

Clinical Trial Agreement Negotiations and Processing

Office of Research Services
Professional Development Knowledge Base

Types of Agreements

Type	Also Known As	Description	Negotiator
Clinical Trial Agreement (CTA)	<ul style="list-style-type: none">• Clinical Study Agreement• Clinical Services Agreement	Typically, between LSUHSC-NO and a pharmaceutical company, with the intent of the study being to test how well a new medical approach or treatment works, or to test the use of an established treatment for a new purpose.	Clinical Trials Office
Confidential Disclosure Agreement (CDA)	<ul style="list-style-type: none">• Confidentiality Agreement• Nondisclosure Agreement	Outlines confidential material, knowledge, or information that the parties wish to share with one another for certain purposes but wish to restrict access to or by third parties. The parties agree not to disclose information covered by the agreement. Protects nonpublic business information.	Office of Innovation and Partnership

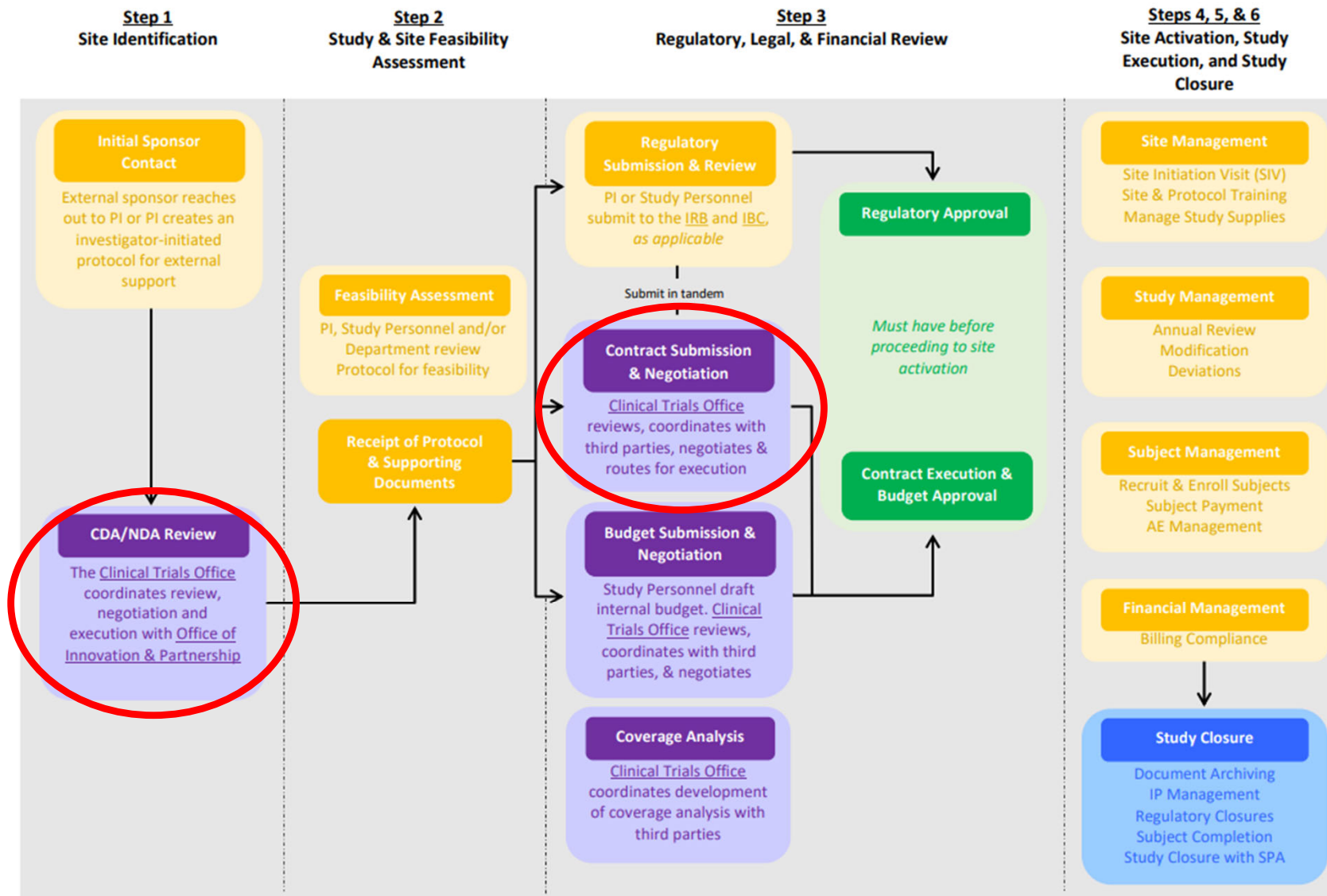
Types of Agreements

Type	Also Known As	Description	Negotiator
Material Transfer Agreement (MTA)	<ul style="list-style-type: none">Uniform Biological Materials Transfer Agreement (UBMTA)	Governs the transfer of tangible research materials between two organizations, when the recipient intends to use the material for his or her own research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives.	Office of Innovation and Partnership
