

**Item 2.**

**Contract Concerns**



# CONTRACTING CONCERNS

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## 1. EASY PROCESSING THROUGH OGC

a. If review by OGC will be necessary, get us involved early - all legal work can be completed well before protocols are even approved; use phone, fax and email without hesitation.

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## 2. USE OF TRANSMITTAL FORMS

a. Use of Forms B and D requires that you be sensitive to when changes to our standard form agreement or a company universal agreement, respectively, are non-substantive.

- Call/fax/email any changes related to the four IP sections for quick feedback on the question of whether a change is substantive.
- If you have to use Form F, it should not entail any extra delay if you contact us early and directly by phone/fax/email.

b. Turnaround time for direct inquiries, faxes and email is usually within a few days, if not the same day. If you need an immediate answer, just say so and it can most often be arranged.

c. The full set of the most current versions of all transmittal forms (A through G, F-S and Q) is available. Instructions on how to get files from the ftp site or view them on your monitor are available also. BPM 45 and a handy chart describing which documents require what kind of review and administrative approvals are available as well.

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## 3. GENERAL DRAFTING TIPS

a. Always start with the appropriate standard or company universal agreement; ***never offer one company's agreement to another company as a first draft.***

- Tell this to your investigators.
- If you will have to work from the company's agreement form, use our standard clauses and checklists to evaluate the company's proposal.

b. Carefully consider who the parties are, who should sign for each, and be sure that the obligations undertaken in the agreement are consistent with the ability of the parties to fulfill

them.

- PI's are not parties to the agreement, so they should not be referred to as though they were. If a Sponsor is particularly troubled by this, offer language like the following:
- "Institution represents that the Principal Investigator and all other investigators that may perform services hereunder are its employees and shall abide by the terms and conditions of this Agreement as if each were a party hereto."
- Third party agreements pose several problems with respect to who signs them and who is obligated by them. The parties to an agreement cannot bind a third party to do anything.

c. Be consistent

- Defined terms
- Outline levels
- Incorporation of clauses from other agreements - always conform "borrowed" terms to the agreement's definitions

d. Take out any paragraphs that are not relevant to your transaction.

e. Avoid implied provisions; make them explicit instead.

- Example: If Sponsor only agrees to pay patent costs with respect to jointly owned inventions, it is implied that Sponsor will not pay such costs with respect to University solely owned inventions. Make it clear that we expect both.
- Example: "If Institution has not received Sponsor's comments within sixty (60) days, it is agreed that approval for publication is granted." This implies that Sponsor could withhold approval for publication. Make it clear that we must have final editorial control over publications and Sponsor has no right to withhold consent or approval.

f. Avoid repetition; do not say the same thing or address the same issues in two different places.

g. Use the parties' names or defined terms as references rather than pronouns (him, his, it, its, them, their) unless the party to whom a pronoun refers is clear from the context.

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## 4. RECITALS

a. Very valuable, especially with an unusual deal.

b. They tell a story, set the stage and fill in background.

c. Imagine that you are someone unrelated to and with no knowledge of the deal and that you are charged with making sense of the transaction two years later. Write the recitals (and, indeed, the whole agreement) so that that person could read them one time and understand the reason for the contract and what it is going to do.

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## 5. ADR

a. Usually acceptable. If the Sponsor has included an arbitration clause, it would be helpful to insert language like, "appropriate method of alternate dispute resolution, including, without limitation, arbitration..." to expand the possibilities to include escalation within the internal hierarchies of the parties (elevating the dispute to less interested persons to resolve), mediation, etc. Alternatively, you may counter-offer with one of our standard clauses.

