HSC Clinical Trial Agreement Language Guide for Departments

This guide is developed for HSC Departments who are participating in clinical trials. This guide shows contractual language areas SPO focuses on negotiating. It also states why we can't move forward with a clinical trial agreement if specific language isn't accepted by both parties.

This language guide is geared toward pharma-initiated clinical studies but can be used for investigator-initiated studies and other clinical research.

A couple of notes:

UNMHSC cannot accept clinical study subcontracts from The Mind Research Network due to legal and IRB issues. UNMHS can however be prime on a clinical trial from pharma and subaward back to The Mind Research Network.

WESTERN IRB: ONLY the Cancer Center and Clinical and Translational Science Center are allowed to use outside-WESTERN IRB-instead of UNMHSC IRB

Ceding Letters: All IRB actions have to be first examined by the HRPO/IRB (Hadya Khawaja or James MacFarlane) and then I as the IO-designee for the IRB sign any waiver or ceding agreement. This is the federal process.

Effective March 1, 2023, all pharmaceutical clinical trial budgets must include a fee for initial and ongoing administrative and ancillary compliance reviews for studies that are reviewed by an external IRB. The current fee structure is $2,500 for New Studies and $500 for Modifications.

*Please note: This is a guide to show departments what must be in clinical trials for UNM HSC to accept them. Departments are not expected to negotiate any of this language, it is the responsibility of the SPO Office to do so.

*AAHRPP/Sponsor communication/conduct

UNM HSC maintains accreditation in the use of human subjects in research via AAHRPP – Association for the Accreditation of Human Research Protection Programs, Inc. In order to maintain this accreditation, all of our clinical trials must include language which is protective of the human research subject. The following is the preferred language SPO will try to negotiate in to all clinical trial agreements. If this language is not accepted and alternate language cannot be approved, it can impact the ability to accept the trial.

"During and for a period of at least two years after the completion of the Study, [the sponsor] shall promptly (within 30 days and in a timely manner appropriate to the level of risk involved) report to the Principal Investigator any information that could directly affect the health or safety

of past or current Study subjects or influence the conduct of the Study, including but not limited to the Study results and information in site monitoring reports and data safety monitoring committee reports as required by the protocol. In each case, the Principal Investigator and Institution shall be free to communicate these findings to each Study subject and the IRB."

*Adherence to Protocol

SPO will add the following to all trials for patient safety.

The Principal Investigator may deviate from the Protocol in order to protect a subject's health, safety, or welfare

*Adverse Effects/Subject injury

SPO will ask for reimbursement for subject injury. The PI/Staff should always follow the protocol application and sometimes adverse events can occur from this. UNM HSC should not be liable for following the instructions written by another company, however, UNM HSC can be liable if the PI/Staff deter from the protocol. Below is the language SPO will insert in all trials. If the sponsor does not accept this language, SPO works with them for similar language. If subject injury is not addressed in a clinical trial, it can result in non-participation of the trial.

Sponsor will reimburse Institution and/or the subject for the reasonable costs and expenses incurred in diagnosing and treating adverse effect, injuries, illnesses or reactions that directly result from the use or application of the Study Drug or other procedures required solely for the Study.

UNM HSC will not agree to bill 3rd party payer before Sponsor's adverse event payment responsibility starts.

Billing/Payment Information

- Payment address will be Contract and Grant Accounting, MSC09 5225 with the Accounting Manager as person who receives the payment. The central C&G Accounting general e-mail (HSC-HSCAR@salud.unm.edu) and phone number will be used. We will also provide our current banking information to receive payments.
- SPO will ensure we obtain the proper billing address for the sponsor in order to send invoices.

- With smaller or start-up pharma companies, UNM HSC sometimes runs the risk of non-payment. In order to help deter this, UNM HSC requires the following:

    - In the event that payment is not made as agreed, a service charge of 1.5% per month will be added to all past due amounts. In addition, you agree to reimburse us for our costs of collection, if they become necessary.

    - All payments are due within 30 days after receipt of invoice, unless otherwise noted. Payments must be made promptly and will be aggressively tracked. Non-payment may result in stop work or termination of this agreement. The University of New Mexico Health Sciences Center, as a state nonprofit entity, reserves the right to submit.

