Checklist for Sponsored Research Agreement

Notes for use:

- This checklist provides a guideline of terms that are generally acceptable to Institution. If a Company is refusing to accept any of Institution’s bottom line terms, please contact the appropriate Legal Officer.
- This checklist only contains terms that are generally in all Sponsored Research Agreements. Please read the entire agreement to ensure there are no unusual terms. If you do not understand the meaning or purpose of any term, check with the appropriate Legal Officer.
- Please note that the term “Study” is used to denote the research study that is the subject of the Agreement.
- The language in this checklist is provided as a guidance and does not need to be used verbatim – it is sufficient to ensure the concept is covered in the Agreement. When copying and pasting language from this checklist, confirm that the defined terms match those in the Agreement.
- Make sure the information in the Agreement matches the information on the RCTS record.
- All italics used in the checklist are merely for internal emphasis, and when copying and pasting language from this checklist, such formatting should be removed.
- Brackets are used to denote a choice or a need for information to be filled in. Please remove the brackets once a selection of the text has been made or the appropriate information has been provided.
- Only add terms if they will benefit MD Anderson.
- Clinical/biomedical studies are treatment or interventional studies involving human subjects. For the purpose of this checklist, all other studies are considered non-clinical, including without limitation, “non-clinical” human research involving human tissues or data (e.g. data use, biospecimen, correlative) or only lab research. Any differences in negotiation standards are noted below.

Before you begin, check for:

(i) a Master Agreement with the Company that covers the Study – ensure the study order under the Master matches the terms in the study agreement template; or
(ii) any similar agreements with the Company in the last two (2) years. Review any such agreements to determine whether they would be good starting points for the current Study and to determine what substantive changes the Company has made.

1. Background Provisions
   a. Party names
      i. Check the name “The University of Texas M. D. Anderson Cancer Center” (watch for the bolded items)
      ii. MD Anderson is a member institution of The University of Texas System, and as such, is a government agency of the State of Texas.
iii. Address of Institution: 1515 Holcombe Boulevard, Houston, Texas 77030

iv. The PI is not a party to the Agreement.

v. For clinical/biomedical studies: The PI should not be defined as or referred to as a “Sponsor-Investigator.” Because the PIs in the Institution do not hold the INDs under any circumstances, they cannot be Sponsor-Investigators, as such term is defined in 21 C.F.R. § 312. Thus, we should not have that language in the Agreement.

b. Recitals

i. Confirm the PI’s name is spelled correctly and has the appropriate degree(s) signifiers.

ii. Description of the Study or the Protocol that is attached as an Exhibit is “attached hereto for reference purposes only.” If Company pushes back on this point, ensure there is language saying the agreement controls over the protocol (or the protocol controls only for medical, clinical or scientific aspects.)

iii. For multi-center studies, the definition of Study should only cover the study/protocol MD Anderson is performing and not the overall study.

c. Signature blocks

i. Check the name “The University of Texas M. D. Anderson Cancer Center”

ii. The PI should not be signing as a party to the Agreement. Only signing as “Read and Understood.” Confirm there is no language stating that by signing the Agreement, the PI is personally bound or liable under this Agreement.

iii. The name and title of MD Anderson’s signatory should be always be left blank because we have more than one signatory. OSP will add this information in at time of signature.

2. Study Drug

a. Definition of Study Drug should be limited to only the study drug provided under the Agreement and/or for the conduct of the Study. This can be important to ensure inventions do not reach beyond the scope of the Study and that any restrictions in the contract regarding the Study Drug are limited to only the Study Drug provided under this Agreement.

b. For clinical/biomedical studies: We can agree to return unused Study Drug at Company’s expense. Ensure that MD Anderson has the right to destroy remaining Study Drug. If Company wants an option to tell MD Anderson to either destroy or return the Study Drug, then MD Anderson must know in writing within 30 days of written notice of MD Anderson’s intent to destroy the Study Drug. If Company requires the return of empty vials of Study Drug, check with the PI/department.

3. Funding/Award
a. Avoid language stating “in consideration for performance of the Study.” Replace with “in support of the performance of the Study.”

b. Include language regarding the refund of any excess funds:

“Upon completion of the Study, Institution shall provide Company with a written itemized financial statement of all work performed by it in connection with the Study. If the amounts paid by Company to Institution in connection with the services provided pursuant to the Study exceed the amount actually expended by Institution in the execution of the Study, then Institution shall promptly refund such excess to Company.”

4. Institution’s Academic Freedom

a. Include the following language:

“Nothing in this Agreement will limit or prohibit Institution or any of its personnel, including the Principal Investigator, from conducting any research or from performing research for or with any entity or person, including any other outside sponsors. Company acknowledges that this provision is intended to preserve the academic freedom and integrity of Institution and its faculty and to ensure that Institution and its faculty are not regarded as exclusive researchers for Company.”

5. Regulatory Language

a. For clinical/biomedical studies:

i. PI-initiated:

1. Obligation on Institution to assume the regulatory responsibilities of sponsor in accordance with 21 C.F.R. § 312 for IND studies (device studies are regulated under 21C.F.R. § 812) only when conditioned by “if applicable to the Study and if the Study is not exempt from such regulation”

2. IMPORTANT: If the Study is a PI-initiated Study or a joint collaboration and Institution will be holding the IND, ensure Company does not have the right to cross-file.

