

Supporting Documents CHECKLIST FOR CTA

version 30 Jan18

Date: _____

Name of CRO: _____

Representative of CRO: _____

Study: _____

To facilitate the review of the proposed Clinical Trial Agreement, please submit to us the following supporting documents indicated with a check mark .

SPONSOR:

- Certificate of Registration or Incorporation showing that the Sponsor is legitimately registered in the country where it holds office
- License to Operate (LTO) issued by the FDA
- Letter of Authority or Power of Attorney designating the Contract Research Organization (CRO) to represent it in the CTA
- Insurance policy for the Clinical Trial (validity should cover duration of trial)
- Letter of Liability/Indemnity (if referred to in the CTA)
- Material Transfer Agreement (if biological specimens are to be collected based on the study protocol)

CONTRACT RESEARCH ORGANIZATION:

- Certificate of registration or incorporation in the Philippines
- Latest SEC General Information Sheet
- License to operate (LTO) issued by the FDA
- FDA approval of the clinical trial
- Secretary's Certificate showing signatory authorized to sign the CTA on behalf of the CRO
- Copy of government-issued I.D. of the signatory to the CTA

PRINCIPAL INVESTIGATOR:

- Protocol
- Informed Consent Form
- Copy of PRC-issued I.D.
- Professional liability insurance (if required)
- Certificate of Attendance in a training on Good Clinical Practice (3 years validity from date of training)
- Appointment issued by the Board of Regents of the University of the Philippines
- Review Ethics Board clearance

Truly yours,

ATTY. JAMES DENNIS C. GUMPAL, M.D.
Chief Legal Officer