MAGI’s Model Clinical Trial Agreement  
Version 1.31 – June 2011

This model agreement attempts to clearly, completely, concisely, consistently and correctly specify the duties and rights of each party to a clinical trial agreement. It is designed for Phase I-IV studies in the U.S. between one industry sponsor and one or more investigative sites. It is not intended for use in government-funded, CRO-contracted, investigator-initiated, observational, registry or multi-sponsor studies, although much of it is applicable to such studies.

MAGI and its members disclaim any responsibility or liability from reliance on the information in this model agreement. The information in this model agreement is not legal or regulatory advice, may become outdated, and may or may not be applicable to specific situations. Consult with your legal or regulatory counsel, as appropriate.

Access, use and adaptation of the model agreement and commentary are restricted to MAGI members. MAGI members may access, use and adapt this model agreement and commentary in part or whole without fee or obligation to MAGI. MAGI members may use the model agreement and commentary for instructional purposes in an educational setting. However, students who are not MAGI members may not use the model agreement and commentary outside of that educational setting.

Please suggest improvements and additions to the MAGI Model Clinical Trial Agreement and commentary to ngoldfarb@magiworld.org.

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Model Agreement

0. Parties & Recitals

__________ ("Sponsor"), a {form of entity} organized under the laws of {State}, ________ ("Site"), a {form of entity} organized under the laws of {State}, ________ ("Investigator"), Site’s {employee/contractor}, and ________, Investigator’s employer, enter into this Agreement ("Agreement") whereby Sponsor engages Site and Investigator to conduct clinical research on ______________ ("Study {Drug/Device/Biologic}") according to the provisions of this Agreement and Protocol __________.[1,2,3,4,5,6,7,8]

[Sponsor has delegated to ____________________ ("CRO"), a {form of entity}, certain of its responsibilities in this Study, including: ____________________________.]  

1. If Investigator is not a party to the Agreement, replace “__________ ("Site"), and __________ ("Investigator"), Site’s {employee/contractor},” with “__________ ("Site"), a {form of entity}, on behalf of itself and __________ ("Investigator"), Site’s employee.

2. If the Investigator, in essence, is the Site, the Investigator should be a Party to the Agreement. Otherwise, if the Investigator is an employee of the Site, he/she is bound to the Agreement by his/her employer’s signature as Party to the Agreement. If, as an employee, he signs “read and understood”, he avoids personal contract (but not tort) liability to the Sponsor, leaving the Site with any contract liability responsibility. If the Investigator is an independent contractor, he/she should sign as a Party to the Agreement because the Site may not have sufficient control over his actions to ensure that he complies with the contract, and to protect his/her own rights. If the Investigator is an owner or officer of the Site, he/she should sign in that capacity for the Site. If the Investigator is employed by a different entity, he/she or someone from that entity should
sign on behalf of that entity.

3. If the Investigator conducts the Study at a separate facility, e.g., a hospital, that facility may also be a party to this Agreement, or to separate Agreements with the Sponsor and Investigator.

4. List Protocol number and title. Sponsor may want to use a non-confidential name for the protocol if site makes its agreements public.

5. Optionally, add: “In the absence of a separately-named Site, Investigator will have all Site responsibilities.”

6. Optionally, add “__________ (“SMO”), a {form of entity}, will provide certain services delegated to it by Site.

7. Optionally, for non-profit sites, add: “WHEREAS, Sponsor wants to enlist the assistance of Site to conduct the Study, and the Study is of mutual interest and benefit to Site and Sponsor, and will further the instructional and research objectives of Site in a manner consistent with its status as a nonprofit educational and health care institution;“ This example reinforces the tax-exempt nature of the Study. Do not include recitals that should be terms in the body of the agreement, or that conflict with such terms. Recitals do not create legally-binding rights themselves, but they do provide a context for legal enforcement of agreements.

8. Many enterprises consist of numerous subsidiaries and affiliates. Verify that the other party to this Agreement has the ability to meet its obligations under this Agreement, e.g., pay its share of court awards. If appropriate, state its relationship to a parent or related entity with the necessary resources. The “Inc.”, “Ltd, etc. in a party’s name is important for correct identification.

1.0. Definitions and Abbreviations

AAHRPP. Association for the Accreditation of Human Research Protection Programs
Affiliate. An organization controlled by, in control of, or under common control of one of the parties to this Agreement.

Agreement. This legally-binding agreement between the parties.[1]

Authorized Third-parties. People and organization that are contractually or legally obligated to protect Confidential Information and who have been informed of their obligations.

Budget. Schedule of fees charged by Site to Study for conducting the Study.


CMS. U.S. Centers for Medicare & Medicaid Services.

Confidential Information. Information specified as confidential in Section 5.1. Confidential Information. Unless stated otherwise, "Confidential Information" is the other party’s confidential information.[2]

Court. A court of competent jurisdiction, regardless of its name.[3]

CRF (Case Report Form). A printed, optical or electronic document designed to record all of the protocol-required information to be reported to the Sponsor on each Subject. (ICH E6 1.11)

CRO (Contract Research Organization). A person or an organization (commercial, academic, or other) contracted by Sponsor to perform one or more of Sponsor’s Study-related duties and functions (ICH E6 1.20); generally is not an agent of the Sponsor, i.e., cannot legally obligate Sponsor in a contract. In this Agreement, the Sponsor contracts with the Site.

CTA (Clinical Trial Agreement). This Agreement is an example of a CTA.

Data. See Source Documents, Sponsor Data.

Day. Unless otherwise specified, a business day, without considering partial days.

Facility. The term “Facility” is not used in this Agreement. Instead, this Agreement uses the terms “Site” and “Location”. In the U.S., a facility is a secondary location where the Site conducts the Study. In Europe, “Facility” is the term used for “Site”.

GCP (Good Clinical Practice). A standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of subjects are protected. (ICH E6 1.24) In the U.S., the standards are set forth in CFR. In Europe, the standards are set forth in ICH E6 Guidelines for Good Clinical Practice. Studies may be governed by CFR, ICH or both standards.

Genetic Data. DNA, RNA and protein sequence, restriction fragment length polymorphism (RFLP), and similar data from a Subject.

a. The Site
b. The Sponsor or its CRO, acting on behalf of Sponsor, but not as its agent
c. The Investigator, unless prohibited by conflict-of-interest laws or acting entirely in his/her capacity as an employee of the Site

2. Alternative definition: Any proprietary information that either party provides to the other party in written or tangible form and designates as confidential when first disclosed.

3. Optionally, specify the name of the court. For example, claims against Tennessee state entities are adjudicated in the Tennessee Claims Commission.

4. Inventions that may be made during a clinical trial include new uses of the study drug, identification of metabolites or biomarkers of the study drug, methods for administering the study drug, dosing regimens, and drug combinations that include the study drug.

5. Rather than listing categories of indemnities, consider listing indemnitees by name. When creating the list of indemnitees, consider the impact of joint vs. several liability (i.e., whether the action of one indemnitee creates a liability for the others). Some sponsor insurance policies cover local IRBs, others do not, and the exclusions vary.

6. Specimen language must be consistent with informed consent form.

7. Optionally, include: “The definitions in ICH Guidance for Industry (E6) Good Clinical Practice: Consolidated Guidance, Glossary, are hereby incorporated by reference, to the extent that they do not conflict with the above definitions. Additionally, the definitions in the U.S. Department of Health and Human Services Public Health Service Grant Application (PHS 398) [PART II Supplemental Instructions for Preparing the Human Subjects Section of the Research
HIPAA. Health Insurance Portability and Accountability Act.

ICH. International Conference on Harmonisation.

IEC (Independent Ethics Committee). Outside the U.S., the ethics committee equivalent to IRBs. IECs go by many names. They may be independent or affiliated with the Site. Indemnified Employees. Employees, medical and professional staff, appointees, fellows, faculty, other persons with academic appointments, trainees and students.[5]

Institution. The term "Institution" is not used in this Agreement. The term "Site" is used instead.

Intellectual Property. Inventions, expressions of ideas, discoveries, devices, data, mechanisms, substances, works, trade secrets, know-how, formulae and methods, including improvements, whether or not protectable by patent, copyright or other intellectual property rights.

Invention. Any Intellectual Property conceived, reduced to practice, made or developed, in whole or in part, by or on behalf of Site pursuant to its conduct of the Study or derived from Sponsor Confidential Information, that relates to the Study {Drug/Device/Biologic}, including its administration or use, alone or in combination with any other drug or device, and any related assay or biomarker.[4]

Inventor. A person who creates, in whole or in part, an Invention.

Investigator. The physician or other qualified person, identified by name in the Agreement as the Investigator, who is responsible for conduct of the Study at the Site. In the U.S., the Investigator signs and is listed in box 1 of Form FDA 1572.

IRB (Institutional Review Board). In the U.S., the ethics committee responsible for ensuring the protection of the rights, safety and well-being of human subjects involved in a trial.. IRBs go by many names. They may be independent or affiliated with the Site.

Location. An entity other than the Site with a physical location where the Study may also be conducted. In U.S. Investigational New Drug (IND) studies, Locations are listed in box 3 of Form FDA 1572.

Owner. The party that owns Confidential Information.

Publication. A paper, article, manuscript, report, poster, Internet posting, presentation slides, abstract, outline, video, instructional material, presentation (in the form of a written summary), or other disclosure of Study Results, in printed, electronic, oral or other form.

Personnel. Investigator, Subinvestigators and other Site employees and contractors who assist Investigator on the Study for the Site.

Protocol. The IRB/IEC-approved description of the Study, attached to this Agreement as Exhibit B. Protocol by reference, including any IRB/IEC-approved amendments. In U.S. IND studies, the Protocol is listed in box 7 of Form FDA 1572.

Recipient. The party to this agreement, including the Investigator, even if not a party,
that receives Confidential Information from its Owner.

**Results.** The methods, data, analysis and conclusions of a Study.

**Site.** The entity that conducts the Study, identified by name in the Agreement as the Site. In U.S. IND studies, Site is listed in box 3 of Form FDA 1572 but may not be the only entity listed there. In Europe, a Site is normally called a "Facility", but this Agreement uses the term “Site.”

**Site Indemnitees.** Site, Investigator and their businesses, owners, Indemnified Employees, officers, trustees, directors, appointees, IRB/IEC, privacy board, agents, contractors, subcontractors and Affiliates, if any, and their heirs and assigns.[5]

**SMO (Site Management Organization).** An entity, identified by name in the Agreement, that performs one or more services such as business development, contract negotiation, and regulatory affairs for Site. SMO may be the payee in the Agreement.

**Source Documents.** Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects’ diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial). (ICH E6 1.52) Excludes CRFs.

**Specimen.** A biological sample, such as blood or tissue, from a Subject, collected per the Protocol.[6]

**Sponsor.** The responsible pharmaceutical, biotech, medical device, or other organization that contracts with the Site and/or Investigator to perform the Study. In U.S. IND studies, Sponsor is identified in box one of Form FDA 1571.

**Sponsor Data.** Study lab test results, CRFs and other reports completed by Site or Investigator per the Protocol, Agreement or other written instruction by Sponsor, excluding Source Documents and Genetic Data. Specifically excludes results derived from analysis of data.

**Sponsor Indemnitees.** Sponsor and its employees, officers, trustees, directors, owners, agents, subcontractors, development partners, and Affiliates, if any, and their successors and assigns.[5]

**Statement of Investigator.** In the U.S., the equivalent of Form FDA 1572 for studies of medical devices under an FDA Investigational Device Exemption (IDE). U.S. 21 CFR Parts 812.43C 812.100 and 821.110 specify the requirements.

**Study.** The clinical research project identified by its title in the Agreement and described by the Protocol attached to the Agreement.

**Study Device.** The device that the Study investigates.
Study Drug. The experimental medication that the Study investigates.

Study Drug Materials. The experimental medication, comparator drugs, rescue drugs, other ancillary drugs, and placebos.

Subinvestigator. A physician or other qualified person who assists Investigator by performing critical study-related procedures and/or making important study-related decisions. In U.S. IND studies, Subinvestigators are identified in box 6 of Form FDA 1572.

Subject. A person who enrolls in the Study. In U.S. IDE studies, a Subject may be a person who contributes a specimen for use with a Study Device. (U.S. 21 CFR 812.3(p))[7,8]

2. Study Governance

2.1. Protocol & Amendments

Sponsor has provided Site with a comprehensive and accurate Protocol and supporting information necessary for Site to evaluate and conduct the Study. The Protocol will be considered effective following its approval by Sponsor, IRB/IEC, Investigator, applicable Site authorities, and the FDA or other applicable regulatory authority. Site will conduct the Study in accordance with the Protocol. (However, see Section 3.16. Protocol Violations & Deviations.) Only the Sponsor may modify the protocol or add an addendum to the Study. Any modification or addendum to the Protocol must be approved by the IRB/IEC to become effective. If the IRB/IEC does not approve a modification within {20/30} Days, Sponsor may terminate this Agreement. If IRB/IEC does not approve an addendum, Site will not perform that addendum.[1,2,3,4]

If, in Site’s judgment, any modifications or addendums, collectively from the beginning of the Study at Site, increase Site’s costs by more than __%, Sponsor will increase the Budget accordingly or Site may terminate this Agreement.[5]

1. Site authorities may include Contacts & Grants, Radiation Safety, Scientific Review, etc.
2. If Site or the IRB/IEC wants to modify the Protocol, it must ask the Sponsor to make the change.
3. An addendum is an additional sub-study that is added to strengthen the data or answer a question raised by the Study.
4. Optionally, add: “If IRB/IEC requires a modification to the Protocol during the Study, Site may terminate this Agreement if Sponsor does not approve the modification within 20 Days.”
5. A reasonable range of increase in costs is generally 0% to 5%.

2.2. Study {Drug/Device/Biologic} and Materials

Sponsor will provide to Site on a timely basis, without charge, the required quantities of properly-labeled Study {Drug/Device/Biologic} and other materials (e.g., CRFs) needed by Site to conduct the Study per the Protocol. Sponsor will also provide to Site any needed replacement Study {Drug Materials/Devices} and instructions for proper handling and storage.

Unless stated otherwise in writing by Sponsor, all such items are and will remain the sole property of Sponsor until administered or dispensed to Subjects during the course of the Study.

1. “Quality” is not included in disclaimer because Sponsor should be able to warranty the quality of Study Drug under Good Manufacturing Practices.
2. In the U.S., the Magnuson-Moss Warranty Act requires that a statement of “No Warranties” on consumer products be distinctive from other text, so it is not applicable to this Agreement.
Sponsor warrants that:

a. It has obtained all necessary governmental and regulatory approvals to conduct the Study and provide the Study {Drug/Device/Biologic} including without limitation, all applicable FDA and IRB/IEC approvals; and that all approvals will be in full force and effect during the Study.

b. Study {Drug/Device/Biologic} has been manufactured, formulated and passed quality control tests in accordance with applicable regulations.

c. It has disclosed to Site and applicable government authorities all relevant, material information concerning the safety, use, efficacy and {drug/device/biologic} experience.

d. To the best of its knowledge after reasonable inquiry, use of the Study {Drug/Device/Biologic} for Study purposes will not infringe the intellectual property rights of any third-party.

e. Any hazardous material packaging provided by Sponsor meets regulatory requirements for Site’s use according to the Protocol.

Without limiting Sponsor’s obligations under Sections 9. Subject Injury and 10. Indemnification, Sponsor disclaims any other representations and warranties, written or oral, express or implied, with respect to the Study {Drug/Device/Biologic}, including any representation or warranty of performance, merchantability or fitness for a particular use or purpose.[1,2]

[3]

2.3. Sponsor Monitoring

Sponsor will monitor Site according to the schedule in Exhibit A. Budget. Sponsor monitors will be suitably qualified by training and experience. Site will ensure that Study records are ready for review prior to each visit. Visits will be at the mutual convenience of the Parties. Sponsor will comply with CFR 312.55(b) in informing Site of any findings that could affect the safety of Subjects or their willingness to continue participation, influence the conduct of the study, or alter the IRB’s approval to continue the study. [1,2,3,4,5]

1. Optionally add: “Initial monitoring visit will be within {2/3} weeks after first Subject enrollment” so monitor can catch errors before they multiply.

