Drexel University College of Medicine

Clinical Trial Agreement Negotiation Guidelines

October 2011

Contents

Instructions

These guidelines should be used in the review and negotiations of agreements between the Institution and private, for-profit third parties who sponsor clinical research where the Institution is serving as a site. The guidelines can be used for some guidance for other clinical research agreements (e.g. investigator-initiated agreements) but note that some provisions (e.g. indemnification, intellectual property, subject injury compensation) may not apply or should be negotiated in a different manner.

Investigator Provisions

As you are reviewing the agreement draft, it is recommended that you alert the principal investigator and/or research staff of any provisions that impose additional or unusual requirements above normal compliance requirements.

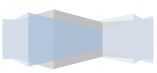
Compensation Provisions

As you are reviewing the contract draft, highlight (in yellow) any provisions that relate to the budget. Add a comment to sponsor in each section explaining that the budget analyst will review and finalize the section. You should still redline these sections for legal issues.

Master Agreements:

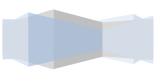
The Institution has entered into Master Clinical Trial Agreements with the following companies:

Sponsor	Effective Date	Term
Abbott Vascular, Inc.	In negotitations	
Amgen, Inc.	03/15/2011	Indefinite (with right to terminate)
Bayer HealthCare Pharmaceuticals, Inc.	07/13/2009	07/12/2014
Biogen Idec.	05/02/2011	05/02/2016
Celgene Corporation	03/31/2009	03/30/2014
Cytokinetics, Inc.	03/01/2010	Indefinite (with right to terminate)
Gilead Sciences, Inc.	09/29/2008	08/28/2013
GlaxoSmithKline (Template)	N/A	N/A
Johnson & Johnson Pharmaceutical Research & Development, L.L.C (This master agreement can be utilized for affiliates by executing the Participating Affiliate Agreement; See Master Agreement Attachment B, Exhibit B) Centocor Ortho Biotech Services, LLC Tibotec Virco Virology, BVBA Tibotec Pharmaceuticals Tibotec Therapeutics, Clinical Affairs, A Division of Centocor Ortho Biotech Services, LLC Janssen Scientific Affairs, L.L.C f/k/a Ortho-McNeil	03/16/2009	03/15/2012
Medtronic, Inc.	08/16/2010	08/15/2015
Novartis Pharmaceuticals Corporation	07/22/2009	07/30/2014
Novo Nordisk	03/30/2010	Indefinite (with right to terminate)
Pfizer, Inc.	06/26/2009	06/25/2014
sanofi-aventis U.S. Inc.	10/15/2008	10/14/2013
Schering Corporation	08/04/2010	Indefinite



		(with right to terminate)
Wyeth Pharmaceuticals, Inc.	07/05/2009	07/04/2014

An addendum (e.g. work order, statement of work) to the Master CTA should be used for clinical trials sponsored by the above companies. In negotiating these addendum, initial drafts of the study-specific addenda should be compared to the corresponding addendum template stored in the Clinicl Research Group electronic share drive. Seek attorney review for any non-study specific deviations from the template language.



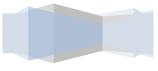
Initial Assessment Review Sheet

Use this form to ensure you have a comprehensive understanding of the clinical research associated with the CTA under review. The section following this page provides further explanation.

Type of Study				
Drug Phase	☐ I	☐ II	☐ III	☐ IV
Device Class	☐ I	☐ II	☐ III	
Device Category	☐ A	☐ B		

Principal Investigator	
Name	_____
Employer	☐ DrexelMed FTE ☐ DrexelMed PTE
	☐ Medical Practice _____(See list)
	☐ Tenet HUH
	☐ Tenet St. Christopher's for Children

Facilities	
Facilities Utilized	☐ DrexelMed only
	☐ Medical Practice _____(See list)
	☐ Tenet HUH
	☐ Tenet St. Christopher's for Children



Initial Assessments

Use the Protocol and other submission documentation/information to determine and evaluate the type of clinical trial involved and the facilities/services needed to conduct the study. If the Protocol is not available, consider whether contract negotiations can even be initiated yet. Discuss with legal.

Steps
I. Characterize the Focus of the Study II. Characterize the Principal Investigator III. Determine Facilities and Services Utilized

I. Characterize the Focus of the Study.

A. Drug Studies - § 21 CFR 312.21

Assess Risk of the Study	
Phase 1:	Phase 1 clinical trials, includes the initial testing of an experimental drug or treatment on humans. This clinical trial usually involves a small number of healthy subjects (20-80 subjects) that are closely monitored. Phase I clinical trials focus on metabolism and pharmacologic actions of the drug in humans, side effects of increasing doses, and if possible, the effectiveness of the drug. Considerations: Consider these clinical trials high risk given its experimental nature and the participation of healthy subjects. With regard to liability, the highest protections should be sought (i.e. indemnification, insurance). In addition, since the nature of the drug is unknown, expect sponsors to aggressively protect intellectual property rights.
Phase 2:	In Phase II clinical trials, researchers of the study further test the experimental drug or treatment in a larger group, usually 100-300 people, to evaluate its effectiveness and further ascertain its safety. Considerations: Consider these clinical trials high risk given its experimental nature and intervention in a subject's standard of care. With regard to liability, the highest protections should be sought (i.e. indemnification, insurance). In addition, since the nature of the drug is unknown, expect sponsors to aggressively protect intellectual property rights.
Phase 3:	In Phase III clinical trials, the experimental drug or treatment is tested on a much larger group, usually 1,000-3,000 people, to validate its effectiveness, examine side effects, further collect data to allow the experimental drug or treatment to be used safely, and compare it against current standard treatments. In comparing the experimental drug or treatment to current standard treatments, one part of the group will receive the experimental drug or treatment and the other part of the group will receive a standard treatment or a placebo (a treatment that has no effect), in a randomized manner. Considerations: Consider these clinical trials high risk given its experimental nature and

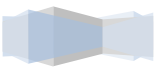
	intervention in a subject's standard of care. With regard to liability, the highest protections should be sought (i.e. indemnification, insurance). In addition, since the nature of the drug is unknown, expect sponsors to aggressively protect intellectual property rights.
Phase 4:	After the drug or treatment is approved by the U.S. Food and Drug Administration (FDA), Phase IV clinical trials (also known as post-marketing studies) may be conducted to collect more information including the drug or treatment's risks, benefits, and the best method to use it. These studies are less risky and tend to be observational studies. Warning! Look out for clinical trial that involves an FDA-Approved drug but is focused on the safety and efficacy of a new indication. If a study involves a FDA approved drug *but* the study appears to be a safety/efficacy study, most likely the sponsor is seeking FDA approval for a new indication. These studies should be treated as a Phase I-III study. The only way to make this determination is to read the protocol.

B. Device Studies

Determine if the Study Device is a Class I, II, or III. For purposes of evaluating the compensation provisions, determine whether it is a Category A or B device.