3. IMPORTANT: The IND Office will not provide the IND file or any regulatory correspondence, including the FDA cover letter, the IND annual reports or other specific reports (e.g. 15-day reports) filed with FDA, to Company. PI can provide Company with documents the PI has been provided, such as the 1571, 1572, IND approval letter, and official IRB final approvals, suspensions, and withdrawals of approval. PI can also submit safety information to Company when PI submits to IND Office.

ii. Company-initiated:

1. We cannot accept the obligation to assume the regulatory responsibilities of sponsor.

2. We will NOT hold the IND.

b. Regulatory inspections and audits
i. Requirement to notify Company if Institution is or receives notice that it will be the subject of an investigation or audit by any governmental or regulatory authority – make sure that the investigation or audit is “related to the Study.”

ii. If there is a requirement for Institution to provide to Company copies of communications with any governmental or regulatory authority or to allow Company to review and approve all such communications or to allow Company to be present during any such an investigation or audit, qualify such requirement with “to the extent permitted by law.”

d. Non-clinical studies:

i. Animal studies, in addition to compliance with applicable laws, can include language about the 3”Rs”, animal welfare principals for protection of the animals, and Institution’s animal care and use program is accredited by the AAALAC (Association for the Assessment and Accreditation of Laboratory Animal Care).

ii. References to MD Anderson labs being compliant with GLP (Good Laboratory Practices) or 21 C.F.R. §58 or being CLIA-certified should be checked with each department for compliance. Most Institution labs are not GLP or CLIA (Clinical Laboratory Improvement Amendments) compliant.

6. IRB and Informed Consent – for clinical/biomedical studies

a. Confirm the Company does not have the right to approve changes required by the IRB. We can notify Company of such changes.

b. Confirm that there is no language stating that Institution cannot deviate from, change or modify the Protocol, or language stating that if Institution deviates from, changes or modifies the Protocol, then Institution would not receive any funds. If any such language is in the Agreement and Company refuses to remove such language, please contact the appropriate Legal Officer.

c. Do not accept any language that specifies what the informed consent will state, other than giving the Company the right to receive the patient’s information as it relates to the study (i.e., secondary research, affiliates, etc.), since we don’t review the informed consents and the IRB doesn’t review the contract.

7. Performance of the Study

a. If the Agreement has an obligation on the Principal Investigator or Institution to perform the Study in accordance with all laws and regulations, confirm that such obligation is only with respect to all applicable laws and regulations. For clinical/biomedical studies also see AHRPP requirements in 10 below.

b. For clinical/biomedical studies: For restrictions on any Study subject’s ability to participate in any other studies, verify with the PI that this limiting subjects from other studies is acceptable. If so:

i. Must be limited to Institution’s enrollment of the Study subject in other studies – we have no control over the subject’s enrollment at other sites.
ii. Must be subject to the Study subject’s doctor’s medical judgment. Insert language similar to: “except to the extent that participation in such study is medically necessary for a subject in the Study, as determined by Institution’s sole medical judgment.”

iii. Carve out non-interventional studies.

8. Term

a. If the term of the Agreement appears too long, like 10 years, confirm with the PI as to whether this term is reasonable in light of the Study. This is especially important where the confidentiality obligations are to survive for a set number of years after the expiration of the Agreement.

b. Allow for the ability for either party to terminate the Agreement by giving thirty (30) days advance notice to the other party. If Company objects to allowing Institution to terminate without cause, we can accept the following as an alternative:

“Notwithstanding anything to the contrary, Institution has the right to immediately terminate this Agreement for (i) health, safety or regulatory reasons, or (ii) if the Principal Investigator is no longer employed by Institution, or (iii) if the Principal Investigator is no longer able to perform his or her obligations due to family, health or medical reasons, or (iv) if Company breaches the Agreement* and fails to cure such breach within thirty (30) days of receiving notice from Institution of such breach, provided however, that before terminating the Agreement on the basis of (ii) or (iii) above, Institution will make a good faith effort to find a substitute researcher who is ready, willing and able to assume the role of Principal Investigator and complete the Study and who is acceptable to Company.”

*One example of Company breaching the Agreement is where Company fails to pay Institution.

c. In the event of early termination:

“Company shall be liable for all reasonable costs incurred or obligated by Institution at the time of such termination.”

i. The financial liability of the Company in the event of an early termination should not only include those costs that have been incurred but also those costs that have been obligated to a third party.

ii. As a compromise to “all reasonable costs incurred or obligated by Institution,” we can agree to “all reasonable costs incurred and all non-cancelable costs obligated by Institution.”

iii. We cannot accept any provisions limiting the amount of funds payable to Institution except in the case where Institution breaches the Agreement, we can agree to Company being responsible for costs up to the time of notice of breach (after trying to push for the above).

d. Survival of provisions or obligations and rights beyond termination and/or expiration – If the Agreement provides that notwithstanding termination and/or expiration of the Agreement, certain obligations survive, limit such
obligations to those that “accrued prior to the termination or expiration of the Agreement.”

9. Audit Rights - If the Agreement allows Company audit or inspection rights:
   a. Company’s right to audit or conduct on-site inspections should only be during normal administrative business hours and upon reasonable notice.
   b. Non-clinical studies: Do not agree to audit rights for lab studies unless PI agrees.
   c. Include the following:
      “Company’s rights in this Section shall be subject to Company’s compliance with Institution’s reasonable measures for purposes of confidentiality, safety, and security, and will be further subject to Company’s compliance with Institution’s premises rules that are generally applicable to all persons at Institution’s facilities. Should Company utilize one or more third party(s) in exercising its rights in this paragraph, Company certifies that such party(s) shall be subject to an obligation of confidentiality consistent with the obligations of confidentiality required of Company hereunder and such third party(s) shall be subject to any and all conditions upon Company’s rights that are set forth in this Section. If Company obtains, learns of, comes in contact with, or otherwise has access to any patient health and medical information, Company will keep such information confidential and will comply with all applicable laws regarding the confidentiality of such information and Company will not use or disclose such patient health and medical information in a manner that would violate any applicable law (including the HIPAA Privacy Regulations) if such use or disclosure were made by Institution.”