2. Optionally, add: “Subsequent visits will be {4/6/8} weeks apart.”

3. Sites may want monitors to review case report forms before regulatory documents so payment is not delayed.

4. An additional monitoring visit may be scheduled prior to an audit or inspection.

5. AAHRPP accreditation standard I.8.B requires: “In studies where Sponsors conduct research site monitoring visits or conduct monitoring activities remotely, the Organization has a written agreement with the Sponsor that the Sponsor promptly reports to the Organization findings that could affect the safety of
2.4. Sponsor-Supplied Equipment
Sponsor will provide to Site on a timely basis, without charge, the equipment specified in Exhibit D. Equipment. Unless stated otherwise in writing by Sponsor, this equipment is the sole property of Sponsor. Sponsor will maintain this equipment in working order. It will maintain property insurance on it. Site will use this equipment only for the Study or such other purposes as Sponsor may approve in writing. Site will return Equipment in working order with normal wear and tear excepted, at Sponsor’s cost, to Sponsor within 20 Days after completion of the Study by Site or termination of this Agreement. Site will compensate Sponsor based on replacement value for negligent loss of, or damage to, Equipment.[1,2,3,4]

1. Delete this section if Sponsor does not supply any equipment.
2. If Sponsor operates equipment, add “Only Sponsor personnel will operate equipment.”
3. Sponsor-supplied equipment has been known to break during non-Study use prior to a study. Use of sponsor-supplied equipment for non-Study purposes potentially exposes Sponsor to liability.
4. When the study is complete, giving equipment to the site may constitute excessive payment. Selling used equipment to the site at its fair market value in situ is permitted.

2.5. CROs
Upon written notice to Site, Sponsor may delegate some of its Study responsibilities to one or more CROs. Site will cooperate with such CROs as if they were the Sponsor. Sponsor warrants that such CROs will comply with those parts of this Agreement for which Sponsor has delegated its Study responsibilities.[1,2,3,4,5]

1. Delete this section if Sponsor has no CROs.
2. If Agreement is with a CRO, define Sponsor’s duties not delegated to CRO e.g., its obligation to comply with applicable laws and regulations, in a separate letter.
3. If Agreement is with a CRO, Sponsor normally signs a separate letter of indemnification that also covers subject injury. Site may want the CRO to have the duty to obtain this letter.
4. Optionally, replace “Sponsor may delegate some of its Study responsibilities to one or more CROs.” with “[Pursuant to CFR 21 Part 312.52,} Sponsor has delegated the following Study responsibilities to the following CROs: __________________________.]”
5. CRO may want to state in the Compensation section that it will pay site only after it receives funds from the sponsor. Site probably will not want to accept this language.

2.6. Audits
Sponsor may audit Site’s performance of the Study and use of Sponsor’s funds from time to time in the facility(ies) where the Study is conducted. Sponsor will conduct audits during Site’s regular business hours with reasonable advance notice and consideration for Site (except in safety-related emergencies). Site personnel will cooperate with auditors and make all Study records and materials available to them, subject to confidentiality and privacy restrictions. Sponsor will communicate any material findings to Site in an exit meeting or in writing within 48 hours, but will not share its internal audit report with Site. Site will promptly correct any deficiencies found during audits. [1,2]

2.7. Inspections

Site will notify Sponsor within {2/5} Days if any government or regulatory authority begins to conduct, or gives notice of its intent to conduct, an inspection pertaining to the Study. Within {3/5} Days, Site and Sponsor will provide the other party with copies of all pertinent written and electronic documents issued by the government or regulatory authority pertaining to such inspection. Within {3/5} Days, Site will also provide Sponsor with a copy of all written and electronic documents that otherwise pertain to the Study that are received from or provided to the government or regulatory authority, subject to confidentiality and privacy restrictions. When practical, Site will consult with Sponsor prior to responding to any such communications. Site will promptly correct any deficiencies found during inspections. [1,2]

2.8 Privacy

Sponsor will comply with the restrictions in any subject authorization regarding the use, disclosure and confidentiality of any protected health information ("PHI"), as defined by HIPAA. Sponsor will have binding agreements with all contractors, CROs and other third-parties that access PHI on its behalf obligating such third parties (a) to maintain the confidentiality of all PHI to which it may have access; and (b) to use PHI solely as permitted by the Subject’s authorization and informed consent.[1]

2.9. Other Sponsor Duties

Sponsor will comply with all applicable federal, state and local laws and regulations.[1] Sponsor will provide Site with a comprehensive and accurate Investigator’s Brochure, especially with respect to information pertaining to the safety of the Study {Drug/Device/Biologic}. It will advise Site of all information for inclusion in the informed consent form that is material to a decision of potential or actual Subjects to participate or continue to participate in the Study. It will inform Site in advance of any requirements beyond GCP. It will inform Site within 3 Days if its FDA Investigational New Drug (IND) for the Study is cancelled, withdrawn, amended or put on clinical hold. It will notify Site one week prior to closing subject enrollment. Prior to or after that date, Site may request approval to enroll a subject within a specified period of time and sponsor will inform site whether it may do so. It will respond to Site questions and issues in a timely manner. [2] When Subject safety could be directly affected by Study results after the study has ended,

1. Site may want to include audit and inspection fees in the Study Budget, except for “for cause” audits and inspections. Inspection fees are uncommon.

2. Sponsor may want the right to verify source data, audit, and inspect the facilities of Site’s third-party contractors where study activities are performed.

1. Sponsor may offer to assist Site in preparing for an inspection.

2. Sponsor may request to be present at an inspection. Regulatory authorities generally frown on its presence. Unless CTA provides otherwise, sponsor’s presence is at Site’s sole discretion. It may be useful for a sponsor representative to be on site in an advisory capacity during the inspection, but not participate directly in the inspection or communicate with the inspector.

1. Site is liable to subjects for HIPAA violations, including those by Sponsor and its CROs and contractors.

Sponsor will notify Site of Study results so Subjects can be informed.[3]

2. AAHRPP accreditation standard I.8.C. requires: “When the Sponsor has the responsibility to conduct data and safety monitoring, the Organization has a written agreement with the Sponsor that addresses provisions for monitoring the data to ensure the safety of participants and for providing data and safety monitoring reports to the Organization.” Therefore, optionally add: “Sponsor will monitor the data to ensure Subject safety and will provide data and safety monitoring reports to Site.”

3. AAHRPP accreditation standard I.8.E. requires: “When participant safety could be directly affected by study results after the study has ended, the Organization has a written agreement with the Sponsor that the Researcher or Organization will be notified of the results in order to consider informing participants.”

1. If Site does not conduct the Study according to the terms in this Section, it is in breach of contract. However, it is not contractually required to perform any activity not specified in this Section. If the terms are ambiguous, the Site’s obligations may become the subject of dispute. To be unambiguous, a term must be clear as to who, what, where and how each activity is to be performed.

3. Duties of Site & Investigator [1]

3.1. Conduct of Study; Protocol

Site has the expertise, time and resources to conduct the Study per this Agreement. Site will conduct the Study in a timely manner and in accordance with this Agreement, the Protocol, and Sponsor’s other reasonable written instructions. (However, see Section 3.16. Protocol Violations & Deviations.) It will accurately collect and record Study data. The Protocol becomes effective upon IRB approval. Sponsor may modify the Protocol, effective upon notice to Site and IRB approval. Site may not modify the Protocol. It may, however, propose Protocol changes to Sponsor. It may also request exceptions to the Protocol, which must be approved by Sponsor and, when appropriate, by the IRB. If Sponsor changes the Protocol, Site may terminate Agreement if, (a) in Investigator’s judgment, the changes

L.1. 473. However, adding this language potentially exposes Sponsor to subject injury litigation claims.

1. Site may deviate from the Protocol for subject safety.

2. The percentage increase in cost that enables termination of the Agreement is negotiable, probably in the range of 0-10%.

3. Optionally, identify protocol name and number in this section.

4. An exception is a protocol deviation that the
have a negative impact on Subject safety or welfare, or (b) the cumulative protocol changes since Agreement was signed increase Site’s cost or risk of conducting the Study by more than 2% and the parties are unable to agree on a revised Budget within 20 Days. The Protocol in Exhibit B is incorporated in this Agreement by reference.[1,2,3,4]

3.2. GCP; Compliance with Laws and Regulations

Site will conduct the Study in conformance with generally accepted standards of good clinical practice and in accordance with all applicable federal, state and local laws and regulations. Investigator is familiar with the contents of ethical standards, including the Belmont Report and the Declaration of Helsinki. [1,2,3,4]

1. Optionally, Agreement may specify applicable laws, regulations (and guidances), such as:
   a. Form FDA 1572 (or Statement of Investigator for device studies)
   b. Regulations and guidances governing the conduct of clinical research and governing the protections of human subjects (“GCP”) (21 C.F.R. § 50 and 21 C.F.R. § 312.50)
   c. Federal Food Drug and Cosmetics Act, as amended
   d. Health Insurance Portability and Accountability Act (HIPAA)
   e. Regulations of the Centers for Medicare and Medicaid Services ("CMS")
   f. Laws and regulations governing the purchase and sale of securities while in possession of material, non-public information about that company
   g. Laws, rules and regulations regarding the federal anti-kickback statute (42 U.S.C. 1320a-7(b)), and (g) Limitation on Certain Physician Referrals, also referred to as the "Stark Law" (42 U.S.C. 1395nn)
   h. International Conference on Harmonisation (ICH) guidelines
   i. Declaration of Helsinki (specify version)

2. Specified laws and regulations must be applicable to Site’s geographical location.

3. If Sponsor requires Site to comply with ICH, The Declaration of Helsinki, the Nuremberg Code, or any other requirements that do not have the force of law in the Site’s country,
3.3. Debarment & Disqualification

Site represents that neither it, nor to the best of its knowledge after due inquiry, any of its Investigators, Subinvestigators, employees, suppliers, agents or other persons or entities (including their employees, partners, shareholders, members, subsidiaries and affiliates) providing services for the Study, has ever been debarred, disqualified, or banned by FDA from conducting clinical trials or is under investigation by FDA or any equivalent regulatory authority outside the U.S. for debarment, disqualification or any similar regulatory action. Site has a system for detecting such actions in the United States. Site will notify Sponsor within 15 Days of any actual or threatened disqualification, debarment or other ban or investigation that comes to its attention during the course of the Study and for five years thereafter.[1,2,3,4,5,6,7]

1. Sponsor’s certification to the FDA may not include qualifying language such as “to the best of its knowledge.” (http://www.fda.gov/cder/guidance/1700dft.pdf)
2. “Due inquiry” means (a) asking the person or organization to certify in writing that they have not been debarred, etc. and (b) checking FDA’s online databases of debarred and disqualified persons.
3. Sponsor may want to specify minimum requirements for the inquiry, e.g., reviewing information on government websites or asking persons to certify in writing that they have never been debarred.
4. Disqualified persons and entities may provide certain Study services, but with limitations.
5. It is essentially impossible for sponsors and sites, especially large ones, to ensure that all personnel, including non-employees, have not been debarred, disqualified, or otherwise banned, e.g., in a different state or country. A practical alternative is to say: “All study personnel will sign the delegation of authority log to certify that they have not been debarred, disqualified, or banned from conducting clinical trials or are under investigation by any regulatory authority for debarment, disqualification, or any similar regulatory action. Site will initial all names to signify that they are not on the FDA
3.4. Financial Disclosure
Site will ensure that, prior to their participation in the Study, Investigator and any Subinvestigators complete and return to Sponsor the Financial Disclosure Certification form provided by Sponsor. Investigator and any Subinvestigators will promptly notify Site and Sponsor of any required revision to their Financial Disclosure Certification during the term of this Agreement and for one year following completion of the Study. Upon Sponsor's written request following completion of the Study, Investigator and any Subinvestigators will provide an updated Financial Disclosure Certification form to Sponsor.[1,2,3]

3.5. Conflict of Interest
Site and Investigator (a) have no conflict of interest that would affect conduct of the Study, and (b) have received no offer by Sponsor or its related party of extra benefit for participation in the Study, including offers to family members. Site and Investigator will promptly notify Sponsor if any conflict of interest arises during the term of this Agreement. Site and Investigator will enter into no financial security transaction based on Study data or debarment or disqualification lists.”

6. Optionally, include other U.S. government sanctions such as FDA Restriction, FDA adequate Assurance, FDA Application Integrity Policy List (firms), Public Health Service Office of Research Integrity Administrative Action, and HHS Office of Inspector General Excluded Individuals & Entities (Medicare/Medicaid). Potential FDA sanctions may be indicated by a Warning Letter, Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE) Letter, Notice of Opportunity for Hearing (NOOH), and Presiding Officer Reports and Commissioner's Decisions in Clinical Investigator Disqualifications Proceedings.

7. FDA draft guidance “Submitting Debarment Certification Statements” requires that sponsors must inform the FDA of anyone who is debarred after participating in a study but during the five years prior to submission of an NDA to the FDA.

1. Financial disclosure is legally required in U.S., but optional in many other countries.
2. In practice, updated Financial Disclosure Certification forms will generally flow from Investigator to Site to Sponsor.
3. E.U. law restricts transfer of personal information to many countries outside the E.U., including the U.S. In such case, obtain written consent to the transfer from Investigator and any Subinvestigators.

1. This section is optional because it goes beyond the financial disclosures required by law in the previous section.
2. Optionally, add “Site has policies and procedures to discover, manage, report, and, where possible, eliminate conflicts of
3.6. Investigator

Investigator will supervise the Study. If Investigator cannot carry out his/her duties under this Agreement, or leaves Site, (or notifies Site that he/she is likely to leave), Site will notify Sponsor within 5 Days. Site may nominate a replacement investigator. Sponsor, at its sole discretion, may approve or reject such replacement. If Sponsor rejects the proposed replacement, it may terminate this Agreement. Otherwise, Site and Sponsor will mutually determine whether the Study will continue at Site, move with Investigator to a different site, or move to another site with a different investigator.

1. Optionally, specify Investigator’s duties when supervising the Study.
2. Optionally, name Investigator in this section.
3. If Investigator is able to carry out his/her duties but wishes not to, the Termination section governs.
4. Optionally, add: “If Sponsor terminates Agreement, it may request Site’s cooperation in transferring Subjects to another Site.”
5. Optionally, add language that specifies what happens if parties cannot resolve future of study when Investigator leaves Site.
6. If the Investigator leaves the study, amend this Agreement with the signature of the replacement Investigator.

3.7. Subinvestigators and Other Personnel

Site will ensure that:

a. Adequate numbers of qualified Personnel are assigned to the Study to meet its obligations under this Agreement.
b. Subinvestigators and other Personnel have the necessary licenses and certifications, and are qualified by education, training and experience to perform their Study responsibilities.
c. Subinvestigators and Personnel perform their Study responsibilities and fulfill their obligations under this Agreement.
d. Subinvestigators and Personnel receive the necessary information and training in GCP, regulatory requirements, and proper performance of the Protocol.

Any Subinvestigator or other person or subcontractor working on the Study who is not employed by Site will execute a written agreement with Site obligating him/her to comply with confidentiality, financial disclosure, and other relevant terms and conditions of this Agreement. Site will notify Sponsor of proposed Subinvestigators; Sponsor may disapprove any proposed Subinvestigator within 5 Days of notification.

