

**The University of Tennessee**  
**Contract Terms**

1. **The Parties.** The parties should be The University of Tennessee (UT) and the sponsor (or CRO). The PI should NOT be a party since he/she is not doing the work as an individual, but as a UT employee.
2. **Confidentiality.** Generally, the definition of Confidential Information should be what the other party provides to UT, so marked and/or identified at the time of disclosure. Generally, UT does NOT like to include study results in the definition of Confidential Information-unless there is specific language in the publication and other sections that gives UT the right to publish study results.

The term "confidential information" (or "proprietary information") as used in the agreement, in the case of documentary information, shall include only that documentary information which is clearly marked as proprietary at the time when it is given to the receiving party. "Proprietary information" which is originally orally disclosed shall include only that information which is identified as being proprietary by written communication sent within a reasonably prompt period of time after it is disclosed.

***Sample Language:***

*The term "Proprietary information" as used herein shall not include any information which the recipient clearly shows by appropriate documentation:*

- (1) Was at the time of receipt both legally and independently known to the receiving party, its agents, or employees;*
  - (2) Without breach of this Agreement by the receiving party has been published or is otherwise within the public knowledge or is generally known to the public at the time of disclosure;*
  - (3) Becomes known or available to the receiving party without restriction from a source other than the disclosing party, unless the receiving party knew or reasonably should have known such source did not have a right to make the disclosure;*
  - (4) Becomes a part of the public domain after disclosure without breach of this Agreement by the receiving party;*
  - (5) Subsequent to disclosure is independently developed by agent(s) or employee(s) of the receiving party without knowledge of the disclosure;*
  - (6) Has been in the possession of the receiving party longer than three (3) years;*
  - (7) Is required by law, including the Tennessee Public Records Act, to be disclosed; or*
  - (8) Is required to be disclosed if necessary for defense of the receiving party in any suit or claim brought as a result of the study.*
3. **Indemnification of UT.** UT requires that the sponsor indemnify UT, its employees, agents, etc. for all claims that arise from the study except those caused by UT's negligence or improper action. UT will agree to cooperate in the defense of any such claim or suit and allow the sponsor to handle the claim, to the extent allowed under Tennessee law. Any settlement involving UT must be approved by the Attorney General of the State of Tennessee. If the contract is with a CRO, UT needs a separate letter of indemnification signed by the sponsor, attached to the contract; and UT needs the CRO to agree to be responsible for its negligence.

4. **Liability** (Indemnification by UT prohibited). UT is an agency of the State of Tennessee and cannot indemnify. UT can agree to be responsible for its actions and those of its employees to the extent allowed by law. Hold harmless and indemnification clauses violate the Constitution of the State of Tennessee (an illegal lending of the State's credit) and are prohibited under UT policy. Waivers or limitations on consequential damages, etc. are the same thing.

***Sample language:***

***Insurance:***

*The University of Tennessee is self-insured under the Tennessee Claims Commission Act, Tenn. Code Ann §§9-8-301 et seq., which covers certain tort liability for actual damages of up to \$300,000 per claimant and \$1,000,000 per occurrence.*

***Liability:***

*Any liability of the University to sponsor and third parties for any claims, damages, losses, or costs arising out of or related to acts performed by the University under this agreement shall be governed by the Tennessee Claims Commission Act, Tenn. Code Ann. §§ 9-8-301 et seq.*

5. **Use of names.** UT can agree to not use the name of the other party for publicity purposes - but not "in any publication" since that would impede UT's right to publish and identify the sponsor as such in the publication. Also, UT must be able to identify the sponsor as such in reports of sponsored activity. UT contracts are NOT confidential. The terms of the contract are NOT confidential.
6. **Third party sponsors/CROs/third-party beneficiaries.** Under Tennessee law, an entity that is not a party to a contract has no standing and cannot enforce a contract; therefore, third-party beneficiary clauses in contracts are prohibited under UT policy. Actions against UT (and other state agencies) are brought before the Tennessee Claims Commission, pursuant to TCA . §§ 9-8-301 et seq. A third party cannot terminate a contract to which it is not a party. A sponsor may terminate a study (by withholding drugs, etc.) and may direct a CRO to terminate a contract, but the sponsor cannot terminate a contract if it is not a party to the contract.
7. **Termination.** UT likes for termination to be reciprocal; either party may terminate with notice. At the least, UT should be able to terminate if the PI is not available and an acceptable replacement cannot be found.
8. **Refunds.** UT will agree to refund moneys paid but not yet earned. In clinical study agreements, payment is usually based on enrollment and procedures done. We do not do an "accounting" for how we spend the money. We can agree to refund amounts not earned, less reasonable start-up costs and non-cancelable obligations.
9. **Publication.** As an academic institution, UT must retain the right for its faculty to publish the results of research conducted at UT. In some cases, reasonable delays may be acceptable, but not more than 12 months after completion of the study at UT. UT will allow the sponsor to review and comment on publications, but does not give the sponsor "approval" rights.
10. **FDA inspections.** UT will agree to notify the sponsor of any anticipated FDA or similar inspection and to allow them to be present, if reasonable, and in accordance with applicable law. UT will NOT agree to let sponsors edit UT's responses to the audit, or to delay UT's response.
11. **Foreign laws.** Generally, UT likes to delete any reference to foreign laws (including foreign equivalents to the FDA). UT studies are not likely to be subject to such laws, and UT employees, in general, are not familiar with such laws.
12. **HIPAA.** UT will agree to be subject to HIPAA (since it may be a covered entity). If UT is providing PHI to the sponsor or CRO, the contract should require that each agree to use PHI only as provided in

the applicable (approved) consent form, authorization, or waiver.

**Sample Language**

***HIPAA.** The parties understand that as part of this Agreement Sponsor will be in receipt of “protected health information” (“PHI” as that term is defined under the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations set forth in 45 CFR §§ 160 and 1634 (“HIPAA Privacy Rule”). As such, PHI created or received by the Study Site shall be disclosed to Sponsor for research purposes only, pursuant to an authorization, waiver of authorization or other applicable provision of the HIPAA Privacy Rule. Sponsor agrees to be bound by limitations on its use and disclosure of PHI (if any) set forth in the informed consent/authorization documents approved by Sponsor. Sponsor agrees to protect the privacy and confidentiality of PHI to the extent required by applicable laws and regulations.*

13. **Export Control** . UT requires that sponsors and/or CROs agree to the export control language since data provided by UT may be submitted for foreign patent applications. This language merely states that UT does not certify that a license will be required but that if one is required, UT will not be responsible.

**Sample Language:**

***EXPORT Control.** Sponsor acknowledges that the export of goods and/or technical data from the United States may require some form of export control license from the U.S. Government. Sponsor agrees that it will not disclose, export or re-export any materials or technical data received under this Agreement to any countries for which the U.S. Government requires an export license unless Sponsor has obtained prior written authorization first from the U.S. Office of Export Control or other authority responsible for such matters. Sponsor agrees that it is responsible for any fees or expenses associated with obtaining an Export License, if required. Institution neither represents that a license shall not be required nor that, if required, it shall be issued.*

14. **Signatures** . The contract should be signed by the parties. If the sponsor wants the **PI** to sign, he/she may sign with our **PI** statement:

**Sample Language:**

*Investigator, while not a party to this agreement, hereby acknowledges that he/she has read the agreement and understands his/her obligations as an employee/faculty member of The University of Tennessee to abide by the terms herein.*