Please note that a provision stating that each party agrees to comply with applicable privacy laws and regulations is not sufficient to address our concerns because the Sponsors are generally not subject to HIPAA laws, and thus are not obligated to obey such laws unless we put such restrictions in the contract. If the Company objects to language referencing HIPAA, propose the following alternative to replace the last sentence of the preceding paragraph:

“If Company obtains, learns of, comes in contact with, or otherwise has access to any patient health and medical information, Company will keep such information confidential and will comply with all applicable laws regarding the confidentiality of such information and Company (i) will not use such information except for purposes of the Study; (ii) will not disclose such patient health and medical information to any third-party unless required to do so by law, regulation, government order, or pursuant to a written request by the patient; (iii) will not remove such information from Institution’s site; and (iv) will not attempt to contact any patients or their families.”

d. We cannot provide Company with a copy of any premises rules/policies – UTPD is an independent policy entity, and we cannot limit their authority to
carry out their police duties as they see fit. Additionally, as a State agency, Institution must be able to adapt its rules readily to changing situations such as legislative requirements.

e. Any references to Company inspecting, reviewing, accessing documents or data (that implies on Institution premises) should be cross-referenced with “subject to and in accordance with” the premises rules language in in 8.b.

f. Clinical/biomedical studies: Company can review and inspect records but should not be broadly allowed to copy IND records. If Company insists on copying state that Company cannot copy any subject’s PHI (or, alternatively, health or medical information).

10. Adverse Event Reporting – For clinical/biomedical studies only
   a. Try to negotiate for Institution to report SAEs in accordance with the protocol. We can agree to report in one (1) administrative business days.
   b. Do not agree to any restrictions on reporting adverse events directly to regulatory authorities. If Company insists on such a restriction, confirm there is an exception “except to the extent required by law.”

11. AAHRPP Provisions (for AAHRPP certification compliance) – For clinical/biomedical studies only:
   a. Ensure that Institution also agrees to conduct the Protocol in accordance with Institution’s ethical standards and/or policies.
   b. Ensure language addressing subject injury is included. Institution does not care if Company reimburses or not, but the issue must be addressed for AAHRPP. Standard minimum language: “Company shall reimburse Institution for the cost of providing necessary medical treatment to a Study subject for any injuries directly resulting from a Study subject’s participation in the Study, unless Institution’s negligence or misconduct causes the injury.” Can also agree that neither party will be responsible for subject injury. As an alternative, we can use: “This Agreement does not obligate any of the Parties to provide medical treatment, except to the extent required by applicable law, nor does this Agreement obligate either Party to provide reimbursement for medical treatment if a Study subject requires medical treatment for physical illness or injury sustained as a direct result of the treatment of such Study subject in accordance with this Agreement and the Protocol.”
   c. Include language requiring the Company to promptly report to us any certain findings that could affect the Study.

   “For the term of this Agreement and for two years thereafter, Institution and Company will promptly notify each other upon identifying any aspect of the Protocol, including information discovered during site monitoring visits, or of the Study results that may adversely affect the safety, well-being, or medical care of Study subjects, or that may affect the willingness of subjects to continue participation of the Study, influence the conduct of the Study, or may alter the IRB’s approval to continue the Study; when possible, such findings shall be submitted to Institution electronically. Institution shall promptly notify the
IRB of any such events. When Study subject safety or medical care could be directly affected by Study results, then notwithstanding any other provision of this Agreement, Institution will send Study subjects a written communication about the results.”

d. Confidentiality provisions 12.d.(vi) and (vii) also address AAHRPP required issues.

12. Visiting Scientists
a. Any time the Company will place scientists or other personnel on the Institution’s sites, please contact the appropriate Legal Officer.

13. Confidentiality
a. Confidentiality obligations should be mutual where the Study is a PI-initiated study or a joint collaboration. If Company pushes back on this point and only wants a one-way confidentiality provision to protect Company’s information, check with the PI as to whether the PI will waive protection on Institution’s confidential information (such as the Protocol, the PI’s ideas).

b. Definition of Confidential Information
i. Results and data of the research should NOT be included – otherwise, make the confidentiality provision subject to Institution’s right to publish AND subject to Institution’s right to use the results and data of the Study for its internal research, academic, and patient-care purposes. (Note: We can agree to delete patient-care.).

ii. Confidentiality obligations should attach only to information provided/disclosed by Company under the Agreement for the conduct of the Study. Confidentiality obligations in the Study agreement should not affect disclosures under any other agreements (and vice-versa).

iii. Where there is an obligation (on MD Anderson) to mark documents “confidential” or reduce to writing verbal disclosures, which are then marked “confidential,” first try to give the parties some leeway: “Notwithstanding the foregoing, any failure by either party to mark documents confidential or to reduce oral disclosures to writing will not relieve the receiving party of its obligations herein if by the nature of the information, would reasonably constitute proprietary or confidential information.” If Company insists on strict marking requirement, check with the PI.

c. Confidentiality and non-use obligations
i. Where disclosure to third parties is prohibited, include an exception for “members of the receiving party’s scientific or institutional review boards, provided, however, that such persons are obligated to maintain the confidentiality of such information consistent with the terms of this Agreement.”

ii. Try to only agree to “use reasonable efforts” to keep the Confidential Information confidential.
iii. No obligation requiring Institution to obtain written agreements regarding confidentiality from anyone to whom Institution provides the Confidential Information.

d. Exclusions to Confidential Information – must include all of the following:
   i. is already in the receiving party’s possession at the time of disclosure by the disclosing party; (can agree to evidence this with written documentation)
   ii. is or later becomes part of the public domain through no fault of the receiving party; (CANNOT agree to evidence this with written documentation)
   iii. is received from a third party who, to the knowledge of the receiving party, has no obligations of confidentiality to the disclosing party; (can agree to evidence this with written documentation)
   iv. is independently developed by the receiving party without use of the Confidential Information of the disclosing party; – avoid “without access to or benefit of the Confidential Information” (can agree to evidence this with written documentation)
   v. is published in accordance with Section [ ] of the Agreement;

