INDEMNIFICATION POP QUIZ

INDEMNIFICATION QUESTION #1

18. Indemnification by AstraZeneca

(a) Except as set forth below, AstraZeneca agrees to defend, indemnify and hold harmless Institution, System and their Regents, officers, agents, employees, Principal Investigator and any other researchers (collectively, the “Institutional Indemnified Parties”), from and against any and all liability, claims, losses, damages and expenses (collectively, “Losses”) for bodily injury or death to Subjects directly caused by the administration of the Study Drug if Institution and Principal Investigator (i) have complied with the provisions of this Agreement, the Protocol, and all written instructions of AstraZeneca concerning administration or use of the Study Drug, (ii) have used reasonable medical judgment in the administration of the Study Drug, and (iii) otherwise acted in conformity with generally accepted standards of the medical community in which they practice and without negligence or willful misconduct. AstraZeneca, subject to the statutory duties of the State of Texas Attorney General, shall have the exclusive right to retain counsel of its choosing to represent the Institutional Indemnified Parties and shall retain exclusive control of the litigation, including, without limitation, the right to make any compromise or settlement, provided that AstraZeneca shall not make any settlement admitting fault on the part of Institution without its written consent, such consent not to be unreasonably withheld. The indemnification provided herein shall also apply to AstraZeneca’s use of the Institution’s research results.

(b) AstraZeneca shall have no obligation to defend, indemnify or hold harmless any Institutional Indemnified Party under this Agreement with respect to a Loss unless Institution or Principal Investigator has provided AstraZeneca with written notice of such Loss within ten (10) business days of receipt of any claim or suit relating to a Loss. The Institutional Indemnified Parties shall allow AstraZeneca to assume the defense of any such Loss, including the right to select defense counsel and the right to settle any Loss as set forth above, and shall cooperate fully with AstraZeneca and its agents and representatives in the investigation and defense of such Loss.

20. Indemnification by Institution

(a) Institution to the extent authorized under the Constitution and laws of the State of Texas shall defend, indemnify and hold harmless AstraZeneca and its officers, directors, partners, employees and agents (“AstraZeneca Indemnified Parties”) from and against any and all Losses caused by a breach of this Agreement by an Institutional Indemnified Party, including, without limitation, the negligence or willful misconduct of Institution, Principal Investigator, or any other person who assists in performing the Study, in performing their obligations under this Agreement or caused by the failure of Institution, Principal Investigator, or any other person who assists in performing the
Study, to comply with the provisions of this Agreement, the Protocol, any written instructions of AstraZeneca concerning the Study or any Applicable Laws. Notwithstanding the foregoing, Institution shall have no obligation pursuant to this Agreement to defend, indemnify or hold harmless an AstraZeneca Indemnified Party from any Losses to the extent caused by a breach of this Agreement by an AstraZeneca Indemnified Party, including by such party’s negligence or willful misconduct.
18. **Indemnification by AstraZeneca**

(a) Except as set forth below, AstraZeneca agrees to defend, indemnify and hold harmless Institution, System and their Regents, officers, agents, employees, Principal Investigator and any other researchers (collectively, the “Institutional Indemnified Parties”), from and against any and all liability, claims, losses, damages and expenses (collectively, “Losses”) for bodily injury or death to Subjects directly[* important – delete “directly” or add “indirectly”] caused by the administration of the Study Drug if Institution and Principal Investigator (i) have complied with the provisions of this Agreement, the Protocol, and all written instructions of AstraZeneca concerning administration or use of the Study Drug, (ii) have used reasonable medical judgment in the administration of the Study Drug, and (iii) otherwise acted in conformity with generally accepted standards of the medical community in which they practice and without negligence or willful misconduct. AstraZeneca, subject to the statutory duties of the State of Texas Attorney General, shall have the exclusive right to retain counsel of its choosing to represent the Institutional Indemnified Parties and shall retain exclusive control of the litigation, including, without limitation, the right to make any compromise or settlement, provided that AstraZeneca shall not make any settlement admitting fault on the part of Institution without its written consent, such consent not to be unreasonably withheld. The indemnification provided herein shall also apply to AstraZeneca’s use of the Institution’s research results generated from the Study.

(b) AstraZeneca shall have no obligation to defend, indemnify or hold harmless any Institutional Indemnified Party under this Agreement with respect to a Loss unless Institution or Principal Investigator has provided AstraZeneca with written notice of such Loss within ten (10) business days of receipt of any claim or suit relating to a Loss. Subject to the statutory duties of the Texas Attorney General, the Institutional Indemnified Parties shall allow AstraZeneca to assume the defense of any such Loss, including the right to select defense counsel and the right to settle any Loss as set forth above, and shall cooperate fully with AstraZeneca and its agents and representatives in the investigation and defense of such Loss.

