

West Virginia University, Office of Sponsored Programs
Clinical Trial Agreement and/or Research Agreement Checklist
Version-January 2011

The following elements represent potential negotiation issues (and guidance) related to extramurally sponsored agreements with public, industry and private sponsors.

Contract Number \ Protocol Number

- Is the Contract Number\Protocol Number consistent throughout the document?

Is the document an amendment to an existing agreement?

Preamble to the Agreement

Names of the parties and principal place of business

- West Virginia University Research Corp.

Address - 886 Chestnut Ridge Road, Morgantown, WV 26506

In most circumstances WVURC is the party to the agreement.

PI should never be a party to the agreement, but may be asked to sign stating that the agreement has been read and acknowledged. PIs are designated as employees of WVU.

Type of Agreement –

fixed price; or

cost reimbursable

No Time & Materials which means hourly rates and time cards\sheets cannot be promised to the Sponsor.

Compensation for Clinical Trials is based on a per patient amount.

Is the Sponsor requiring a Site Agreement with University Health Associates or West Virginia University Hospital?

WVURC has been advised not to enter into a three party agreement with UHA or WVUH as the third party because of the *Queen* case. For a copy of the Queen case see attached. Also, please find attached a copy of a recent agreement with Wyeth, and the accompanying Site agreement.

Statement/Scope of Work

Period of Performance (p.o.p)–

Start Date
End Date

Is it consistent throughout the agreement?

Does it match what the PI proposed?

If not, does it match what the PI expected?

Important for Award set-up because p.o.p should reflect when work actually started so that project may post expenditures as they are incurred.

Budget

- Is the total project cost and line items the same as proposed?
 - If not, is the total project cost and line items what the PI expected?
- Has the applicable F & A been applied to the project?
- Has the applicable fringe rate been applied?

For Federal or federal flow-through projects,
Is the Category of Federal Domestic Assistance listed in the Agreement?

Termination

Institution must have the right to terminate the agreement for cause.

(Examples)

Adverse Event – Clinical Trial Agreement only

Safety and Health of Patients compromised – Clinical Trials Agreement only.

Material Breach by Sponsor.

IRB, FDA approval withdrawn – Clinical Trial Agreements only

If PI leaves the Institution, can Institution negotiate for replacement pre-termination?

Does the Institution have the right to prorate payment based on the amount of work performed prior to termination?

In the event of termination, will the Institution be reimbursed for funds irrevocably committed pre-termination?

If Sponsor terminates the agreement for material breach by the Institution, Institution prefers a 30 days written notice of the breach with an opportunity to cure.

Institution also wants to reserve the right to terminate the agreement without cause.

Confidentiality

Does the agreement require the Disclosing party to mark confidential information as such?

If not, is the definition of Confidential Information, so broad as to preclude publication rights?

Are there exceptions as to what is considered Confidential Information stated in the agreement?

There are five exceptions to the definition of Confidential Information.

- 1) is or later becomes generally available to the public by use, publication or the like, through no fault of the Institution or the Principal Investigator;
- (2) is obtained from a third party without restriction who had the legal right to disclose the same to the Institution or the Principal Investigator;
- (3) is already possessed by the Institution or the Principal Investigator, as evidenced by recipient's written records predating receipt thereof from Sponsor;
- (4) is independently developed by the Institution and the Principal Investigator without the use or benefit of Confidential Information belonging to Sponsor as evidenced by the Institution's or the Principal Investigator's written records; or
- (5) is required to be disclosed by any law, rule, regulation, subpoena, order, decree, or decision or other process of law.

-- Does the Sponsor require Institution to seek a protective order?

-- is the notice required by Sponsor before disclosure reasonable?

Notice of Inspections by regulatory agency

Is the notice required by Sponsor before disclosure reasonable?

Does Sponsor request the right to respond to regulatory correspondence?

Confidential Nondisclosure Agreements

Is there a reference to a Nondisclosure Agreement (NDA) \Confidentiality Agreement (CDA)?

If so, do we have a copy of the NDA\CDA?

Are WVU - WVURC employees required to sign an NDA\CDA?

CDA and NDA are reviewed and negotiated by the Office of Technology Transfer.

Publications

Institution must have publication rights without the written approval of the Sponsor.

Check Federal Acquisitions Regulations (FAR) clauses because limitations on publications can be embedded in the clauses.

The Institution does not grant excessive pre-publication review periods (30 days for review, 60 days for patent protection, 12 month delay for multi-center publications (if applicable)). Insert standard publication language when needed.

Does the limitations on publication effect student's course work\graduation?

Limitations on publications are a red flag to the applicability of the Export Control regulations because limitations on publication remove the fundamental research exclusion.

Export Control

Does the agreement reference the Export Control regulations?