Assess Risk of the Study…	
Class I **General Controls**	Class I devices present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices. These devices are subject only to general controls. *Examples: tongue depressors, bedpans, elastic bandages, examination gloves, and hand-held surgical instruments and other similar types of common equipment.*
Class II: **General Controls with Special Controls**	Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness. Therefore, Class II devices are also subject to special controls. Special controls may include special labeling requirements, mandatory performance standards, and postmarket surveillance. Devices in this class are typically non-invasive. *Examples: X-ray machines, oxygen masks, PACS, powered wheelchairs, infusion pumps, surgical drapes, surgical needles and suture material, and acupuncture needles.*
Class III: **General Controls and Premarket Approval (PMA)**	Class III devices are devices in which insufficient information exists to assure safety and effectiveness through the general or special controls. Premarket approval by the FDA is required to ensure safety and efficacy. Devices with the following characteristics: (1) there is insufficient information to determine if Class I or II controls provide reasonable assurance of their safety and effectiveness; (2) they are represented as used to support or sustain human life or as being of substantial importance to prevent impairment of health; or (3) they present a potentially unreasonable risk of illness or injury. Class III devices are subject to pre-market controls in addition to general controls to ensure safety and effectiveness. *Examples: Replacement heart valves, silicone gel-filled breast implants, implanted cerebral stimulators, implantable pacemaker pulse generators and endosseous (intra-bone) implants.*

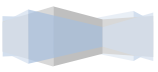
Determine Medicare Reimbursement Eligibility…	
Category A (Experimental)	Experimental – Innovative devices believed to be in a class III for which absolute risk of the device type has not been established (i.e., initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type is safe and effective). The CMS does not cover Category A devices under Medicare because they do not satisfy the statutory requirement that Medicare pay for devices determined to be reasonable and necessary. This means that costs associated with the studies of Category A devices (e.g., the device, all physician fees, inpatient and outpatient services) will not be covered by Medicare. Other insurers have followed Medicare's example and are unlikely to cover Category A devices. Thus, if a study involves a Category A device, make sure all compensation is covered by the sponsor.
Category B (Investigational; Non-experimental)	Non-experimental and/or investigational devices believed to be in classes I or II or devices believed to be in Class III where the increment risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. CMS may cover Category B devices if they are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met. Before initiating study, the PI and Research staff will need to contact CMS for approval.



II. Characterize the Principal Investigator.

There are many different arrangements in which DrexelMed researchers are associated with the Institution. Research by an investigator who is not a full-time employee of the Institution is not permitted unless the investigator's employer and the Institution have entered into a services agreement. Below is a list of the different arrangements between the Institution and investigators.

Employer	Specific Instructions
DrexelMed (Full-time Employment)	Covered under Institution's risk management program. Follow guidelines.
DrexelMed (Part-time Employment)	Not covered under Institution's risk management program. Determine the investigator's full-time employer. If principal investigator is not a member of a medical practice listed below, then notify the legal department before moving forward.
DrexelMed (Volunteer)	Not covered under Institution's risk management program. Determine the investigator's full-time employer. If principal investigator is not a member of a medical practice listed below, then notify the attorney before moving forward.
Hospitals	
Tenet – Hahnemann (Full-Time)	Not covered under Institution's risk management program. However, Institution and Tenet have managed risk under a written agreement. Sponsor will be required to provide indemnification for Tenet under the same terms and conditions as it provides for Institution. See indemnification guidelines.
Tenet – St. Christopher's Hospital for Children (Full-Time)	Not covered under Institution's risk management program. However, Institution and Tenet have managed risk under a written agreement. Sponsor will be required to provide indemnification for Tenet under the same terms and conditions as it provides for Institution. See indemnification guidelines.
Medical Practices	
Cardiology Consultants of Philadelphia (CCP)	Sponsor will be required to provide indemnification for the medical practice under the same terms and conditions as it provides for Institution. See indemnification guidelines.
I. Brodsky Associates	Same as above.
Philadelphia Urological Associates (PUA)	Same as above.
Rittenhouse Hematology and Oncology	Same as above.
Urologic Consultants of Southeastern PA, LLP	Same as above.



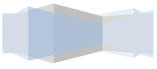
III. Determine Facilities and Services Utilized.

If the facilities, services, or records of the hospital(s) and/or any of the medical practice(s) listed below are being utilized, indemnification must be obtained for such entities. The PI and research staff will identify if such facilities, services, or records are being used in the CTA Request form. Below is a chart to assist any additional evaluation to make your determination. Also review the protocol, FDA Form 1572 and the budget to determine what facilities will be needed for the clinical trial.

Tenet will not be a named party to the agreement. If a sponsor requires

Hospital
Hahnemann
St. Christopher's Hospital for Children
Medical Practices
Cardiology Consultants of Philadelphia (CCP)
I. Brodsky Associates
Philadelphia Urological Associates (PUA)
Rittenhouse Hematology and Oncology
Urologic Consultants of Southeastern PA, LLP

Services Associated with Hospital/Medical Practices
Use of health records kept by Hahnemann/St. Christopher's Hospital for Children
Pharmacy (in-patient)
Radiology
Laboratory
Hospital- or Medical Practice owned equipment
Physician services



Clinical Trial Agreement Guidelines

I. Named Parties

1. Does the agreement correctly name the Institution?

☐ Yes.
☐ No. See below for correct legal name.

For DrexelMed:	Philadelphia Health & Education Corporation d/b/a Drexel University College of Medicine.
For SPUH:	Saint Peter's University Hospital, Inc.

2. Does the agreement correctly list the Institution's principal place of business?

☐ Yes.
☐ No. Add only if sponsor's principal address is included.

For DrexelMed:	245 N. 15th Street, Philadelphia, PA 19102
For SPUH:	254 Easton Avenue, New Brunswick, NJ 08901

3. Does the agreement list the principal investigator as a named party?

☐ Yes. The principal investigator should never be a named party to an agreement. Delete the provision appropriately. If the signature page includes a line for the principal investigator's signature, delete the signature line or add the below the signature lines for the named parties.
☐ No.

Sample: Although not a party to this Agreement, I have read and understand my obligations herein.

_____
<<PI Name>>

4. Does the agreement designate the principal investigator by name?

☐ Yes.
☐ No. Modify the agreement to designate the principal investigator by name.

Sample: _____ shall serve as the principal investigator to the Study ("**Principal Investigator**").

II. Describing the Clinical Trial

5. Does the agreement describe the clinical trial by title?

☐ Yes.
☐ No. Modify the agreement to identify the title and protocol number of the clinical trial.

Notify

6. Does the agreement define the protocol as the version approved by the IRB?

☐ Yes.
☐ No. Modify the definition of protocol to reference to the IRB approved version.

Rationale: Version control. When a protocol is being developed, many versions are generated in the process. To avoid disagreement, the parties should agree on which version the Institution will be required to follow in conducting the trial. In addition, Principal Investigator is required under regulation to conduct the clinical trial in accordance with the Protocol as approved by the IRB.

7. Does the agreement incorporate the protocol by reference?

☐ Yes.
☐ No. Modify the agreement so the protocol is incorporated into the agreement.

8. Does the agreement address in what circumstances the agreement supersedes the protocol? the protocol supersedes the agreement?

☐ Yes.
☐ No.

For non-clinical terms, the agreement should supersede the protocol. For clinical terms (including adverse event reporting), the protocol should supersede the agreement.

Sample: In the event of a conflict between the terms of this Agreement and the Protocol, this Agreement shall govern all legal (and budgetary) matters and the Protocol shall govern all clinical matters (including adverse event reporting).

III. Describing the Facilities Utilized

9. Will the clinical trial involve the use of any non-Institution (e.g. HUH, St. Christopher's Hospital for Children, medical practices) facilities or services that will be utilized in conducting the clinical trial? Will the clinical trial be conducted by an investigator or sub-investigator that is not employed by the Institution?

☐ Yes. Modify the agreement to include an acknowledgement by sponsor of such use of non-Institution facility, services, or employees. Also, modify the indemnification and HIPAA sections. See applicable sections.
☐ No.

Sample — Sponsor acknowledges that the Institution may perform certain of its obligations under this Agreement at a hospital facility or medical practice facility or <<Insert specific name of facility if required by sponsor>> which is not owned by the Institution ("Health Facility") and that the clinical trial may be performed by the employees or agents of such Health Facility under the supervision of the Principal Investigator.

Sample — Sponsor acknowledges that the Institution may perform certain of its obligations under this Agreement at a hospital facility or medical practice facility or <<Insert specific name of facility if required by sponsor>> which is not owned by the Institution ("Health Facility") and that the principal investigator is an employee of such Health Facility.

Alternative — Institution and Health Facility have entered into an agreement to allow Institution to conduct clinical research using the services and facilities of Health Facility. Institution shall ensure Health Facility abide by the terms and conditions herein.