Budget Review

Below are the expenses generally proposed in a clinical trial budget. Please note that SPO does not negotiate clinical trial budgets. The staff is not trained in these types of negotiations and are expected to be done by the PI/Clinical Staff.

- Nonrefundable start up fee – paid upon execution of contract
- IRB fees – new, continuing and revision (to include those using an external IRB)
- 28% F&A on all costs
- Document storage fees
- Close out fee
- Hold back percentage – no greater than 25% (payment upon completion of the study – do not tie to a study close out visit which the sponsor can delay at their discretion)
- Per patient/per visit costs
- Testing (e.g. Pathology, Radiology) – both the hospital fee and the professional fee
- Screen failures payments
- Unscheduled visit payments
- Pharmacy fees (include a startup fee and then a fee/prescription)
- Advertising/recruitment
- Shipping if samples being sent to sponsor
- Publication preparation costs

Clinical record storage:
Iron Mountain
555 Gallatin Place NW
Albuquerque NM 87121
Phone: 505-507-9808

- Procedures: Julie Alliman (jalliman@salud.unm.edu) or Bonnie White (bwhite@salud.unm.edu)
- Professional fees & CPT codes: contact the director of the unit/department in which the procedures will be performed to get the correct CPT code and professional fees associated with the procedure
- Wilda McDonough at Tricore does CPT codes for labs for the referral billing/guarantor numbers.

Confidentiality

Confidentiality is critical to UNM HSC in order to keep information and patients/patient information safe. Often times, this area can be tricky for UNM and the sponsor to agree on. SPO must have the following in all clinical trial agreements:

- Institution may retain one copy of confidential information for archival purposes.
- Limit to 3 to 5 years
- "Marked as confidential" to the Sponsor's description of confidential information that could be released
- If the sponsor includes verbal communications as confidential, add "which is identified as confidential at the time of disclosure and reduced to writing within thirty (30) business days"
- Exceptions to Confidentiality
  - Information which is or becomes publicly known through no fault of the Institution;
  - Information learned from a third party entitled to disclose it;
  - Information already known to or developed by the Institution before receipt from the Sponsor, as shown by the Institution's prior written records;
  - Information reasonably necessary to protect the Institution's interests in a law suit, alternative dispute resolution process, or government investigation;
  - Information reasonably necessary to process insurance claims;
  - Information required by law to be disclosed;
  - Information developed independently, by Institution or Principal Investigator, without use or reference to information provided by Sponsor or CRO.

The following must be added for patient safety:

- Patient study records may be disclosed without limitation for patient care purposes. Sample: "Nothing herein shall restrict or prohibit disclosures to other healthcare providers to the extent necessary to provide urgent patient care for any patient

participating in the Study. In the event the patient's medical complaint is not of an urgent nature, Investigator and Institution shall contact (sponsor) to discuss what information, if any, may be disclosed to another healthcare provider as it relates to the diagnosis and/or treatment of the patient"

Data Rights

Anytime research is applied in contracts and/or Investigated-Initiated Clinical Trials, UNM HSC must retain all rights to the data. However, if participating in a multi-center clinical trial, UNM HSC can give up data ownership rights as long as we can retain the right to USE the data for research purposes. SPO will add the following to ensure that use of data:

- Institution retains the right to use the data, including study records, for educational, research, patient care, quality assurance, and publication purposes, as well as to comply with federal, state, or local laws or regulation.

If the clinical trial is not multi-center and/or not sponsor-initiated, UNMHSC will want to retain ownership of the data so SPO will add the following:

- Institution will own all data arising out of its participation in the Study. Except as provided elsewhere in this contract, Sponsor will have access to the data and may use such data in connection with is research, development, marketing or promotional activities and may disclose such data to other investigators, consultants, or federal, state, or local regulatory authorities.

Data Transfer and Security

Data, patient or otherwise, is generally transferred back to the sponsor for evaluations. If you are participating in a multi-center clinical study, UNM HSC does not require a separate Data Use Agreement (DUA). However, a PI/Clinical staff must transmit data to sponsor via a HIPAA compliant system. If it is not, SPO may ask you to initiate the DUA process.

