Award Processing Case Study

Heather Winters
Assistant Director, OCGA
• IRB approval
  ▪ Updated CITI’s delayed approval
• Coverage Analysis approval
  ▪ Delayed IRB approval
• IDC exception required
  ▪ Pre-agreed amount with Consortium
  ▪ Required vital interest approval
  ▪ Required UCOP approval (federally funded)
• 40+ unique inquires with sponsor and/or UCOP
• Pending IP Policy exception
  ▪ Campus management plan
  ▪ TTO management plan
• Required review and input from:
  ▪ Insurance/Risk Management
  ▪ Clinical Trials Office
  ▪ OIP/ISR Office
  ▪ PI/Department
  ▪ UCOP
  ▪ Sponsor
  ▪ Other UC Campus
• Began review

• Informed by sponsor, no changes could be made

• Multiple requests regarding IDC rate

• Communication with sponsor regarding status
• Received requested information for IDC

• Communication with sponsor regarding status

• IDC exception sent to Vice Chancellor for review and ultimate UCOP approval

• Provided status update to PI
• Learned another UC campus received same agreement via listserv

• Sponsor provided list of other sites, attempted reaching counterparts

• Coordinated negotiation strategy with other campus

• Provided status update to PI
• Conference call with UC and OIP
• Sought guidance from UCOP
• Conference call with UC’s and UCOP
• Multiple email correspondence with sponsor, UCOP and UCLA
• Provided status update to PI
• Under review by UCOP

• Multiple email correspondence with sponsor, UCOP and UCLA

• Communication with sponsor regarding status

• Provided status update to PI
• Conference call with PI

• Conference call with PI, sponsor PI, sponsor contracts rep

• Multiple email correspondence with sponsor, UCOP and UCLA
• Reached agreement with sponsor on SOME terms
• Under new review by UCOP in accordance with policy exception
• Multiple email correspondence with sponsor, UCOP UCLA
• Provided status update to PI
• Multiple email correspondence with sponsor, UCOP UCLA

• Provided status update to PI
• Conference call with UCLA and UCOP regarding policy exception requirements

• Side agreement drafted and sent to sponsor for review

• Provided status update to PI
• Side letter pending review with sponsor

• Campus and Tech Transfer management plans under consideration

• Pending informed consent from PI
QUESTIONS???