IV. Conduct of the Clinical Trial

10. Does the agreement require the Institution or principal investigator to conduct the clinical trial in compliance with:

a) all applicable federal, state, and local laws and regulations?
b) The terms of the agreement?
c) the IRB-approved protocol or sponsor's written instructions?
d) Good Clinical Practices (GCP)

☐ Yes.
☐ No.

It is acceptable for sponsor to require a) thru d) above. However, if it is not included, modify the agreement to at least include a), b) and c).

Sample: Institution or principal investigator shall conduct the clinical trial in accordance with the IRB-approved protocol and applicable laws and regulations.

Notify

11. Does the agreement permit DrexelMed or principal investigator to deviate from the protocol to protect the safety, rights or welfare of a study subject?

☐ Yes.
☐ No. Modify the agreement stating that such deviations are (1) allowed, (2) do not constitute breach of the agreement, (3) do not constitute noncompliance of the protocol or sponsor's written instructions, and (4) shall not excuse sponsor from its obligations under the agreement.

Sample: Deviations from the Protocol necessary for the safety, rights, or welfare of a Study subject shall not constitute a breach of this Agreement, a failure to comply with the Protocol or Sponsor's written instructions, and shall not excuse Sponsor from its obligations herein, specifically its obligations of indemnification and patient injury compensation.

Rationale The Institution (and principal investigator) should have the right to deviate from the protocol or sponsor's instructions in order to protect a subject's safety, rights, or welfare. This right is necessary for several reasons. First, if a subject is having an adverse reaction to a study drug or procedure, the investigator must take all clinically necessary actions to treat the subject. The subject's well-being should take precedence over the conduct of the study. Second, the principal investigator is required to deviate from the protocol if necessary to protect subject safety, rights, or welfare under FDA Form 1572. Note also that ICH Guideline 4.5 allows principal investigators to deviate from the IRB-approved protocol to eliminate immediate hazards to subjects. Third, such deviations will alleviate any potential liability for both the institution and the sponsor by reducing any harmful effects to the subject potentially caused by the study.

V. Effective Date and Term

12. Has the study already begun? Does the agreement define the effective date?

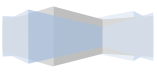
☐ Yes. Modify the agreement to be retroactively effective on the date in which the clinical trial activities first took place (e.g. IRB submission)?

☐ No. Modify the agreement to define the effective date as the last date of signature.

13. Does the agreement list a term for which the agreement will remain in effect?

☐ Yes. The term should begin from the effective date to completion of the study. If the agreement expires at a specified time, modify so the term ends upon completion of the Study.

☐ No. Modify the agreement. See above.



VI. Termination & Survival

14. Does the agreement allow the sponsor to unilaterally terminate the agreement for cause? (See below for example).

☐ Yes. This is acceptable. However, if the study is high risk or the sponsor is not stable, modify the agreement to make the provision mutual so both parties may terminate for cause. Discuss with legal is necessary.

☐ No.

Example This agreement may be terminated for cause by sponsor at any time upon thirty (30) days written notice.

Sample This agreement may be terminated for cause by ~~sponsor~~ either party at any time upon thirty (30) days written notice.

15. Does the agreement allow the sponsor to unilaterally terminate the agreement for identified causes:

a) Replacement of principal investigator not mutually agreeable.

☐ Yes. Modify the agreement to allow both parties to terminate for this reason.

☐ No.

b) Lack of IRB approval

☐ Yes. Modify the agreement to allow both parties to terminate for this reason.

☐ No.

c) Lack of enrollment.

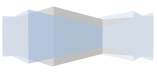
☐ Yes. Delete this provision. If sponsor insists on including this provision, seek legal review. Provisions that are based on volume conflict with the principal investigator's obligations of enrolling only subjects that meet inclusion/exclusion criteria. In addition, volume based financial arrangements may violate the Anti-Kickback Statute.

☐ No.

d) Bankruptcy.

☐ Yes. Modify the agreement to allow both parties to terminate for this reason.

☐ No.



16. Does the agreement allow the sponsor to unilaterally terminate the agreement without cause? (See example below)

☐ Yes. This is acceptable. However, Sponsor should provide reasonable notice. See below examples.

☐ No.

Example — This agreement may be terminated by sponsor at any time upon thirty (30) days written notice.

Notify

17. Does the agreement allow Institution to terminate the study to protect subject safety, rights, or welfare?

☐ Yes.

☐ No. Modify the agreement to add this right of termination. Instiutiton must be given this right of termination.

Sample — This agreement may be immediately terminated by Institution to protect the safety, rights and/or welfare of Study subjects.

18. Does the agreement require principal investigator <u>to cease</u> all enrollment of new subjects and <u>safely withdraw</u> currently enrolled subjects upon receiving notice of termination?

☐ Yes.

☐ No. Modify the agreement to add this requirement. See sample language below.

Sample — Upon receipt of a notice of termination, the Principal Investigator shall cease enrollment of new study subjects and shall safely withdraw study subjects enrolled in the Protocol to the extent medically permissible and appropriate.

19. Does the agreement allow termination of the agreement without requiring sponsor to provide compensation for services performed?

☐ Yes. Modify the agreement to require sponsor to pay for work actually performed on a pro rata basis and noncancellable costs. See sample below.

☐ No.

Sample — Sponsor shall compensate Institution on a pro rata basis in accordance with the study budget for services performed and noncancellable costs incurred prior to the date of termination <u>or the date in which the last Clinical Trial subject is safely withdrawn</u> from the Study, whichever is later.

20. Does the agreement identify the provision that will survive expiration or termination of the agreement?

☐ Yes. Assess if the provisions listed below will survive the agreement. Assess if any additional provisions should survive the agreement..
☐ No. Assess which provisions should survive termination of the agreement and add a survival provision to the agreement.

- Termination
- Confidentiality
- Publicity
- Indemnification
- Insurance
- Sponsor's HIPAA obligations
- Intellectual Property
- Publications
- Patient Injury Compensation
- Notice

Alternative #1	The rights and obligations under Section/Paragraph/Articles _____ shall survive termination or expiration of this Agreement.
Alternative #2	The terms of this Agreement that contain obligations or rights that extend beyond the completion of the Study shall survive termination or completion of this Agreement.

VII. Compensation and Compensation Terms

21. Highlight in yellow. Identify terms that relate to or affect compensation. Add comment to sponsor stating that budget analyst will review and finalize the terms.

22. Consistency. Are the payment terms consistent throughout the agreement? Compare body of the agreement to the Exhibit containing the budget.

☐ Yes.
☐ No. Discuss with CRG financial team if necessary.

23. Exhibit. Are the terms of the budget/compensation contained in a separate document (e.g. exhibit)? If so, is the separate document incorporated into the agreement.

☐ Yes. Modify the agreement to incorporate budget into the agreement.
☐ No.

Sample Sponsor shall compensate Institution in accordance with the terms and conditions contained in the Study budget attached hereto as Exhibit __, which is herein incorporated by reference.

24. Noncompliant payment terms. Do the payment terms provide for non-compliant or inappropriate payments (see list below)?

☐ Yes. Delete provision and highlight yellow for CRG financial team. If sponsor insists upon retaining provision, seek attorney review.
☐ No.

▪ Payments seem too high for services rendered
▪ Payments conditioned on volume of subjects enrolled
▪ Payments conditioned on results
▪ Payments conditioned on time lines
▪ Payments based on identifying subjects

SAINT PETER'S UNIVERSITY HOSPITAL
Notify

25. IRB Fees. Does the agreement include IRB fees invoiced by and paid directly to WIRB?

☐ Yes.
☐ No. Modify agreement to require Sponsor to be invoiced directly by WIRB and to make these payments.

Sample A one-time IRB Review Processing fee will be reimbursed upon receipt of an original invoice. If necessary, IRB renewal fees will be reimbursed upon receipt of an IRB invoice. Central IRB Fees will be paid directly through invoicing to Sponsor from IRB.