Data Transfer and Use Agreement (DTUA)	<ul style="list-style-type: none">Data Use Agreement	Governs the sharing of research data between two organizations, either when the recipient is collaborating with LSUHSC (and not other agreement in is place) or when the recipient intends to use the data for their own research purpose.	Clinical Trials Office
Subcontract	<ul style="list-style-type: none">Subaward AgreementSubrecipient Agreement	Between a party to an original contract and a third party to provide all or a specified part of the work or materials required in the original contract.	Contract Management Office

Types of Agreements

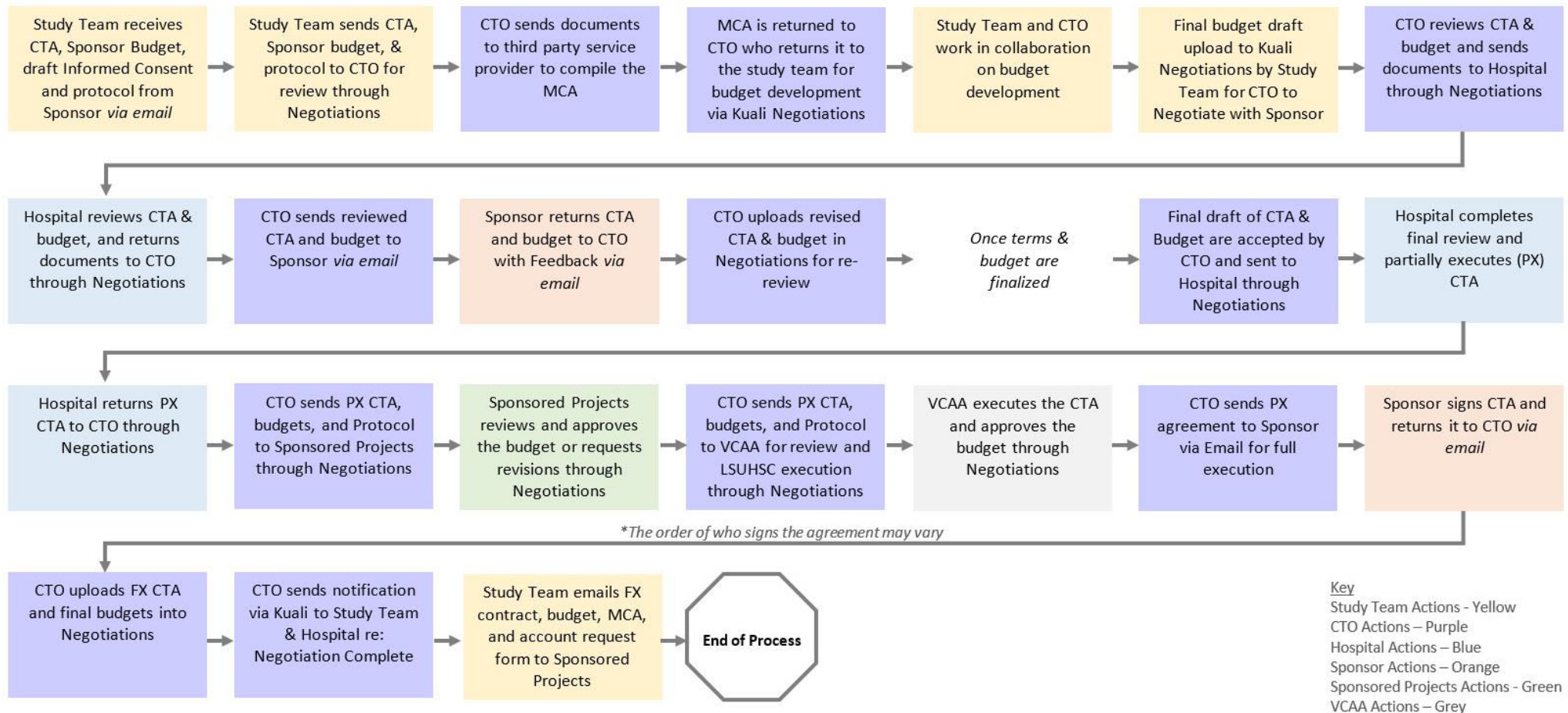
Type	Also Known As	Description	Negotiator
Research Agreement	<ul style="list-style-type: none">• Collaborative Agreement• Scientific Services Agreement	Like Clinical Trial Agreement except that typically, human subjects are not involved.	Clinical Trials Office
Grant Award Agreement		Differs from a Notice of Grant Award in that an agreement must be signed and returned to the sponsor	Office of Grants & Contracts
Purchased Services Agreement		Sometimes used in lieu of a subcontract; typically, between a party to an original contract or grant award and a third party to provide award-specific services.	Contract Management Office
Professional Services Agreements		Provides unique, technical, and/or infrequent functions performed by an independent contractor qualified by education, experience, and/or technical ability to provide services	Contract Management Office