1. Sponsor may want to add: “e. there is at least one Subinvestigator.” to cover for Investigator when he/she is unavailable.
2. Sponsor may want to provide the Subinvestigator Agreement template or approve its form.
3. If Site is a HIPAA Covered Entity, Subinvestigators and other personnel not employed by Site and not stated in the informed consent form as possible recipients of Subject’s private information must sign a HIPAA Business Associate agreement. A standard confidentiality agreement is not adequate.
4. In the USA, submission of a Form FDA 1572 identifies a Subinvestigator and constitutes notification to the Sponsor.
5. Device studies use a Statement of Investigator instead of a 1572.
3.8. Delegation of Investigator Duties

Investigator will personally supervise the Study and may not delegate this duty. He/she may, however, delegate other duties to qualified personnel per protocol and regulatory requirements. Site may not replace Investigator or substantially reduce his/her role in the Study without Sponsor’s prior written approval. If Investigator is to be absent from Site for more than ___ Days, Site will designate a Subinvestigator to temporarily supervise the Study on the Investigator’s behalf. Site will document this designation notify Sponsor of this designation prior to its commencement if possible, and certainly within three Days after its commencement. If Investigator is, or is to be, absent for more than ___ Days, Sponsor may terminate Agreement if Site and Sponsor cannot agree on a replacement Investigator within that number of Days.[1,2,3]

1. Temporary absence period generally ranges from a minimum of 0 to 15 Days, with 5 to 10 Days most common.
2. Maximum absence period generally ranges from 10 to 20 Days before a replacement must be found.
3. Prior to signing Agreement, Site may notify Sponsor of anticipated Investigator absences, and Sponsor may approve such absences as an amendment to Agreement.

3.9. Facilities

Site will conduct Study only at facilities that are listed on its Form FDA 1572 and found to be adequate by Sponsor. Site will ensure that they remain adequate during the Study. Adequate facilities, at minimum, are safe, secure, hygienic, include adequately-maintained and calibrated equipment, and provide for secure and accessible storage of study materials and records. Sponsor may inspect facilities during monitoring visits. It may also, on mutually-agreeable dates during Site’s normal business hours, inspect facilities to determine their continued adequacy. Site will notify Sponsor within 5 Days of a significant detrimental change in its facilities’ adequacy.[1,2,3,4,5]

1. Device studies use a Statement of Investigator instead of a 1572.
2. Sponsor may want to add: “Site will conduct Study at a single location.” Multiple locations make site monitoring and Study Drug/Device/Biologic management more difficult and time-consuming.
3. Sponsor may want to detail specific requirements, e.g., for specialized equipment required for the study. It may also want to specify requirements for a monitor workspace.
4. Although U.S. CFR 312.61 (Control of the investigational drug) does not require controlled storage of Study Drug Materials, most sponsors want double-lock security. U.S. CFR 312.69 (Handling of controlled substances) requires storage of controlled substances, e.g., narcotic study drugs, in "a securely locked, substantially constructed
3.10. IRB/IEC

3.10.1. IRB/IEC Selection. Site will conduct Study with the initial and continuing approval of an IRB/IEC. If Site does not use the Sponsor-designated central IRB/IEC, it will notify Sponsor of its choice of IRB/IEC with documentation of compliance with 45 CFR 46, and/or 21 CFR Part 56, as appropriate. Site will not replace its initial IRB/IECs without written notification to the replaced IRB/IECs [and Sponsor’s prior written approval].[1,2,3]

3.10.2. Study Initiation. Site will initiate Study only after the IRB has approved the Study’s protocol, informed consent form, and subject recruitment materials, as applicable, Sponsor has received a copy of these approvals, and this Agreement has been fully executed. Site will obtain IRB and Sponsor approval of any protocol amendments before implementing such amendments, except when necessary to eliminate apparent immediate hazard(s) to the safety or welfare of Subjects, or when the change(s) involve only logistical or administrative aspects of the Study. It will discontinue the Study if it does not obtain any required periodic approvals. Site will notify Sponsor of any refusal of, withdrawal of, or suspension of IRB approval within 5 Days of receiving such notification.

3.10.3. Compliance. Site will comply with government, IRB and Sponsor requirements to keep the IRB informed of progress of the Study, particularly with respect to serious adverse events, IND safety reports, and protocol violations affecting Subject eligibility or subject safety. Site will comply with the IRB’s directives and inform Sponsor if any such directives vary from the Protocol.

3.10.4. Other Reviews. Site will obtain reviews from other internal review committees in a timely manner.

3.11. Study Documents

Site will prepare, maintain and retain complete, current, accurate, organized and legible Source Documents, Regulatory Documents, and other Study Documents. Site will submit CRFs, unless collected by Sponsor at Site Visits, within __ Days following data collection for each page. Site will prepare and submit other documents required by the Protocol to the Sponsor within __ Days. If Sponsor provides Site with source document templates, Sponsor has no responsibility for their design or contents.[1]

3.12. Reporting and Meetings
Upon the request of Sponsor, Site will submit oral and written progress reports in a timely manner. Upon the request of Sponsor, Site will meet with Sponsor at Site’s location at mutually-convenient times. Site will submit to Sponsor a final report on the Study within \{20/30/40\} Days of completion or earlier termination of the Study.[1]

3.13. Record Retention & Destruction

Site will retain in a safe and secure location one copy of all printed and electronic Source Documents and Sponsor Data for the longer of (a) two years after the last marketing authorization for the Study Drug has been approved or Sponsor has discontinued research on the Study Drug or (b) such longer period as required by regulatory requirements. Sponsor will notify Site within 30 Days after this retention requirement has expired. Sponsor will reimburse site for any subsequent storage costs plus management fee annually, upon receipt of invoice and supporting documentation. When Site destroys records, it will do so in a manner that ensures that their confidentiality is protected. Site and Investigator will notify Sponsor of any accidental loss or destruction of Data. Contact Sponsor regarding record retention matters at: ____________.[1,2,3,4,5,6]

1. U.S. CFR §312.62 and §812.140. Other countries have other record retention requirements. (See ICH E6 §4.9.)
2. Parties may agree that electronic records will be printed on paper for retention.
3. Sponsor may want to replace “for the longer of…” with “for ___ years after termination of the Study.”
4. Sites generally have no way to determine when the CFR §312.62 retention period ends, so a fixed period may be preferable, even if it is longer than the regulatory requirement.
5. Optionally, add language allowing Site to ship records to Sponsor or third-party storage facility after X years, or charge for continued storage.
6. Inadvertent loss or destruction of records becomes more likely over a long period of time.

3.14. Enrollment

Enrollment in Study is competitive. Site will use its reasonable efforts to enroll ___ Subjects within the enrollment period of ___ months after Study initiation, including ___ Subjects within the first ___ months. Sponsor may change the enrollment period at its sole discretion, upon ___ Days notice to Site.[1,2,3,4,5,6,7,8,]
3. “Reasonable efforts” means that Site will give Study average priority and conduct it in a professional manner, with the due care and diligence that is customary in the industry. “Best efforts” means that Site will give Study top priority and conduct it in an exceptionally good manner.

4. Replacing “close enrollment” with “review for possibly closing enrollment” adds flexibility.

5. The number of subjects to enroll may be stated as a minimum, maximum or exact number.

6. Stating an exact number requires a CTA amendment if the Site exceeds it. Changing an exact number requires IRB approval. A range is thus more flexible.

7. The enrollment period for the Study may begin before a specific Site is initiated.

8. Sponsor should give Site adequate notice before closing enrollment so Site does not incur unnecessary costs or disappoint potential Subjects that are in the recruiting process. 5 to 10 Days should be adequate.

9. The termination part of this section is redundant to termination-without-cause rights in the termination section.

3.15. Adverse Events

If any Study Personnel concludes that a death, other Serious Adverse Event (SAE), Unexpected Adverse Event (UAE), or other event specified in the Protocol probably occurred during the Study, regardless of cause, Site will report the event within 24 hours to Sponsor, and follow-up with a written report of the event to Sponsor within 48 hours of concluding that such event probably occurred. Site will comply with other Sponsor and IRB reporting instructions. It will not delay the report because of incomplete information, which can be supplied later. Site will record other adverse events in the adverse event log.[1]

Site will not report adverse events directly to regulatory authorities, except (a) with 5-Days prior notice to Sponsor, (b) to protect public safety and welfare, and (c) if Site believes Sponsor is not reporting adverse events according to regulatory requirements.

Sites may discuss adverse events among themselves.

3.16. Protocol Violations & Deviations

1. If Site verbally reports a probable event and later concludes that an event did not occur, it should so inform Sponsor and write a note to file.
Site will notify Sponsor and IRB within [3/5] Days after becoming aware of any material Protocol violation. It will record Protocol deviations in the Study records. Site may deviate from the Protocol to protect Subject from an immediate hazard. (See ICH E6 4.5.4.) Any such deviation will not constitute a failure to comply with the Protocol. To the extent possible, it will make its best efforts to quickly remedy violations and deviations. Sponsor will provide Site with a list of violations that it wants Site to report.[1]

3.17. Informed Consent

Investigator will ensure that informed consent is obtained from Subjects prior to screening for, or participation in, the Study. Subject’s dated signature on the current IRB-approved informed consent form will signify informed consent.[1] Both parties will ensure that the informed consent form is consistent with Section 7.4. Data & Specimen Ownership and Section 9. Subject Injury Claims.[2,3] Both parties will approve the form. When Subject safety or medical care could be directly affected by Study results, Site will communicate that information to Subjects in an amended informed consent form. Site warranties that it will inform Sponsor of its changes to the informed consent form.[4]

3.18. Study {Drug/Device/Biologic}

Sponsor owns the Study {Drug/Device/Biologic}. It will provide the Study {Drug/Device/Biologic} to the Site at no cost. Site will verify to Sponsor receipt of the Study {Drug/Device/Biologic}. Site will store the Study {Drug and empty containers/Device} in a safe and securely-locked area per Protocol requirements. Site will maintain complete and accurate records on the receipt and disposition of Study {Drug and empty containers/Device}. Site will use {Drug/Device/Biologic} only for Study Purposes according to the Protocol. Site will not dispense expired Study {Drug/Device/Biologic} to Subjects.

1. The definitions of violations and deviations, and their reporting requirements, vary by sponsor and IRB, so Site may request guidance when classifying an event.

1. Although the Subject’s dated signature constitutes informed consent for the purposes of this Agreement, Site is responsible for ensuring that Subject’s consent is, in fact, informed and voluntary.

2. Sponsor, at minimum, should review and comment on the informed consent form because it is the only party with sufficient information to determine if the informed consent form includes complete and accurate information about the Study {Drug/Device/Biologic}.

3. Sponsor may want to approve the informed consent form, but it may create a legal liability for the Sponsor if there is litigation due to Subject injury. On the other hand, if Sponsor does not approve the informed consent form, it may be liable to a claim of negligence.

4. This Agreement and the informed consent form should be consistent, which is easier if this Agreement references language in the informed consent form. However, informed consent forms are typically written less precisely than clinical trial agreements.

1. Return of Study {Drug/Device/Biologic} to Sponsor is covered in the “Return of Study Materials” section.

2. Sponsor may not require retention of empty Study Drug Materials containers.

3. Although it is not a regulatory requirement, Sponsor may want Study
3.19. Genetic Data & Specimens

Site provides Specimens to Sponsor "as is" for Study purposes only. Site makes no representation or warranty, express or implied, that Specimens are free from harmful biological or infectious agents or organisms and are otherwise merchantable or fit for a particular purpose or use. Sponsor assumes all risk of liability in connection with its use of Genetic Data and Specimens. Any use of Genetic Data and Specimens, whether such use occurs as part of or outside of the Study, will be in accordance with the Protocol, other written instructions, the informed consent form, the HIPAA authorization, and applicable law.

3.20. Electronic Data and Signatures

Site will submit Study data using the electronic system provided by the Sponsor. Sponsor warrants to Site that the system complies with U.S. 21 CFR Part 11 and HIPAA. Site will comply with Sponsor’s instructions, U.S. 21 CFR Part 11, and HIPAA. Site will prevent unauthorized access to the data by maintaining physical security of the computers and ensuring that Personnel maintain the confidentiality of their passwords. Prior to using the system, Site will certify to the FDA that its electronic signatures are the legally binding equivalent of handwritten signatures.

3.21. Data Clarification Queries

Sponsor will make its best efforts to submit only legitimate data queries to Site. Site will respond within {3/5/10} Days to Sponsor's timely queries. If Site is unable to resolve a query within this timeframe, it will instead respond with an explanation and expected date of resolution.

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3.22. Communication of Results to Subjects

After conclusion of Study, Sponsor will consider Site’s request to break the Study blind, so Site can inform Subjects which treatment they received. Sponsor will inform Site of study results when the information is available to Sponsor. For a period of ___ years after the Study, Sponsor will inform Site of observed Study (Drug/Device/Biologic) side effects so Site can inform Subjects.[1]

3.23. Return of Study Materials

Within 20 Days following the conclusion or premature termination of the Study or termination of this Agreement, Sponsor will instruct Site to return or destroy unused study materials, including Study {Drug/Device/Biologic}, devices, clinical supplies, CRFs and equipment furnished by Sponsor. Within 20 Days thereafter, Site will comply with Sponsor’s instructions. Sponsor will provide shipping materials and pay Site’s out-of-pocket shipping costs. During the Study, Site may return unused materials to Sponsor with prior Sponsor approval.[1,2,3,4]

1. Sponsor may want to include destruction and/or return instructions in the Agreement, for example: “Within 30 Days following the conclusion or premature termination of the Study or termination of this Agreement, Site will return unused Study {Drug/Device/Biologic} to Sponsor and destroy unused CRFs.”

2. Site may want 30 or 40 Days to return materials.

3. If Sponsor does not provide shipping materials, it should reimburse Site for the cost.

4. Site may want to return unused, bulky materials to Sponsor during a long study.

3.24. Disaster Preparedness

Site has a current disaster preparedness plan. The plan includes measures to safeguard Study and Subject records and data from loss or damage from disasters such as fire, earthquake, flood, electrical interruption, and biological contamination. Site maintains and provides contact information to enable the site to contact study personnel and Subjects in the event of a disaster, and vice versa.


3.25 Shipment of Hazardous Materials

Site will ensure that only trained and certified Personnel prepare shipments of hazardous materials such as Specimens and dry ice. Site will package and ship Specimens and infectious substances in compliance with the requirements of the U.S. Department of Transportation (DOT), the International Civil Aviation Organization (ICAO), the Protocol and all other relevant laws and regulations. Sponsor will supply Site with necessary shipping materials that are compliant with DOT and ICAO requirements.[1,2]

1. The International Air Transport Association (IATA) is an industry association. ICAO is a regulatory authority.

2. U.S. Department of Transportation (DOT) requirements apply only to shipments originating or terminating in the U.S. Optionally, specify other relevant national requirements.
4. Compensation

4.1. Budget

Sponsor will pay Site in accordance with the fee schedule in Exhibit A. Budget and this Section 4. Compensation. Changes to Exhibit A. Budget may be documented by letter or email.[1,2,3,4]

4.2. Initial Payment

Within __ Days after receiving {two/three} copies of this Agreement signed by Site and Investigator, Sponsor will make an initial, non-refundable payment to Site of $____. Subject to Section 4.13. Study Cancellation, Suspension or Early Termination, Sponsor will not provide any other compensation to Site for costs incurred prior to signing this Agreement.[1,2,3,4,5]
3. Detail purposes of initial payment to document compliance with anti-kickback Sarbanes-Oxley laws.

4. If Site believes it is incurring too many costs prior to signing this Agreement (e.g., for local IRB review), it may request Sponsor to agree in writing to reimburse a specified amount of the costs if Site does not participate in the study, regardless of the reason.

5. Although this payment is non-refundable, Site must make a good-faith effort to perform.

4.3. Advance Payment

Within ___ Days after receiving {two/three} copies of this Agreement signed by Site and Investigator, and documentation of IRB/IEC approval of the Study, Sponsor will make an advance, refundable payment to Site of $____. This advance payment will be applied to ___% of amounts owed by Sponsor to Site until exhausted.[1,2]

4.4. IRB/IEC Fees

If the IRB/IEC is an independent body selected by Sponsor, that IRB/IEC will charge Sponsor for its services, and Site will not be liable for any fees. If the IRB/IEC is affiliated with or designated by Site, that IRB/IEC will charge Site for its services, and Sponsor will reimburse Site for its actual costs upon receipt of invoice from Site in an amount not to exceed $___ for initial review, and an amount not to exceed $___ per year for renewals and other fees.[1]

1. Optionally, replace “for initial review, and an amount not to exceed $___ per year for renewals and other fees” with “for initial and continuing review and for ___ years”.

