

## **Item 1.**

# **Hierarchy of Options/Business Procedure Manual (BPM) 45/Who Signs?**

- **Introduction to Contract Review and Processing**
- **BPM 45's Approval Requirements at a Glance – Who Signs?**
- **Business Procedures Memorandum 45-09-06, Processing of Sponsored Research Agreements**

# Introduction to Contract Review and Processing

## Health Components

The Office of General Counsel and the Office of Health Affairs have worked together to streamline our procedures for review and processing of component contracts for Sponsored Research, including Clinical Trials, Material Transfers and Lab Studies. Our goal has been to provide more efficient and effective service to our U.T. System Health Component Institutions. If you have suggestions, comments or questions, please do not hesitate to let us know.

### Hierarchy of Options

- Always think, "***What is the simplest, easiest way to document this study, transfer, or research project?***"
- ***Start with the easiest approach*** available and move on to more complicated ones only if necessary.
- The approach you choose to document your study, transfer or project will affect how much time and effort is required of you and how the document gets processed through your administration and through U.T. System.

#### 1. Universal Agreement

***This is the easiest approach.*** Always check our online listing to see if U.T. System has negotiated an agreement with the company you will be working with. If we have a Universal with the company, all you have to negotiate are the "deal" terms (the time frame, the payments) and possibly some minor nonsubstantive modifications. Universals are processed on Forms C or D, depending on whether they contain nonsubstantive changes.

Keep in mind that if there is a Universal with the company, but it is for the wrong kind of study, you may still avoid negotiating most if not all of the usual sticking points by urging that the parties rely on the already-negotiated provisions in the Universal for publication, confidentiality, and, to the extent they apply, intellectual property and indemnification sections.

#### 2. System Standard Agreement

If we do not have a Universal with the company you want to work with, offer the company our Standard Agreement for the type of study or transfer you

plan to do. The company will make changes to the Standard in all likelihood, and you will have to evaluate their changes. You should respond to their changes in the same way you approach this whole process: ***try the easiest and quickest approach first***. For example, try to substitute an appropriate standard clause in place of their suggestions first (number 3, below), then, if that is unacceptable, evaluate their clauses using our checklist and edit them as necessary to conform them to the checklist requirements (number 4, below).

Standard Agreements are processed on Forms A or B, depending on whether they contain nonsubstantive modifications. If they are substantively changed through the process of negotiation, they will be processed on Form F.

### 3. **Nonstandard Agreement Edited to Include Standard Clauses**

Sometimes a company wants to start with their document, so you don't have the option to offer a U.T. System Standard. You may still be able get over the rough spots by offering our standard clauses in those areas where we typically have differences of opinion about contract terms: Publication, Confidentiality, Intellectual Property and Indemnification.

Nonstandard Agreements edited to include standard clauses are processed on Form F.

### 4. **Nonstandard Agreement Edited in Accordance with Checklist Requirements**

If the company will not accept the substitution of our standard clauses, you will have to carefully read and revise the company's contract to make their clauses reflect the essence of our requirements. Our Sponsored Research Checklist will help you do this.

If the agreement you negotiate, review and revise ***conforms to the Checklist requirements*** in the end, ***and it is a Clinical Trial***, it will be processed on Form Q. If a Clinical Trial cannot be conformed to the Checklist requirements, it will have to be processed on Form G. All other agreements that are negotiated, reviewed, revised and conformed to the Checklist requirements will be processed on Form F.

## **Who Signs? Who Reviews? Who Approves?**

This depends entirely on what happened in the process of your negotiations. We have prepared a Contract Processing Chart to help our contract specialists determine who must sign, review and approve their agreements. The contents of the chart are derived from applicable Regents' Rules and the Docketing Manual. It covers other types of intellectual property agreements besides the 4 we address here (Sponsored Research, Clinical Trials, Material Transfers and Lab Studies), so if you know of others who might find it helpful, do not hesitate to give them the URL (<http://www.utsystem.edu/ogc/intellectualproperty/kprocess.htm>).

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*Last updated: August 28, 2001*

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## BPM 45's Approval Requirements at a Glance

<b>BPM 45</b>	<b>Prior REVIEW by OGC</b>	<b>BOARD or EXECUTIVE VICE CHANCELLOR (EVC) Approval REQUIRED</b>
<b>Business Procedures Memorandum for Processing Research Agreements</b>		
<b>Grant, Clinical Trial, SRA, MTA, Option &amp; License Agreement, CDA</b> <ul style="list-style-type: none"> <li>• Forms A-E</li> </ul>	Not required	Board approval not required; appropriate EVC approval required if over \$1M
<ul style="list-style-type: none"> <li>• Form F</li> </ul>	Yes; prior to signature	Board approval not required; appropriate EVC approval required if over \$1M
<ul style="list-style-type: none"> <li>• Form G</li> </ul>	Not required.	Board approval not required; appropriate EVC approval required if over \$1M
<ul style="list-style-type: none"> <li>• Form F-S</li> </ul>	Yes; prior to signature	Board approval not required; appropriate EVC approval required if over \$1M
<ul style="list-style-type: none"> <li>• License or Option</li> </ul>		
<b>Clinical Trial (Forms A-E, &amp; Q), Lab Studies, MTA, License Agreement</b>	Not required so long as agreement conforms to applicable OGC Checklist requirements	Board approval not required; appropriate EVC approval required if over \$1M
<b>Software (acquiring) (These are not Board IP Agreements)</b>		