For clinical/biomedical studies and for non-clinical studies involving human data/tissue:

   vi. is required to be disclosed in order to obtain informed consent from patients or subjects who may wish to enroll in the Study, provided, however, that the information will be disclosed only to the extent necessary and will not be provided in answer to unsolicited inquiries by telephone or to individuals who are not eligible Study candidates; or
   vii. is disclosed to a Study subject for the safety or well-being of the Study subject. There should be NO obligations to make the PATIENT/SUBJECT keep any such information confidential.

e. Exception for disclosure required by law or regulation
   i. Ensure there is an exception for disclosures required by law: “is required by law or regulation to be disclosed.”
   ii. Where the receiving party is required to give the disclosing party advance notice of any disclosures required by law or regulation so as to allow the disclosing party an opportunity to seek a protective order, include language such as “if practicable” or “if reasonable.” Institution can agree to assist with Company’s efforts to obtain such protection but should not agree to have the obligation to seek such protection.

f. In order to ensure that we will not have any more restrictions than the general public on the use of data and results of the Study or any information relating to the Study when such data, results or information has been published or otherwise falls into one of the above exceptions, include the following language:
“Notwithstanding anything to the contrary, if and when Confidential Information is subject to one of the exclusions mentioned above or is no longer confidential as a result of an authorized disclosure of such information under the terms of this Agreement, including any publication in accordance with Section [___], then the receiving party will not have any restriction upon its use or disclosure of such information.”

g. Duration of obligations of confidentiality and non-use
   i. Timing of the end of the confidentiality obligations
      1. 5 years or 10 years (if pushed)
      2. Try for: “after the Effective Date of the Agreement” or “after disclosure of such Confidential Information”
      3. Can agree to: “after termination of the Agreement” but will NEED to confirm that the term of the Agreement is reasonable.
   ii. If there is an obligation to keep trade secrets confidential until such time the trade secret is no longer confidential, trade secrets must be identified as such. Add:
       “provided, however, the disclosing party shall have identified all such trade secrets in writing.”

h. Keep an archival copy of Company’s CI if Company asks for Institution to return or destroy all of Company’s CI: “except that Institution may retain one archival copy solely for purposes of determining future compliance with the terms of this Agreement and as necessary for legal, regulatory, compliance, or insurance purposes.”

   Where data and results were defined as Company’s Confidential Information, add: “For clarification, notwithstanding the foregoing, Institution shall have the right to keep and use data [and Inventions] for purposes as permitted by this Agreement, including publication under Section [__].”

14. Publication
   a. Institution must have the right to publish or present the results and data of its research. Generally, unless the study is a Company-initiated study or a multi-center study where MD Anderson is not the lead site, PIs prefer to be the first to publish. “Institution has the right to [first] publish or present any results or data of its Study.” If the other site is asking for joint publication, please check with the PI.
   b. PI-initiated clinical studies: “Notwithstanding anything to the contrary, Institution has the right to register the Study in a manner consistent with the requirements of the International Committee of Medical Journal Editors (i.e., register the Study on clinical trial public registries and post the results of the Study on such public registries).”
   c. Institution should not have the obligation to publish.
   d. Allow Company a maximum of 45 days to review and comment on the manuscript. Preference is 30 days. If Company insists on a longer review period, obtain the PI’s approval.
   e. Institution has the final say as to what is published. Institution will only take into consideration Company’s comments and will not give Company the right
to approve the publication or be obligated to make the changes suggested by Company.

f. If Company is given the right to delay publication to protect IP rights, allow Company a maximum of 90 additional days. Preference is 30 or 60 additional days.

g. Confirm there are no provisions in the Agreement that makes the Study data or results confidential. If Company is not willing to carve Study data and/or results out of the confidentiality obligations, subject this provision to Institution’s right to publish and Institution’s right to use the Study data and results for its internal research, academic and patient-care purposes. (Note: We can agree to delete “patient care.”).

h. If Company is given the right to require that Confidential Information be removed from the publication and the definition of Confidential Information include results and/or data of the Study, include:

“provided, however, Institution shall not be required to remove from the publication the results of the Study or any other information that may be required by the publishing source.” The following may be tried as alternate language for the preceding portion in italics if the Company objects: “or any information that is necessary for the accurate presentation and interpretation of the results of the Study or which is required by the publishing journal to enable other researchers to reproduce the results.” The portion in italics may be waived by the PI. Make sure that the PI does not need to publish the structure or composition of the compound.

i. Multi-Center Publication: Where the independent publication rights of the Institution are tied to the completion of the study at all sites, propose to have the publication rights tied to the earlier of (a) twelve (12) months after the completion, termination, or abandonment of the Study at all sites or (b) the multicenter publication. (Note: We can agree to up to eighteen months after the completion, termination, or abandonment of the Study – Please check with the PI.)

j. Copyrights: If the Company insists on MD Anderson granting the Company a non-exclusive right to use any publications regarding the Study even after being told that MD Anderson does not assert any ownership rights with respect to our faculty’s academic publications, make any such grant of to the extent permitted by copyright laws. Many publishers will require the authors to assign the copyright to the publisher, and thus, the Institution and the PI are only able to grant any non-exclusive license to the copyright to the extent permitted by law.