2. Sponsor is responsible for paying IRB fee for initial IRB review regardless of whether protocol is approved. Sponsor should pay fee prior to review, both to ensure payment and to avoid conflict of interest for IRB.

4.5. Subject Recruiting

Sponsor has provided Site with an initial recruiting budget to cover Site’s third-party costs for design, production, media and postage for print, electronic, direct mail, and event Subject recruiting communications costs, direct and indirect, as specified in Exhibit A. Budget. Any Site request for additional recruiting funds will be accompanied by detailed

1. Direct recruiting includes, for example, radio ads. Indirect recruiting includes, for example, “dear physician” letters.

2. Optionally, replace this entire section with:
4.6. Payment for Study Visits & Milestones

Sponsor will pay Site for completed Subject visits and milestones according to the Budget. A completed visit or milestone includes the proper completion of all Protocol activities and delivery to Sponsor of complete and accurate CRF data for that visit or milestone. Sponsor will not pay Site for incomplete visits or milestones (a) without Sponsor approval or (b) unless Subject leaves the Study. Site has sole responsibility for any extra costs or liabilities incurred by visits at a location not specified in the Form FDA 1572.[1]

4.7. Screen Failures

Sponsor will pay Site for visits prior to screen failure according to Exhibit A. Budget. Site must obtain prior written authorization from Sponsor for additional screen failures or to rescreen a potential Subject.[1,2,3,4]
screen failures, (b) screen failures as a percentage of enrolled subjects, or (c) total cost. Note that (b) provides no payment if no subjects are enrolled.

3. If there is no limit, replace “for up to ___ potential Subjects. Site must obtain prior written authorization from Sponsor for additional screen failures.” with “Site will make a good-faith effort to not screen potential Subjects who are not appropriate for the Study.”

4. Sites often have difficulty tracking the number of screen failures vs. the contractual limit, and requesting written authorization. Site should therefore report every screen failure to the Sponsor with a statement of the limit and an automatic request for an increase.

4.8. Incomplete Subjects

Sponsor will pay Site for Study activities related to Subjects that leave the Study voluntarily or because of injury, based on Investigator’s judgment of their welfare, or other legitimate reasons. However, Sponsor will not pay Site for any activity, even if conducted according to the Protocol:

a. after a Subject leaves the Study, except for early termination activities,

b. that generated unusable data,

c. at the time and after a Subject becomes ineligible to continue in the Study because of a Protocol violation by Site, or

d. related to a Subject enrolled in the Study despite being ineligible for the Study, whom Site had good reason to know was ineligible.

If Sponsor has already made payment to Site, Site will refund such payment.

If Sponsor terminates the enrollment period, it will pay Site for its good faith screening visits and related activities conducted prior to termination, subject to early warnings by Sponsor.

4.9. Third-party Costs

Unless stated otherwise in this Agreement, Site is responsible for all third-party costs it incurs during its conduct of the Study.[1] If Site contracts with third-parties to provide products or services for the Study and charges Sponsor for its actual costs, Site will pass through to Sponsor any discounts, rebates, profit-sharing and commissions it receives from

1. Third-party costs include, for example, supplies, lab fees, and hospital charges for procedures.

2. This provision does not cover Site’s profits.

1. Third-party costs include, for example, supplies, lab fees, and hospital charges for procedures.

3. This provision does not cover Site’s profits.
those third-parties.[2]

4.10. Hold-back & Final Payment

Sponsor will hold ___% of all payments due to Site, except for start-up fees, advance payments, and pass-through costs specified as such in Exhibit A. Budget, until Site’s completion of the Study[1], not to exceed $____. Sponsor will pay any open balance in a final payment to Site when (a) all required Subject visits have been completed, (b) Site has submitted all CRFs to Sponsor in a form suitable for use, (c) all data clarification queries have been resolved to Sponsor’s satisfaction, (d) the Study close-out visit has been completed, (e) Sponsor has verified that all required regulatory documentation is complete, and (f) Site has returned all required equipment, drugs and other material to Sponsor. Sponsor will conduct close-out visit after completion of Site’s Subject visits and within 15 Days of Site’s written request.[1,2,3,4,5,6,7]

1. Hold-back is optional. Its purpose is to retain Site’s cooperation until the final payment. If it exists, it should not be larger than 20%. If it is larger than Site’s eventual profit or contribution from the Study, probably much less than 20%, it will create negative cash flow for the Site in and of itself.

2. Hold-back may apply to the last payment due prior to study completion.

3. If Sponsor includes pass-through costs such as subject stipends and third-party tests in the hold-back, the hold-back percentage should be reduced accordingly.

4. Symmetry suggests that the hold-back be capped at the amount of the original advance payment.

5. The hold-back may be capped or smaller than normal for Sites with which the Sponsor has had positive experiences. It may also be divided into two pieces: half when the CRFs are all submitted and half when everything else is complete.

6. Sponsor should not delay payment because of an ongoing Site audit; it should just complete the audit in a timely manner. If the audit finds an important problem, it can dispute payment under the terms of the Agreement.

7. Sponsor may want to set a deadline for Site to submit invoices, say 30 or 60 days after the close-out visit. Such a deadline should not apply to ongoing events like adverse event treatment.

4.11. Change Orders & Unanticipated Costs

Sponsor will reimburse Site for cost increases due to protocol amendments, Sponsor instructions, and other reasonable unanticipated costs that it incurs during the Study. However, Sponsor’s obligation to pay for out-of-scope services is limited to only those services Sponsor authorizes in advance.[1]

1. Exhibit A. Budget assumes that Site will cover all costs not specified in the budget. There may, however, be costs that were not clear from the protocol and that would not be
4.12. Payment Schedule

Sponsor will pay Site for completed {procedures/visits/CRF pages ({submitted/collection})/Subjects/milestones/enrollment log} and reimbursable costs within {30/45/60} Days after completion of billable event or receipt of proper invoice. Site will invoice Sponsor for _________.[1,2,3,4,5]

1. Optionally, replace entire section with
   "Sponsor will consolidate each calendar {month's/quarter's} payments into one payment within {10/20/30} Days after the end of that calendar {month/quarter}.”

2. A calendar-quarter payment schedule is a cash-flow problem for sites, especially if monitoring visits are infrequent or delayed.

3. Sites may want to add: “Sponsor will pay Site interest of 1-1/2% per month on payments that are late by more than two weeks.”

4. Sites may instead want to add: “Site will pay Sponsor interest of 1-1/2% per month on advances that have not been charged against billable Study activities within 40 Days of receipt. Sponsor will pay Site interest of 1-1/2% per month on billable activities not paid within 40 Days of their completion, excluding any requirement for site monitor verifications.”

5. Sites may want to add: “Sponsor will reimburse Site for Site’s reasonable third-party costs to collect delinquent payments.”

4.13. Study Cancellation, Suspension or Early Termination

Sponsor may, subject to Section 12.3 Termination, cancel, suspend or terminate the Study, and notify Site of its decision. Site will immediately comply with Sponsor’s instructions, subject to protecting Subject safety and welfare. Sponsor will pay Site for:

a. Study activities, partial or complete, that Site performed prior to receiving notice
b. Non-cancellable third-party obligations
c. Medically-necessary continuing care of Subjects

1. If cancellation, suspension or termination is the fault of the Site, Sponsor may not want to pay some of these costs. It may, however, be difficult to determine fault, especially if there are multiple sites.
d. Reasonable costs incurred because of the cancellation, suspension or early termination, excluding lost profits[1]

4.14. Charges to Third-Parties

Site will not seek or accept from Subjects or third-party payors compensation for any Study {Drug Material/Device}, procedure, test, treatment or other material or service provided or paid for by Sponsor. If a third-party payor refuses to reimburse fees covered under the National Coverage Decision and is refused, Sponsor will pay those fees, provided they are listed in Exhibit A. Budget. Otherwise, Site is responsible. If either party represents that specific third-party reimbursement will be available, that party is responsible for those costs, if not reimbursed.

Compensation under this Agreement is consistent with fees charged for similar research in Site’s geographical area, has been negotiated at arms-length, and is unrelated to the volume or value of any referrals or other business otherwise generated between Sponsor and Institution.[1,2,3,4,5,6,7,8]

1. In the United States, government third-party payors include Medicare, Medicaid, the Veterans Administration, and others. Private payors are principally insurance companies and managed care providers. Only Medicare is bound by the National Coverage Decision. Other third-party payors may follow its rules. The Veterans Administration is allowed to seek reimbursement from Medicare and Medicaid.
3. Site may seek compensation for standard-of-care materials and services not provided or paid for by Sponsor. Medicare may reimburse for non-standard-of-care drugs and devices, with pre-approval.
4. Optionally, add “Site will inform subcontractors and affiliates associated with the Study that they are subject to this obligation.”
5. Optionally, in U.S., replace “Site will not seek or accept from Subjects or third-party payors compensation for any Study drug, procedure, test, treatment or other material or service provided or paid for by Sponsor.” with “Site will comply with the National Coverage Decision.”
6. National Coverage Decision is applicable in the U.S.
7. Informed consent form may state that unreimbursed costs are charged to the Subject. Subject is not, however, legally bound by the informed consent form.
8. The “fair market value” sentence complies with anti-kickback laws in the U.S.

4.15. Payment Accounting & Discrepancies
With each payment, Sponsor will identify the Sponsor and Protocol number, and provide a detailed accounting of the items and amounts covered by that payment. Site must notify Sponsor of any payment discrepancy or other request for additional payment within 20 Days after receipt of final payment.[1,2]

Within 90 days after the closeout visit, Site will deliver to Sponsor a final accounting of amounts due from Sponsor (with reasonable supporting documentation). Sponsor will pay undisputed amounts within 60 days thereafter.

### 4.16. Overpayment

If Sponsor has overpaid Site, it may deduct the amount of such overpayment from its next payment to Site. Otherwise, Site will refund any overpayment according to the payment terms in Section 4.13, Payment Terms.[1]

### 4.17. Invoices

Any invoice to Sponsor must include an invoice number and identify the Sponsor name, Protocol number, and Investigator name. Submit invoices to the following person and address:[1,2]

1. Instead of refunding an overpayment, Site may want to submit an invoice for unanticipated costs to offset that amount.

### 4.18. Budget Adjustments

The Budget will not change during the initial {1/2/3} year period after execution of this Agreement. If the Study is not completed by the end of that period, Sponsor will adjust compensation to Site annually thereafter based on actual third-party charges and, in the U.S., on the increase in the U.S. City Average Medical Care Services Consumer Price Index from the middle of the initial period.[1,2,3,4]

1. This Section is optional. For studies shorter than 3 years, inflation is unlikely to be a significant problem. Note, however, that the Budget can be revisited if the Study is extended.
2. Set the Budget for the initial period based on anticipated cost changes during that period.
3. The U.S. City Average Medical Care Services Consumer Price Index increased by 4.4% per year over the five years from 1999 to 2004. The index is available at data.bls.gov.
4. Government price indices are available in many countries. If not, the “Big Mac” index can be used. Alternatively, the parties can negotiate in good faith.

### 4.19. Contingent Fees

Site will invoice Sponsor with adequate documentation for any contingent fees specified in Exhibit A, Budget.[1]

1. Bonus and incentive fees, if any, may be included in this section. Bonus and incentive fees are problematic if they encourage Site to
4.20. Payee

Site authorizes the single payee designated below to receive all of its payments under this Agreement. Site must inform Sponsor of the payee’s taxpayer identification number before Sponsor can process the first payment. (See Exhibit A. Budget.) Payee:[1,2,3,4,5]

1. If Investigator is a party to this Agreement, replace “Site authorizes” with “Site and Investigator authorize”.
2. Site may provide Taxpayer ID separately to Sponsor for confidentiality.
3. The allocation of payments between Site and Investigator is their own private matter.
4. If the Payee is neither the Site nor the Investigator, Sponsor should review the relationship of the Payee to the Site and Investigator.
5. Unusual terms such as payment to an account in a third country or lack of payment to a government facility may be cause for concern. Due diligence in verifying payee information is recommended.

4.21 Taxes

Each party will pay its own taxes except as specified in Exhibit A. Budget.

5. Confidential Information

5.1 Confidential Information

Sponsor’s Confidential Information includes this Agreement and attached exhibits, including but not limited to the Budget, Protocol and Investigator’s Brochure; Study reports and data; other information disclosed by Sponsor to Site; Sponsor Data; and Sponsor’s other proprietary information of a technical, business or other nature, in any format, written, verbal or electronic, and derivatives thereof.[1,2,3,4]

Site and Investigator Confidential Information includes operating procedures, information about other studies, the identity of referring physicians, and other proprietary information of a technical, business or other nature, in any format, written {, verbal} or electronic, and derivatives thereof.[2,5]

1. This section has two purposes: (a) prevent disclosures of confidential information and (b) establish that the owner of the confidential information has taken reasonable precautions to protect it. If the owner does not take reasonable precautions, it may lose its confidentiality rights.
2. If verbal communications are not followed up in writings marked “confidential,” Sponsor is relying on Site’s judgment.
This Section does not apply to information that is not confidential because it:

a. is in the public domain at the time of disclosure by Recipient to a third-party, through no breach of this Agreement by Recipient;
b. was lawfully in Recipient's possession prior to disclosure by Owner, as shown by written records;[6]
c. was lawfully disclosed to Recipient by a third-party that Recipient reasonably believed was not under an obligation to keep such information confidential; or
d. has been lawfully developed independently by Recipient, as evidenced by contemporaneous written documentation.

Confidential information may be disclosed if it:

e. is required to be disclosed in a government inspection, or by a government order, order by a court of competent jurisdiction, or other legal requirement;
f. is required from a Subject by a third-party payor, to the extent necessary to determine coverage;
g. is required to verbally answer Subject's reasonable questions during the informed consent process;[7]
h. is required by Site, Investigator or third-party physician for medical treatment or counseling of Subjects or other persons exposed to Study {Drug/Device/Biologic};
i. is required to be disclosed to protect the public's health;
j. is reasonably required (a) for peer review by other Study sites, (b) by scientific standards for publication of the Study results, or (c) for other scholars to verify the results of the Study; or
k. is required by Site or Investigator to defend itself in subject injury litigation, subject to 20 Days prior written notification to Sponsor and right of Sponsor to seek a protective order from a court of competent jurisdiction.[8]

5.2. Disclosures

Disclosures under Section 5.1 (e) through (k) are limited according to the Recipient's reasonable judgment to the extent necessary after consultation with the Owner to the extent practical, and will be protected by obtaining confidentiality agreements (with terms no less strict than those set forth in this Agreement) from Recipients to the extent practical.

If a disclosure of Confidential Information is required by a government order, court of law, other legal requirement, Subject or third-party payor, Recipient will disclose, to the extent legally permitted, only such Confidential Information as is required and only to the party that requires the disclosure. It will also request confidential treatment of the disclosed Confidential Information. It will otherwise maintain the confidentiality of Confidential Information to the extent possible; and will notify the Owner immediately and, if possible, at least 5 Days prior to the disclosure. In addition, Recipient will cooperate with any attempts by Owner to limit such disclosure by appropriate legal means. These disclosure

3. Some public entities in the U.S. must disclose at least summary information about all contracts.
4. Some sites make public the terms of their clinical trial agreements but may maintain the confidentiality of certain attachments.
5. Mutual confidentiality is especially important for investigator-initiated studies.
6. If, for example, the Investigator originally developed and maintained as confidential an assessment tool, that tool would remain the confidential property of the Investigator. It would not become Sponsor Confidential Information. The confidentiality of that tool would be compromised unless this Agreement requires the Sponsor to protect it.
7. This term does not authorize Site to give a potential Subject documents containing Confidential Information.
8. Upon Site or Investigator's request, a court of competent jurisdiction can subpoena confidential information from the Sponsor, but not from the Site or Investigator that already possesses it (e.g., source documentation).
provisions are subject to applicable Open Records, Freedom of Information Act, and similar statutes.