Clinical Trial Start-Up



Clinical Trial Agreement Negotiation and Processing Workflow

CLINICAL TRIALS INVOLVING HOSPITALS



Notable Clauses & Language

- Legal Name
- Parties to the Agreement
- Amendments
- Arbitration
- Assignment
- Attorney's Fees
- Confidentiality
- Conflict Between Protocol & Contract
- Control of Defense
- Export Control
- Force Majeure
- Governing Law
- HIPAA
- Indemnification
- Insurance
- Intellectual Property
- March-In Rights
- Monitoring & Audits
- Ownership
- Publication
- Publicity
- Severability
- Subject Injury
- Term
- Termination
- Travel Expenses
- Warranties

Legal Name

The Board of Supervisors of Louisiana State University and Agricultural and Mechanical College herein represented by **Louisiana State University Health Sciences Center – New Orleans**

- If a sponsor requires that the institution's name on the agreement match SAM Registration, that is an acceptable exception.

Parties to the Agreement

Agreements should be between the *Sponsor* and *LSUHSC*. Hospitals may also be parties to the agreement if they are involved.

The PI cannot be party to the agreement.

- They should be named within a clause/section of the agreement, not in the preamble.
- Language stating that the Investigator “Agrees” to the Contract is not acceptable, as this language creates legal obligations and liability for investigators.
 - Investigators are covered under institutional liability and risk management provisions
- Site Investigators should be included in signature portions of agreements, but only to acknowledge that the agreement has been read and understood; and that investigator obligations are accepted as stated in the agreement.

Amendments

- Amendment to the Protocol

- Appropriate Language: “No changes may be made to the Protocol without the Prior written consent of the Sponsor. Implementation of such changes will be **subject to IRB approval** and, provided that, if the changes to the Protocol cause an increase in cost of performance, payment terms shall be modified in writing and agreed on by both Parties

- Amendments to the Agreement

- Appropriate Language: Amendments to the Agreement must be in writing and signed by both parties.
- Language in contracts that allow sponsors to unilaterally amend agreements are **unacceptable**

Arbitration

- What is arbitration?

- Arbitration is a form of Alternative Dispute Resolution that resolves disputes by one or more individuals.
- Arbitration decisions are **legally binding** for all parties and are **enforceable** in the courts
- Arbitration allows parties to choose the arbitrator, while judicial proceedings do not allow parties to choose a judge. **Parties waive their rights to access the judicial system,** courts, and juries.

- Arbitration in Agreements

- Any language mentioning Arbitration as the means of resolving contract disputes are **unacceptable and should be removed from agreement language.**
- LSUHSC cannot bind itself to arbitration.
- Exception:
 - Contract provisions related to **Intellectual Property Rights** may be resolved through arbitration.

Assignment

• Assignment

- What is assignment?
 - Assignment of a contract occurs when one party to an existing contract hands off the contract's obligations and benefits to another party
- Assignments in LSUHSC Agreements
 - LSUHSC requires written consent for assignments by other parties so that LSUHSC can know who we are contracting with.
 - Changing a legal entity could raise conflict of interest issues.
 - Written notice prior to assignment is mandatory
 - Assignment does not relieve the Sponsor of accrued obligations
- Exceptions:
 - Subcontractors that perform research activities that perform the activities in a manner consistently with the terms of the agreement and the PI and Investigators have no direct or indirect financial interest in the third party
 - Consulting and Social Service contracts as required by state law.