Below is sample language SPO may use for any data that is transferring in/out to UNM HSC.

Data-In

- All Data will be transferred in compliance with UNMHSC Data-In process as handled by UNMHSC central IT to ensure that the transformation is secure and compliance with UNMHSC policies. On a date and time mutually agreed between the Parties, Sponsor will transfer the Data directly to UNMHSC's centralized IT office. Notwithstanding individual requests from individual programs and/or researchers at UNMHSC, Sponsor

understands and agrees that it will not transfer the Data directly to individual programs or researchers. Sponsor agrees that all Data will be transferred in compliance with UNMHSC's IT Security protocols and processed to ensure that information is secure in transit and maintained in compliance with UNM's privacy and security policies.

Data-Out

- The transfer of outgoing data from UNMHSC will be in compliance with UNMHSC's central IT Security protocols and processes to ensure that information is secure in transit and maintained in compliance with any applicable UNMHSC's privacy and security policies

Coordination of data transfer concerns can be addressed by contacting IT Security through: HSC-ISO@salud.unm.edu

General Language Changes

UNMHSC cannot accept the term "warrants" in any fashion. This is a form of indemnification which is against NM State Law. SPO will attempt to replace "warrants" with "certifies," "assures," or "represents"

SPO will request to replace "immediately" with "promptly" as it provides sufficient time for compliance.

General Law and Venue

UNMHSC cannot agree to laws and venue's of another state or country. They must be in NM and if the Sponsor doesn't agree, often times we will remain silent on this issue which implies we will address the issue if it ever comes up.

*Good Clinical Practices

UNMHSC adds the following language to all industry sponsored clinical trials:

Institution commits to compliance with the International Conference on Harmonisation-Good Clinical Practices ("ICH-GCP") E6 to the extent ICH-GCP E6 is consistent with applicable federal regulations.

This protects the rights of human subjects participating in clinical trials and ensures the scientific validity and credibility of the data collected in human clinical studies.

Identification of Parties to Agreement

As in all contractual obligations, the PI or other individual should NOT be a Party to the Agreement. Only The Regents of the University of New Mexico can be party to a contractual obligation and the authorized signatory can sign. Please refer to UNM Policy 2010.

However, the PI/Individual can be referred to as UNM's employee (see below) and may be required to sign as "acknowledge as an employee of the University"

Example:

Institution Name: "The Regents of the University of New Mexico, for its public operation known as the Health Sciences Center, specifically for the XXXXX, whose PI is XXXXX, and with a central business office location at HSC Sponsored Projects Office, MSC09 5220, 1 University of New Mexico, Albuquerque, NM 87131-0001"

Indemnification/Warranty

UNMHSC must be indemnified by Sponsor/Funder for all sponsor-initiated clinical studies. A sponsor-initiated trial is a clinical trial where the protocol is written by the sponsor. This is due to the University taking on the risk by following something that was written by an outside entity. Although these should be low risk, there can be a situation in which a patient may get hurt and want to sue a third party – if we are not indemnified, this cannot happen. The sponsor bears responsibility when they indemnify the Institution.

If the clinical trial is Investigator-initiated (this means a faculty member from UNMHSC developed a protocol and the sponsor is willing to fund it), the SPO Officer will try for full indemnification by the sponsor prior to settling to alternative language that has been reviewed and provided to the SPO Office by Legal and approved by SPO Management.

Below is an example of an Indemnification the SPO Office may attempt to use:

Sponsor will indemnify, defend, and hold harmless Institution, its regents, officers, agents, students and employees from any demands, claims, or costs of judgments that may be made or instituted against any of them by reason of injury (including death) to any person or damage or property, arising out of or connected with the performance of the clinical study; provided, however, Sponsor will have no liability for loss or damage to the extent resulting from the Institution's (1) failure to adhere to material terms of the Sponsor's protocol or Sponsor's written instructions concerning use of the Study drug or device, (2) failure to comply with applicable FDA or other government

requirements, or (3) negligence or willful misconduct by the Institution, its regents, officers, agents, and employees finally determined by a court of Law.