26. IRB Submitted. Will the protocol be or has been submitted to WIRB prior to execution of the agreement?

☐ Yes. Discuss with the study coordinator and CRG financial team to make sure sponsor has approved WIRB costs. If the contract is not executed, DrexelMed will be held responsible for the WIRB costs if sponsor does not agree to make payment or WIRB may assess late fees if sponsor will not make payments until contract is executed.

☐ No.

27. Does the contract, funding agreement, or associated budget include "finder's fees" (Payments to professionals in exchange for referrals of subjects)?

☐ Yes. Remove them from the contract as they are prohibited by Drexel's Human Research Protection Program Policy.

☐ No.

28. Does the contract, funding agreement, or associated budget include "bonus payments" (Payments to investigators or research staff in exchange for referrals of subjects)?

☐ Yes. Remove them from the contract as they are prohibited by Drexel's Human Research Protection Program Policy.

☐ No.

29. Billing Information. Does the agreement require billing information?

☐ Yes. Make sure all the information listed below is included.

☐ No. Add the below information.

Checks made payable to :	Philadelphia Health and Education Corporation
Name of organization, attention:	TD Bank PHEC Grant Lockbox
Reference:	(<<Insert PI Name>> / Project # <<Institution Id No>>)
Address:	PO Box 95000-1010 Philadelphia, PA 19195-1010
Tax Identification #:	23-2979433

Checks made payable to :	Saint Peter's University Hospital, Inc.
Name of organization, attention:	TBD
Reference:	(_____/ _____ /SPUH Id. No. XXXX)
Address:	Office of Research 254 Easton Avenue New Brunswick, NJ 08903
Tax Identification #:	221-487-330

VIII. Supply of Study Drug and Cost of Study Procedures

30. Does the agreement state that the sponsor will provide the drug/device free of charge?

☐ Yes.

☐ No. Determine whether sponsor will be providing the drug/device free of charge. If a device is involved in the study, determine if specialized pricing is needed/offered and whether the health facility (e.g. hospital) requires a separate device cost agreement.

31. Will the sponsor pay for drug/device/procedures required by the protocol with regard to <u>all</u> clinical trial subjects?

☐ Yes.

☐ No. If sponsor is only paying for drug/device/procedures required by the protocol for only some of the clinical trial subjects, determine how this will be determined. Will it be determined on the Study subject's ability to pay? Will such payment of drug/device/procedures create an undue influence to participate in the clinical trial? Seek legal review.

32. Does the agreement require that the Institution not charge or seek reimbursement from the subject, any federal or state program or any third party insurance for the drug, device, or any procedure or other service required by the Protocol <u>and</u> for which Sponsor provides reimbursement or payment to Institution?

☐ Yes. This is acceptable since double billing is prohibited under law (i.e. sites cannot seek reimbursement for drugs/devices/services it receives free of charge from sponsors)

☐ No.

33. Does the agreement require the Institution and/or the investigator to handle, store, maintain the drug or device properly? in accordance with Good Clinical Practice?

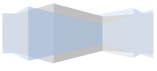
☐ Yes. This is acceptable. However, the Institution should not be liable for loss or damage to drugs or devices.

☐ No.

34. Does the agreement require the Institution and/or the investigator to return or destroy drug or device?

☐ Yes. This is acceptable as long as such return is paid by sponsor and upon sponsor's request or upon completion of the clinical trial or upon expiration/termination of the agreement.

☐ No.



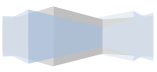
IX. Agreement Research Organizations and Other Sponsor Agents

35. Is sponsor utilizing a CRO to manage, monitor, administrate or conduct the clinical trial?

☐ Yes. Modify the agreement to require sponsor to bind the CRO in writing to the terms of the agreement and be responsible for non-compliance by the CRO.

☐ No.

Sample If Sponsor designates a contract research organization or other agent ("**CRO**") to manage, monitor, or conduct the Study, Sponsor shall bind such CRO in writing to the terms of this Agreement and shall be responsible for ensuring CRO is comliant with the terms and conditions herein.



X. HIPAA and Reporting and Monitoring of Clinical Trial

36. Does the agreement require the Institution to provide sponsor, CRO, and other agents and monitors access to facilities and records for purpose of auditing and monitoring?

☐ Yes. Make sure such access can be given at mutually agreed upon times. Such access should only be given for auditing and monitoring.

☐ No.

Sample

Institution shall permit Sponsor and/or its agents and monitors at a mutually agreed upon time during normal business hours access to Study site(s) to monitor the conduct of the Study as well as audit records, case report forms, source documentation, and other data relating to the clinical trial, in order to verify Institution's compliance with its obligations herein. Additionally, Institution shall permit regulatory authorities including, but not limited to, the United Stated Food and Drug Administration (FDA), access to the same. Sponsor and/or its agents and monitors shall abide by Institution and Health Facility policies and procedures to access such records and facilities.

Notify

37. Does the contract or funding agreement obligate the sponsor to promptly provide study monitor reports to the investigator?

☐ Yes

☐ No. Modify the agreement to obligate the sponsor to promptly provide study monitor reports to the investigator. *(When clinical trials are monitored, sponsors or CRO representatives periodically review whether the research is being conducted according to the protocol. The intent of this requirement is that sponsors require monitors to share the results of their monitoring with the investigator so the investigator can take corrective action when necessary.)*

☐ N/A (If the sponsor will not be monitoring the research)

38. Does the agreement require the Institution to provide governmental agencies or regulatory authorities access to facilities and records for purpose of auditing and monitoring?

☐ Yes. This is acceptable. Access can be given at any time since regulatory authorities are permitted to audit at any time.

☐ No.

Notify

39. Does the agreement require sponsor to abide by policies and procedures to access facilities and records?

☐ Yes.

☐ No. Modify agreement to require sponsor and its agents and monitors to abide by the policies and procedures of Institution as well as any health facilities utilized for the conduct of the clinical trial. See last sentence in the above sample language.

Sample

Institution shall permit Sponsor and/or its agents and monitors at a mutually agreed upon time during normal business hours access to Study site(s) to monitor the conduct of the Study as well as audit records, case report forms, source documentation, and other data relating to the clinical trial, in order to verify Institution's compliance with its obligations herein. Additionally, Institution shall permit regulatory authorities including, but not limited to, the United Stated Food and Drug Administration (FDA), access to the same. Sponsor and/or its agents and monitors shall abide by Institution and Health Facility policies and procedures to access such records and facilities.

Notify

40. Does the agreement require the sponsor to ensure the confidentiality of clinical trial subject's health information? To comply with applicable laws with regard to such health information? To comply with the signed HIPAA authorization?

☐ Yes. The below provision is required. Copy and paste this provision into the agreement or ensure that all acknowledgements and requirements are included.

☐ No. See above.

Sample

Sponsor and CRO acknowledge that Institution and Health Facility are patient care facilities and considered covered entities under HIPAA. As a patient care facility and covered entity, Institution and Health Facility must protect and secure patient care areas as well as patient health information. Sponsor, CRO and their monitors and agents hereby acknowledge that they will be asked to comply with Institution and Health Facility's security policies and procedures in order to access any Study facilities and records including but not limited to the above referenced original source documentation and that failure to follow such policies and procedures may result in a denial of such access. In the event Sponsor, CRO, its agents and monitors come into contact or otherwise have access to a Study subject's medical records or any Protected Health Information as defined under HIPAA ("PHI"), then Sponsor shall ensure such information and the identity of such Study subject is held in confidence and treated in accordance with all applicable laws and regulations as well as the HIPAA Authorization provided by the subject. If Sponsor, CRO or their agents or monitors, gain access to medical records and PHI of a patient not participating in the Study, Sponsor and CRO shall ensure that such information and the identity of such patient is held in confidence. Sponsor shall also ensure that if any records containing such information, is removed from Institution or Health Facility's facilities, such records are immediately returned to Institution.

Notify

41. Does the contract or funding agreement obligate the sponsor to communicate to the investigator results uncovered after study closure that directly affect subject safety? This obligation may be limited to a number of years after study closure.