• Contract Language

- This agreement, and the rights and obligations herein, may not be assigned or transferred by either party without the prior written consent of the other party with the following exceptions:
 - The Institution may subcontract the performance of certain research activities to qualified third parties, provided that such third parties perform such activities in a manner consistent with the terms and conditions in the Agreement and the PI or other Investigators have no direct or indirect financial interest in the third party
 - The Institution shall comply with the requirements for consulting or social services contracts, as stated in Louisiana Revised Statutes 39:1503 in the purchase of goods and/or certain services as provided therein

Attorney's Fees

- Language referencing responsibility for Sponsor's Attorney's Fees ***should be removed***
- Unacceptable language: Responsibility for "Reasonable Attorney's Fees"
- If LSUHSC is responsible for Attorney's Fees, language should be added to reflect that the responsibility is "***to the extent allowed by law.***"

Confidentiality

- Confidential Information

- As a public institution, LSUHSC is subject to the Louisiana State Public Records Act (R.S. 44:1 et seq). The Institution can not protect or hold confidential any information or results associated with the project, ***unless the information or the results are proprietary*** (see, specifically, 44:3:2)
- Even if no publications arise from the project, LSUHSC could be required, under the ***Public Records Act***, to provide information regarding a project to an external individual or entity.
- Information submitted must be ***clearly marked that it is Confidential***, so that entities will have knowledge on what is, or isn't, subject to public records laws.
- This is remedied in ***the Confidential Information Cover Sheet***. LA R.S. 44:3.2 states that all records containing proprietary or confidential information submitted to a public body shall contain a cover sheet in bold type.

- Acceptable language

- “CONFIDENTIAL INFORMATION” shall mean any information that is disclosed or submitted in writing from one party to another that is clearly marked “CONFIDENTIAL INFORMATION” in bold letters, in conspicuous locations by the disclosing party. Confidential Information shall also include information that is initially disclosed orally, provided that within seven (7) days of the initial oral disclosure, the disclosed information is reduced to writing by the disclosing party; and providing that the writing is clearly marked “CONFIDENTIAL INFORMATION” in bold letters in conspicuous locations; and provided that the writing thus marked is delivered to all personnel of the receiving party in strict confidence and shall not be disclosed to any third party.

Confidentiality

- Some information is **not covered by Confidentiality clauses** and nothing in the agreement can restrict or impair the other party's disclosure of that information
- These exceptions should be laid out in the agreement terms.
- *Note that the exceptions pertaining to required disclosure by courts, governing bodies, concerns for public health or safety require notice to be given to the providing party and an opportunity to contest the disclosure is provided to them.*
- **Exceptions:**
 - Information that, at the time of receipt, is **public knowledge**, or after receipt, becomes public knowledge through no act or omission of the receiving party
 - Information that was **known to the receiving party**, as evidenced by written records prior to the disclosure by the providing party
 - Information **received from a third party** who do not, indirectly or directly, obtain the information or material from the providing party
 - Information that is required to **be disclosed by a court or governmental agency** provided that the providing party is provided reasonable *notice and opportunity to contest* the disclosure
 - Information that is reasonably believed by either party to have **significant implications for public health or public safety**, provided that the providing party is given reasonable *notice and opportunity to contest* the disclosure
 - The information is published in accordance to the Publication provisions.

Confidentiality

- Return/Destruction of Confidential Information
- Contract Term: “Upon completion of the Study or termination of this agreement, Institution shall, at the direction of the Sponsor, return or destroy all Confidential Information, at the Sponsor’s sole expense. Institution and its IRB may each retain one archival copy of all Confidential Information for the purpose of demonstrating its compliance with its obligations.”
- Breakdown:
 - “Institution shall . . .return or destroy all Confidential Information”
 - This clause states that if the Sponsor so desires, they can request that LSU return or destroy the Confidential Information provided to them.
 - If the Sponsor elects this provision, the destruction or return of this information will be ***paid for by the Sponsor.***
 - LSUHSC ***requires*** that both LSUHSC and its IRB retain an **archival copy** of this Confidential Information to enable them to demonstrate ongoing compliance with their obligations as stated in the agreement.

Confidentiality

- **Trade Secrets**

- LSUHSC does not want to be in receipt of trade secrets and, thus, any reference to trade secrets should be removed from agreements.

Conflict Between Contract & Protocol

Situation:

- The terms of the protocol conflict with the terms of the contract. How is this conflict resolved?

Conflict Contract Provision

- The Terms of the **Contract** control business and legal matters
- The Terms of the **Protocol** control technical research and scientific matters.