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## 6. DEBARMENT STATEMENT

**This Statement regarding debarment fulfills the regulatory requirements and is acceptable without further review by OGC.**

INSTITUTION represents that it has never been and, to the best of its knowledge after reasonable inquiry, its Principal Investigator or any other individual who will be rendering services under this Agreement has never been 1) debarred or 2) convicted of a crime for which a person can be debarred, under section 306(a) or 306(b) of the Generic Drug Enforcement Act of 1992 ("Section 306(a) or (b)"). INSTITUTION represents that it has never been and, to the best of its knowledge after reasonable inquiry, its Principal Investigator or any other individual who will be rendering services under this Agreement has never been 1) threatened to be debarred or 2) indicted for a crime or otherwise engaged in conduct for which a person can be debarred, under Section 306(a) or (b). INSTITUTION agrees that it will promptly notify SPONSOR in the event of any such debarment, conviction, threat, or indictment. The terms of the preceding sentence shall survive the termination or expiration of this Agreement for a period of three (3) years.

or

INSTITUTION certifies and Principal Investigator certifies to INSTITUTION that it has never been and, to the best of its knowledge after reasonable inquiry, its Principal Investigator or any other individual who will be rendering services under this Agreement has never been 1) debarred or 2) convicted of a crime for which a person can be debarred, under section 306(a) or 306(b) of the Generic Drug Enforcement Act of 1992 ("Section 306(a) or (b)"). INSTITUTION certifies and Principal Investigator certifies to INSTITUTION that it has never been and, to the best of its knowledge after reasonable inquiry, its Principal Investigator or any other individual who will be rendering services under this Agreement has never been 1) threatened to be debarred or 2) indicted for a crime or otherwise engaged in conduct for which a person can be debarred, under Section 306(a) or (b). INSTITUTION agrees that it will promptly notify SPONSOR in the event of any such debarment, conviction, threat, or indictment. The terms of the preceding sentence shall survive the termination or expiration of this Agreement for a period of three (3) years.

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## 7. SPECIFIC INTELLECTUAL PROPERTY PROVISIONS

### a. Publication

- Preserve inviolate the absolute right of the Institution (PI) to publish the results of the study.
- There are UBIT implications if we are just performing laboratory work for commercial entities.
- Keep delays for review to a reasonable limit.
- If the study is multi-site, try to preserve the right of the Institution (PI) to publish separately if, after a reasonable time, multi-site publications have not been forthcoming.
- Make sure that the right to publish is properly cross-referenced in confidentiality provisions and in any provisions establishing ownership of data.
- Remember that the owner of the copyright in publications pursuant to UT System Policy will be the PI, so Institution cannot give away licenses to or other rights in the PI's publications.
- Problem-Solver Checklist

### b. Confidentiality

- Short form is appropriate where we do not anticipate much exchange of confidential information.
- Always include limitations to information marked "confidential."
- Include appropriate exceptions, especially where the clause is otherwise onerous.
- Problem-Solver Checklist

### c. Intellectual Property

- Most allocations are on the basis of inventorship; differences are usually a function of whether clause addresses all the possibilities.
- Intellectual Property Outline
- Problem-Solver Checklist
- Sample clauses

### d. Indemnification

- Strive for the broadest indemnity appropriate under the circumstances.
- When the protocol is ours, Sponsor has little control over what we will do, and should only be asked to indemnify us with respect to Sponsor's use of the results of the study.
- Product liability claims are interesting; we would not be likely target, and if we were, we would not waive immunity; and yet, given the state of plaintiff's practice, an indemnity would be appropriate to defray defense costs.
- Indemnification Outline
- Problem-Solver Checklist
- Sample clauses

## 8. SOFTWARE/DATABASE LICENSES

This interactive form provides suggestions to help you edit proprietor offered software and database license clauses that may be inadequate for your needs or unacceptable under System policy.

- [Problem-Solver Checklist](#)
  - [Sample clauses](#)
  - [Copyright in the Library: Acquisition Under Contract](#)
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## 9. MISCELLANEOUS CLAUSES

This is a collection of clauses that are not strictly related to intellectual property concerns in all cases, but that address issues that seem to come up frequently in agreements involving intellectual property.

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