The SPO Officer will always insert UNM's Tort Claims/Liability language as UNM's liability is restricted to the NM Tort Claims – example below:

Institution acknowledges that it will be responsible for claims or damages arising from personal injury or damage to persons or tangible property to the extent they result from negligence of its employees. Sponsor understands that the Institution is not indemnifying Sponsor for the acts or omissions of the Institution, its employees, or students. The liability of the Institution shall be subject in all cases to the immunities and limitations of the New Mexico Tort Claims Act, Section 41-4-1, et seq., NMSA 1978, as amended.

Occasionally a company will claim the right to control litigation and decide settlement and/or admitting "fault;" in those cases, the SPO Officer will add the following:

Sponsor will not settle a claim or suit naming an individual indemnitee without the prior written consent of the Institution and named Indemnitee.

If the SPO Officer cannot negotiate the above language, he/she will contact the PI for approval to let it remain in the agreement. The consequence is this can be reported to the National Practioner's Databank http://www.npdb.hrsa.gov/

In no form or fashion will UNMHSC warrant the results of a study.

Inspection, Monitoring, and Audit

Most Clinical Trials will request they are able to inspect our practice, monitor the CTA and/or audit. We will agree to these conditions if:

- Inspections, if requested, should be done with reasonable notice from Sponsor, and patient medical records reviewed in accordance with applicable federal/state law. The SPO officer will ensure this language is fair.
- If it is a Regulatory inspection by government or legal authority, the SPO Officer will add: "in accordance with applicable federal/state law" to limit the inspection to what might be necessary.
- The SPO Officer will never agree to inspection of our IRB or our entire facility. Inspection is only of the direct study records or facility in direct performance of the study.
- The Sponsor can be informed of external agency audit if allowed by the regulatory agency doing the audit

Insurance

UNM carries insurance provided by the New Mexico Risk Management Division. This is professional and general liability coverage up to a certain amount and the SPO Officer will provide the sponsor with this certificate if requested.

Notices section and Signature blocks – PI & Institution

Notices to UNMHSC should always come to the central office, attention to the SPO Associate Director utilizing the HSC-Preward@salud.unm.edu email address. This notices are generally administrative (i.e. notifying of a sponsor name change or such) and the SPO Officer will process and notify the department as necessary.

The signature block should always reference The Regents of the University of New Mexico as this is our legal entity name for accepting and authorizing contracts.

If the PI is required to sign, it will not be in the capacity of an Authorized Representative, instead it will read something like, "The undersigned Principal Investigator, as an employee of the Institution, acknowledges the Institution's obligations under this Agreement." This means that the PI will comply with the obligations stated in the agreement as an employee of the institution.

Intellectual Property

UNMHSC should not hold any title to any Intellectual Property (IP) that could come out of a multi-center clinical trial. The IP should vest with the sponsor as they have developed the idea and the protocol to test that idea.

If the clinical trial is initiated by the PI (i.e. the PI developed the protocol, Investigator-initiated, UNMHSC shall retail all rights to Intellectual Property. The PI essentially developed the potential IP therefore should follow polices and procedures for handling IP.

*Protocol and Agreement governance

UNMHSC recognizes there could be conflicting terms based on the actual contract and the protocol. To avoid any confusion in these circumstances, the SPO Officer will insert one of the two following clauses:

- If a provision of the Performance of Study 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.

- In the event of any inconsistency between this Agreement and the Protocol, this Agreement shall govern and control as to any legal issue, and the Protocol shall govern and control as to any issue regarding treatment of Study subjects.

Publications

The PI needs the right to publish study data after multi-site publication no later than 12 – 18 months after completion of study (**AAMC standard**). The SPO Officer will not agree to give the sponsor the right to "approve" or "provide consent" for a publication. However, UNMHSC can agree to submit a publication for 30 – 60 days for review prior to that publication. This allows the sponsor to request deletion of proprietary or confidential information. UNMHSC will also allow 3 – 6 months delay in publication in order to allow sponsor to file patent application.

Publicity

Add:
As a State Public Controlled Institution, we required the announcement of the receipt of a clinical study or research contract from Sponsor in its institution publication, disclosing Sponsor's name, the estimated dollar amount of the funding, and the full title of the Study. The taxpayers have the right to see the funding provided to the institution and its purpose. This information is often times provided in HSC's Annual Award Booklet and in various reports provided to HSC Leadership.