15. Results and data

a. Ownership of results and data of the Study

i. PI-initiated Study: Institution should own the results and data of the Study.

ii. Joint Collaboration: Institution and Company jointly own the results and data of the Study.
iii. Company-initiated Study: Company can own the results and data of the Study, but:
   1. Institution must have the right to publish the results and data of the Study in accordance with the publication section; AND
   2. Institution can use the results and data of the Study for its internal research, academic and patient-care purposes. (Note: We can agree to delete “patient care.”)

iv. Regardless of the outcome of negotiations on the ownership of the results and data of the Study, the following must be excluded from data owned by the Company:
   1. Original laboratory notebooks, and
   2. For clinical/biomedical studies: Original medical records (including, without limitation, X-rays, MRIs, etc.).

v. The definition of results and data of the Study should not include biological materials and/or samples (e.g., the inclusion of “materials”).

b. For non-multi-center studies: “Institution discloses the results and data of the Study to Company in confidence, and Company should keep results and data of the studies confidential until the earlier of (i) publication or other public presentation of such results and data by Institution, or (ii) twelve (12) months after the conclusion of the Study.” For a shorter period of time, check with the PI. In the event the Company refuses to agree to this, and the PI wants the first right to publish, add: “Notwithstanding anything to the contrary, the Institution shall have the first right to publish the results or data of the Study.”

c. Company data use:
   i. For clinical/biomedical studies
      1. Company’s general use of Study data should be qualified as follows (if not already in the Agreement): “For the avoidance of doubt, Company shall access and use any patient identifiable information provided to it or which it obtains or comes in contact with under this Agreement only as (i) authorized by an applicable subject’s informed consent and/or HIPAA authorization; (ii) as necessary to conduct the Study; and (iii) as permitted by applicable law and Institution’s IRB.”
      2. If Institution is or will be holding the IND, cross-reference the language in paragraph 4(b)(ii)(1) above.

   ii. For non-clinical studies involving the use of human data/tissue: If there is a provision that states that Company can do anything with the results and data of the Study add the following at the end of such sentence:
      “, provided, however, to the extent any results or data of the Study includes Protected Health Information (as such term is defined by HIPAA), Company shall only use such Protected Health Information in accordance with the informed consent and the authorization document.”
d. Try to keep provisions addressing data use and ownership separate from provisions addressing IP/invention ownership. Generally, data is not treated the same way as IP/inventions.

e. Record Retention Periods
   i. We can agree to have the Institution retain all records and documents pertaining to the Study in accordance with and for as long as required by applicable law or regulation and for a reasonable period thereafter.
   ii. After the expiration of such period, we can agree to give Company prior notice of our destruction of such records and documents, and if Company requests Institution to retain the records and documents for a longer period or to transfer to Company, we can agree to do so as long as it is at Company’s expense.

16. Intellectual Property/Inventions
   a. Definition of “Inventions”
      i. Inventions should be limited in time and scope to the Study under this Agreement. Inventions cannot reach outside the scope of this Agreement to past or future inventions of Institution. “Inventions” must be:
         1. During the conduct of the Study AND
         2. arising from the performance of the Study
      ii. Term of this Agreement, we can agree to Inventions that are made during the term of this Agreement and for the six (6) month period thereafter. At a maximum, we can agree to one (1) year after the term of the Agreement.
   b. Disclosure of Inventions to Company
      i. Tie the obligation on Institution to disclose the Inventions to the receipt of notification by OTC:
         “Institution will promptly disclose to Company, in writing and in confidence, all Inventions after notification of any such Inventions is received by Institution’s Office of Technology Commercialization.”
      ii. Level of detail in the disclosure CANNOT be sufficient as to support the preparation and/or filing of a patent application (or even a provisional patent application). Institution will NOT provide a “fully enabling” disclosure.
   c. Rights in Inventions for clinical/biomedical studies that are Company-Initiated Studies or Joint Collaborations
      1. Company can own the Inventions.
      2. Reserve Institution a NERF for internal research purposes if Institution makes an inventive contribution. For example, if there is language stating that Institution hereby assigns all Inventions to Company, include:
         “subject to Institution retaining a non-exclusive, royalty-free license to internally use any Invention to which Institution makes an inventive contribution for research, academic and patient care purposes.”
d. Rights in Inventions for clinical/biomedical studies that are PI-Initiated Studies or for non-clinical/lab studies

i. Ownership: “Inventions that are made solely by Institution or its employees and agents shall be solely owned by Institution. Inventions that are made jointly by Institution and Company and their employees and agents shall be jointly owned by Institution and Company. Inventions that are made solely by Company or its employees and agents shall be solely owned by Company. Inventorship will be determined in accordance with United States patent law.” Confirm Company-owned Inventions does not include Inventions (made by Institution or jointly with Institution) related to Company’s Study Drug or the like.

ii. Unless an exception to the tax-exempt bond regulations is approved through the Form G process, Company cannot own Institution inventions. In the event the Company is asking to own all IP generated in the course of the Study, as an exception to the tax-exempt bond regulations, ensure Institution reserves a NERF for internal research and academic purposes.

iii. Rights granted to the Company. We can generally start with our bottom line position if we have agreed to that position in a previous agreement with the same company – unless we are informed of a specific IP concern.

Bottom line position (Form Gs):

Institution grants to Company a NERF for all purposes with an option for an exclusive, royalty-bearing license:

“Institution hereby grants Company a non-exclusive, royalty-free license to any Inventions in which Institution has an ownership interest. Institution also hereby grants to Company an exclusive option to negotiate an exclusive (subject to Institution’s internal right to use such Invention for research, academic and patient care purposes), royalty-bearing license to any Invention in which Institution has an ownership interest, provided that Company pays all patent expenses for such Invention in the event Company exercises its option. Company must exercise its option to negotiate a license to any Invention by notifying Institution in writing within thirty (30) days of Institution disclosing such Invention to Company (the “Option Period”). If Company fails to timely exercise its option within the Option Period with respect to any Invention, Company’s right to negotiate a license agreement with respect to such Invention will automatically terminate, and Institution will be free to negotiate and enter into a license with any other party. If Company timely exercises its option, the terms of the license shall be negotiated in good faith within ninety (90) days of the date such option is exercised, or within such time the parties may mutually agree in writing (the “Negotiation Period”). If,
however, Company timely exercises its option, but Institution and Company are unable to agree upon the terms of the license during the Negotiation Period, Company’s right to license such Invention will terminate, and Institution will be free to enter into a license with any other party. If Company does not obtain an exclusive, royalty-bearing license to any Invention, then in accordance with applicable law, Institution shall grant an equivalent non-exclusive, royalty-free license to such Invention to any person requesting a license to such Invention."