This Section does not limit Site’s disclosure rights under Sections 8. Publications & Presentations; 3.1.11. IRB/IEC; 3.3. Inspections & Audits; 4.14. Charges to Third-parties; or Section 14.2. Publicity and Use of Names; nor does it limit Site’s or Investigator’s right to disclose Confidential Information to the extent necessary to protect the public from severe health hazards, or to protect the safety and welfare of Subjects, provided, however, that Site will notify Sponsor prior to making such disclosure and limit such disclosure to the extent feasible.

5.3. Confidentiality Obligations

During the term of this Agreement and for __ years thereafter, Recipients will use Confidential Information only for the purposes set forth in this Agreement. Recipients will protect Confidential Information with at least the same care as they protect their own Confidential Information of a comparable nature, and in no event will they use less than reasonable care. They will disclose Confidential Information only to their Personnel involved in conducting the Study, who are bound by a similar obligation of confidentiality, on a need-to-know basis, and have been informed of their obligations, and to Authorized Third-parties.[1,2,3,4,5,6]

The parties will make reasonable efforts to mark or otherwise identify their Confidential Information as confidential. However, unmarked information that a reasonable person knowledgeable about clinical research would judge confidential will still be treated as Confidential Information. Any information marked or identified as confidential remains confidential even if subsequently disclosed to Recipient without such marking or identification.[7]

This Agreement is Confidential. Study Results are Sponsor’s Confidential Information except as required for publication in refereed journals.

If a third-party discloses to Recipient what a reasonable person would consider the other party’s Confidential Information, it will notify the Owner within 3 Days and treat that information as confidential, unless informed otherwise by the Owner.

If a Recipient discovers any loss or compromise of Confidential Information, it will notify the Owner within 3 Days and cooperate with the Owner to mitigate the loss or compromise.

Within 30 days following termination or expiration of this Agreement and request by the Owner, Recipient will destroy (with certification to Owner) or return to Owner at Owner’s expense, Confidential Information that it is not required to retain by law, regulation or other legal requirement. However, Recipient may retain one copy of Confidential Information for its records in a secure location.[8]

A breach of this Section may cause irreparable damage that cannot be addressed adequately by money damages. In addition to any other remedies that may be available, the parties are therefore entitled to seek injunctive relief to prevent or restrain a breach of

1. 3 to 10 total years of confidentiality is common, and 5 to 7 years most common.
2. Sponsors often do not know how long they need to maintain confidentiality on drugs in development. Confidentiality in perpetuity requires Site to maintain this Agreement in perpetuity, which is not reasonable. If either party wants a very long confidentiality period that is unacceptable to the other party, this language may be acceptable to both parties: “In the one year period prior to expiration of this confidentiality obligation, either party may extend the period of confidentiality by an additional __ years.”
3. Certain trade secrets may require long-term or perpetual protection.
4. Optionally, replace reasonable standard of care with an absolute obligation to protect the information.
5. This entire Section 5 is optional for large, Phase IV studies.
6. For example, Subinvestigators and referring physicians must sign a confidentiality agreement prior to seeing Sponsor’s Confidential Information.
7. Optionally, delete this paragraph and replace definitions of Confidential Information (except for exclusions) with “Confidential Information includes information of a technical, business or other nature, in any format, written, electronic or verbal, that is marked by its
this Section{, without having to post bond or other security}.\[9\]

Ordinary backup of electronic data is permitted without consideration of geographical location.

**6. Protected Health Information and Use of Data**

Site and Investigator will comply with applicable laws and regulations governing the privacy and security of Subject information, including HIPAA. Site will obtain written authorization from Subjects or IRB/IEC waivers to use and disclose their information to the extent necessary to conduct the Study and provide Study data to Sponsor for its legitimate use. These authorizations or waivers will allow disclosures to Sponsor to the extent necessary for Sponsor to comply with this Agreement, applicable laws, regulations and legal requirements. Sponsor is not a HIPAA Covered Entity, but it will not:

a. Use Subject information except for purposes of the Study and as authorized by Subject.
b. Disclose Subject identifying information or disclose Subject private information to any third-party unless required to do so by law, regulation, government order, or pursuant to a written request by the Subject.
c. Leave Subject private information unsecured.
d. Remove Subject information from Site.
e. Attempt to contact any Subjects not previously known to Sponsor or if required to protect the Subject’s welfare.

Sponsor’s legitimate use of Subject information outside the Study includes (a) reviewing the safety and effectiveness of the [Study Drug/Study Device]; (b) conducting retrospective reviews of the Study and Sponsor Data; (c) evaluating other products and therapies; (d) developing a better understanding of disease; and (e) improving the efficiency of clinical trials.\[1,2,3,4,5,6,7\]

**7. Intellectual Property**

Owner as confidential, and derivatives thereof.” Sites may require that confidential information be marked “Confidential” because unmarked information imposes a difficult burden on the Site. On the other hand, it is very difficult for the Sponsor to ensure that every confidential document and communication is marked. One failure to mark opens the barn door.

8. This copy is for legal purposes only, for example, if Owner accuses Recipient of disclosing Confidential Information.

9. Including this phrase facilitates frivolous injunctions; excluding it may place an onerous burden on the damaged party.
7.1. Separate Property

Intellectual Property that either party owned prior to execution of this Agreement, or develops independently of the Study and other Party’s Confidential Information, is that party’s separate property. It is not affected by this Agreement. Neither party has any claims to or rights in such Intellectual Property of the other party.[1]

7.2. Site Authority

Site represents and warrants that it has the authority to grant all of the rights granted in this Section, and that its potential Inventors are and will be obligated to assign their Inventions to Sponsor and will not to enter into agreements with third-parties that would interfere with this obligation.

7.3. Disclosure

Within 30 Days of becoming aware of any Invention, Site will disclose the Invention to Sponsor with a full written description. Site will make available to Sponsor, at Sponsor’s request and expense, all work, reports, writings, ideas, designs, methods, computer software, and data, recorded in any form, that relate to the Invention.

7.4. Data & Specimen Ownership

Site owns all Source Documents. Sponsor owns all Sponsor Data. Site owns all Specimens and Genetic Data, and grants Sponsor access to such property only for purposes of the Study. Sponsor and Site may freely use their own data subject to Subject consent and IRB approval. In addition, Site may freely use Sponsor Data after first multicenter Publication is published or Sponsor waives right to a multicenter Publication. Sponsor has no right to Site’s pre-existing biological samples, genomic database, or other proprietary database {except for purposes that relate directly to the Study}.[1]

7.5. Ownership of Inventions

Sponsor will own Inventions to the extent that they relate to Site’s conduct of Study made with or derived from, in whole or in part, Study {Drug/Device/Biologic}, or concerning methods of using Study {Drug/Device/Biologic}. However, Sponsor and Site will jointly own inventions made by Site with Sponsor’s Intellectual Property, but not contemplated by the Protocol, with Sponsor having the right of exploitation, subject to royalties that reflect the contributions of the parties. Site will retain the right to use such inventions internally for patient care, research, education and publication, provided such use does not violate Sponsor’s confidentiality rights or impede commercialization. The sole or joint ownership of all other Inventions will be determined in accordance with U.S. patent law, regardless of whether the Invention is patentable. Sponsor and Site may independently exploit joint Inventions without compensation, liability or other obligation to the other party, subject, however, to Sponsor’s option to license Site’s rights in Section 7.6 Licenses.[1,2,3,4,5]

1. The intellectual property section can be streamlined or deleted in later-stage studies, in which inventions are unlikely.

1. Sponsors may want non-exclusive, royalty-free licenses to databases and biological sample banks created with funding from multiple sponsors. Sites may want to charge sponsors for their use, but any fees should be prorated for the Sponsor’s contribution.

1. Sponsors argue that they deserve ownership without further payment because of their large investment developing the Study {Drug/Device/Biologic}. Sites may argue that they deserve compensation or partial ownership because budgets are not large enough to justify Sponsor sole ownership of Inventions, they played a role in making the Invention, or they partially made the Invention prior to the Study.

2. U.S. patent law considers the relative contribution by the parties to the Invention.
Without Sponsor’s prior approval, Site will not knowingly use in the Study any of its own or third-party Intellectual Property that may interfere with Sponsor’s rights to Inventions.

Except as stated elsewhere in the Agreement, the Parties authorize the use and grant a royalty-free license on their respective Intellectual Property to the other Party(ies) to the extent necessary to accomplish the purposes of the Study.

This Agreement is not a "work-for-hire" agreement under the copyright laws of any country.

3. Optionally, add “In accordance with the terms of this Section 7. Intellectual Property, Site grants to Sponsor a perpetual, royalty-free license to use Site works and data, excepting ____________, including the rights to use, market or sublicense the works and data throughout the United States, including all copyrights in the works and in all derivative works, together with all exclusive rights granted to an author under the copyright laws of the United States, foreign countries, and international copyright conventions, and the right to grant these rights or any part of them to third-parties.”

4. Sponsor may want to replace this paragraph with “All Inventions will become the sole property of Sponsor with no further payment to Site. Site will irrevocably assign to Sponsor all of its rights, titles and interests worldwide in Inventions. Site may want to replace this paragraph with “Site will own all or part of any Invention it creates in whole or in part, during its conduct of the Study. Any Invention made jointly by Site and Sponsor will be owned jointly by the parties, according to U.S. patent law, regardless of whether the Invention is patentable.”

5. If a sponsor wants ownership of all inventions, site can offer sponsor ownership of inventions based on the protocol. A compromise may then result.

7.6 License

Site hereby grants Sponsor an exclusive option, without fee, exercisable within 90 calendar days following written notice of an Invention, to obtain an exclusive or nonexclusive, worldwide, royalty-bearing commercialization license, upon reasonable commercial terms and conditions (including measurable provisions for due diligence in development, commercialization and marketing), to all rights, title and interest that Site may have or obtain in that Invention. This license will include the right to sublicense, make, have made, use, and sell the Invention or products incorporating the Invention. Upon Sponsor’s exercise of its option with regard to any particular Invention, Site and Sponsor will negotiate in good faith for up to {6/9/12} months in an attempt to reach a license agreement satisfactory to both parties. If an agreement is not reached by the end of that
period, Sponsor’s rights to that Invention will expire, and Site may license Invention to third-parties without obligation to Sponsor. Site grants Sponsor, for the term of the negotiation period, a non-exclusive, worldwide, royalty-free license on Site’s rights to the Invention for Sponsor’s internal research purposes.[1,2,3,4,5]

Any such license agreement will include reimbursement to Site for its reasonable past and Sponsor-approved future costs of filing, prosecuting, and maintaining any patent or other intellectual property applications related to licensed Invention.

If Sponsor does not exercise its option on Site’s ownership of Joint Inventions, Site may exercise an option to license Sponsor’s ownership share of that Invention, under the symmetrical terms of this Section 7. Intellectual Property.

Any license rights of a party under this Agreement include the party’s affiliates and co-development partners, to the extent the party is obligated by contract to that co-development partner to share applicable intellectual property.[6]

4. U.S. Revenue Procedure 97-14 says that any promise to license the results of an invention created in a facility funded by a state or municipal bond voids the bond’s tax exemption. There is an exception for facilities used less than 10% for privately-funded research. The IRS has not yet enforced this Revenue Procedure.

5. If Sponsor exercises its right to a non-exclusive license, it blocks Site from granting an exclusive license to a third-party.

6. Sponsors often operate globally with multiple corporate affiliates. Sites may also operate multiple hospitals, medical schools, and educational foundations.

7.7. Filings

At Sponsor’s request and expense, Site will execute, or cause to be executed by its Inventors, all documents and perform all acts deemed necessary by Sponsor to evidence Sponsor’s ownership of Inventions, obtain patents in any country, and otherwise protect Sponsor’s interests in Inventions.

Sponsor has the exclusive right to incorporate any Source Document data in any regulatory filing concerning any Study {Drug/Device/Biologic} or other product. The inclusion of Source Document data in any regulatory filing gives Site no ownership, license or access rights in, or to, such regulatory filing(s) or Study {Drug/Device/Biologic}.[1]

For joint Inventions, Sponsor may elect to file joint patent or other intellectual property applications at its own expense. It will notify Site within 15 Days of such election, and will provide Site with copies of any applications it files and of any written communications to or from the applicable patent or other intellectual property office regarding any such Invention. If Sponsor does not file such application(s) within 3/6 months after disclosure of the Invention to Sponsor by Site, Site will obtain the rights to joint filing for such Invention.[2]

7.8. License to Site

Upon Site’s request, after Sponsor has filed patent applications or otherwise protected its Intellectual Property according to this Section 7. Intellectual Property, and subject to Section 5. Confidential Information, Sponsor will grant Site a perpetual, non-exclusive, royalty-free license to use Inventions to perform the Study, for its internal educational, non-commercial research, and patient care purposes, and to comply with any applicable the effect is to create a cap but not a floor on the rate.

1. Optionally, add: “At Sponsor’s request and expense, Site will assist Sponsor in preparing and submitting new drug applications to the FDA, and attend meetings with the FDA regarding such applications.”

2. Optionally, add: “Site irrevocably appoints Sponsor, and will ensure that Inventors irrevocably appoint Sponsor, as attorney-in-fact for the purpose of executing such documents in their respective names as may be necessary or desirable to carry out the purposes this paragraph.”
laws and regulations.

7.9. Other Funding[1]

Site will not knowingly support the Study with any third-party funding that may adversely affect Sponsor’s intellectual property rights under this Agreement. The Study falls outside the planned and committed activities of any U.S. government-funded project undertaken by Site and will not diminish or distract from the performance of such Government-funded Activities within the meaning of 37 CFR §401.1(a)(1). If any aspect of the Study Conduct is found to be Government-funded, Site will take all actions necessary to retain title to any Invention made under this Agreement, including those required by 37 CFR §401.14(c)(1), (2), and (3). If any Invention is controlled by federal law in accordance with 37 CFR §501.1 - 501.11, any license will be subject to the right of the U.S. government to retain an irrevocable, royalty-free right to use the Invention throughout the U.S. government.

8. Publication

8.1. General

Site may publish, present and use for instruction and research any Results arising out of its conduct of the Study provided that Site does not disclose Sponsor Confidential Information as described in Section 5. Confidential Information, and allows Sponsor time to protect its proprietary rights, as provided below. Sponsor will make available to Site for publication purposes Sponsor Data and Tangible Property created at Site.[1,2]

At least {30/45} calendar days prior to submission for publication or presentation, Site will submit a copy of any proposed Publication to Sponsor for review and comment.[3,4]

Sponsor may review the Publication to (a) determine whether the Publication discloses Sponsor Confidential Information, (b) provide information that Site may not have, and (c) determine whether the Publication discloses any potentially-patentable inventions.

Sponsor will submit to Site any comments and requirements for deletion of Sponsor Confidential Information, other than Results, within {14/21} calendar days of receipt. Site will consider Sponsor’s comments, but is not required to modify the Publication based on them. It will, however, prior to submission for publication or presentation, delete any Sponsor Confidential Information and provide a revised copy of Publication to Sponsor. However, such deletions are not required if they cause the Publication to be incomplete, inaccurate, misleading or preclude publication by Site of the Study’s Results.[5,6]

However, if requested by Sponsor, Site will withhold Publication from submission for {30/60/90} calendar days in addition to the initial review period to allow Sponsor to file patent applications to establish and preserve Sponsor’s proprietary rights. Alternatively, Site may delete information pertaining to the potential invention from the Publication.

Sponsor will use its reasonable efforts to complete its reviews and filings prior to end of the

1. Inventions are unlikely in Phase I and II studies, and even less likely in Phase III and IV studies. The parties should therefore be relatively flexible in later-stage studies.

1. In the U.S., if a non-profit academic or other tax-exempt Site accepts contractual restrictions on its ability to independently publish its Study Results, it may lose its tax-exempt status for the Study or, if repeated, for the entire entity.