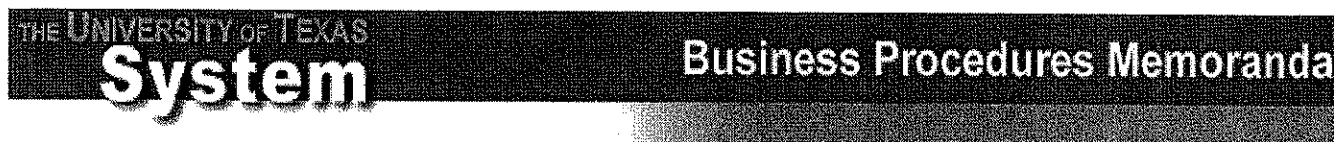
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*Comments to Georgia Harper  
gharper@utsystem.edu  
Last updated: September 14, 2006*

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## Business Procedures Memorandum 45-09-06 Processing of Sponsored Research Agreements

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### I. Most Sponsored Research Agreements Do Not Require U.T. System Review Prior to Execution

- A. The following types of sponsored research agreements do not need to be sent to the Executive Vice Chancellor (EVC) for Health Affairs or Academic Affairs or to the Office of General Counsel (OGC) prior to execution:
1. Standard sponsored research agreements designated by OGC;
  2. Standard sponsored research agreements with specified modifications that are not substantive, as determined by the chief administrative officer or an approved designee;
  3. Company universal agreements designated by OGC;
  4. Company universal agreements with specified modifications that are not substantive, as determined by the chief administrative officer or an approved designee;
  5. Renewal or specified extension of previously approved sponsored research agreements continuing the same or related research with specified modifications that are not substantive, as determined by the chief administrative officer or an approved designee;
  6. Clinical trial agreements, material transfer agreements and laboratory studies that conform to the requirements set forth by OGC in relevant online checklist procedures; and
  7. Sponsored research agreements, clinical trial agreements, material transfer agreements and laboratory studies that do not conform to the U.T. System Intellectual Property Policy or Guidelines, provided that, *prior to execution of any such agreement*, (a) each such agreement has been approved by the President of the institution (or an approved designee), and (b) the President (or an approved designee) has executed a Form G for that agreement approving the agreement with full knowledge of the scope of the deviations from the U. T. System Intellectual Property Policy or Guidelines.
- B. The agreements listed above will require administrative approval by the EVC or an approved designee when they are for a dollar amount above \$1,000,000. The request for administrative approval must be accompanied by a letter from the President or an approved designee in a form specific for the type of agreement submitted. (Attachments A-E, G and Q.)

### II. Agreements Requiring Office of General Counsel Review and Approval Prior to Execution

- A. *Prior to execution*, an electronic copy of all other proposed sponsored research agreements must be forwarded to the OGC for review and approval pursuant to the Regents' *Rules and Regulations*.
- B. Each agreement shall be accompanied by a form letter (Attachment F or FS) from the President or an approved designee for agreements that conform to U.T. System Intellectual Property Policy.
- C. The agreements listed above will require administrative approval by the EVC or and approved designee when they are for a dollar amount above \$1,000,000. The request for administrative approval must be accompanied by a letter from the President or an approved designee in a form specific for the type of agreement submitted. (Attachments F and FS.)

- D. The institution may send the original signed sponsored research agreement to the sponsor after OGC approval.

NOTE: Institutions are encouraged to contact OGC directly for legal advice and assistance at any stage of negotiation or contract preparation. Institutions should contact OGC upon identification of all proposed agreements that should be developed as company universal agreements.

### III. Criteria for Approval of Certain Agreements

The following guidelines should be considered in order for sponsored research agreements containing alterations to the U.T. System Intellectual Property Policy or Guidelines to be approved by OGC in accordance with Regents' Rules Series 90105 where the benefits from the level of funding for the proposed research and/or other consideration from the sponsor outweigh any potential disadvantage that may result from the policy deviation (these are usually referred to as "Form G Agreements"):

- A. In the event that funding is conditioned on the grant to the sponsor of a royalty-free, non-exclusive license or other substantial intellectual property right, it is important that fair value be received for such rights because the State of Texas cannot subsidize private research. Consequently, consideration from the sponsor should include the following:
1. Funding and/or other consideration (whether received in the form of cash, equipment, services or supplies) should have an estimated value of at least \$50,000; and
  2. Overhead should be included at the rate normally charged by the institution.
- B. Any grant of rights, whether in data, inventions or intellectual property, should be limited to results of research (a) conducted by the identified investigators; (b) directly funded by the sponsor; (c) arising directly from the performance of the agreement; and (d) arising during the term of the agreement.
- C. The proposed agreement must indemnify the institution and The University of Texas System and their Regents, officers, agents, representatives and employees (including the principal and other investigators) against any claim, loss or judgment arising from the sponsor's exercise of rights with respect to or use of the research results.
- D. The likelihood of patentable inventions and significant potential commercial benefits arising from the research should be carefully considered.
- E. The proposed agreement must conform to the Constitution and applicable laws of the State of Texas and applicable federal laws and regulations.
- F. The proposed research should comport with legitimate academic and university research interests, should not incur unrelated business income tax liability, and should not be conducted solely for the proprietary interests of the sponsor.

#### Attachments

Forms A-G

Forms A-G for electronic transmission

Form F-Software

Form L

Form L for electronic transmission

[Form Q](#)

[Form Q for electronic transmission](#)

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Provided by the Office of General Counsel

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