Note: We can agree to delete “patient care” for our reserved rights. On the option period, we can agree to a maximum of 60 days. For the time frame in which the parties must negotiate the license, we can agree to a maximum of 120 days.

1. We can also agree to joint ownership of Inventions with Company, as long as the joint ownership is governed by principles like those under U.S. patent law, namely, each joint owner has the ability to grant licenses, etc. without accounting to the other joint owner. This joint ownership is treated like a NERF.

e. Background IP: Typically defined as intellectual property owned or controlled by a Party prior to the Effective Date or which is developed by, or on behalf of a Party, outside the scope of this Agreement. Do NOT grant Company any rights to use any of Institution’s background IP or any other actual license (aside from NERF when necessary) to any inventions. If there is language that states that this Agreement does not grant Institution any rights or licenses to use any of Company’s background IP, make this a mutual provision. “Each party owns all of its intellectual property existing prior to this Agreement or developed independently of this Agreement. Nothing herein is intended to grant to either party any license or other rights in and to such pre-existing or independently developed intellectual property of the other party.”

f. Right of First Refusal
i. This section should only be applicable if Company has NOT been granted a NERF because if Company has a NERF, no other party can exclusively license the Invention, and at most, a third party will only be able to obtain a NERF (hence, no better option). If Company insists, use the below standards.

i. If a right of first refusal is requested, limit the time period for such right to 180 days, or at a maximum, 1 year, from the time negotiations between the parties terminate.

ii. Limit the time frame in which Company must exercise its right of first refusal:

“Company must notify Institution in writing that it is exercising its right of first refusal within thirty (30) days of
Institution notifying Company of the terms that have been agreed-upon with a third party. If Company fails to timely exercises its right of first refusal, Institution will be free to enter into a license with such third party.”

iii. The right of first refusal should only be available if Company exercised its option to negotiate an exclusive license and thereafter the parties failed to reach an agreement. Company should not be granted a right of first refusal if Company never exercised its option and attempted to obtain an exclusive license.

g. Patent Filing
   i. Institution is not obligated to file any patent applications. If Company would like Institution to file patent applications at its request, we can agree to the following: “Institution shall not be obligated to file a patent application for any Inventions in which it has an ownership interest, but Institution will file such patent application upon Company’s request, provided Company pays all such patent expenses for such Invention.”
   ii. If Company has the right to file for patents, Institution may use reasonable efforts to provide information for Company’s efforts to obtain a patent, but Institution should NOT help defend or maintain patents for Company.

17. Federal Funding
   a. Indicate that if federal funding is used with the Study, the federal government may have rights to the inventions and copyrighted materials that arises from the performance of the Study.
      “Notwithstanding anything to the contrary, the parties acknowledge that Institution may use U.S. Government funding in conducting some aspects of the study, that the U.S. Government may consequently also have rights and interest in some Inventions, and that this Agreement is subject to any such governmental rights and interests.”

18. Indemnification
   a. One way or mutual or silent
      i. For clinical/biomedical studies: No one-way indemnification where Institution is the only party providing the indemnification. We can have a mutual indemnification provision or we can agree to remain silent. If the Agreement does not include an indemnification provision, we do not need to add one.
      ii. For lab studies: If the Agreement does not include an indemnification provision, do not add one. If there is a one-way indemnification provision, first try to make the provision mutual. But one-way indemnification where Institution is the only party providing the indemnification is acceptable because Institution is not putting Company’s drug into patients. We can also have a mutual indemnification provision or we can agree to remain silent.
   b. Parties being indemnified
      i. Indemnification to Institution must include the following parties:
ii. Indemnification from Institution should not be from the System but only from Institution

iii. Indemnification from Company to Institution

1. Only add this #1 for clinical/biomedical studies (a warranty that the Study Drug has been made in accordance with cGMP can replace this): **personal injury (including death) or property damage arising out of or connected with Company’s failure to manufacture and provide the Study Drug in accordance with Good Manufacturing Practices** or alternatively, “personal injury (including death) or property damage arising out of or connected with the performance of the Study”; **AND**
2. “the use by Company of the results of the Study”; **AND**
3. if Company-initiated Study, “the activities to be carried out pursuant to the Agreement” (if the Company pushes back, we can limit this to the activities to be carried out by Company pursuant to this Agreement), or
4. if PI-initiated Study, “the activities to be carried out by Company pursuant to the Agreement.”

ii. Allow (but no need to require) the following carve outs from Company’s indemnification obligation: “judgments and claims arising from”:

   1. “the negligent failure of Institution to comply with any applicable governmental requirements or to adhere to the terms of the Protocol; or”
   2. “the negligence or willful malfeasance by a Regent, officer, agent, or employee of Institution or System.”

iii. If the indemnification language includes the word “defend,” use “defend, subject to the statutory duties of the Texas Attorney General” or alternatively, add the provision: **This provision is subject to the statutory duties of the Texas Attorney General.”**

iv. If the indemnification provision requires Institution to allow Company to take over the defense or the handling of any claims, include the following language: **This provision is subject to the statutory duties of the Texas Attorney General.”**

v. If the indemnification provision requires Institution to give Company control over settlements, include the following language: **provided, however, such settlements shall not require Institution to contribute to the settlement, admit fault or require Institution to change its operations or business practices.”** If the indemnification provision provides that Company will not make any settlement admitting fault or incur any liability on the part of Institution without
its written consent, confirm that the following language is NOT included “such consent not to be unreasonably withheld.”