☐ Yes

☐ No. Modify to obligate the sponsor to communicate to the investigator results uncovered after study closure that directly affect subject safety. This obligation may be limited to a number of years after study closure. *(This is NOT the same as adverse event reporting. The intent of this provision is that if*

the sponsor discovers through analysis of data after study closure (e.g., the research put the subjects at long term risk for heart attacks even after stopping the study drug), the sponsor will tell the investigator so that the investigator can take appropriate actions to provide clinical care for the subject (e.g., screening for risk of heart attacks with interventions to reduce other risk factors.)

Sample

For a period of up to two years after study closure, if the sponsor or CRO uncovers findings through the analysis of collected data that directly affect subject safety, the sponsor and CRO agree to communicate those findings to the investigator.

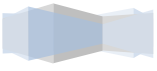
☐N/A (The research does not involve medical procedures)

42. Does the contract or funding agreement obligate the sponsor to provide data and safety monitoring reports to the investigator within a specified time-frame? The time frames should cover routine and urgent reports. Alternatively, the time frame may be left open-ended or the requirement can be included or referred to in a survivor clause.

☐Yes
☐No. Include langeuage that obligates the sponsor to provide data and safety monitoring reports to the investigator within 30 days.
☐N/A (The research involves no more than Minimal Risk or injury, the research does not have a data and safety monitoring plan or the investigator is responsible for the data and safety monitoring plan).

43. Does the agreement require the sponsor to ensure the confidentiality of health information of patients who are not clinical trial subjects? Does the agreement require sponsor to return any records containing such records?

☐ Yes.
☐ No. Modify the agreement to require the above.



XI. Confidentiality

44. Does the definition of "Confidential Information" limit the disclosures to information relating to the study and/or the study drug/device? Information disclosed in connection with the clinical trial or the agreement?

☐ Yes.

☐ No. Modify the definition to information disclosed by or on behalf of the sponsor relating to the study and/or the study drug/device in connection with the agreement. See the CDA template for sample language

45. Does the agreement expressly state that the Institution shall not disclose the Confidential Information to third parties or individuals who are not conducting the clinical trial?

☐ Yes.

☐ No. Modify the agreement to obligate the Institution to not disclose such information to third parties who are not conducting the study. See the CDA template for sample language.

Notify

46. Does the agreement require the Institution to not disclose or use Confidential Information for a definite period of time (e.g. 5 years)?

☐ Yes. Limit the obligation to 5-10 years. Does the period begin upon disclosure? If so, modify the agreement so the period begins upon the effective date or expiration/termination of the agreement. The same time period should apply to all disclosures. This will ensure compliance with the terms of confidentiality and non-use.

☐ No. Modify the agreement to limit the Institution's obligation to 5-10 years following expiration or termination of the agreement.

47. Does the agreement identify the following Confidential information as excepted from the Institution's obligations of confidentiality and non-use?

a) Confidential Information that is public knowledge?

☐ Yes. This is acceptable. However, the Institution should not be required to provide written records that such Confidential Information is public since the information should be readily available to the sponsor. Also, the exception should not require that such Confidential Information became public through no fault of the Institution. In this instance, if the Institution disclosed the Confidential Information to the public prior to the effective date of the agreement, it was under no obligations of confidentiality or non-use to the sponsor, and such provision would create a breach of agreement by the Institution.

☐ No. Modify the agreement to include this exception. See the CDA template for sample language.

'

b) Confidential Information that has become public knowledge after disclosure?

☐ Yes. This is acceptable. However, the Institution should not be required to provide written records that such Confidential Information is public since the information should be readily available to the sponsor. It is acceptable to require that public disclosure of the Confidential Information occur through no fault of the Institution since the Institution is under an obligation of confidentiality and non-use for disclosures subsequent to the effective date of the agreement.
☐ No. Modify the agreement to include this exception. See the CDA template for sample language.

c) Confidential Information that is disclosed by a third party?

☐ Yes. This is acceptable. It is also acceptable to require that the third party have a legal right to disclose such information. However, the Institution should not be required to provide written records that such third party has such a legal right. Such records would be held by the third party and the Institution may not have the right to require the third party to provide such written record. Alternatively, written records may not exist (e.g. if the third party independently developed the Confidential Information).
☐ No. Modify the agreement to include this exception. See the CDA template for sample language.

d) Confidential Information that is already known or possessed by the Institution?

☐ Yes. This is acceptable. It is also acceptable to require that the Institution provide written records of such prior knowledge or possession. However, any type of legal standard should not be imposed on the Institution in providing such written records. See examples below.
☐ No. Modify the agreement to include this exception. See the CDA template for sample language.

Example	is already known or possessed by Institution at the time of disclosure provided that such prior knowledge or possession is ~~evidenced~~ by written record.
Example	is already known or possessed by Institution at the time of disclosure provided that Institution demonstrates through ~~competent evidence~~ of such prior knowledge or possession.

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Notify Deal Breaker

e) Confidential Information that is independently developed by the employees or agents of the Institution?

☐ Yes. This is acceptable. It is also acceptable to require that the Institution provide written records of such independent development. However, any type of legal standard should not be imposed on the Institution in providing such written records. See examples above. Also, the exception should apply to the employees or agents of the Institution. See the CDA template for sample language. In addition, the exception should not exclude Institution employees or agents (e.g. principal investigator) to whom confidential information has been disclosed. See example below.
☐ No. Modify the agreement to include this exception. See the CDA template for sample language.

Example	Is independently developed by employees or agents of Institution, who ~~have not participated in the conduct of the clinical trial~~, without the aid, or use of Confidential

	Information, provided the Institution can provide written record of such independent development.
Example	Is independently developed by employees or agents of Institution, except ~~those individuals who have participated in the conduct of the clinical trial~~, without the aid, or use of Confidential Information, provided the Institution can provide written record of such independent development.
Example	Is independently developed by employees or agents of Institution, except ~~the principal investigator and/or other investigators~~, without the aid, or use of Confidential Information, provided the Institution can provide written record of such independent development.
Example	Is independently developed ~~prior to disclosure of Confidential Information~~ by employees or agents of Institution without the aid, or use of such Confidential Information, provided the Institution can provide written record of such independent development.

f) Confidential Information that is required by a governmental authority to be disclosed

☐ Yes. This is acceptable. However, it is not acceptable to require the Institution to take steps to limit the disclosure or seek confidential treatment from the governmental authority. See example below. It is acceptable to allow the sponsor to take steps to limit the disclosure or seek confidential treatment from the governmental authority. It is acceptable to require the Institution to only disclose information that it is required to disclosure under the governmental order and not offer additional Confidential Information.

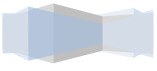
☐ No. Modify the agreement to include this exception. See the CDA template for sample language.

Example	Is required by law, regulation, rule, act, or any other order of any governmental authority or agency to be disclosed by Institution ~~provided that Institution take steps to limit such disclosure or seek confidential treatment from such governmental authority~~, which notice of such requirement shall be timely provided to allow Sponsor to seek protective order or other similar order.
Example	Is required by law, regulation, rule, act, or any other order of any governmental authority or agency to be disclosed by Institution provided that Institution only disclose Confidential Information that is required under such order and, which notice of such requirement shall be timely provided to allow Sponsor to seek protective order or other similar order.

48. Does the agreement require the Institution to destroy or return Confidential Information?

☐ Yes. This is acceptable. However, the Institution must be permitted to keep one copy in a secure location for the sole purpose of ensuring compliance with its confidentiality and nonuse obligations under the agreement.

☐ No.



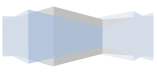
XII. Use of Data and Results

49. Does the agreement prohibit the Institution from using the data and results of the clinical trial? Does the agreement prohibit the Institution from using the data and results of the clinical trial for commercial purposes?

☐ Yes. Modify the agreement to permit the Institution to use the data and results of the clinical trial for its own clinical, educational, and research purposes.

☐ No. Modify the agreement to permit all three uses. See example below.