Control of Defense

- Control of Defense: In the realm of Indemnification (to be discussed fully later on), a party agrees to defend and hold harmless the other party in claims against a third party for whom the party may be liable. This duty to defend generally includes a provision that grants the party with this duty the ability to control the defense of the other party they are defending against legal action.
- LSUHSC requires the right to control our own defense in cases against the Institution brought about by third parties. LSUHSC must be able to control their defense, have the right to participate in any lawsuit with counsel of their choosing, and reach settlement only when LSUHSC grants its written approval.
- Any language allowing the Sponsor to control our defense in civil actions must be removed.

Export Control

- Export control is legislation that regulates the export of goods, software, or technology. Some of these items may still be potentially useful for purposes of the exporting country. These items are considered to be “controlled” and the export of these controlled items is regulated to restrict the harmful use of those items.
- Export controlled items include goods with military potential, precious stones or metals, endangered animals, or medicines in short supply in the country.
- ***LSUHSC does not wish to be in receipt of export controlled materials without agreeing to that receipt in advance. LSUHSC must have the right to refuse to accept export controlled materials after being provided with notice that such materials will be provided.***
- **Contract Language:** “Sponsor will not provide export controlled materials without notifying the institution. The Institution has the right to refuse to accept export controlled materials.

Force Majeure

- Force Majeure clauses essentially free both parties from liability or obligation with an extraordinary event or circumstance beyond the control of the parties prevents one or both parties from fulfilling their obligations under the contract.
- Contract Language: “No party shall be liable for any failure to perform its obligations, either temporarily or permanently, in connection with any action described in this Agreement, if such failure results from any Act of God, riot, war, civil unrest, flood, earthquake, or other cause beyond such Party’s reasonable control, including any mechanical, electronic, or communications failure, but excluding failure caused by a party’s financial condition or negligence.

Governing Law

- Choice of Law provisions involve instances when laws from different jurisdictions (like state or local laws) conflict with each other. Such provisions state which jurisdiction's law will control in instances where a breach in a contract needs to be resolved.
- Louisiana State Law (LA R.S. 9:2778) precludes LSUHSC from accepting agreement provisions that require interpretation of a contract to be governed by the laws of another state and/or dispute resolution in a forum outside of the state.
- Contract Term Example: "This agreement shall be governed by the laws of the State of Louisiana. Any controversy of fact or law arising out of or related to this Agreement that cannot be satisfactorily resolved by the parties shall be adjudicated only in a court of competent jurisdiction in East Baton Rouge Parish, State of Louisiana.
- Terms stating that another state's law will control or that alternative dispute resolution will occur in another state must be replaced with clauses that place control in East Baton Rouge Parish and the State of Louisiana. If the other party does not agree to this term, LSUHSC can remain silent on Choice of Law provisions, but **cannot** accept control from another state.

HIPAA: Confidentiality of PHI

- Confidentiality of Protected Health Information
 - Sponsor acknowledgement of Irreparable Harm
 - Contract language stating that both parties agree that disclosure of PHI causes irreparable harm, an acknowledgement clause will provide support for an injunction should the Sponsor misuse PHI
 - Recommended language:
 - “The sponsor acknowledges that disclosure of Protected Health Information in violation of the patient authorization or in breach of this Agreement will cause irreparable damage to the Institution. Both parties, therefore, agree that all PHI will be kept confidential and will not be released for any purpose other than those authorized by the patient, enumerated in this agreement, or as provided by law.”

HIPAA: Disclosure of PHI

- Requirement of protection of Protected Health Information and use of PHI only in accordance with the signed HIPAA Authorization
 - Required Language:
 - “The Sponsor agrees that the Sponsor, and any of its agents, will disclose Protected Health Information only to those individuals who agree to be bound by the terms of this section and who reasonably require such information for the performance of this Agreement.”

HIPAA: Unauthorized Disclosure

- Since a breach of a Subject's PHI brings about potential legal issues and liability, a clause in agreements is required that mandates notice that a breach has occurred. LSUHSC requires that the Sponsor notify the Institution of any breach within a legal amount of time.
- Example of contract language:
 - "Sponsor shall provide written notice to the Institution of any unauthorized access to or disclosure of individually identifiable information within five (5) business days of becoming aware of such occurrence. Such notice shall include the timing and nature of the breach. Sponsor shall take all responsible measures to remedy the breach. The Sponsor further agrees to indemnify and hold harmless the Institution for any and all damages arising out of the Sponsor's unauthorized release/re-disclosure of Protected Health Information including, but not limited to, damages, fines, penalties, attorney's fees, and interest.

