



Office of the Chancellor
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The Health Sciences Center

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15 November 2024

MEMORANDUM NO. CMLT-2024-307

TO : Contract Research Organizations and Sponsors
Principal Investigators
Research Grants Administration Office

THROUGH : The Deans, Directors, and Heads of Offices/Units

SUBJECT : **Guidelines on the standard provisions to be incorporated in Clinical Trial Agreements and Material Transfer Agreements**

To further streamline our processes, particularly the review and approval of Clinical Trial Agreements (CTAs) and Material Transfer Agreements (MTAs), where the University of the Philippines (UP) Manila is the study site and provider institution, please be guided by the following:

1. Sponsors and/or Contract Research Organizations are highly encouraged to develop a **Master Clinical Trial Agreement** and **Master Material Transfer Agreement**. Upon favorable endorsement of the UP Manila Legal Office and approval of the Chancellor, these Master Agreements will be used when several studies involve the same Contract Research Organization and/or Sponsor.
2. The following provisions **shall be** incorporated in every Master Agreement or standalone CTA and MTA:
 - a. **The University as Party to the Contract.** All contracts (CTA and MTA) are entered into by the **University of the Philippines, through its constituent unit, the University of the Philippines Manila**. The Contracting Parties section of the agreement must contain the following information, in any suitable phrasing:

Contracting Party: University of the Philippines, through its constituent university, University of the Philippines Manila¹

Authorized Signatory: Chancellor of the University of the Philippines Manila²

Representation: University of the Philippines Manila represents the Study Site (for CTAs) or the Provider Institution (for MTAs)

¹ Sec. 18 of R.A. No. 9500 in relation to the 987th BOR Meeting.

² 987th BOR Meeting, 24 April 1986.

- b. **Business Address of the Principal Investigator** (for CTAs and MTAs). The business address of the Principal Investigator shall be incorporated, indicating the Room No., Floor, Building, Compound (if any), Street, Barangay, and City.
- c. **Governing Law** (for CTAs and MTAs). The Governing Law in the interpretation and application of the provisions shall be the Republic of the Philippines. Otherwise, the clause on Governing Law should be deleted.
- d. **Indemnity and Insurance** (for CTAs):
- i. **On Indemnity:**

The INSTITUTION³ and PRINCIPAL INVESTIGATOR shall enter into a compromise agreement with a third party only with the written authority of the Sponsor.

- ii. **On Insurance to be Procured by the Sponsor:**

The Sponsor shall take out appropriate insurance to cover any potential liability for personal injury or death of a Clinical Trial Subject as a result of their participation in the clinical trial. The insurance policy referred herein shall remain in full force and effect from the commencement of the clinical trial up to at least six (6) months from the termination thereof.

Before the commencement of the clinical trial, the Sponsor shall provide the Institution certified true copies of the insurance policies.

3. No provision in the agreements should be included that would contravene or circumvent those enumerated in number 2 of this Memorandum.
4. Submissions which do not conform with number 2 shall be edited and returned to the Contract Research Organization and/or Sponsor until the provisions enumerated in number 2 have been complied with.
5. Refer to the UP Manila Legal Office CTA checklist, which is attached to this Memorandum, on the documentary requirements to be submitted prior to the review of the Agreements.

For your information, guidance, and compliance.


Dr. Michael L. Tee
Professor and Chancellor 

³ Ibid.



LEGAL OFFICE

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CLINICAL TRIAL AGREEMENT CHECKLIST

Procedure for the Submission of Documentary Requirements:

1. **Initial submission** of the documentary requirements shall be through the submission of **hardcopies and softcopies**.
2. Upon verification of the documentary requirements, the Sponsor, Contract Research Organization, and Principal Investigator will each be provided a **Control Number**. In lieu of the documentary requirements, the Control Number should be indicated in the Clinical Trial Agreement Checklist. **Reminder: Control Number will only be provided upon verification of the documentary requirements.**
3. Contract Research Organizations and Principal Investigators are required to update their documentary submissions **annually**. The submission of the updated documents shall be considered as an initial submission subject to verification.

