will still need to be manually entered into Cerner (Keck and CHLA EHRs) until EPIC can automatically transfer orders from ONCORE to Cerner (EPIC has not been implemented yet)
- There are plans to give coordinators an opportunity to meet with an ONCORE Specialist to build power trials orders and a calendar. This would require indicating what procedures are clinical and what is research. Knowing the right CPT codes for a study will help calendaring go faster. After calendar is produced, an IOF can be retrieved from ONCORE
- ONCORE company can do calendaring for a fee. This is under consideration.
- CTO has a backlog of 230 trials and 158 amendments. CTO will be contacting PIs to find out if their backlogged studies should be activated or closed
- New CTO Director is being sought. Candidates are being interviewed.
- An additional MCA person is being considered

- April Armstrong, Associate Dean for Clinical Research, is setting up the research support office for non-cancer, investigator initiated studies: biostatistics, audits, regulatory. A Research Navigator has been hired for that office.
- CTSI is recruiting a Director for a Research Coordinator pool. CHLA started a coordinator pool 18 months ago. CISO has a successful pool, so does the surgery dept.

Clarifying Research v. Clinical Care in Consent Forms – Darcy Spicer, HSIRB Chair

- Informed consent discloses whether examinations, procedures, and drug or device administration done at specific time points are required for research any other visits, procedures will be done as standard care. The term “clinically indicated” is frequently used to describe these.
During the development of a Medicare coverage analysis (MCA) and budget, each interaction is determined to be either clinically indicated or done for research. The Research Order Form then indicates who to bill for each interaction – 3rd party payer or sponsor.

At the time of IRB review it is frequently unclear what visits, tests and procedures are done as clinically indicated and which are done solely because the individual is on a research study for research purposes.

- To capture more accurate information, the IRB is considering adding the following question to the ISTAR application:
  
  Identify and list the visits and procedures that are done for research purposes. These are typically billed to the study sponsor. These exclude visits and procedures that are done for routine medical care that are conventionally billed to third party payers. This should be consistent with the information provided in the informed consent and protocol documents. (If a Medicare Coverage Analysis has been done, you may upload it below instead of answering this question.)

- By defining clinically indicated procedures verses those done for research:
  
  - The informed consent will more accurately reflect reality in the procedures, risks and costs.
  - Participant complaints will be reduced.
  - Liability for the institution will be reduced.
  - IRB approval process will speed up.

- Feedback on the new ISTAR question is welcome.

- Your suggestions are also welcome regarding how to improve the IRB review process