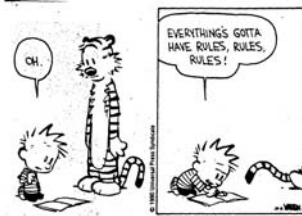
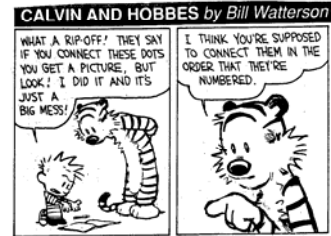


## Clinical Trial Agreements

Review Procedures  
Contractual Issues  
Document Requirements

Deborah K. Davis  
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## Confidential Disclosure Agreement

- Usually precedes discussion of trial and receiving copy of protocol
- Agreement to keep the company's information confidential for a specified period of time
- *Do not sign*; forward to Roxane Poskin and she will coordinate review by Don Keach

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## If you decide to participate...

- Request draft agreement
- Forward to:  
OSPA Clinical Trial Administrator:  
Michael Brown  
305G Wethington  
Phone: 257-5714 FAX: 323-1060

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## Helpful Information

- ✓ Copy of contract and protocol
- ✓ Contact at sponsoring company or CRO and Phone, fax, e-mail
- ✓ Contact in department
- ✓ PI name
- ✓ Phase of Study
- ✓ Approved drug, unapproved use

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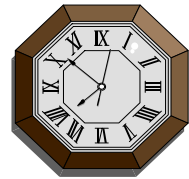
## OSPA Review Process

- Review Agreement
- Seek input as needed
  - ❖ Investigator or Coordinator
  - ❖ Legal counsel
  - ❖ IRB
  - ❖ UKCRO
- Send written comments to company

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## Follow Up

- Follow up regularly with company
- Timely reaction to each company response
- Keep PI and/or Coordinator posted of negotiation status via e-mail
- *New:* access to Michael's status spreadsheet



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### CTAs in PROGRESS

Investigator	Department	Sponsor	Date Received	CTA Finalized	Date Ready to Est Acct	Contacts	Comments
Arnold	Cancer Center	Acenta	7/7/2007			Dr. K. Berry S + D. Buchanan	Reviewed agreement and sent revisions to contract person. Awaiting response. MBB 9/13/07. Followed up in an effort to move this matter along. Continuing to await response. MBB 9/10/07. Provided comments as to those issues that remain and sent to contract person via e-mail. Awaiting response again at this point. MBB 9/10/07.

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## What are our goals in contract negotiation?

- Protect the Investigator
- Protect the interests of the University
- Aim for clear, unambiguous terms
- Be as timely as possible

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## Common Contractual Issues

- Adverse reaction coverage
- Controlling law
- Correct second party, payee, addresses
- Company insurance coverage
- Payment terms
- IRB fee
- Termination

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## Contractual Issues

- Adequate budget
- Reasonable reporting requirements
- Company audits during business hours and with advance notice
- Reasonable time period to report adverse reactions

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## Contractual Issues

- Lengthy confidentiality requirements
- Specific statements to include in informed consent
- Restrictions on participating in other trials
- Out of scope work
- Involvement of Affiliates

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## Added per AAHRPP

- Increased awareness of consistency between CTA and Informed Consent
- CTA provision requiring sponsor to notify us about findings that could effect subject safety, willingness to participate
- Additional requirements for COI disclosure

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## The “Sticklers”

- Payment of Subject Injury Cost
- Indemnification
- Confidentiality
- Publication Rights

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## Subject Injury

- For company developed protocols, the sponsor should pay for medical expenses related to injury or illness caused by study drug or device
- Usual limits
  - Subject and PI must follow protocol
  - Not attributable to negligence or misconduct
  - Not due to underlying disease/illness

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## Subject Injury

- CTA subject injury provision must agree with informed consent
- When CTA language is acceptable, Michael will email to PI and coordinator
- ORI and OSPA will coordinate any non-standard language

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## Subject Injury

- April 2004 letter from DHHS, Centers for Medicare & Medicaid Services
- Cannot agree to bill Medicare first and allow company to pay what's left
- Issue not specifically addressed in proposed update to clinical trial/research policy

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## Indemnification

If the study drug or device is not approved by the Food and Drug Administration and the protocol has been provided by the industry sponsor, the sponsor must defend, indemnify and hold harmless the university and Investigators against claims brought in connection with study participation.

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## Indemnification

- In other words, the company must pay for the lawyers and any settlement
- However, this protection will not apply if there is gross negligence or willful misconduct or if we fail to adhere to the protocol
- ❖ *Company will not normally provide indemnity for PI-initiated protocols – these must be reviewed through non-indemnified trials process*

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## Confidentiality

- Identified in writing
- Standard exceptions
- Reasonable time period
- Should not include results
- Tied to publishing rights

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## Publication Rights

- PI must be free to publish results
- Company may review and comment
- Limited delay for patent filing
- Limited delay for multi-site publication

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## Publication

- Sept 2004 ICMJE issued policy that member journals would publish results only if trials were registered
- Sponsor must register their trials
- PI must register PI-initiated



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## Why is this important?

- UK is an Academic Institution
- UK is a PUBLIC Academic Institution
  - ❖ Freedom to publish is a significant factor in support of clinical trials as appropriate to a university's tax exempt mission

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## Required Documents

### UNIVERSITY OF KENTUCKY Internal Approval Form

Revised 3/06

MIS # \_\_\_\_\_

ONLY NOTED (●) ITEMS MUST BE COMPLETED FOR NONCOMPETING OR CONTINUATION PROPOSALS UNLESS THERE ARE CHANGES FROM THE ORIGINAL APPROVED PROPOSAL.

#### FIXED-PRICE AGREEMENT BUDGET FORM

Principal Investigator \_\_\_\_\_ Account No 30 \_\_\_\_\_  
Sponsoring Agency \_\_\_\_\_ Start/End Dates \_\_\_\_\_

### UNIVERSITY OF KENTUCKY Staff/Faculty Disclosure Of Financial Interest Form

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## Required Documents

- To legally accept agreement
  - ✓ Acceptable agreement, including budget
  - ✓ Completed and signed Internal Approval Form
  - ✓ Fixed-Price Budget Sheet, Column A completed
  - ✓ Financial Disclosure Forms
  - ✓ Proof of Insurance in some cases

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## Required Documents

- To establish an account, all of the above PLUS
  - ✓ Copy of Protocol
  - ✓ IRB Approval or signed exception letter for pre-enrollment only

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## Information Available

<http://www.research.uky.edu/ospa/industry.html>  
<http://www.mc.uky.edu/ukero/>



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