DOCUMENTS FROM THE SPONSOR

T A B	DOCUMENT DESCRIPTION	Please submit hardcopy and softcopy
A	☐ Certificate of Registration or Incorporation showing that the Sponsor is legitimately registered in the country where it holds its principal office	
B	☐ License to Operate (LTO) issued by the FDA (if Sponsor is directly conducting a clinical trial without a Contract Research Organization (CRO))	
C	☐ Insurance policy for the Clinical Trial (validity should cover duration of trial)	
D	☐ Letter of Liability/Indemnity (if liability clause is not included in the CTA but referred to by the CTA in a separate document or by way of Annex to the CTA)	
E	☐ Material Transfer Agreement (if biological specimens are to be collected based on the Protocol)	

DOCUMENTS FROM THE CONTRACT RESEARCH ORGANIZATION

T A B	DOCUMENT DESCRIPTION	Please submit hardcopy and softcopy
F	☐ Certificate of registration or incorporation in the Philippines or country of domicile	
G	☐ Latest SEC General Information Sheet	

H	☐ Letter of Authority or Power of Attorney designating the CRO to represent SPONSOR in the CTA	
I	☐ License to operate (LTO) issued by the FDA	
J	☐ FDA approval of the clinical trial	
K	☐ Secretary's Certificate showing that the CTA signatory is authorized to sign the CTA on behalf of the CRO	
L	☐ Copy of government-issued I.D. of the signatory to the CTA	

DOCUMENTS FROM THE PRINCIPAL INVESTIGATOR

T A B	DOCUMENT DESCRIPTION	Please submit hardcopy and Softcopy
M	☐ Protocol and Application for REB Approval	
N	☐ Informed Consent Form	
O	☐ Copy of PRC-issued I.D.	
P	☐ Professional liability insurance (if required in the CTA)	
Q	☐ Certificate of Attendance in a training on Good Clinical Practice (3 years validity from date of training)	
R	☐ Appointment issued by the BOR of UP/Chancellor of UP Manila, <u>or</u> a Certification from the Human Resources on the current employment of the principal investigator, <u>or</u> a certified copy of the recent and validated UP ID of the principal investigator	
S	☐ Copy of government-issued I.D. of the signatory to the CTA	

OTHER SUBSTANTIVE MATTERS FOR REVIEW

	PROVISION IN THE CTA	COMMENTS OR REMARKS BY SPONSOR/CRO/INVESTIGATOR
T	Incorporation of the following information in the Contracting Parties section of the CTA Contracting Party: University of the Philippines through its constituent university, University of the Philippines Manila Authorized Signatory: Chancellor of the University of the Philippines Manila Representation: University of the Philippines Manila represents the Study Site	
U	The CRO's name must be consistent with the SEC documents and those submitted to the FDA	

V	Specific description of biological materials to be transferred subject of an MTA	
W	Specific business address of the Principal Investigator, indicating the Room No., Floor, Building, Compound (if any), Street, Barangay, and City.	
X	Governing law in the interpretation and application of the CTA shall be the laws of the Republic of the Philippines otherwise, we delete the clause on governing law.	

COMPROMISE AGREEMENT CLAUSE

	PROVISION IN THE CTA	EXPLANATION OR REMARKS BY SPONSOR/CRO/INVESTIGATOR
Y	Incorporation of the standard compromise agreement clause The INSTITUTION and PRINCIPAL INVESTIGATOR shall enter into a compromise agreement with a third party only with the written authority of the Sponsor.	

INSURANCE CLAUSE

	PROVISION IN THE CTA	EXPLANATION OR REMARKS BY SPONSOR/CRO/INVESTIGATOR
Z	Incorporation of the indemnity clause on the part of UP and the Principal Investigator The INSTITUTION and PRINCIPAL INVESTIGATOR warrant that the INSTITUTION and PRINCIPAL INVESTIGATOR have sufficient financial resources to cover their indemnification obligations hereunder.	
Z-1	Incorporation of the insurance clause to be procured by the Sponsor The Sponsor shall take out appropriate insurance to cover any potential liability for personal injury or death of a Clinical Trial Subject as a result of their participation in the clinical trial. The insurance policy referred herein shall remain in full force and effect from the commencement of the clinical trial up to at least six (6) months from the termination thereof. Before the commencement of the clinical trial, the Sponsor shall provide the Institution certified true copies of the insurance policies.	