Example	Institution may use the data and results of the Clinical Trial for its own internal clinical, educational, and research purposes.



XIII. Publicity

50. Does the agreement allow the sponsor to use the Institution's or principal investigator's name in any advertising, endorsement, or promotion?

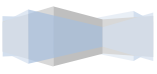
☐ Yes. Delete this provision. However, sponsors may use the Institution's or principal investigator's name in regulatory filings as required by governmental agencies to identify the Institution's and principal investigator's participation in the clinical trial. If the sponsor insists on using the Institution's or principal investigator's name for any other purpose, seek advice from legal counsel.

☐ No.

51. Does the agreement allow the sponsor to post the study and other required information on www.clinicaltrials.gov ?

☐ Yes. This is permitted.

☐ No.



XIV. Publications and Presentations

The agreement should not restrict the Institution's right to publish any data and results of the clinical trial, particularly the sponsor should not be given the right to restrict or prohibit publication. However, the Institution/PI may be required to submit the publication to sponsor for review, comment and to ensure protection of certain information. See below.

52. Does the agreement require that the Institution submit any proposed publications to sponsor prior to such publication?

☐ Yes. This is acceptable provided that sponsor only be permitted to review, comment and/or ensure that no confidential information or potential patentable information is being disclosed. The Institution may provide sponsor a copy of the proposed manuscript up to thirty (30) days prior to such publication. Upon review, sponsor may only request that confidential information or patentable information be deleted, or delay publication for an additional sixty (60) days to allow sponsor to seek protect the patentability of such information. Such review period should not exceed sixty (60) days and such review and delay period should not exceed a total of sixty (60) days. If sponsor requests an extended total review and delay period, seek advice from legal counsel. See underlined sample below.

☐ No.

Sample	If Institution or Principal Investigator prepares any presentation or publication, Institution or Principal Investigator shall provide Sponsor with a manuscript of the presentation or publication thirty (30) days prior to such presentation or publication for the sole purpose of ensuring protection of Confidential Information or patentable information. If requested by Sponsor, Institution shall delay submission of manuscripts for publication up to sixty (60) days to permit preparation and filing of related patent applications.

53. Does such requirement provide sponsor with the ability to prohibit such publication?

☐ Yes. Delete this provision. Sponsor should not have the ability to prohibit a publication. Sponsor, however, may have the right to review and comment on a publication and require the Institution to delete confidential information.

☐ No.

Sample	If Institution or Principal Investigator prepares any presentation or publication, Institution or Principal Investigator shall provide Sponsor with a manuscript of the presentation or publication thirty (30) days prior to such presentation or publication for the sole purpose of ensuring protection of Confidential Information or patentable information. If requested by Sponsor, Institution shall remove identified Confidential Information or delay submission of manuscripts for publication up to sixty (60) days to permit preparation and filing of related patent applications. Sponsor shall also be permitted to comment on the manuscript for the Institution's consideration. The Institution shall have sole consideration and ultimate approval of such publication.

54. Does such requirement provide sponsor with the ability to require change, addition, or deletion of all or part of the publication?

☐ Yes. The only information for which Sponsor will have a right to require deletion is confidential information. See above example.

☐ No.

Notify

55. Does the agreement require the Institution to delay such publication to allow sponsor to patent or otherwise seek protection of intellectual property?

☐ Yes. This is acceptable. See above for acceptable time period for delay in publication. For SPUH, seek 60 days in the first round and 90 days in the second round.

☐ No.

Notify

56. For multi-site trials, does the agreement restrict the Institution's ability to publish the clinical trial results prior to a publication of the multi-center results?

☐ Yes. This is acceptable provided the Institution may publish after publication of multi-center results, twelve ((12) months after completion of the clinical trial, or it is decided not to publish the multi-center results, whichever is later. Publication can be delayed up to eighteen (18) months.

☐ No.

Sample Institution and Principal Investigator each acknowledge that the Study is part of a multi-center study, and that an independent, joint publication may be authored by investigators in the multi-center study, including Principal Investigator. Therefore, Institution and Principal Investigator each agree not to publish or present the results of the Study before the publication of the multi-center publication, but in no event shall Institution or Principal Investigator be restricted after the expiration of twelve (12) months from completion of the Study or it is decided that such multi-center results will not be published.

XV. Intellectual Property

Provisions relating to intellectual property should be reviewed by legal. Rights and obligations of each party should be considered as whole when negotiating these provisions. It is important to assess whether there is potential for inventions during the conduct of the study and the PI's expertise.

57. Does the agreement affirmatively state that no right or license in any intellectual property is being granted or otherwise transferred by the Institution or sponsor unless specifically indicated in the agreement?

☐ Yes.
☐ No. Modify the agreement to include this provision.

58. Does the agreement require that any intellectual property or invention discovered as a result of the clinical trial be owned by the sponsor?

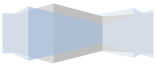
☐ Yes. Modify the agreement to permit sponsor to own only intellectual property or inventions relating to the clinical trial drug/device that are discovered during the conduct of the study. In addition, such inventions should be conceived and/or reduced to practice during the conduct of the clinical trial.
☐ No. Does the agreement give the sponsor an option to obtain such ownership rights? If so, see below guidelines regarding option rights.

59. Does the agreement permit the Institution to own all other intellectual property (e.g. inventions)?

☐ Yes. Does the agreement also give the sponsor an option to obtain such ownership rights? Such option should be limited to ownership rights to intellectual property (e.g. inventions) that are created during the conduct of the study or created as a direct result of the conduct of the study.
☐ No. Consider adding an acknowledgment that the Institution shall own intellectual property (e.g. inventions) that are not owned by sponsor. This is not required unless the PI notifies that there is a potential for discovery of inventions.

60. Does the agreement address intellectual property created by both the sponsor and Institution?

☐ Yes. If the provision gives sponsor sole ownership, limit such ownership as directed above. In addition, consider adding a provision giving sponsor an option to obtain ownership as described above.
☐ No. This is ok.



61. Does the agreement require the Institution to prepare, prosecute, and/or maintain any patents and patent applications?

☐ Yes. Determine who owns the patent:

If the Institution owns the patent, this requirement is acceptable. However, if the agreement includes an option for sponsor to obtain a license in such patent and sponsor exercises such option, then modify the agreement to require sponsor to pay for such preparation, prosecution, and maintenance.

If the sponsor owns the patent, sponsor should be responsible for preparing, prosecuting, and maintaining the patent and patent application. However, the Institution may be required, at sponsor's expense, to cooperate with sponsor, provide clinical trial information, and/or provide support to sponsor in the preparation and prosecution of such patent.

If both the Institution and sponsor jointly own the patent, then modify the agreement so both parties automatically share the expense and, if sponsor decides not to share in the expense, the Institution is permitted to prepare, prosecute, and maintain such patents and sponsor loses its option, if applicable, to obtain ownership rights in such joint patent.

☐ No. Modify the agreement to acknowledge that the Institution shall own intellectual property (e.g. inventions) that are not owned by sponsor.

62. Does the agreement give sponsor an option to obtain a license in any intellectual property (e.g. inventions) owned by the Institution?

☐ Yes. Sponsor's option should not be a right of ownership. It should be an option to negotiate a license to use the intellectual property. The below provisions should be added.

☐ No.

a) Does the agreement identify the type of license the option covers?

☐ Yes. The option may include a right to negotiate an exclusive, worldwide license to make, use, sell and/or import such intellectual property.

☐ No.

b) Does the agreement require a time period for sponsor to exercise the option? Does the agreement require a time period for the parties to negotiate the license?

☐ Yes. Such option should begin upon receiving sixty (60) day notice from the Institution. The sponsor must exercise its option within the sixty (60) day period. Upon exercising its option, the negotiations for the license should not exceed ninety (90) days. Both the notice and negotiations period may be adjusted but together should not exceed one hundred fifty (150) days.