20. **Indemnification by Institution**

(b) Institution to the extent authorized under the Constitution and laws of the State of Texas shall defend, indemnify and hold harmless AstraZeneca and its officers, directors, partners, employees and agents (“AstraZeneca Indemnified Parties”) from and against any and all Losses such party may sustain or incur as a result of any negligent act or omission of the Institution (including its agents and employees) in performing its obligations under this Agreement, caused by a breach of this Agreement by an
Institutional Indemnified Party, including, without limitation, the negligence or willful misconduct of Institution, Principal Investigator, or any other person who assists in performing the Study, in performing their obligations under this Agreement or caused by the failure of Institution, Principal Investigator, or any other person who assists in performing the Study, to comply with the provisions of this Agreement, the Protocol, any written instructions of AstraZeneca concerning the Study or any Applicable Laws. [this is way too broad; we’ll only indemnify them as to our negligence; and, just because we did not file a certain report doesn’t mean we were negligent – it’s just that we were sloppy.] Notwithstanding the foregoing, Institution shall have no obligation pursuant to this Agreement to defend, indemnify or hold harmless an AstraZeneca Indemnified Party from any Losses to the extent caused by a breach of this Agreement by an AstraZeneca Indemnified Party, including by such party’s negligence or willful misconduct.
INDEMNIFICATION QUESTION #2

In accordance, therefore, with our standard practice, Company will indemnify and hold harmless:

1. The Investigator,
2. The Institution,
3. All persons working under the guidance of the Investigator in the conduct of the clinical trial,

from and against all claims for damages and liabilities imposed by law for adverse drug experiences resulting in bodily injury to patients caused directly from the administration of Company’s study drug [_______] or from Company’s use of the research results in the above referenced clinical trial.

This obligation of indemnification does not pertain to liabilities which may result from any act of negligence or the failure to act on the part of any party seeking indemnification.

Company’s obligation of indemnification is further contingent upon the following:

1. The terms of the Protocol are strictly adhered to, including obtaining signed consent forms from each patient, which has been approved by the IRB and Company.
2. The study drug was administered in strict accordance with the terms of the final study Protocol.
3. The Institution and the Principal Investigator have used reasonable medical judgment in the administration of the study drug.
4. The Institution and the Principal Investigator have strictly complied with applicable federal, state, and local laws, the regulations of the Food and Drug Administration, and have conducted the study in accordance with the generally accepted standards of Good Clinical Practice.
5. The Institution and Principal Investigator have maintained proper records concerning the receipt, storage, handling and administration of the study drug and have made such records available the Company.
6. The Institution and Investigator and subject to the statutory obligations of the State of Texas Attorney General permit Company’s attorneys, at Company’s discretion and cost, to manage and control the defense and settlement of any claims or suits, subject to timely consultation with and input from Institution and Investigator.
7. The Institution and Investigator shall have given Company prompt written notice of any claims involving Product and shall have cooperated fully with Company in the defense thereof, including, but not limited to, affording Company complete access to all relevant records.
8. Investigator and Institution agree that Company will not be responsible for, and that Investigator and Institution shall jointly and severally indemnify and hold Company harmless against any loss, claim, demand or costs and expense, including reasonable attorney’s fees, arising from any injuries or damages incurred which result from any
negligent act or omission on the part of Investigator, Institution, or Investigator’s agents. Investigator further agrees to hold Company harmless if claims result from any of Investigator’s clinical research activities which are not performed in accordance with the Protocol or other information provided to Investigator by Company. Company will not be liable for, or a party to, unauthorized warranties made by Investigator or Investigator’s agents relating to drug product or devices used in Study.
INDEMNIFICATION QUESTION #2

ANSWER

In accordance, therefore, with our standard practice, Company will indemnify and hold harmless:

1. The University of Texas System
2. Its Regents
1.3. The Investigator,
2.4. The Institution, and Employees and agents
3.5. All persons working under the guidance of the Investigator in the conduct of the clinical trial,

[Note: the above revisions are critical]

from and against any loss, demand, or all claims and suits against them for personal injury, including death, [this limits the broad scope of their indemnity] for damages and liabilities imposed by law for adverse drug experiences resulting in bodily injury to patients caused directly-[never agree to “directly” – add “indirectly and” or delete “indirectly”] from the administration pursuant to the Protocol of Company’s study drug [_______] or from Company’s use of the research results in the above referenced clinical trial.

This obligation of indemnification does not pertain to liabilities which may result from any act of negligence or the failure to act on the part of any party seeking indemnification.

