Office of Research Affairs (ORA)
The Pennsylvania State University – College of Medicine – The Milton S. Hershey Medical Center

Contract Review Procedure For Clinical Trials

**Research Approvals Required before Statement of Award Issued:**
IRB Approval Memo, Internal Budget, IRB Approved Patient Consent Form, Fully Executed Contract

**Internal Documents Required before Contract Negotiations Begin:**
Confidentiality Agreement, Contract, Protocol (x2), Proposal Clearance Form, Draft Budget, Draft Consent

Department Initiates AURA for Advance Fund Number
(Add University Restricted Account)
AURA Routes to ORA and Controllers Office for Approval
Research Accounting (University Park) Assigns Fund # for Account

Clinical Trial May Begin
Site Initiation / Enrollment

ORA Receives Draft Contract and *Internal Documents From:
Clinical Trials Office (CTO) or Department

ORA Reviews Draft Contract
(In accordance with ORA Contract Review Checklist and University Policy)

Contract Negotiations Initiated by ORA
Budget Negotiations Initiated by CTO or Department

Contact / Budget Negotiations Complete
Contract Execution Process Begins
Signatures Obtained upon receipt of Internal Budget/BARA Worksheet or University Files Only Budget (UFO)

Award Process Initiated Upon Receipt of Executed Contract and All **Research Approvals
Statement of Award Issued by ORA
Statement of Award Packet Distributed to:
Principal Investigator, Study Coordinator, Department Budget Office, Controller's Office, HMC Finance

Conflict Managed?

Conflict Resolution Process

Unmanaged Conflict of Interest?

STOP

Updated: February 27, 2009