Indemnification

- What is indemnification?
 - Indemnity is a contractual obligation of one party to compensate the loss incurred to the other party due to the acts of the indemnitor or any other party.
- Context in Clinical Trial and Other Agreements
 - Generally speaking, LSUHSC asks that the Sponsor will compensate and hold LSUHSC harmless in any claim for losses caused by the actions of the Sponsor in the performance of the agreement.
 - Example: A subject is injured in a clinical trial. In most cases, all parties involved will be sued. Clinical Trial Agreements typically include mutual indemnification that protects each party from the cost of defending a lawsuit where the party is not at fault.

The Indemnified Parties

- In all Indemnification clauses, **LSU's Board of Supervisors** must specifically named as an Indemnatee.
 - Example: “The Sponsor shall indemnify, defend, and hold harmless the Institution and the ***Institution's Board of Supervisors***, agents, students, officers, Board Members, employees, and anyone for whom the Institution may be liable (collectively, the “Indemnitees”).)
- Indemnifying Third Parties:
 - LSUHSC does NOT accept responsibilities for Third Parties and, therefore, any mention of responsibility for Third Parties must be removed.

The Indemnification Clause

- In all cases, LSUHSC requires reciprocal indemnification or, at minimum, the Sponsor must agree to defend LSUHSC in a claim or litigation.

“Sponsor shall indemnify, defend, and hold harmless the Institution, its Board of Supervisors, agents, students, officers, employees, and anyone for whom the Institution may be liable against any and all claims, costs, or liabilities,

Clauses that only require LSUHSC to indemnify the Sponsor are unacceptable and should be negotiated to have both parties agree to indemnify each other.

Insurance

Sponsor

- Sponsor should maintain insurance at a minimum of no less than \$1,000,000 and should provide proof of insurance upon request.
- Contract language:
 - “The Sponsor agrees to carry and keep in force, at its expense, product liability insurance at an amount acceptable to the Institution and shall provide evidence thereof within ten (10) days of request from Institution.

Institution

- Sponsor terms stating an amount of insurance LSUHSC is required to carry must be within LSUHSC cover limits. Insurance is regulated by the State.
- Contract Language:
 - Institution shall maintain professional liability insurance with limits as mandated by applicable state law.

Intellectual Property

- Types of Intellectual Property
 - Copyright: Describes the rights that creators have over their literary and artistic works
 - Patents: An exclusive right granted for an invention. Generally, patent provides the patent owner with the right to decide how, or whether, the invention can be used by others. In exchange for this right, the patent owner makes technical information about the invention publically available
 - Trademarks: A sign capable of distinguishing goods or services of one enterprise from those of another enterprise

Intellectual Property: Separate Property

- Contract Term:

- All intellectual property belonging to either Party prior to the execution of an agreement shall remain the separate property of that Party. In addition, all IP developed by a party during the study term *independent* of the Study AND the other Party's confidential information shall be the separate property of the Party that developed it. Nothing in agreements shall give either Party claim or right to the separate IP belonging to the other party

- What does this mean?

- All IP belonging to either Party before signing the contract shall remain the separate property of that Party.
 - IP belonging to the Sponsor and IP belonging to LSUHSC prior to signing the agreement will remain the property of the parties separately throughout the course of the agreement.
- All IP developed by a Party during the study term independent of the Study and the other Party's confidential information shall be the separate property of the Party that developed it.
 - LSU team develops IP during the term of an agreement that is not related to the study and does not rely on the Sponsor's proprietary information remains the property of LSU
- Neither party can claim ownership or a right to use separate IP belonging to the other.

Intellectual Property: Study Inventions

- Study Inventions
 - Inventions and discoveries conceived and reduced to practice in the direct performance of the study and which necessarily use or necessarily incorporate Sponsor's study Drug or Device
- “In the direct performance of the study”
 - Conception and the use of those ideas in the performance of the study via the protocol
- **And**
- “Which necessarily use or necessarily incorporate . . .the study drug or device”
 - Is the Sponsor's drug or device necessary for the new invention or discovery?
- If the answer to **both** of those questions is “yes”, then it is a study invention.

