

Introduction to Contract Review and Processing

Health Components

Throughout the years, the Office of General Counsel and the Office of Health Affairs have worked together to streamline our procedures for review and processing of institutional 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 UT System Health 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 chose 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 UT System.

1. Universal or Master Agreement

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

Keep in mind that if there is a Universal or Master Agreement 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 or Master Agreement for publication, confidentiality, and to the extent they apply, intellectual property and indemnification sections.

2. UT System Standard Agreement

If we do not have a Universal or Master Agreement 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 non-substantive 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 UT System Standard Agreement. You may still be able to 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 a 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 chart entitled "UTS125 At-a-Glance" to help our contract specialists determine who must sign, review and approve their agreements. The contents of the chart are derived from UT System Policy UTS125 Processing of Intellectual Property Agreements.