Record Storage

It can cost money to store records, therefore if a Sponsor is requesting a retention period outside of UNM's approved periods, we will ask that the PI request these storage fees in their budget.

A Sample Clause might be:

- Institution shall maintain all Medical Records and Study Data for as long as required by applicable laws and regulations, at Sponsor's expense.

  For adult studies: 7 years maximum allowed, for pediatric studies you can accept a longer retention period, e.g. 15 years. If sponsor's record retention request exceeds these limits, request PI and Department Chair approval and acceptance of

responsibility, and notify department administrator or clinical administrator that they need to request record retention fees for that period of time in their budget negotiations

Release of Personal Information and Sunshine Act reporting

- If the contract requests the release of the Investigator's personal information, e.g. name, title, CV, etc., notify Investigator
- We agree to allow funds received to be reported as needed under the federal "sunshine" act, even if the reporting is done in the investigator's name, not the institution.

Termination clauses

Termination for research contracts should be bilateral, this means both Institution and Sponsor should have the right to terminate equally. Your SPO Officer will verify there is bilateral termination language and if not, add the following to protect the PI, Patients, and University.

Institution may terminate if PI becomes unavailable and no substitute acceptable to both parties is available

Sponsor will reimburse Institution for all reasonable, non-cancelable expense incurred prior to termination.

There is a difference between suspending the performance of a clinical study and terminating the agreement. Terminating requires the safe transition of participants out of the study and the PI will no longer receive funds for the protocol. Suspension can occur if safety is at stake, the protocol changes midstream, and/or absence of performance.

This clause discusses immediately ceasing the action of performance of the study for the patient's safety, not terminating the contract.

*****Institution may immediately cease performance of the Study if, within its sole judgment, such immediate termination is necessary based upon considerations of safety of the subjects. Any procedures or health care provided to any subject shall not terminate until the subject can be transitioned out of the Study without adverse medical effects.

UNM as Prime Contractor

Pursuant to that certain Settlement Agreement (Revised 11/16/12), entered into between MRN and the Regents of the University of New Mexico, for its public operation known as the Health Sciences Center (UNM), UNM is to serve as prime contractor for all clinical trials involving UNM faculty. In order to continue to operationalize the Settlement Agreement requirements, as specified above, below are some additional definitions and guidance regarding the appropriate process or setting up a study and for UNM faculty to act as Principal Investigators.
Clinical Trial – (HRP-001, Definition) A biomedical or behavioral research study involving human subjects designed to answer specific questions about diagnostic procedures or therapeutic interventions (drugs, biologic products, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are designed to determine whether new diagnostic procedures or therapeutic interventions are safe and efficacious.

Principal Investigator (PI, NIH, Definition) - the individual who is responsible and accountable for conducting the clinical trial. The PI assumes full responsibility for the treatment and evaluation of human subjects, and for the integrity of the research data and results.

PI's Role and Responsibilities include but not limited to the following*:

- Review and approve protocol
- Supervise or personally conduct the study according to the protocol
- Negotiate budget with Sponsor (UNM is to be Prime on Clinical Trials)
- Ensure that patient incentives are included in UNM budget, and that they are administered within UNM & IRS policies (when applicable)
- Oversee regulatory paperwork
- Ensure that UNM HRPO is IRB of record – obtain initial review approval and continuing review approvals from the IRB.
- Assume full responsibility for proper study implementation and data integrity (know the protocol)
- Responsible for overseeing recruitment and ensuring informed consent is appropriately obtained
- Report adverse events in a timely manner
- Assemble and lead study team
- Maintain and retain adequate and accurate study records as required by law or policy
- Make ethical patient care decision consistent with best practice
- Ensure that a clinical investigation is conducted according to the signed investigator statement for clinical investigations of drugs, including biological products or agreement for clinical investigations f medical devices, the investigational plan a, and applicable regulations
- Protect the rights, safety and welfare of subjects under the investigator's care
- Control drugs, biological products, and devices under investigation
- Certify that proper and applicable standards of care are applied in all aspects of a study.

*Note that solely recruiting patients for a clinical trial does not constitute PI status on a study.