ITEMS TO CONSIDER FOR CERTAIN CONTRACT CLAUSES

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Section of Agreement	Items to Consider
Throughout document	• We should never "warranty" or "guarantee" • We can "certify" or "represent"
Introductory Section/Legal Name/Investigator as Party	• We should be referred to as "The University of Texas _____", a member institution of The University of Texas System ("System") The investigator should not be a party to the agreement; instead we name him/her and make other references.
References to Protocol	• References or revisions to protocol or modifications should be "written"; e.g., written protocol and any written modifications

Publication	• PI must always have the right to
	  ○ Publish the results of the study
	  ○ Have final say on content of publications

Indemnification	• Strive for broadest indemnity appropriate for study
	• When protocol is ours, Sponsor has little control over what we will do, and should only be asked to indemnify with respect to Sponsor's use of our results.
	• If by Sponsor: always need for clinical studies when we are using their protocol. Use UT standard clause if at all possible. Must include them indemnifying us for their use of our results.
	• If by Institution: only use when they ask for it. Can only indemnify for negligence (again use UT standard clause if at all possible). We have to limit our indemnification by using the phrase: "To the extent allowed by the laws and Constitution of the State of Texas."
	• Control of claims/limitation
	  ○ Can allow sponsor to control legal proceedings for processing and settling claims, lawsuits, but must use language "subject to the statutory duties of the Attorney General of the State of Texas."
	  ○ Can allow Sponsor to choose legal representation that will be employed in litigation, but must use language "subject to the statutory duties of the Attorney General of the State of Texas."

Confidentiality	• We can agree to hold Sponsor information confidential • Make sure that all such information is appropriately labeled "confidential" • Make sure you define the term "Confidential Information" • Put the following in the appropriate place in the clause, "Subject to Institution's right to publish as set for in {Article x}" • Be careful that our data and results aren't in the definition; if they are, then we have to carve out for their use in publications • Term: Confidential information can only be maintained for a limited period of time, 3-5 years, 7 at the most AFTER THE TERMINATION OF THE AGREEMENT (don't allow the clock to start ticking when each piece of confidential information is received). Always try to get the least number of years. If you agree to 7 years, include in

	your file an explanation as to why Sponsor had to have 7 years. The term for confidentiality must be defined in the Agreement. • There are six standard exemptions to confidentiality which should be cited in the Agreement: 1. Information that is not disclosed in writing or reduced to writing and so marked with an appropriate confidentiality legend within thirty (30) days of disclosure (this one is tough to get from a sponsor, but try at least) 2. Information that is already in our possession at the time of disclosure by Sponsor 3. Information that is or later becomes part of the public domain through no fault of ours 4. Information that is received from a third party having no obligations of confidentiality from the Sponsor 5. Information that is independently developed by us 6. Information that is required by law or regulation to be disclosed.
Intellectual Property	• We have good latitude here in clinical studies; we may give sponsor ownership of all inventions "that arise in the conduct of the research as contemplated by Sponsor protocol" or use other similar language • Try to maintain Institution's rights to "other inventions"
Applicable Law	• Needs to be Texas or silent (we are an agency of the State of Texas and cannot subject ourselves to other governing laws)
Alternative Dispute Resolution	• Various options of alternative dispute resolution allowed • Binding arbitration is never allowed; it would take an act of the Texas Legislature to authorize
Insurance	• UT System handles our insurance needs; we are generally self-insured • We have medical malpractice insurance and worker's comp insurance; we should substitute our med mal clause for sponsor's clause • General liability claims would be handled in accordance with the Texas Tort Claims Act
Debarment	• Do not guarantee that no one working on the study is debarred from working on clinical studies, etc. Instead, "represent that it has never been and, to the best of its knowledge after reasonable inquiry, that its employees have never been."
Regulatory References	• Cannot accept Good Clinical Practices (capitalized term) because this brings us legal obligations; use "standards of good clinical practices" instead • ICH Harmonization of GCP also troublesome for same legal reasons; try to use "principles of the ICH Harmonization …"
Signature Lines	PI should sign under the following words: "I have read this Agreement and understand my obligations hereunder"