2. AAHRPP accreditation standard I.8.D. requires: “Before initiating research, the Organization has a written agreement with the Sponsor about plans for disseminating findings from the research and the roles that Researchers and Sponsors will play in the publication or disclosure of results.”

3. If Sponsor objects to publication or presentation of a Publication because it would disclose its confidential information, it may claim breach of contract and seek injunctive relief to stop publication.

4. The parties may agree on a two-tier review and comment system with a shorter period for abstracts and presentations than for scientific papers.

5. If Sponsor believes that a Publication is inconsistent with academic standards, is false
above time periods. If Sponsor does not exercise its rights under this Section within the time periods stated in this Section, Site may submit the Publication for publication or presentation.

Sponsor’s rights under this Section 8. Publications and Presentations expire at the end of the Confidentiality Period.

8.2. Multicenter Articles

Sponsor may invite Site to participate in a multicenter article for a professional journal. The parties will determine the terms of such participation outside this Agreement.[1]

Sponsor will diligently pursue completion of the Study, database lock, and publication of any multicenter article. Until 30 calendar days after Site submits data for its last Subject, Sponsor may notify Site that a multicenter article in a professional journal is planned. In this case, Site will not submit any Publication for publication or presentation until after the multicenter article has been submitted. Sponsor will have {12/15/18} months after completion of the last Study Subject visit to any site to arrange for the submission of the multicenter article. However, this restriction will not extend for more than {12/15/18} months after completion or early termination of Study at Site.[2]

Upon Site’s request, Sponsor will notify Site within 5 Days after the multicenter article has been cancelled or accepted for publication, and provide a copy of the article manuscript to Site.

Publications that Site submits after receipt of the multicenter article manuscript will reference the multicenter article.

Prior to submission for publication of a multicenter paper, if any, Site may notify Sponsor that it intends to submit a Publication for publication or presentation that presents findings tangential to the objectives of the Study. Sponsor may, within 10 Days, prohibit Site from publishing or presenting this Publication if its proposed contents will be included in the multicenter paper. Site may also notify Sponsor that it intends to submit a Paper for publication or presentation that is important for the protection of public health. In such case, Site will consult with Sponsor on the contents of the Paper and Sponsor will not unreasonably withhold permission for Site to publish the Publication.

8.3. Multicenter Data

Within 15 Days after request by Site and provided that data are available, Sponsor will provide to Site the final de-identified data from all sites participating in the Study. Site may use that data in Publications.

8.4. Confidentiality
Site may disclose Results in Publication. Site may provide Publication prior to publication to anyone bound by confidentiality under this Agreement according to Section 5. Confidential Information. Subject to Section 3.11. Study Documents, Site is not obligated to disclose its raw data, calculations, testing procedures, or any information regarding its proprietary methods to Sponsor.

8.5. Copyright
To the extent permitted by the publisher, Investigator will own (or share with other authors) the copyright on his/her publications and other copyrightable material that he/she produces as a result of the Study. To the extent that Investigator has such sole, joint or shared rights, Investigator grants Sponsor a perpetual, irrevocable, royalty-free license to make and distribute copies of such publications.

8.6. Authorship
Unless otherwise required by the journal in which the Publication appears, or the forum in which the presentation is made, authorship will comply with the ICMJE’s current Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication and the Food and Drug Administration Amendments Act of 2007.[1,2,3]

1. ICMJE is the International Committee of Medical Journal Editors. The ICMJE guideline requires registration as a condition of publication.
2. Food and Drug Administration Amendments Act of 2007 (FDAAA – Public Law 110-85) does not address publication, but requires registration information with some results data.

8.7. Statement of Support
In any publication or presentation based in whole or in part on data generated from the Study, Investigator will include a statement that creation of the data was supported in part by Sponsor.

8.8. Communication
Investigator and Sponsor will comply with the communication requirements of the then-current version of PhRMA’s Updated Principles For Conduct Of Clinical Trials And Communication Of Clinical Trial Results.[1,2]

1. Optional section.
2. PhRMA is the Pharmaceutical Research and Manufacturers of America trade association. See PhRMA’s “Principles on Conduct of CLINICAL TRIALS and Communication of CLINICAL TRIAL RESULTS” at http://www.phrma.org/files/Clinical%20Trials.pdf

8.9. Registry
Sponsor will comply with FDA requirements to register studies and ICMJE’s current Uniform

1. Optional section; regulations may change.
8.10. Acknowledgement

If requested by Sponsor or required by a journal, Publications will acknowledge Sponsor’s financial or editorial contribution to the research and Publication. If Site is one of the top enrollers and otherwise complies with its obligations under this Agreement, Sponsor will make its best efforts to ensure that the first multicenter publication, if any, acknowledges Site’s contributions.[1]

8.11. Publications Committee[1]

A Publications Committee consisting of one Sponsor representative, one participating lead investigator, and one participating investigator jointly appointed by them, will assume Sponsor’s authority over the following decisions:

a. Which investigators will author and submit the first multicenter Publication based on the Study;
b. Whether an investigator, if any, may submit or present Study Results prior to (submission/publication) of the first multicenter Publication;
c. Which investigators may have access to multicenter Study data (if not granted to all investigators);
d. The Publication Committee will also attempt to mediate disputes between Sponsor and Site related to publications.[2]

8.12. License to Sponsor

Site grants Sponsor a worldwide, royalty-free, non-exclusive license to reproduce and distribute copies of any paper or article relating to the Study in which the Site or Investigator holds the copyright.

9. Subject Injury

If any party to this Agreement (that knows this Agreement exists) becomes aware of a claim or potential claim, relating to a Subject injury or illness that may have been caused by the Study, that party will, within 5 Days of such awareness, notify the other parties of the claim.[1]

Whether or not the Subject has made a claim, the parties will cooperate to determine the
relationship, if any, of the Study to the injury or illness. If, in the Investigator’s judgment, it is or might be related, the parties will cooperate to diagnose and deliver a course of treatment for the injury or illness, with the Subject’s consent. If the parties cannot agree on these issues, they will attempt to resolve them through mediation.

Sponsor will pay all reasonable and customary fees for standard-of-care diagnosis, care and treatment of the injury or illness:[2,3]

a. to the extent that the injury or illness was not caused by Site’s deviation from the Protocol, other current written instructions consistent with the Protocol and provided by Sponsor to Site, applicable laws and regulations, or this Agreement, except to protect the safety and welfare of the Subject;
b. to the extent that the injury or illness was not caused by the negligence or misconduct of Site or Investigator;[4]
c. to the extent that the injury or illness is not attributable to any underlying illness, unless such injury or illness was exacerbated by the Study {Drug/Device/Biologic};
d. provided the apparently-causative Study {Drug/Device/Biologic} was {administered/used} or Study procedure performed in accordance with the Protocol;
e. to the extent permitted by law and government rules, such costs are not covered by the Subject’s private insurer, government payor, or other responsible third-party; and [5,6]
f. to the extent such fees are not paid for by a third party, providing that neither Site nor Subject will be obligated to seek reimbursement from a third party insurer.

Should the injury or illness prevent substantial restoration of the Subject’s health to the condition prior to the injury or illness and long-term care be required as a result, Sponsor will pay reasonable and customary fees for such care, subject to the same limitations listed above.

If, in Investigator’s judgment, medical testing is required to determine or confirm the existence or cause of the injury or illness, Sponsor will pay all reasonable and customary fees for the testing. If, in the judgment of the Investigator, the injury or illness is found not to exist or, in Investigator’s judgment, was not caused by the Study, Sponsor will pay only the reasonable and customary costs for the diagnosis, and not the cost of treatment.[7]

Investigator will make a good-faith effort to obtain advance authorization by Sponsor before incurring costs under this Section.[8]

Sponsor’s agreement to pay the foregoing costs does not limit its right to seek financial reimbursement from Site to the extent that the injury or illness resulted from (a) the negligence or misconduct of Site; or (b) failure by Site to follow accepted standard of care (including emergency treatment), the Protocol, precautions or instructions furnished by Sponsor, or the terms of this Agreement.

Sponsor will reimburse Subject’s reasonable and customary diagnosis, care and treatment costs, subject to the above conditions.
Sponsor will pay the fees of third-party providers and pharmacies to which Investigator delegates any diagnosis, prescriptions, care or treatment, subject to the above conditions.

Sponsor will reimburse Subject’s insurance co-payments or deductibles charged by his/her private insurer, government payor, or other responsible third-party, consistent with the Informed Consent Form.[9]

Except as stated above, Sponsor will not compensate Subject for lost wages or any other damages, expenses, or losses, or for medical expenses that have been covered by the Subject’s medical or other insurance.[5]

[10]

resolve the 3rd party payor issue, as Sponsors may have conditional language in the clinical trial agreement that does not trigger payment and thus, until a payment is actually made, they are not providing liability insurance. However, should such payments be made, Sponsors would be required to report them and may require information regarding Subjects in order to report to CMS. Passive language in the informed consent form might not trigger the secondary payor issue, e.g., “You will be reimbursed.”

6. Research subjects should not bear the financial burden of participation in the development of products for companies. Therefore, even if the complications were covered by insurance, subjects may still have to bear the financial burden of co-payments, deductibles and lifetime limits.

7. Optionally, replace this clause with “such costs have not been reimbursed by (or submitted for reimbursement to) the Subject’s private insurer, government payor, or other responsible third-party; neither Subject nor Site are obligated to seek such reimbursement.”

8. Some sites do not allow Investigator to determine medical testing.

9. Optionally, replace "Investigator will make a good-faith effort to obtain advance authorization” with "Investigator will obtain advance authorization" or "Investigator is not required to obtain advance authorization”. It is reasonable for the Sponsor to authorize expenditures of its own funds, but sometimes impractical for Investigator to obtain authorization on short-notice.

10. Review wording of Informed Consent Form to ensure consistency with this Section. To ensure that Sponsor complies with this section, the parties may want to add “Notwithstanding Section 14.10., Subjects are third-party beneficiaries of this Section 9.”
10. Indemnification

10.1. Indemnification by Sponsor

Sponsor will defend, indemnify and hold harmless Site Indemnitees from any and all third-party liabilities and expenses, including reasonable attorneys’ and experts’ fees and costs, to the extent that they arise from claims, actions and lawsuits for property damage, personal injury, or death resulting in whole or in part from:[1,2,3,4,5,6,7,8,9,10]

a. Site Indemnitees’ participation in the Study, {due to/including} administration or use of any Study {Drug Materials/Devices}, proper performance of any Study test or procedure that is not standard of care, use of any equipment or supplies {provided by Sponsor/manufactured by Sponsor {or customized for Sponsor}}, or complying with the Protocol or any non-conflicting written instructions provided by Sponsor; or

b. any:
   1. patent infringement, copyright violation, or trade secret misappropriation caused by use of the Study {Drug/Device/Biologic} by Site;
   2. the handling, use or subsequent transfer of Specimens and Genetic Data shipped by Site per Sponsor’s instructions;
   3. Sponsor’s use, non-use, interpretation or disclosure of Study data or Results;
   4. the design, manufacture, sale, promotion or use in commerce by Sponsor or its licensee of any product, service or process relating to the Study; or
   5. (i) violation of any law or regulation, (ii) material breach of this Agreement, or (iii) negligent or wrongful act or omission by Sponsor or its employees, agents, subcontractors or other authorized third-party that takes on those roles; or
   6. Sponsor’s negligence in designing Study, writing the Protocol, or providing instructions to Site.

This indemnification obligation does not apply to the extent that the potential liability:

a. was caused by any Site Indemnitee not conducting Study in accordance with (a) the Protocol, (b) then-current written instructions provided by Sponsor, (c) other applicable laws and regulations, and (d) this Agreement, provided that Site Indemnitee’s actions were not necessary to protect the safety or welfare of the claimant;[18]

b. was caused by the negligence, willful misconduct, or criminal act of any Site Indemnitee or person under his/her control (e.g., an employee or contractor); or

1. Parties to a contract use indemnification to allocate the risk of claims by third-parties. Indemnification is the right of the “indemnitee”, who is potentially liable for a loss, to shift that risk to the “indemnitor”. Often the party best able to minimize or understand the risk is the party that takes on the potential liability.

2. If this Agreement includes Indemnification by Site, the two indemnification sections will probably be symmetrical to some extent. (See related comment in Section 10.2)

3. Defense costs can be substantial. However, if one party agrees to indemnify and hold-harmless, but not defend a second party, the second party may accept responsibility for liabilities for which the first party must pay.

4. Sponsor’s products liability insurance probably covers cost of defending Site and Investigator.

5. Optionally, identify subcontractors, affiliates and partners by name or category in Exhibit C. Site Indemnitees.

6. “Resulting in whole or in part” means that if Sponsor or a third-party contributed to the cause of claim, Sponsor still indemnifies Site Indemnitees fully.

7. The words “directly or indirectly” are not included as types of claims because (a) indirect claims are very unlikely, speculative and difficult to prove, (b) “in whole or in part” probably covers indirect claims, (c) leaving “directly” in would imply the exclusion of “indirectly”. An indirect injury may occur if a
c. is covered by Site’s general liability insurance but not its medical malpractice or professional liability insurance.[21]

Any Site Indemnitee may elect to defend itself and waive its indemnification rights for any specific claim. This waiver does not apply if a Court of competent jurisdiction orders a Site Indemnitee to retain its own counsel. If the Site Indemnitee elects to defend itself, it and the Sponsor will cooperate in the defense consistent with attorney-client privilege and to the extent their interests are aligned.

Site Indemnitees will notify (with all material information) Sponsor promptly upon becoming aware of any claim or reasonable likelihood of a potential claim of indemnification rights under this Section. Site Indemnitees will cooperate fully, at Sponsor’s reasonable expense, in the defense or settlement of any claim, action or lawsuit. In the event of litigation, such cooperation includes attending hearings and trials, assisting in securing and giving evidence, and obtaining the attendance of necessary and proper witnesses; but not disclosing information privileged under law. Site Indemnitees will permit Sponsor or its insurance carrier to defend or settle such claim or lawsuit with the cooperation and participation of Site Indemnitees’ insurance carrier. Indemnitee may hire its own counsel, at its own expense, to monitor the defense. Site Indemnitees will not compromise or settle any claim or action that is the subject of Sponsor’s indemnification obligations without Sponsor’s prior consent. Site Indemnitees’ failure to cooperate or give prompt notice as provided above will relieve Sponsor of its indemnification obligations to the extent that such failure prejudices the defense of the claim, action, suit or complaint. If Site Indemnitee does not elect to defend itself, Sponsor has the sole right to select defense counsel, subject to consent by Site Indemnitees as permitted under Sponsor’s insurance policy, and to control the defense or settlement of any such claim, action or lawsuit.[22,23]

However, Sponsor may not effect any compromise or settlement of a third-party claim without Site Indemnitees’ consent, and Site Indemnitees have no liability with respect to any compromise or settlement of any third-party claim effected without its consent, except if:

a. there is no finding or admission of any violation of law or any violation of the rights of any person and no effect on any other claim that may be made against the Site Indemnitee;[24]

b. the sole relief provided is monetary damages that are paid in full by Sponsor; and

c. the compromise or settlement includes, as an unconditional term, the claimant’s or the plaintiff’s release of the Site Indemnitee, in form and substance satisfactory to the Site Indemnitee, from all liability in respect to the claim.

If the litigation generates a monetary judgment or settlement in favor of the defendants, that judgment or settlement will be applied first to Sponsor’s out-of-pocket defense costs.

8. Most sponsors are unaccustomed to indemnifying for property damage unless their personnel directly cause it. Examples of potential property damage include:

a. Radioactive material leaks from a defective container

b. Flammable material catches fire

c. Defective medical device starts a fire

d. Depressed Subject burns down a building to cheer himself up (indirect)

9. The Site’s local IRB/IEC is a Site Indemnitee. If Site contracts with an independent IRB/IEC, Site will probably indemnify it. IRB/IEC may want separate indemnification from Sponsor.