Intellectual Property: Study Inventions

- Study inventions belong to the sponsor. It is their drug or device and it is their study.
- If LSUHSC conceives a Study Invention, LSU will assign all title and interest in the invention to the sponsor and will cooperate with the Sponsor in their pursuit of a patent.
- Contract language:
 - Institution shall promptly and fully disclose to Sponsor all patentable inventions and discoveries conceived and reduced to practice in the direct performance of the Study and which necessarily use or necessarily incorporate the Study Drug/Device (the “Study Inventions”). Institution shall assign all right, title, and interest in and to any Study Inventions to the Sponsor. Institution will reasonably cooperate to effect the foregoing , including providing reasonable assistance in connection with prosecuting relevant patents, at the sole expense of the Sponsor.

Intellectual Property: Other Inventions

- Other Inventions:
Other inventions that are not study inventions. (See previous slide for definition)
- Contract Language”
 - “Title to other inventions other than Study Inventions shall reside with the Sponsor if Sponsor personnel are sole inventors, with Institution if Institution personnel are sole inventors, and shall be held jointly if both Institution and Sponsor personnel are inventors, with each party having the full right to practice and license such other inventions subject only to the similar rights of the other Party.”
- LSU must own, or jointly own intellectual property conceived or created by LSUHSC employees during the course of the project that do not necessarily incorporate the Study Drug/Device or Sponsor Confidential Information. *LSUHSC tax exempt status is affected if we give away our rights to IP*

Intellectual Property: Retained Rights

- LSUHSC should not only recognize compensation from Sponsors for performance of the study. It should also consider compensation in consideration for the Sponsor's use of IP created by LSUHSC due to the Principal Investigator's knowledge and expertise. LSUHSC often retains rights in results produced, including results that are protected by patents and copyrights.

Intellectual Property: Retained Rights

- In LSUHSC contracts with Sponsors, LSU enumerates these retained rights to intellectual property conceived by LSUHSC study teams.
- Contract Language:
 - “In the event the Institution is an inventor, Sponsor shall have a first right to negotiate for an exclusive world-wide royalty bearing license to all rights in the invention. The Institution shall promptly notify the Sponsor of any such invention and shall assist Sponsor in gaining patent protection for the invention at Sponsor’s sole cost. If Sponsor commercializes the invention, Sponsor shall pay Institution a reasonable royalty rate based on the relative contribution to the invention and the commercial value of the invention. If the Sponsor and Institution fail to finalize a license agreement in 180 days, the Institution is free to negotiate with any other entity without obligations to the Sponsor.”

Intellectual Property: March-In Rights

- If a contract is federally funded or uses technology from federal funds, a March-In Rights clause should be included.
- Any entity that receives government money and has inventions and patent applications made with such funding is required to disclose and secure ownership to those inventions from the agency providing the funding.
- Contract Language:
 - “35 U.S.C. Sect. 200-212 holds or may hold a non-exclusive license and certain other rights under patents on inventions made as a consequence of research whose funding includes funding supplied by the United States Federal Government. In the event the United States Federal Government has such rights or in the future is found to have such rights with respect to all and any new Inventions or Discoveries, any license contemplated under this Agreement, even if termed “exclusive” license, shall be understood to be subject to the rights of the United States Government, without any effect on the parties’ remaining obligations as set forth in the license or in this Agreement.”

Monitoring & Audits

By the Sponsor

- LSUHSC should provide the sponsor access to the research site to enable them to monitor the activities of the study.
- Sponsor monitoring of the site and project does not relieve LSUHSC of its Regulatory responsibilities.
- The Sponsor may also choose to audit study records.

By the Regulatory Agency

- All studies are subject to inspection and audits by Regulatory agencies worldwide, including the FDA.
- These inspections can occur during and after completion of the study and can include audits of Study records.

Monitoring/Audits

- Data and Safety Audits
 - All studies involving human subjects must include this language
- Contract Language:
 - “For a period of three (3) years after the Study, the Sponsor shall promptly report to LSUHSC any findings from monitoring or safety reporting of this Study or studies using the same or similar Drug/Device, whether ongoing or ended, that could:
 - Affect the safety of the Study Subjects
 - Affect Study Subject’s willingness to continue participation
 - Influence the conduct of the research
 - Alter the IRB’s approval to continue the study
 - Sponsor must also acknowledge and agree that LSUHSC may communicate any of the findings listed to current and former Study Subjects and participants in Studies using the same device, drug, or treatment regimen.