Company’s obligation of indemnification is further contingent upon the following:

1. The terms of the Protocol are strictly adhered to, including obtaining signed consent forms from each patient, which has been approved by the IRB and Company.
2. The study drug was administered in strict accordance with the terms of the final study Protocol.
3. The Institution and the Principal Investigator have used reasonable medical judgment in the administration of the study drug.
4. The Institution and the Principal Investigator have strictly complied with applicable federal, state, and local laws, the regulations of the Food and Drug Administration, and have conducted the study in accordance with the generally accepted standards of Good Clinical Practice. [Does institution agree to Good Clinical Practices as defined by ICH and CFR?]
5. The Institution and Principal Investigator have maintained proper records concerning the receipt, storage, handling and administration of the study drug and have made such records available the Company. [We cannot agree to this: if we do something stupid and not negligent, then #5 wipes out their indemnifying us completely].
6. The Institution and Investigator and subject to the statutory obligations duties of the State of Texas Attorney General permit Company’s attorneys, at Company’s discretion
and cost, to manage and control the defense and settlement of any claims or suits, subject to timely consultation with and input from Institution and Investigator.

7. The Institution and Investigator shall have given Company prompt written notice of any claims involving Product and subject to the statutory duties of the Texas Attorney General, shall have cooperated fully with Company in the defense thereof, including, but not limited to, affording Company complete access to all relevant records.

8. Investigator and Institution agree that Company will not be responsible for, and that Investigator and-[Investigator is not a party to this Agreement] to the extent authorized by the Constitution and laws of the State of Texas, Institution shall jointly and severally indemnify and hold Company harmless against any loss, claim, demand or costs and expense, including reasonable attorney’s fees, arising from any injuries or damages incurred which result from any negligent act or omission on the part of Investigator, Institution, or Investigator’s Institution’s employees or agents pertaining to the activities and obligations under this Agreement. Investigator further agrees to hold Company harmless if claims result from any of Investigator’s clinical research activities which are not performed in accordance with the Protocol or other information provided to Investigator by Company. Only if we are negligent, we will pick up the tab. Company will not be liable for, or a party to, unauthorized warranties made by Investigator or Investigator’s agents relating to drug product or devices used in Study.
INDEMNIFICATION QUESTION #3

12. Indemnification

Millennium will defend, indemnify, save and hold Institution and its trustees, officers, employees and agents (together, the “Indemnitees”) harmless from and against any claims, demands, suits, actions, causes of action, losses, damages, fines and liabilities, including reasonable attorney’s fees (“Institution Claims”) arising out of a Clinical Trial and will pay any costs and damages which, by final judgment, after exhaustion of all reasonable appeals, may be assessed against them, provided that Millennium is given prompt written notice of the Institution Claims and is given information, reasonable assistance and sole authority to defend and/or settle the claim. Millennium’s obligations under this Section 12 shall not apply to the extent that an Institution Claim is the result of (a) the negligence, gross negligence, or willful misconduct of any Indemnitee, or (b) the failure of any Indemnitee to adhere to the terms of this Agreement (including any Protocol) or other written instructions from Millennium or to comply with any applicable FDA or other governmental requirement.
12. Indemnification

Millennium will defend, indemnify, save and hold The University of Texas System, Institution and their Regents, its trustees, officers, employees and agents (together, the “Indemnitees”) harmless from and against any claims, demands, suits, actions, causes of action, losses, damages, fines and liabilities, including reasonable attorney’s fees (“Institution Claims”) arising out of activities to be carried out pursuant to the obligations of this Agreement and a Clinical Trial, including but not limited to the use by Millennium of the Clinical Trial data and results, and will pay any costs and damages which, by final judgment, after exhaustion of all reasonable appeals, may be assessed against them, provided that Millennium is given prompt written notice of the Institution Claims and is given information, reasonable assistance and, subject to the statutory duties of the Texas Attorney General, sole authority to defend and/or settle the claim. Millennium’s obligations under this Section 12 shall not apply to the extent that an Institution Claim is the result of (a) the negligence, gross negligence, or willful misconduct malfeasance of any Indemnitee, or (b) the failure of any Indemnitee to adhere to the terms of this Agreement (including any Protocol) or other written instructions from Millennium or to comply with any applicable FDA or other governmental requirement.

OPTION #2

12. Indemnification

Millennium will defend, indemnify, save and hold The University of Texas System, Institution and their Regents, its trustees, officers, employees and agents (together, the “Indemnitees”) harmless from and against any claims, demands, suits, actions, causes of action, losses, damages, fines and liabilities, including reasonable attorney’s fees (“Institution Claims”) arising out of activities to be carried out pursuant to the obligations of this Agreement and a Clinical Trial, including but not limited to the use by Millennium of the Clinical Trial data and results, and will pay any costs and damages which, by final judgment, after exhaustion of all reasonable appeals, may be assessed against them, provided that Millennium is given prompt written notice of the Institution Claims and is given information, reasonable assistance and, subject to the statutory duties of the Texas Attorney General, sole authority to defend and/or settle the claim. Millennium’s obligations under this Section 12 shall not apply to the extent that an Institution Claim is the result of (a) the negligence, gross negligence, or willful misconduct malfeasance of any Indemnitee, or (b) the negligent failure of any Indemnitee to adhere to the terms of this Agreement (including any Protocol) or other written instructions from Millennium or to comply with any applicable FDA or other governmental requirement.