



COLLEGE  
OF MEDICINE

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# CLINICAL STUDY INVOICE ITEMS

INVOICEABLE COSTS MAY INCLUDE ANY OR ALL OF THE FOLLOWING ITEMS:

## PATIENT RELATED COSTS

- Screen Failures
- Re-consents
- Patient Tests
- Patient Reimbursements (subject fees, travel reimbursement, overnight stays, food)
- Unscheduled visits
- Serious Adverse Event
- Advertising
- IND Safety letter Reporting

## ANNUAL FEES

- Annual Informatics fee
- Annual Regulatory annual maintenance fee
- Annual pharmacy fee
- Yearly regulatory continuing review fee

## PROTOCOL RELATED COSTS

- Contract amendments
- Protocol amendments
- IRB Renewal fee

## SPONSOR RELATED COSTS

- Monitor change fee
- Conference calls
- Study related expenses
- Additional administrative time required by the sponsor
- Equipment Use and Supplies
- Monitoring Visits
- Audits from sponsor, CRO or FDA

## STUDY COMPLETION

- Long term record storage fee
- Study close out fee