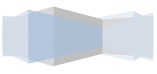
☐ No. Modify the agreement to require the above time period.

c) Does the agreement require the parties to negotiate certain terms?

☐ Yes. Seek legal advice.

☐ No. Modify the agreement to require a royalty to the Institution.

Sample The agreement shall contain reasonable terms and conditions that are usual and customary for such invention, which shall include a royalty for such license based upon the commercial value of the Inventions.



XVI. Indemnification

Notify The Entire Section

63. Does the agreement require Sponsor to indemnify, defend, and hold harmless?

☐ Yes. Make sure all three obligations are included.

☐ No. Modify the agreement to obligate the sponsor to indemnify, defend, and hold harmless. In order to ensure that sponsor will provide complete protection from liability, all three obligations should be secured. If a sponsor refuses any of the three obligations, seek legal counsel. When a sponsor agrees to indemnify the Institution, it agrees to compensate or reimburse Institution for losses or damages incurred. When a sponsor agrees to defend the Institution, it agrees that it will provide the Institution with legal defense to demands, claims, actions, or law suits. When a sponsor agrees to hold the Institution harmless, the sponsor agrees to assume the potential liability for injury that may arise from a situation and relieve the Institution of such liability.

Sample	Sponsor shall indemnify, defend, and hold Institution, its IRB, and their directors, officers, employees, and other agents ("Institution Indemnitees") harmless from and against any and all liability, claims, demands, lawsuits, actions, losses, damages, costs or expenses (including reasonable attorneys' fees) ("Claims") for any injury

64. Does the agreement require the Sponsor to indemnify, defend, and hold not only the Institution but also its IRB and their directors, officers, employees, and other agents, harmless?

☐ Yes. Make sure that the indemnification includes all individuals described above.

☐ No. Modify the agreement to include the Institution as well as the Institution's directors, officers, employees, and other agents. See sample language above.

65. If non-Institution owned facilities (e.g. Health Facilities such as Tenet or the medical practices listed in the assessment) are being utilized, does the agreement require the Sponsor to indemnify, defend, and hold not only the Institution but also Health Facilities and their directors, officers, employees, and other agents, harmless?

☐ Yes. Make sure that the indemnification includes Health Facilities and their directors, officers, employees and other agents.

☐ No. Modify the agreement to include the Health Facilities and their directors, officers, employees, and other agents. See sample language above.

66. Does sponsor's indemnification cover all liability, claims, demands, lawsuits, actions, losses, damages, costs and expenses (including attorney's fees)?

☐ Yes. Make sure that sponsor's indemnification includes all the above ways in which the Institution could be liable.

☐ No. Modify the agreement to include all the following ways in which the Institution could be liable:

Liability	This is a general term and serves as a catchall.
Claims, lawsuits, actions	These terms refer to formal methods (i.e. via court system) in which a third party can seek retribution.
Demands	This term refers to an informal method (e.g. sending a letter to the Institution and requesting a settlement in exchange for not filing a

	claim or law suit) in which a third party can seek retribution.
Losses/Damages	These terms refer to the amount the Institution will be required by a court or governmental entity to pay or agrees to pay by settlement to a third party as a result of a claim, lawsuit, action, or demand.
Costs/Expenses	These terms refer to the cost of handling a claim, lawsuit, action, or demand, such as court costs and attorney's fees.

67. Does sponsor's indemnification cover the following liability:

a) Injury from the use of the study drug or device?

☐ Yes.

☐ No. If the coverage includes indemnification for conduct of the clinical trial, modification is not necessary. Otherwise, modify the agreement to include this coverage.

b) Injury from procedures required by the Protocol?

☐ Yes.

☐ No. If the coverage includes indemnification for conduct of the clinical trial, modification is not necessary. Otherwise, modify the agreement to include this coverage.

c) Injury from use of the clinical trial results, data, and source documentation including but not limited to health records and information, by Sponsor and its agents?

☐ Yes.

☐ No. Modify the agreement to include this coverage.

Rationale: As a covered entity, the Institution must protect patient health information and obtain authorization from clinical trial subjects for the disclosure and use of health information by sponsor. If sponsor fails to abide by the authorizations provided by the clinical trial subjects, the Institution may be liable for such unauthorized use. Note that the agreement will most likely require the Institution to obtain sponsor approval on the authorization form submitted to the IRB and obtained from the clinical trial subjects.

d) Injury from the negligence or willful misconduct of Sponsor or its agents?

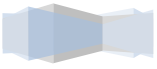
☐ Yes.

☐ No. Modify the agreement to include this coverage. This coverage aims to cover liability that is not covered by a) thru c) above. This coverage is often considered a standard provision.

e) Injury from breach of this Agreement by Sponsor?

☐ Yes.

☐ No. Modify the agreement to include this coverage. This coverage aims to cover liability that is not covered by a) thru c) above. This coverage is often considered a standard provision.



68. Does the agreement require or infer any type of proof of causation in order to trigger sponsor's indemnification obligation? See example below.

☐ Yes. Modify the agreement by removing the causation requirement.
☐ No.

Example	Sponsor shall indemnify Institution, its IRB, and their directors, officers, employees, agents, and representatives ("Institution Indemnitees") from and against any and all liability, claims, demands, lawsuits, losses, damages, costs or expenses (including reasonable attorneys' fees) ("Claims") for injury ~~resulting from~~ arising from (a) the use of the Study Drug, (b) procedures required by the Protocol, …
Example	Sponsor shall indemnify Institution, its IRB, and their directors, officers, employees, agents, and representatives ("Institution Indemnitees") from and against any and all liability, claims, demands, lawsuits, losses, damages, costs or expenses (including reasonable attorneys' fees) ("Claims") for injury ~~caused by~~ arising from (a) the use of the Study Drug, (b) procedures required by the Protocol, …

69. Does the agreement provide for circumstances in which sponsor will <u>not</u> indemnify the Institution?

☐ Yes. Sponsor's indemnification should not apply <u>only to the extent</u> that injuries are <u>caused by</u> the Institution's negligence and willful misconduct. Modify the agreement only to allow this exception. All other exceptions should be deleted. Also, modify the agreement so the exception does not completely nullify sponsor's indemnification obligations but rather nullifies sponsor's indemnification to the extent the injury is caused by the Institution's negligent or willful misconduct. This is important since it is possible that the sponsor and the Institution will both be liable. Such a provision ensures that sponsor will still be obligated to indemnify the Institution to the extent a) thru e) above.
☐ No.

70. Does the agreement require sponsor to not settle any claims or otherwise dispose of a claim that requires an admittance of fault by the Institution or requires specific performance?

☐ Yes.
☐ No. Modify the agreement to include this provision. See sample language below.

Sample	Sponsor shall not settle any claims in which settlement involves the admission of fault by Institution Indemnitees or specific performance without written consent from Institution.

71. Does the agreement require the Institution to indemnify sponsor?

☐ Yes. Delete this provision. If sponsor requires indemnification, the Institution will indemnify for its negligence and willful misconduct. Modify agreement so the Institution will not indemnify sponsor for claims for injury caused by the Sponsor's negligence or willful misconduct or breach of agreement. In addition, modify the agreement to require sponsor to provide prompt notice of any claims.
☐ No.

XVII. Compensation for Research Related Injury

Notify The Entire Section

This provision requires legal review. The Institution requires sponsors to compensate for research related injuries. Please see the Institution's policy on Research Related Injuries.

72. Does the agreement require sponsor to compensate for medical treatment for study subjects who have sustained injuries due to their participation in the clinical trial?

☐ Yes.

☐ No. Using the below chart, evaluate whether sponsor should be required to provide compensation for injury sustained by clinical trial subjects.

Patient Injury Compensation Required	
Safety/Efficacy Trials	Phase I, II, and III clinical trials.
Device Trials	All clinical trials involving investigational devices. Exceptions may be given for clinical trials involving FDA-approved devices.

