

SAMPLE INDEMNIFICATION PARAGRAPHS

KEY:

Green: The parties

Red: The claims

Blue: The heart of the indemnification – standard coverage

Orange: Standard exclusions

Purple: Certain conditions

[This is the basic one-way Sponsor indemnity, including liability for claims arising from our performance of our obligations and Sponsor’s use of the study results.]

1. INDEMNIFICATION

1.1 Sponsor agrees to indemnify and hold The University of Texas System (“System”), the University, their Regents, officers, agents and employees harmless from any liability, loss or damage they may suffer as a result of **claims, demands, costs or judgments** against them arising out of the activities to be carried out pursuant to the obligations of this Agreement, including, but not limited to, the use by Sponsor of the results obtained from the activities performed by University under this Agreement; **provided, however**, that any such liability, loss or damage resulting from the following Subsections “a” or “b” is excluded from this Agreement to indemnify and hold harmless:

- a. the negligent failure of University to substantially comply with an applicable FDA or other governmental requirements; or
- b. the negligence or willful malfeasance of any Regent, officer, agent or employee of University or System.

[This paragraph is used when Sponsor indemnifies us with respect to our performance of the Protocol and Sponsor’s use of the results of the Study.]

2.2 Sponsor shall indemnify and hold System, Institution, their Regents, officers, agents and employees harmless from any liability or loss resulting from **judgments or claims** against them arising out of the activities to be carried out pursuant to the obligations of this Agreement, including but not limited to the use by Sponsor of the results of the Study; **provided, however**, that the following is excluded from Sponsor’s obligation to indemnify and hold harmless:

- a. the negligent failure of Institution to substantially comply with any applicable governmental requirements or to adhere to the terms of the protocol attached hereto as Exhibit A; or
- b. the negligence or willful malfeasance by a Regent, officer, agent, or employee of Institution or System.

[This is a one-way Sponsor indemnity for the use of results only, for when the protocol is ours and Sponsor is not providing drugs, materials or devices, or such drugs, materials or devices are being supplied for already approved (FDA) uses.]

4. INDEMNIFICATION

4.1 Sponsor agrees to indemnify and hold The University of Texas System (“System”), the University, their Regents, officers, agents and employees harmless from any liability, loss or damage they may suffer as a result of claims, demands, costs or judgments against them arising out of use by Sponsor of the results obtained from the activities performed by University under this Agreement; provided, however, that any such liability, loss or damage resulting from the following Subsections “a” or “b” is excluded from this Agreement to indemnify and hold harmless:

- a. the negligent failure of University to substantially comply with any applicable FDA or other governmental requirements; or
- b. the negligence or willful malfeasance of any Regent, officer, agent or employee of University or System.

[This indemnification is for use when Sponsor is obtaining our results, but the protocol is University’s.]

12. INDEMNIFICATION - PRODUCT LIABILITY

To the extent authorized by the Constitution and laws of the State of Texas, Institution shall indemnify and hold Sponsor harmless against any and all claims, demands, damages, liabilities and costs incurred by Sponsor which *directly or indirectly* result from, or arise in connection with, any negligent act or omission of Institution, its agents, or employees, pertaining to its activities and obligations under this Agreement.

Sponsor shall indemnify and hold Institution, System, their Regents, officers, agents, and employees harmless against any and all claims, demands, damages, liabilities and costs which *directly or indirectly*** result from, or arise in connection with defects in the design or manufacture of the Study Drug or from Sponsor’s use of the results of the Study.

** NOTE: If “directly” appears, either strike it or add “or indirectly”.

[This is more or less a standard indemnification except that Sponsor limits its liability to claims for personal injury or death and places several conditions upon its obligation to indemnify: (1) proper conduct of the study, (2) notification, and (3) right to control defense. The indemnification also gives University a right to select its own counsel.]

5.1 Institution shall, to the extent authorized under the Texas Constitution and the Texas Tort Claims Act, TEX. CIV. PRAC. & REM. CODE ANN., Title 5, 101 et. seq., indemnify and hold Sponsor harmless from liability resulting from the negligent acts or omissions of Institution, its agents, or employees pertaining to the activities to be carried out pursuant to the obligations of this Agreement; provided, however, that Institution shall not hold Sponsor harmless from claims

arising out of the negligence of Sponsor, its officers, agents, or any person or entity not subject to Institution supervision or control.

- 5.2 Sponsor shall indemnify and hold System, Institution, their Regents, officers, agents, and employees harmless from any liability or loss resulting from judgments or claims for personal injury, including death, and property damage against them arising out of the activities to be carried out pursuant to the obligations of this Agreement, including but not limited to the use by Sponsor of the results of the Study; provided, however:
- a. that the Study is conducted in accordance with the protocol, all written instructions delivered by Sponsor concerning administration of the study drug and control drug, regulations set forth in FDA Form 1572, 21 CFR Part 50 and Part 56, and such other requirements as may be published by FDA from time to time, and in the exercise of Investigator's own medical judgment;
 - b. that Sponsor is notified promptly but in no event later than thirty (30) working days after receipt of notice of the injury or claim of suit, with same identified so as to advise Institution that it is related to the Study; and
 - c. that, to the extent to which Sponsor is required hereunder to provide an indemnification for any claim or suit, to the extent permitted by law, and subject to the statutory duties of the Texas Attorney General, Sponsor shall have the right to select defense counsel and to direct the defense or settlement of any such claim or suit.

In the event that representation of indemnitees and Sponsor by the same counsel would be a conflict of interest for such counsel, indemnitees may select independent counsel without relieving Sponsor of its obligations of indemnification and defense as set forth above.

- 5.3 The following is excluded from Sponsor's obligation to indemnify and hold harmless:
- a. the negligent failure of Institution to comply with any applicable governmental requirements or to adhere to the terms of the Protocol attached hereto as Exhibit ; or
 - b. the negligence or willful malfeasance by a Regent, officer, agent, or employee of Institution or System.

[This indemnity is for use in materials transfer agreements - University receiving. Please see our Material Transfer Agreement Checklist for information about indemnification and other issues arising in this context.]

7. INDEMNIFICATION

Institution, to the extent permitted by the law and constitution of the State of Texas, will hold Sponsor harmless from any claims or liability resulting from use of the Product(s) in accordance with Texas Civil Practice and Remedies Code, Title 5, Section 101, et. seq., except insofar as such claims or liability arise out of the negligence or wrongdoing of the Product(s) provider.

[This indemnity is for use in patent and technology license agreements.]

8. INDEMNIFICATION

Licensee shall hold harmless and indemnify Board, System, University, its Regents, officers, employees and agents from and against any claims, demands, or causes of action whatsoever, including without limitation those arising on account of any injury or death of persons or damage to property caused by, or arising out of, or resulting from, the exercise or practice of the license granted hereunder by Licensee, its Subsidiaries or their officers, employees, agents, or representatives.