d. Indemnification from Institution to Company
   i. Add to the bottom of this section: “This Section is subject to the statutory duties of the Texas Attorney General and is applicable to Institution only to the extent authorized under the Constitution and the laws of the State of Texas.”
   ii. Institution only indemnifies “To the extent authorized under the Constitution and the laws of the State of Texas”
   iii. Try not to include attorney’s fees
   iv. We should not indemnify for [material] breach of contract claims (but can accept if Company insists).
   v. Carve out from Institution’s obligation “claims arising from or related to the negligence or willful misconduct of Company, its officers, agents or employees, or any person or entity not subject to Institution’s supervision or control.”

e. Notice of claims provision
   i. If there is a notice provision as to when Institution must give notice of any claims in order to be indemnified:
      1. Where notification of the disclosing party is required, we prefer there is no requirement for notifying the indemnifying party within a set number of days. Include language stating that the indemnified party either will “use reasonable efforts to promptly notify” or will “promptly notify” the indemnifying party.
      2. If there is a provision that would relieve Company of its obligation to indemnify Institution if Institution is delayed in giving Company notice of any indemnification claims, only allow such language to the extent our failure to give notice materially adversely affects the Company’s ability to defend against the claim: “provided, however, the failure to promptly notify the indemnify party shall not relieve the indemnifying party of its indemnification obligations unless the indemnifying party is materially adversely affected by such failure.”
      3. Include a similar notice provision for the Company

   a. Use of the parties’ name
      i. If there is a restriction on Institution’s use of the other party’s name, there should also be a restriction on the other party’s use of Institution’s name.
      ii. All press releases regarding Institution need to be approved by Institution’s Office of External Communications.
      iii. Provide for the following exceptions to the restriction on Institution’s use of the other party’s name:
         1. “Except as required by law or regulation”
2. “Except as required by academic or scientific standards for publication”; or “Institution has the right to acknowledge Company’s support [and provision of Study Drug or materials] of the Study in scientific or academic publications and other scientific or academic communications without Company’s approval”

b. Waiver or Limitation of Warranty
   i. For clinical/biomedical studies:
      1. Include a warranty on manufacture of Study Drug (we can waive this requirement if Company is indemnifying us for the failure to manufacture the Study Drugs in accordance with cGMP): “Notwithstanding the foregoing, Company represents that the Study Drugs have been manufactured in accordance with Good Manufacturing Practices in the United States of America.”
      2. Warranty on no adverse effect from use of Study Drug - If there is a disclaimer of warranty, add: “Notwithstanding the foregoing, except as may be expressly disclosed in a Protocol, Company is not aware of any defects in, or hazardous or adverse effects from, the Study Drugs.”
   ii. IP warranty: If there is a disclaimer of warranty for non-infringement, add the following: “Notwithstanding the foregoing, Company represents that to the best of its knowledge, Company has not received any [written] claims that the use of the Study Drug infringes any patent, patent application, trade secret, or other property or proprietary rights.” Alternatively, the above warranty may be limited to the knowledge of a subset of people at Company.
   iii. Avoid Institution making any representation or warranty that the Agreement is enforceable against the Institution in accordance with its terms.

c. Assignment
   i. No need to add a provision if Company has not included one.
   ii. Company may assign its rights and obligations under this Agreement:
      1. with our consent; OR
      2. to an affiliate or to a third party who purchases substantially all of the assets of Company that relates to this Agreement.

d. Applicable/Governing Law
   i. Texas law or silent
   ii. If Company insists on foreign laws, can accept foreign laws with Texas State Agency Notice added
   iii. If foreign laws and no Notice, then Form G – NO IPOC Needed

e. Alternative Dispute Resolution
   i. No binding arbitration is allowed – Under Texas law, Institution cannot submit to binding arbitration.
ii. We prefer not to agree to mediation or non-binding arbitration. These proceedings may be just as time-consuming and costly as trials, but there is no guarantee as to the outcome because either side could still decide to bring suit.

iii. If Company really insists on having some dispute provision, we can accept some general working together terms, such as: “Each party shall use its best reasonable endeavors to settle amicably any dispute which may arise with the other party in relation to the construction, performance or termination of this Agreement but if no such settlement is made within a reasonable timeframe after the date on which the dispute first arises, the parties may seek any other avenues of recourse.”.

f. Insurance

i. Institution is self-insured and will agree to maintain insurance of financial resources to cover its indemnification obligations, as set forth below. Any other requirements for insurance, including requirements for PI or study staff insurance, are not acceptable.

ii. If insurance language is required, we can agree to the following:

1. Professional Medical Liability Benefit Plan (medical malpractice self-insurance) – “Each member of The University of Texas System is self-insured pursuant to The University of Texas Professional Medical Liability Benefit Plan under the authority of Chapter 59, Texas Education Code. Institution has and will maintain in force during the term of this Agreement adequate insurance or financial resources to cover its indemnification obligations.”