10. Site Indemnitees may want to expand indemnification to all claims, etc. “arising out of their performance of this Agreement.” This scope would include (hypothetical to-date) claims such as denial of admission into a study.

11. Sponsors prefer “due to” because “including” opens the door to claims that may not be under Sponsor’s control. Sites prefer “including” because it provides protection against legitimate, unspecified risks. In some states, the cause of action must be specified for the indemnification paragraph to be valid.

12. Sponsor may want to exclude any liability that is outside its control, e.g., not resulting from use of the Study {Drug Materials/Device}. Sponsor does not have control of Investigator’s performance of Study procedures or condition of his/her office. On the other hand, Site can argue that the injury would not have occurred in the absence of the Study. “Bodily injury” is too narrow.

13. Under the Learned Intermediary Doctrine, Sponsor has the right to rely on the Investigator’s competence. Sponsor therefore may not want to indemnify for injuries caused...
by, for example, procedures. The Learned Intermediary Doctrine may not be applicable if the injury was caused in part by negligent selection of the Investigator or negligence in training, instructing, warning or monitoring of Site personnel.

14. Sponsors usually indemnify for claims arising from procedures involving the surgical use or implantation of a Study Device. Sponsor’s products liability insurance probably does not cover other procedures.

15. Standard-of-care procedures are those that would have been performed anyway in the absence of the Study.

16. Sponsor may not want to indemnify for third-party equipment because it does not have control over that equipment, and manufacturer’s warranty should suffice. Site may want indemnification on the grounds that it is Sponsor’s responsibility to ensure that the equipment operates safely and properly. Manufacturer’s warranty may not extend to Site, or may not include indemnification consistent with this Section of the Agreement. If neither Site nor Sponsor is at fault, Site can argue that Sponsor should be responsible because it is Sponsor’s study.

17. Different people at Sponsor (and any CRO) may issue conflicting instructions without realizing it. If an instruction states that it supersedes all previous instructions or modifies a specific previous instruction, then it is not in conflict. If, however, the Site cannot determine which instruction governs, then a conflict exists.

18. Optionally, add “Good Clinical Practice”.

19. Sponsor’s argument for ordinary negligence is that (a) it is contracting with Site to carry out its responsibilities in a responsible manner, and (b) Site’s negligence is not under Sponsor’s control. A simple error by Site can cause serious harm, for which Sponsor should not be liable. For example, if a nurse neglects
to record that he/she administered the Study Drug, a second dose may be given 10 minutes later, injuring the Subject. Site’s argument for gross negligence is that simple negligence may be an unintentional and relatively minor act or omission that is not serious enough to void Sponsor indemnification. Regardless of the text in the Agreement, the law in many jurisdictions does not allow a party to contractually transfer losses arising from its gross negligence to the other party. This policy is based on the principal that the other party cannot be expected to take such risks into account, and is not receiving adequate consideration to take such risks. Sponsor’s insurance policy probably does not cover willful misconduct, a major overlap with gross negligence.

20. If Subject is injured because of faulty instruction by Site, then Site was negligent and indemnification is void. If Subject is injured because he/she did not follow proper instructions, indemnification stands, but Sponsor has a good legal defense.

21. General liability insurance covers “slip and fall” liabilities, but not medical or professional liabilities.

22. Optionally, replace “at Sponsor’s reasonable expense” with “at Sponsor’s reasonable expense for third-party costs”, i.e., travel and lawyers, but not personal or employee time.

23. If insurance carrier has the unilateral right to select defense counsel, not even the Sponsor may have the right of consent.

24. The claimant may, for example, offer to settle a frivolous claim for $10,000 if Investigator admits malpractice, to be reported to the state medical board.

10.2. Indemnification by Site

Subject to Section 10.1. Indemnification by Sponsor and to the extent permitted by State law, Site will defend, indemnify and hold harmless Sponsor Indemnitees from any and all

1. This section is optional and highly objectionable to many sites. One alternative
third-party liabilities, including reasonable attorneys’ and experts’ fees and costs, to the extent that they arise from Study-related claims, actions and lawsuits for property damage, personal injury, or death to the extent due to any (a) violation of any law or regulation for which Site has assumed responsibility under the Study, (b) material breach of this Agreement, or (c) negligent or wrongful act or omission by Site or its employees, officers, agents, subcontractors or other authorized third-party that takes on those roles.[1,2,3,4,5,6,7,8,9,10]

This indemnification obligation does not apply to the extent that the potential liability was caused by:

a. administration of the Study {Drug Material/Device};
b. any defect in Study design, Protocol, or Sponsor Indemnitee instructions to Site;
c. any failure by Sponsor Indemnitee to disclose any known, material side effect of the Study {Drug Material/Device};
d. any Sponsor Indemnitee’s non-compliance with (a) the Protocol, (b) applicable laws and regulations, and (c) this Agreement, provided that Sponsor Indemnitee’s actions were not necessary to protect the safety or welfare of the claimant; or[11]
e. the negligence, willful misconduct, or criminal act of any Sponsor Indemnitee.

Any Sponsor Indemnitee may elect to defend itself and waive its indemnification rights. This waiver does not apply if a Court of competent jurisdiction orders a Sponsor Indemnitee to retain its own counsel.

Sponsor Indemnitees will notify (with all material information) Site promptly upon becoming aware of any claim or reasonable likelihood of a potential claim of indemnification rights under this Section. Sponsor Indemnitees will cooperate fully, at Site’s reasonable expense, in the defense or settlement of any claim, action or lawsuit. In the event of litigation, such cooperation includes attending hearings and trials, assisting in securing and giving evidence, and obtaining the attendance of necessary and proper witnesses. Sponsor Indemnitees will permit Site or its insurance carrier to defend or settle such claim or lawsuit with the cooperation and participation of Sponsor Indemnitees’ insurance carrier. Indemnitee may hire its own counsel, at its own expense, to monitor the defense. Sponsor Indemnitees will not compromise or settle any claim or action that is the subject of Site’s indemnification obligations without Site’s prior consent. Sponsor Indemnitees’ failure to give prompt notice as provided above will relieve Site of its indemnification obligations only to the extent that such failure prejudices the defense of the claim, action, suit or complaint. If Sponsor Indemnitee does not elect to defend itself, Site has the sole right to select defense counsel, subject to consent by Sponsor Indemnitee as permitted under Site’s insurance policy, and to control the defense or settlement of any such claim, action or lawsuit.[12]

However, Site may not effect any compromise or settlement of a third-party claim without Sponsor Indemnitees’ consent, and Sponsor Indemnitee has no liability with respect to any compromise or settlement of any third-party claim effected without its consent, except if:

is a Statement of Responsibility, such as: "Site and Investigator are responsible for the acts and omissions of their employees, officers, directors and agents with respect to their failure to adhere to the terms of the Protocol, applicable regulations, and this Agreement. This section is only a statement setting forth the limited responsibility of the Site and Investigator for the sole purpose of judicial determination of negligence or willful malfeasance, and will not be construed as any contractual or other obligation to defend, indemnify or hold harmless Sponsor or any third party.”

2. Indemnification by Site is also known as “cross-indemnification”.
3. Sponsor may argue that indemnification responsibilities should be symmetrical. Site may argue that the relationship is not symmetrical because of authorship of the protocol and investigator’s brochure, differences in potential financial rewards, and Sponsor’s authority over conduct of the study and training of Site personnel.
4. Most or all U.S. state and federal entities either assert sovereign immunity or are legally prohibited from creating open-ended liabilities and therefore cannot indemnify sponsor.
5. Commentary on Section 10.1. Indemnification by Sponsor is largely applicable to this Section as well.
6. If both parties have simultaneous indemnification obligations to the other, the Sponsor’s obligation governs.
7. Medical malpractice insurance probably does not cover cost of defending Sponsor.
8. Medical center medical malpractice insurance generally covers the legal costs of indemnification, but individual investigators and small sites generally do not have this coverage. Indemnification costs would
a. there is no finding or admission of any violation of law or any violation of the rights of any person and no effect on any other claim that may be made against the Sponsor Indemnitee;

b. the sole relief provided is monetary damages that are paid in full by Site; and

c. the compromise or settlement includes, as an unconditional term, the claimant's or the plaintiff's release of the Sponsor Indemnitee, in form and substance satisfactory to the Sponsor Indemnitee, from all liability in respect to the claim.

Site's obligation under this Section is limited to the amount, nature and terms of insurance coverage available to Site under any medical malpractice, errors & omissions, general liability, or other insurance.”[13]

If the litigation generates a monetary judgment or settlement in favor of the defendants, therefore come out of their own pockets.

9. Site may not want to accept responsibility for its subcontractors, e.g., hospitals that perform procedures and local laboratories.

10. Replacing “negligence” with “gross negligence” makes this indemnification more palatable to Site.

11. Optionally, add “Good Clinical Practice”.

12. If insurance carrier has the unilateral right to select defense counsel, not even the Sponsor may have the right of consent.

13. Optionally, replace this sentence with “Site’s obligation under this Section is limited to {$_/____ times the Total Fees to Site in Exhibit A. Budget}.”

11. Insurance & Liability

11.1. Site Insurance

Site carries general liability insurance with limits of at least $____ per occurrence and $____ in the aggregate. It also carries medical malpractice insurance with limits of at least $____ per occurrence and $____ in the aggregate. Site's insurance (or comparable self-insurance) covers the Study, specifically covers the actions of investigators and other study personnel, and is not materially encumbered by existing claims. Site will maintain this coverage for the duration of this Agreement and, if the policy is claims-made, for {two to five} years thereafter. Site will provide certificates of insurance or evidence of self-insurance to Sponsor upon request. Site will notify Sponsor within 20 Days of any notice of cancellation or non-renewal of, or material change in, or claim against, its insurance coverage. Insurance carriers will have an AM Best rating of A-VII or better.[1,2,3,4,5,6]
11.2. Sponsor Insurance

Sponsor carries general liability insurance with limits of at least $____ per occurrence and $____ in the aggregate. It also carries products liability insurance, including clinical trial coverage, with limits of at least $____ per occurrence and $____ in the aggregate. Sponsor's insurance (or comparable self-insurance) covers the Study and is not materially encumbered by existing claims. Sponsor will maintain such coverage for the duration of this Agreement and if the policy is claims-made, for {two to five} years thereafter. Sponsor will provide certificates of insurance or evidence of self-insurance to Site upon request. Sponsor will notify Site within 20 Days of any notice of cancellation or non-renewal of, or material change in, or claim against, its insurance coverage. Insurance carriers will have an AM Best rating of A-VII or better.[1,2,3,4,5,6,7]

1. Sponsor insurance limits are generally in the range of $5M/$10M.
2. Large sponsors and private institutions may self-insure.
3. Products liability insurance may not include clinical trial coverage. An endorsement to the policy may be required. The policy may cover only injuries due to the Study {Drug/Device/Biologic}, or may cover activities such as procedures performed according to the protocol.
4. Alternative self-insurance clause: “Site/Sponsor has the financial capacity to self-insure for limits of at least $____ per occurrence and $____ in the aggregate. Sponsor/Site will notify Site/Sponsor within 20 Days of any material change in its self-insurance financial capacity.”
5. Claims are likely to be made during the study or in the subsequent two years. “Tail policies” of three to five years are common, with implantable medical devices at the long end. Statutes of limitations vary by state and may be longer than two years.
6. Certificates and carrier ratings apply only if the party is not self-insured.
7. Parties may request this language if the other party is not self-insured: “Upon Sponsor’s/Site’s request, Site/Sponsor will make reasonable efforts to have Sponsor/Site added to the certificate as an additional insured.” Additional insured status enables Sponsor to contact Site’s insurance company directly and settle claims without Site’s cooperation. It is thus not to Site’s advantage. However, if Site goes out of business, insurer probably will otherwise not respond to Sponsor.
11.3. Limit of Liability

Neither party has any right to special, indirect, consequential or punitive damages for breach of contract or tort claim under this Agreement. Without limiting Site's and Investigator's obligations under Sections 9. Subject Injury and 10. Indemnification, Site's and Investigator's potential liability to Sponsor under this Agreement will not exceed ______________________.[1,2]

12. Effective Date, Term & Termination

12.1. Effective Date

This Agreement becomes effective when signed below by all parties, on the date of the last signature.[1]

12.2. Term

The term of this Agreement is {3/5/7} years from the Effective Date. However, unless terminated earlier, this Agreement will expire when (a) Site has submitted all CRFs to Sponsor, has resolved all data clarification queries, has submitted the closeout report to the IRB and Sponsor, and has met all other close-out obligations; and (b) all payments, reimbursements and refunds have been made.

12.3. Termination

The parties may terminate this Agreement under the following circumstances:

a. Breach. Upon material breach by a party, the other party may terminate this Agreement provided that the other party fails to cure the breach within 20 Days after notice.[1,2,3]

b. Subject Safety. Either party may terminate immediately based on Subject safety or welfare concerns, e.g., if the informed consent form required by the IRB/IEC or other party is unacceptable, or if the IRB terminates the Study at the Site. Alternatively, Parties may agree that Site will discontinue enrolling Subjects and attempt to agree if and how the Study will proceed at the Site.
c. **Insolvency.** Either party may terminate immediately upon notice by the other party that it has filed for protection under any bankruptcy laws, has been declared insolvent, ceases or threatens to cease to carry on its business, or an administrator or receiver has been appointed over all or part of its assets.

d. **Investigator Successor.** Either party may terminate if Investigator is unable for any reason to continue in that role and the parties are unable to agree upon a successor.

e. **Government Exclusion.** Site may terminate immediately if Sponsor is excluded from any FDA, OHRP or Medicare/Medicaid, or other state or federal government program.[4]

f. **Without Cause.** Either party may terminate without cause, upon 20 Days’ prior notice.[5]

Upon termination, Site will immediately stop enrolling Subjects and, subject to protecting Subject safety and welfare, cease Study activities and complete its normal Study completion responsibilities.

**12.4. Compensation**

Sponsor will compensate Site for services provided up to effective date of termination and for any services provided after termination that are necessary to safeguard subject safety or to comply with applicable laws, rules, regulations or Sponsor’s requirements. Site will return any unused refundable advances within 20 Days after invoice by Sponsor. Sponsor will pay Site for all reasonable non-cancelable obligations properly incurred for the Study by Site prior to termination. If Sponsor terminates Agreement without cause or for subject safety, Sponsor will reimburse Site for its reasonable unamortized costs incurred for the Study.[1]

**12.5. Survival**

Rights and obligations which by their nature should survive or which this Agreement expressly states will survive will remain in full force and effect following termination or expiration of this Agreement. The parties will cooperate with each other during and following termination or expiration of this Agreement to safeguard subject safety and continuity of treatment, and to comply with all applicable laws, rules, and regulations.[1,2]

If, for one year after the effective date of this Agreement, the parties enter into another agreement for the same services, that agreement will call for approximately the same compensation as in this Agreement.[3]

3. Some U.S. states are “first breach states,” which means that a breach of contract by one party can be offset by a breach by the other, e.g., in nonpayment for deficient services. Other states limit recourse to litigation.

4. Government Exclusion clause is somewhat symmetrical to the Debarment and Disqualification section. Per Social Security Act section 1128A, investigators may not enter into a contract with any debarred entity; sponsors are entities.

