Key points for the Principal Investigator and their coordinators concerning contracts, budgets and hospital services:

- THR research policy requires THRE directly receive the revenue from the sponsor for research studies if the total of all research related hospital services is 50% or greater than the total research study budget.

- The non-THPG Principal Investigator may directly receive the revenue from the sponsor for research studies if the total of all research related hospital services is less than 50% of the total research study budget.

- For all contracts in which hospital services will be rendered during the research study, the contract must have that THR entity as a party to the contract and the contract must have a signatory line for that THR entity **AND** a signatory line for acknowledgment by THRE.

- For all contracts in which hospital services will be rendered during the research study, but the Principal Investigator receives the revenue, Research Administration must do a budget analysis (a Hospital Service Agreement) and provide to Principal Investigator and/or the Sponsor, the cost of the hospital services.

- If the Principal Investigator directly receives the revenue from the sponsor, the Principal Investigator shall be billed monthly for any hospital research services rendered by THRE on behalf of the hospital and payment is required within 30 days of receipt of invoice.

- A Hospital Service agreement, as applicable, must be executed with THRE and the Principal Investigator prior to enrollment of a research subject.

- The executed contract **with** the attached budget and Hospital Service Agreement (if applicable) is required prior to the release of study approval by the IRB.

- A fully executed [Study Coverage Analysis](#) is required to be uploaded to all studies as part of the IRB submission.

- The contract and its associated budget must be sent to Research Administration to be reviewed and approved by THRE/THR.

- In order to bill standard of care costs for category A or B device trials, you must obtain Medicare approval. THRE will submit the paperwork to Medicare on behalf of the hospital, however the physician must submit their own paperwork.
• For category A or B device trials, an approval from Medicare must be uploaded be received by THRE prior to release of the IRB approved consent.

• Within 24 hours of a research subject being admitted into the THR hospital or the hospital service being rendered (if service is provided as an outpatient service), the coordinator must provide the signed Special Admissions form to the Research Administration office.