2. General liability claims in accordance with the Texas Tort Claims Act

iii. There should not be any numerical limits included in the contract because our limits are set by statute and could be modified by the Texas legislature.

iv. Company Insurance – “During the term of this Agreement, Company will maintain comprehensive general liability insurance at levels sufficient to support its obligations, including indemnification obligations, under this Agreement.”

v. Notice should be given to:
The University of Texas
MD Anderson Cancer Center
7007 Bertner Avenue, 1MC11.3343
Legal Services, Unit 1674
Attn: Chief Legal Officer
Houston, TX 77030
Phone: (713) 745-6633; Facsimile: (713) 745-6029

vi. A copy of the notice should be given to:
The University of Texas
MD Anderson Cancer Center
vii. A copy of the notice may be given to the PI.
g. Conflicts between Protocol and/or Exhibits and the Agreement
   i. Include language to the effect that “Any conflicts between the Protocol or any Exhibits and this Agreement will be governed and controlled by this Agreement.”
h. Conflicts between terms and other agreements
   i. We cannot agree to language whereby the Institution represents or otherwise agrees that the Institution is not conducting any research related to the Study (or to any language that similarly restricts Institution’s ability to conduct other research). Propose the following language as an alternative: “Institution acknowledges and represents that the Institution has not entered into other agreements that conflicts with or results in inconsistent obligations with the terms of this Agreement.”
i. Company’s Consulting Agreement
   i. Include the following language or ensure the concepts are included in the Agreement:
      “If the Principal Investigator and Company are or become parties to a consulting agreement or other outside agreement to which Institution is not a party. Company acknowledges and agrees that Institution has no involvement with or responsibility for these consulting or outside agreements.”
j. Subject to Applicable Law
   i. Include the following language or ensure the concepts are included in the Agreement:
      “Institution will not be required to perform any act or to refrain from any act that would violate any law. This Agreement is subject to, and the parties agree to comply with, all applicable local, state, federal, national and international laws, statutes, rules and regulations. Any provision of any law, statute, rule or regulation that invalidates any provision of this Agreement, that is inconsistent with any provision of this Agreement, or that would cause one or any of the parties hereto to be in violation of law will be deemed to have superseded the terms of this Agreement. The parties, however, will use all reasonable endeavors to accommodate the terms and intent of this Agreement to the greatest extent possible consistent with the requirements of the law and will negotiate in good faith toward amendment of this Agreement in such respect. If the parties cannot reach agreement on an
appropriate amendment, then this Agreement may be immediately terminated by either party.”

OR

If Company objects to entire language above, just keep the first sentence.

k. Texas State Agency language

i. Has the following provision been added?

“Notice of Texas State Agency. Institution is an agency of the State of Texas and under the Constitution and the laws of the State of Texas possesses certain rights and privileges, is subject to certain limitations and restrictions, and only has such authority as is granted to it under the Constitution and laws of the State of Texas. Notwithstanding any provision hereof, nothing in this Agreement is intended to be, nor will it be construed to be, a waiver of the sovereign immunity of the State of Texas or a prospective waiver or restriction of any of the rights, remedies, claims, and privileges of the State of Texas. Moreover, notwithstanding the generality or specificity of any provision hereof, the provisions of this Agreement as they pertain to Institution are enforceable only to the extent authorized by the Constitution and laws of the State of Texas; accordingly, to the extent any provision hereof conflicts with the Constitution or laws of the State of Texas or exceeds the right, power or authority of Institution to agree to such provision, then that provision will not be enforceable against Institution or the State of Texas.”

If Company objects to entire state agency paragraph, 1st alternative is to delete the bottom portion of the provision, starting from “Moreover.”

20. General Considerations

a. Obligations on the PI

i. Generally, have the obligations in the Agreement be on Institution and not on the PI.

ii. Few exceptions to the above rule are okay, especially for:

1. Obligations to deliver reports or other source documents

b. Obligations on the signatory

i. Avoid language whereby the signatory is representing and/or warranting that it has the authority to bind the Institution.

ii. If a compromise is needed on this point, we can accept language that states that Institution represents that the signatory has the authority to bind the Institution. (This should be mutual.)

c. Reasonable and best efforts (good practice but not necessary)

i. If applicable, Institution and/or its representatives should only agree to use “reasonable efforts,” “commercially reasonable efforts” or “reasonable best efforts” but not “best efforts.”
ii. If applicable, Institution or its representatives should be required to use “reasonable efforts” and not “all reasonable efforts.”

21. Foreign Sponsors – If the Agreement is with a foreign Company or if the Agreement is with a U.S. entity who is contracting on behalf of a foreign entity (such as a U.S. CRO contracting on behalf of a foreign Company), the following items should be addressed:

a. Add export control language:

“Notwithstanding any other provision of this Agreement, it is understood that the parties are subject to, and shall comply with, applicable United States laws, regulations, and governmental requirements and restrictions controlling the export of technology, technical data, computer software, laboratory prototypes, and other commodities, information and items (individually and collectively, “Technology and Items”), including without limitation, the Arms Export Control Act, the Export Administration Act of 1979, relevant executive orders, and United States Treasury Department embargo and sanctions regulations, all as amended from time to time (“Restrictions”) and that the parties’ obligations hereunder are contingent on compliance with applicable Restrictions.”

b. “English is the official language of this Agreement. Accordingly, all notices, documents and communications relating to the Agreement, and all dispute resolution proceedings arising under this Agreement must be, in their entirety, in English.”

c. “All rights in inventions arising from or developed during the Study will be governed by U.S. patent law.”

d. Venue – Also known as jurisdiction or location of court proceedings

i. If Company is not willing to go silent and insists on venue outside of Texas, please contact the appropriate Legal Officer.

22. Multi-Company Agreements

a. Please contact the appropriate Legal Officer before sending revisions or comments to the Company.

23. Form G Requirements – the following situations require Form G processing

a. When Company is given a NERF for any purposes or given ownership rights. The only exceptions are for a Company-initiated clinical/biomedical study (which Company can own such inventions) and for a separate correlative study to a Company-initiated clinical/biomedical study that Institution is conducting (which is considered equivalent to the Company-initiated clinical study because the correlative could have been included with the original agreement).

b. In the case of a Master Agreement for PI-initiated clinical/biomedical studies or for non-clinical/lab studies, each separate study order requires Form G processing if the Master Agreement includes IP language set forth in (i).

c. If an amendment changes the initial work scope of the research, the amendment must be sent through Form G processing.

d. If the Study agreement tries to change a previously approved royalty rate, this needs to be approved by OTC (outside Form G process).