Is there a limitation on publication?

Does the agreement prohibit the hiring of foreign nationals for the project?

Is there an NDA\CDA?

Reporting

Are we allowed to acknowledge the existence of the agreement?

- If not, are we allowed to use a generic project title?

- If not, were other deviations from the standard language negotiated?

- If so, has ROADS been changed to reflect the final contract language?

Ownership Rights

Who owns rights to:

- data

- inventions

joint inventions/joint ownership

- If so, is there licensing language?

Does the Institution maintain a right to use data for internal, educational, research?

or patient treatment purposes? – Clinical Trial Agreements only.

Does the Institution have the right to retain copies of the data, or other information resulting from the project for archival purposes?

Does the PI/Institution retain the copyright to publications that result from the agreement?

Warranties

Is there a Disclaimer by Sponsor?

- If so, has the mitigating language been inserted?

“Notwithstanding the aforementioned disclaimer, Sponsor does warrant that it is authorized by FDA to manufacture the study drug and cause its use in human studies, and that it is not adulterated, that it has been manufactured accordingly to Current Good Manufacturing Practices, and if the Study Drug is used and administered as specified in this Agreement and the Protocol such use and administration will not infringe the rights, patent or otherwise of any third party.”

Does the Sponsor require the Institution to warrant the work being performed?

- If so, has the mitigating language been inserted?

“WVU\WVURC shall use best efforts to fulfill our obligations and responsibility under this agreement. However, due to the subject matter, no warranty is given or implied.”

What certifications are contained in the agreement?

Are they specific to the PI and the Work being performed?

Governing Law also referred to as Applicable Law.

Conflict of Law which means laws to be used in deciding the case – Must be WV or remain silent.

Jurisdiction which means authority given to the courts to hear legal matters. – Must be WV, court of competent jurisdiction, or remain silent

Venue which means the location of the case – Must be WV, court of competent jurisdiction, or remain silent

Insurance

Is our insurance coverage properly state in the agreement.

- is a Certificate of Insurance required?
- is there Additional Insured Language? If so, are the conditions accurate?

Indemnification

Institution cannot indemnify or hold harmless. We agree to be responsible for intentional or negligent acts or omissions only.

Indemnity language may not contain the word indemnification. Other words of similar import may be used.

In some cases, especially Clinical Trials, we expect indemnification from our Sponsor. The exception is a Clinical Trial Agreement which governs a PI initiated Protocol. For Clinical Trials, there is no distinction made between Phase I, II, III, or IV in the requirement that we be indemnified by the Sponsor.

Alternative Dispute Resolution (ADR)

Institution cannot agree to binding arbitration, Mediation, or non-binding arbitration.

Association for the Accreditation of Human Research Protection Programs (AAHRPP) language

Standard Operating Procedure: When a Data & Safety Monitoring Plan (DSMP) is required (whether by our IRB or the Sponsor) Sponsored Programs will be notified by ORIC immediately after the IRB meeting in which the protocol has been reviewed as to whether or not a DSMP is needed and the timelines associated with the DSMP (also includes PI name, protocol number & title, and ORIC referenced number). Once OSP knows that it is the Sponsor's responsibility to conduct the DSMP, OSP will ensure that the agreement contains language that addresses provisions for monitoring the data to ensure the safety of participants and for providing data and safety monitoring reports to the Principal Investigator.

Standard Operating Procedure: The OSP will ensure that all clinical trial agreements and other Research Agreements wherein human subject participants' safety may be affected by study results, contain a written requirement with Sponsor that the Principal Investigator will be notified by the Sponsor of the results in order to consider informing participants.

Suggested contract language is as follows:

"If applicable to this Study, within thirty (30) days after data lock, Sponsor will inform Site that it may break the Study blind and inform subjects which treatment they receive.

Additionally, Sponsor will inform Principal Investigator of Study Results when the information is available to Sponsor. For a period of three (3) years after the Study. Sponsor will inform Principal Investigator of observed Study side effects so Principal Investigator can inform subjects," or

"Sponsor shall keep each the Institution, IRB, and the Principal Investigator informed of new observations and research findings discovered by or reported to Sponsor on the Product, particularly with respect to adverse effects and safe use, and any research results that directly affect safety or medical care of current or former patients."

In requesting from the Sponsor that the AAHRPP language be added to the agreement, there is no distinction made between Phase I, II, III, or IV. We make the request all Clinical Trial Agreement regardless of the Phase.

Has the Protocol been submitted to the IRB for review?

Signature Block

Signature Line Correct use of party name throughout?

- is the signatory a representative of the party?

- if not, is there a Letter Of Indemnification in place? - applicable to CTAs only

FAR Clauses

review any regulations incorporated by reference - n/a to CTAs