5. Sponsor’s right to terminate if Site does not meet subject enrollment objectives may constitute an inappropriate incentive. The right to terminate without cause serves the purpose.
12.6 Continuing Treatment

If Sponsor terminates this Agreement before completion of the Study, except to protect the safety and welfare of the Subjects, Sponsor will, free of charge, if requested by Site and permitted by law and regulations, {provide materials and support to ensure Subjects can exit the Study in a medically safe manner/use its reasonable efforts to supply Site with sufficient Study Drug to complete the treatment of randomized Subjects/allow Subjects to keep Study Devices in their possession} as specified in the Protocol.[1]

13. Notice

13.1. Provision and Time of Notice

Any notice, authorization, approval, consent or other communication will be in writing and deemed given (within the U.S.):[1]

a. Upon delivery in person
b. Upon delivery by courier
c. Upon promised delivery date by a nationally-recognized overnight delivery service such as FedEx
d. Five Days after USPS registered or certified mailing with postage prepaid and return receipt requested
e. Upon delivery by fax, with transmission confirmed by sending machine
f. {Upon delivery by email, when recipient confirms receipt by reply email} [2]

Except for payments to Site, address communications to the person at the address set forth below, or such other person or address subsequently designated.[3,4]

13.2. Notification Parties and Addresses

IF TO SPONSOR:
For Agreement Matters:
For Payment Matters:
For Legal Matters:
For Study-related Matters:

IF TO SITE:
For Study-Related Matters:
For Administrative Matters:

1. Optional.

1. Some delivery options may be deleted.
2. Email is usually not included in this list, but confirmation of receipt may make it acceptable.
3. It is more reliable to specify a role such as “President” than the name of a person, which may change.
4. In addition to mailing addresses, list fax numbers, telephone numbers, and email addresses.

1. Include physical address, mailing address, telephone number, fax number, and email address.
2. Legal matters include authorization to dispose of study records.
14.0. General

14.1. Governing Law & Jurisdiction

The laws of _______ govern this Agreement, without regard to conflict-of-laws provisions. The Courts of _______ have legal jurisdiction.[1,2,3,4,5,6,7]

1. Legal jurisdictions can be states/provinces and countries.
2. Governing law and jurisdiction may be different.
3. Most or all U.S. state entities cannot accept the governing law or legal jurisdiction of another state (or country) because of sovereign immunity.
4. If the parties cannot agree on governing law and jurisdiction, they can compromise by (a) choosing a neutral state or country or (b) using the governing law and jurisdiction of the defendant. The second alternative discourages legal action.
5. Delete clause entirely. The courts will decide when the time comes. Most sites and sponsors accept this alternative.
6. If the Agreement is silent on jurisdiction and the parties are in two different states, the
plaintiff can file the case in its choice of
venue. The defendant can request a change
of venue with that court. The court will
decide jurisdiction based on numerous
factors. The most important factor is usually
where the Agreement was performed.

7. If the parties are in different countries, a
treaty may determine jurisdiction, or litigation
may proceed in parallel in both countries.

8. Unless specified in the Agreement, governing
law is usually that of the jurisdiction where
the case is heard.

9. By disregarding the conflict-of-laws
provisions, the contract explicitly determines
the governing law.

10. In some jurisdictions, lawsuits based on tort
(e.g., misrepresentation, fraud, conversion,
and misappropriation of trade secrets) would
not be covered by the first sentence in this
Section. Therefore, optionally, replace “The
laws of ___________ govern this Agreement.”
With “This Agreement and all disputes
(regardless of the cause or form of action,
including without limitation, actions in tort,
strict liability, breach of warranty or fiduciary
obligations, and other common law and
statutory cause) arising from or related to
this Agreement, or related to any
performance carried out in connection with
this Agreement, and all remedies sought or
obtained on account of such disputes, will be
interpreted, governed, resolved, granted and
enforced solely in accordance with the laws of
the ___________, excluding its
conflict of laws provisions.

14.2. Publicity & Use of Names

The use by any Party of the name, trademark, trade name, logo, or any adaptation thereof,
of any other Party in any publication, press release, advertisement, announcement,
promotional material, or promotional activity relating to the Study requires the prior
written consent of the other Party, subject, however, to the following:

a. Sponsor may, without prior consent, identify Site as the entity that conducted the
Study, and identify Investigator as conducting the Study at the site. This paragraph

a. Sites and investigators rely on previous
experience to demonstrate their competence
to new sponsors.

b. The clause “relating to the Trial” is required to
prevent the Agreement from interfering with
other business relationships between the
does not apply to information of Subinvestigators or other study personnel.

b. Site and Investigator may, without prior consent, disclose their participation in the Study (including the name of the sponsor, name of the study, protocol number, funding amount, and any information available in a public registry) as required by law, Court order, or state regulation; or in (1) C.V.s, (2) their website, (3) industry directories, (4) brochures and marketing materials, (5) internal reports, (6) publications and presentations, (7) grant applications to non-commercial funding sources, (8) government reports and filings, and (9) conflict-of-interest reports. This paragraph applies to Subinvestigators and other study personnel.[1,2,3,4,5]

c. Depending on the nature of the site, disclosures (7) to (9) may be required by law.

d. Option: Require deletion of Study Drug/Device/Biologic name in some types of disclosures.

e. Conform disclosure (6) to publication rights section or delete it.

14.3. Entire Agreement; Modifications

This Agreement, together with any attachments or exhibits, sets forth the entire understanding among the parties about the Study. Any prior agreements, promises or representations, whether oral or written, such as agreements of confidentiality, have no force or effect. Any modification or waiver to this Agreement must be in writing and signed by all parties to this Agreement. However, IRB-approved changes to the Protocol are incorporated by reference into this Agreement, subject to agreement on appropriate Budget modifications.

14.4. Counterparts

This Agreement may be executed in two or more counterpart copies, each of which constitutes an original and all of which together constitute the Agreement. Execution will be complete when each party holds a copy of this Agreement, {transmitted by facsimile or in publication or portable document format (.pdf) form,} signed by the other parties, even though the signatures of all parties do not appear on the same copy.[1]

14.5. Freedom to Contract

The parties represent that they have the right to enter into this Agreement, that existing obligations do not materially interfere with their duties and responsibilities under this Agreement, and that the terms of this Agreement are valid and binding. During the term of this Agreement, the parties will not enter into other obligations that materially interfere with their duties and responsibilities under this Agreement.[1,2]

1. An existing obligation for the Site may, for example, be a previous agreement that requires exclusive access to its patient population. An existing obligation for the Sponsor may be a legal dispute involving patents on the study drug.

2. This section may be deleted on the basis that when the parties sign the Agreement, they are accepting their obligations under the Agreement.

14.6. Authorized Representatives

Each signatory to this Agreement personally represents that, to the best of his/her knowledge, he/she has authority to legally bind his/her respective party to this Agreement. The signatories are not otherwise parties to this Agreement, except as elsewhere set forth
14.7. Assignment
Any party may assign this Agreement to an Affiliate or in connection with the merger, consolidation or sale of all or substantially all of its assets, upon 20 Days’ prior written notice to the other party, provided that the Affiliate or acquirer agrees to assume all responsibilities and obligations under this Agreement. Any other assignment of this Agreement, and the associated rights and obligations, requires the prior written consent of the other party. If Site or Investigator terminates this Agreement, it will assign to Sponsor its contracts with subcontractors, if any, so Sponsor can continue study without that party.

14.8. Delegation
Site may delegate Investigator duties under this Agreement according to Section 3.6. Investigator may delegate his/her duties under this Agreement according to Section 3.8. The parties may delegate other duties under this Agreement to third-parties, provided, however, that (a) such third parties perform such duties in a manner consistent with this Agreement, and (b) the delegating party remains fully responsible for such third parties’ performance under this Agreement.1

1. “Delegation” means the contracting with someone, e.g., an employee or third-party, to perform certain duties under the Agreement.

14.9. Relationship of the Parties
Site is an independent contractor to Sponsor, and not a partner, agent, employee, representative or joint-venturer of Sponsor. Investigator is Site’s {employee/subcontractor/owner/principal}. Except as set forth in this Agreement, no party, or its employees, agents or subcontractors, has any right or authority to bind or act on behalf of another party.1,2

1. If there is a CRO, add “CRO is Sponsor’s contractor.”
2. A joint venture is a legally-constituted partnership for mutual profit. If, for example, the site and sponsor have an agreement to jointly develop the study drug, it would be a joint venture.

14.10. Third-party Rights
This Agreement creates no legal rights for any third-party.1

1. If a contract implies that a “third-party beneficiary” will have certain rights, that third-party may be able to legally enforce those rights against the parties to the contract.

14.11. Severability
If a court of competent jurisdiction finds any provision of this Agreement legally invalid or unenforceable:

a. Such finding will not affect the validity or enforceability of any other provision of this Agreement.

b. The parties will negotiate to revise the provision to make it valid and enforceable. If the
parties cannot agree on such revisions, the Agreement will be performed in the absence of such provision. If such performance is impossible, this Agreement will terminate upon 20 Days' written notice by one party to the other party.

14.12. Remedies and Waivers
In case of breach or default of this Agreement, the Parties may pursue all contractual and other remedies, both legal and equitable. Any waiver of a provision of this Agreement will be in writing. Failure to enforce any provision will not constitute a general waiver of that provision.[1]

14.13. Conflict between Agreement and Protocol
If a provision of the Study Conduct section of this Agreement conflicts with a provision of the Protocol, the Protocol takes precedence on matters of medicine, science and conduct of the study. This Agreement takes precedence in any other conflicts.[1,2,3,4]

No party will be liable for failure or delay in performing its obligations under this Agreement if the failure or delay is required to (a) comply with a government law, regulation or order (not the result of its own conduct), or (b) is caused by other circumstances beyond the reasonable control of such party, that could not have been avoided by that party’s due care, and are not specified elsewhere in this Agreement. A party claiming force majeure will notify the other party in writing, with an explanation, within 10 Days. It will use its reasonable efforts to resume performance of its obligations under this Agreement. If it is unable to resume performance within __ Days after the force majeure event ends, the other party may terminate this Agreement. If reasonable efforts will not enable resumption or completion, the non-performing party may terminate this Agreement.[1,2]

14.15. Geographic Exclusivity
Sponsor will contract with no other site for this Study within __ {miles/kilometers} of Site location working on Study.[1,2]

1. "Terms" and "conditions" are both "provisions." Payment "within 30 calendar days" is a term. Payment "for a completed visit" is a condition.

1. The Protocol is normally attached as an exhibit to the Agreement.
2. The IRB approves the Protocol, so that document has to take precedence with respect to study conduct (unless the IRB also approves the Agreement).
3. No other language in the protocol should overlap with the Agreement.
4. Optionally, list sections of the Agreement for which the protocol takes precedence.

1. IRB orders to terminate the study or put it on hold are covered by the IRB Section.
2. If specific events are listed, present them as examples to ensure that a court will not interpret the list as complete.

1. Optional section.
2. Section may exclude Subinvestigator locations.
14.16. Non-solicitation of Employees
Neither party nor its contractors (associated with the Study only) will take intentional action to solicit or cause to be solicited any employee or contractor (associated with the Study only) of the other party for employment or contracting for ___ months after execution of this Agreement.[1,2,3]

1. If the term of the Study cannot be predicted accurately at the beginning of the Study, replace “for ___ months after execution of this Agreement” with “during the term of the Study and for a one-year period after the close-out visit.”

2. Large organizations generally object to this language, arguing that they are unable to control the actions of their employees and contractors.


14.17. Language
The official language of this Agreement and any subsequent amendments and notices is English. Any translations will be certified. If there is a conflict of interpretation between the English version of this Agreement and the certified translation, the English version will take precedence.[1,2,3,4]

1. This section is optional.

2. Substitute another language, as appropriate.

3. A certified translation is optional.

4. A certified translation is (a) performed by a translator certified by an organization such as the American Translators Association, (b) accompanied by an attached notarized statement by the translator that the translation is “true, accurate and correct to the best of my knowledge and ability”, and (c) initialed on each page by the translator.

14.18. Currency
All monetary amounts stated in this Agreement are in U.S. Dollars, unless specified otherwise. All payments under this Agreement will be made in U.S. Dollars.[1,2]

1. Substitute other currency, as appropriate.

2. Determine exchange rates at date of invoice per OANDA (www.oanda.com).

14.19. Alternative Dispute Resolution
The parties will resolve any dispute pertaining to this Agreement with the Alternative Dispute Resolution (“ADR”) process set forth below. However, any dispute regarding the validity or enforcement of an issued patent shall be heard by a court of competent

1. Patent law is a highly technical area in which arbitrers may not be competent. Other potential areas of dispute can also be
jurisdiction in the country where such patent exists.[1]

A party may initiate an ADR proceeding by giving written notice to the other party of the issues to be resolved. Within 10 Days after receipt of such notice, the other party may, by written notice, add additional issues to be resolved. Within 20 Days after receipt of the original notice, the parties will select a mutually-acceptable neutral party ("Arbiter") to preside over the proceeding. If the parties are unable to agree on an Arbiter, they will request the American Health Lawyers Association (www.healthlawyers.org/) to select an Arbiter. The parties will convene in a mutually-agreeable location to conduct a hearing before the Arbiter no later than 40 Days after selection of the Arbiter.[2]

At least 10 Days prior to the hearing, the parties will complete an exchange of exhibits and summaries of witness testimony, proposed rulings and remedies, and a supporting brief not to exceed 20 pages. The Arbiter will resolve any disputes relating to this exchange. There will be no discovery process such as depositions, interrogatories or document production.

Unless decided otherwise by the Arbiter, the hearing will take place on 2 consecutive days, with each party presenting its case in no more that 5 hours, excluding cross-examination. Within 20 Days after the hearing, the Arbiter will issue a written ruling. For each disputed issue, this written ruling will adopt in its entirety the proposed ruling and remedy of one of the parties. The Arbiter will not explain the ruling. The Arbiter's ruling will be binding, and may be entered as a final judgment in any court of competent jurisdiction. The parties will share equally the joint expenses of the ADR process, with each party bearing its own costs and expenses.[3,4,5,6,7]

14.20. Tax-Exempt Bonds

This Agreement is intended to be interpreted and implemented so the Site’s facilities in which Study is conducted that have been financed with the proceeds of tax-exempt bonds are not used in the trade or business of Sponsor within the meaning of Section 1.141-3 of Treasury regulations or successor provision. However, if the Internal Revenue Service concludes that this Agreement causes such facilities to be used in the trade or business of Sponsor within the meaning of such regulation, or if Site is unable to borrow with tax-exempt bonds in the future or refinance such borrowing because of a determination by

excluded from this section.
2. Outside the U.S., the CPR Institute for Dispute Resolution (www.cpradr.org) can be used.
3. This section is optional.
4. Because of law or sovereign immunity, government entities generally cannot accept binding arbitration, or can accept it only with certain limitations. Tennessee law, for example, requires that all claims against the State are heard before the State Claims Commission.
5. Optionally, replace “The Arbiter’s ruling will be binding, and may be entered as a final judgment in any court of competent jurisdiction.” with “The Arbiter’s ruling will be non-binding.” Non-binding ADR allows subsequent litigation, so may just be a prelude to a full trial.
6. The parties may agree to modify the ADR procedures, e.g., to allow limited document production, or to permit multiple rounds of document exchange. However, adding complexity to the process defeats the point of the exercise to some extent.
7. Binding ADR resolves disputes much more quickly, cheaply and privately than litigation, but without litigation’s extensive discovery process, arguments and right to a trial by jury and appeal. The specter of full litigation may encourage the parties to resolve disputes, but they often spin out of control so even the prevailing party is a net loser because of legal fees.
bond counsel that the terms of this Agreement cause such facilities to be used in the trade or business of Sponsor, the parties agree to negotiate amendments to this Agreement in good faith to correct this issue. If the parties are unable within 60 days to agree on an amendment that is acceptable to the IRS or bond authorities, as applicable, either party can terminate this Agreement on 45 days’ notice.

14.21. Miscellaneous

"Unless stated otherwise" means "Unless stated otherwise in this Agreement or an amendment." Unless stated otherwise, all notifications are in writing. Unless stated otherwise, any approval or consent required by this Agreement must be in writing, must be in advance, and will not be unreasonably withheld. The term "including" means "including without limitation of any kind." "Laws and regulations" means "current and future laws and regulations." All references to "sections" refer to the sections of this Agreement. All section and other titles are solely for convenience and do not constitute a substantive part of this Agreement. All appendices and exhibits to this Agreement are incorporated into this Agreement. Words meaning the singular mean the plural and vice versa. Words meaning one gender mean both genders. References to persons include organizations.