Ownership

- Who owns data?
 - Study Data: any data generated by the Institution and its Principal Investigator in the course of performing the study.
 - Examples: case report forms, clinical findings, and results.
 - Study data is the exclusive property of the Sponsor, but the Institution must have the **right to use** this data for their own patient care and internal teaching/research purposes and to show compliance with regulatory requirements
 - Source Documents: A Study Subject's original medical records and other Institutional records kept in the ordinary course of its operations
 - Source Documents are the property of the Institution

Publication: The Right to Publish

- The Sponsor must recognize that the Institution must have the right to publish the results of a Study and allow Institution presentation of methods and results of the Study.
 - As a non-profit academic institution, LSUHSC must have the right to publish.
- The copyright of these works belong to the Institution, unless ownership by LSU is waived in favor of the author's under LSUHSC's bylaws

Publication: Sponsor Review

- Institution will provide Sponsor with a copy of any proposed publication of presentation for review and comment at least sixty (60) days prior to presentation or submission for publication
- Sponsor can notify Institution that the publication includes Confidential Information and the Institution must agree to change or delete such information to protect the Sponsor
- Sponsors do not have editorial control over the content of the publications

Publicity

- Neither Party may use the other Party's name, marks, insignia, or logos of the name of any Employee of the other Party without the other Party's written permission.
 - Institution may acknowledge the Sponsor as the source of support for the Project without Sponsor's consent
 - Sponsor may use Institution's name without approval as necessary for Sponsor to comply with applicable law
 - Sponsor may not state or imply that Institution endorses or supports a particular investment, stock purchase, product, or treatment.

Severability

- In the event one of the agreement provisions is found to be invalid, the rest of the agreement is not disregarded as void. The invalid term will be “severed” from the rest of the agreement.
- The rest of the agreement remains in full force when one or more of its provisions is found to be invalid.

Subject Injury

- All studies involving *human subjects* must have this term in the agreement.
- The Sponsor must agree to indemnify LSUHSC for research-related subject injury.
- If a subject is injured, the Sponsor must agree to reimburse the institution, other accredited medical care providers, or the injured subjects themselves (if appropriate) for any medical care occurring as a direct result of the subject's participation in the Study that is not covered by the Subject's insurance.

Subject Injury

- The institution will bill the patient's insurance for items and services needed for the reasonable and necessary care arising from the provision of an investigational item or service, in particular, for the diagnosis and treatment of complications.
- If expenses remain after billing the patient's insurance and the appeals process has been exhausted, the Sponsor will be responsible for all costs.

Subject Injury

- The Sponsor shall be responsible for all costs, including
 - All reasonable and associated costs incurred and associated with the diagnosis of an adverse event involving the Study Drug/Device/Protocol Procedure
 - All reasonable and associated costs incurred for treatment of an injury to the Subject if the Sponsor and the Institution both determine that the adverse event was reasonably related to the administration of the Drug/Device/Protocol Procedure that was *not*:
 - Attributable to the negligence or misconduct by the Institution, the Investigator, Sub-investigator, or any agent of the Institution
 - Attributable to any underlying illness, whether previously diagnosed or not, and
 - The Drug/Device/Protocol Procedure was administered in accordance with the Protocol

Term

- The agreement must have a specific begin date and specific end date for it to be acceptable.
 - The term may also end upon the completion of some specific event, like the completion of all Study activities required under the Protocol.

Termination

- If the Agreement must be terminated before its completion date, either party should have the right to terminate the agreement, with written notice (generally 30 days) to the other party or the occurrence of any of the following events:
 - The Institution or Sponsor cannot secure a substitute Investigator;
 - If the Institution or Sponsor determines that termination is necessary to protect the safety of the subjects;
 - If approval for the study is not granted or is revoked or suspended by the IRB;
 - If the study is placed on hold by a regulatory agency; or
 - Upon the occurrence of an event specifically mentioned in the Protocol that calls for termination

Termination

- Agreements that only allow the Sponsor to terminate the agreement are unacceptable. LSUHSC must also have the right to terminate an agreement.
- If the Agreement is terminated before completion of the Study, LSUHSC shall immediately cease enrollment of Study Subjects and shall cease conducting the procedures set out in the Protocol to the extent that doing so is medically permissible and appropriate for the safety and well-being of the Study Subjects

Termination: Accrued Obligations

- If the study is terminated before completion of the study, the Sponsor shall pay the Institution the following:
 - Fees and cost items set forth in the budget that have been earned or incurred prior to the effective date of termination; and,
 - Any expenses incurred by the Institution in terminating the Study, including the non-cancelable commitments made prior to the Institution's receipt of the notice of termination.

Warranties

- In all agreements, LSUHSC will make no warranties as to the ownership, merchantability, or fitness for a particular purpose of the study results or any invention arising from the study results.

Questions?

Appendix