Patient Injury Compensation Not Required	
Observational Research	Review the protocol. Even if a protocol states that the research is observational in design, review the procedures required by the protocol and discuss with CRG financial. If any procedure is not standard of care, the research is not observational and compensation for RRI is required. If the protocol only requires standard of care treatment, compensation for RRI is not required.
Chart Review	If the research only involves reviewing a subject's existing medical records, compensation for RRI is not required.
Post-Marketing Research	Since the trial involves a FDA-approved drug, most sponsors will not provide compensation for RRI since drug treatment is most probably standard of care. However, evaluate the research and make sure all procedures are standard of care. If non-standard of care procedures are required, PIC is required.

73. Does compensation for RRI cover medical treatment provided by other healthcare facilities?

☐ Yes.

☐ No. Modify the agreement to require sponsor's compensation to cover the cost of medical treatment provided by third party healthcare facilities. During emergency situations, subjects may only be able to seek medical treatment at healthcare facilities not owned by the Institution. In addition, after incurring injury, subjects may not wish to be treated by the Institution.

74. Does the compensation for RRI exclude compensation covered by clinical trial subject's insurance or third party carrier?

☐ Yes. This exclusion should be deleted.

☐ No.

75. Does PIC exclude any of the following:

a) Injuries caused by the natural progression of the disease?

☐ Yes. This is acceptable.
☐ No.

b) Injuries caused by the Institution's negligence or willful misconduct?

☐ Yes. This is acceptable.
☐ No.

c) Injuries caused by the subject's failure to follow the protocol?

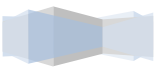
☐ Yes. This is not acceptable. If sponsor requires this provision, seek advice from legal counsel.
☐ No.

76. Are the above questions consistent with the following standard consent document language?

> The medical treatment for your research-related injury will be provided at no cost to you. A "research related-injury" means injury caused by any Study [drugs/device] or procedures required by the research which you would not have experienced if you had not participated in the research study. You or your medical insurance will be responsible for other medical expenses resulting from your medical condition. You will not be paid for any other injury- or illness-related costs, such as lost wages. However, you are not waiving any legal rights by you participating in this study. If you have questions, please call Dr. [name] at telephone no. (XXX) XXX-XXXX.

☐ Yes
☐ No
☐ N/A (The research involves no more than Minimal Risk of injury).

NOTE: INSTITUTION CURRENTLY ESTABLISHING CLINICAL TRIAL INSURANCE. THIS SECTION MAY BE MODIFIED BASED ON INSURANCE REUQIREMENTS.



XVIII. Insurance

77. Does the agreement require sponsor to maintain insurance?

☐ Yes. Make sure such insurance coverage requirement listed below are required.
☐ No. Modify the agreement to include the below insurance requirements.

Type	Coverage
General Liability	$5Million per occurrence / $5Million in the aggregate
Products Liability	$5Million per occurrence / $5Million in the aggregate
Contracts Liability	$5Million per occurrence / $5Million in the aggregate

78. Does the agreement require the Institution to maintain insurance coverage?

☐ Yes. Modify agreement to require the Institution to maintain insurance coverage as required by state law. If sponsor requires additional coverage, see below for the Institution's insurance coverage. If any other coverage is required, seek attorney review.
☐ No.

Type	Coverage
General Liability	$1M occurrence / $3M aggregate
Professional Liability	$1M occurrence /$3M aggregate

79. Does the agreement require sponsor to provide the Institution a certificate of insurance upon request?

☐ Yes.
☐ No. Modify agreement to include this requirement.

80. Does the agreement require sponsor to notify the Institution upon cancellation or material change to its insurance coverage?

☐ Yes.
☐ No. Modify the agreement to include this requirement.

XIX. General Provisions

81. Independent Contractors. Does the agreement affirmatively state that the sponsor and the Institution are independent contractors and that neither have the authority to bind or act on behalf of the other?

☐ Yes.
☐ No.

Sample	The relationship of Institution and Sponsor is that of independent contractors and neither Party has the authority to bind or act on behalf of the other Party.

82. Assignment. Does the agreement prohibit either party from assigning the agreement to a third party?

☐ Yes. This is acceptable.
☐ No.

Sample	This Agreement shall not be assignable by any party without the prior written consent of the other parties.

83. Assignment. Does this agreement permit Sponsor to assign the agreement to a third party or an affiliate?

☐ Yes. This is acceptable only if the agreement is assigned to an affiliate of Sponsor or to a third party as part of a transfer or sale of all or substantially all Sponsor's assets or stock.
☐ No.

Sample	This Agreement shall not be assignable by any party without the prior written consent of the other parties, except that Sponsor may assign some or all of its rights and obligations under this Agreement to: (a) any of its affiliated entities; and/or (b) any purchaser of all or substantially all of Sponsor's assets or stock.

84. Entirety. Does the agreement state that the agreement contains the entire understanding of the parties and that the agreement supersedes all prior verbal or written agreements between the parties?

☐ Yes.
☐ No. Modify the Agreement to include the below provision.

Sample	This Agreement contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous verbal or written agreements and undertakings with respect thereto.

85. Severability. Does the agreement require remaining valid provisions of the Agreement not be effected in the instance that a specific provision is found to be unenforceable or invalid by a court of competent jurisdiction?

☐ Yes.
☐ No. Modify the agreement to include the below provision.

Sample	If any of the provisions, or a portion of any provision, of this Agreement is held to be unenforceable or invalid by a court of competent jurisdiction, the validity and enforceability of the other portion of any such provision and/or the remaining provisions shall not be effected thereby.

86. Notice. Does the agreement include a notice provision?

☐ Yes. Ensure that proper
☐ No. Modify the agreement to include the below sample language.

Sample	All legal notices to be given by either Party to the other shall be made in writing by hand delivery or by registered or certified mail, return receipt requested or by other method reasonably capable of proof of receipt thereof and addressed to the Parties at its respective addresses set forth below: If to the Institution, to: Chief Operating Officer, Clinical Research Operations Drexel University College of Medicine Clinical Research Group 1601 Cherry Street, Mail Stop 101021 3 Parkway Building, 10th Floor, Suite 1000 Philadelphia, PA 19102 Facsimile (215) 255-7882 With required copy to: Drexel University College of Medicine Office of the General Counsel 1601 Cherry Street, Suite 10627 Philadelphia, PA 19102 Facsimile (215) 255-7856 If to the SPONSOR, to: <<Enter Sponsor information>> or to such other address as either may designate from time to time to the other. Any notice shall be effective as of its date of receipt.

Notify

87. Governing Law. Does the agreement identify which state law will govern the terms of the agreement?

☐ Yes. Modify the agreement to require the agreement to be governed by Pennsylvania law for DrexelMed or New Jersey law for SPUH.

☐ No. Modify the agreement to require the agreement to be governed by Pennsylvania law for DrexelMed or New Jersey law for SPUH.

Sample	This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania, excluding its conflicts of laws provisions.

88. Force Majeure. Does the agreement include a force majeure provision?

☐ Yes.

☐ No.

Sample	Neither Party shall be liable for any failure to perform as required by this Agreement to the extent such failure to perform is due to circumstances reasonably beyond such party's control, including, without limitation, labor disturbances or labor disputes of any kind, failure of any governmental approval required for full performance, civil disorders or commotions, acts of aggression, acts of terrorism, acts of God, energy or other conservation measures imposed by law or regulation, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, accidents, fire, failure of transportation, or any similar cause beyond the reasonable control of either party.

89. Counterparts. Does the agreement allow it to be executed in one or more counterparts (e.g. copies) and state that such copies that are executed and delivered will be considered one agreement when taken together?

☐ Yes. This is acceptable.

☐ No. Modify the agreement to include the below sample language.

Sample	This Agreement may be executed and delivered in one or more counterparts, each of which when executed and delivered shall be deemed to be an original but all of which when taken together shall constitute one and the same Agreement.

90. Other Provisions. Does the agreement contain any other provisions that are not covered in this checklist?

☐ Yes. Highlight these provisions and seek attorney review.

☐ No.