Istinye University Faculty of Medicine

Points to Consider During the Clinical Trial Contract Review Process

The minimum requirements to be considered in the contract are listed below and are not limited to these items. Additional changes may be requested during the institution review.

- **The laws and regulations** specified in the convention should be inclusive in terms of the law of all countries that are parties to the convention. Reference should be made to the laws and regulations of the Republic of Turkey.

  In disputes, it must be stated that the Courts and Enforcement Offices of the province where the Hospital is located are authorized.

- **Drug and protocol-related Adverse Event and Serious Adverse Event:**

Please add the following language. If your contract has similar language with the same meaning, your original text may remain.

Sponsor agrees to cover the full billed costs for all medical services, including but not limited to diagnosis, treatment, hospitalization, and medical interventions, as a result of any adverse event (AE) or serious adverse event (SAE) that occurs, possibly related/related with the investigational product or protocol procedures.

- **Annual or 6-month price increases will be at the rate of price increase announced by the Turkish Medical Association at regular intervals. The language that needs to be added as an example is written below.**

The fees for the services in this Agreement are calculated based on the relevant clinical trial multiples of the prices provided within the scope of the "Turkish Medical Association". In the event of any updates to the Price Tariffs Procedures and Principles provided under the Turkish Medical Association, this will be automatically reflected in the service elements of this Agreement.

- **Screen failures**

According to the Regulation on Clinical Trials of Medicinal Drugs for Human Use, all procedures related to the study must be paid by the sponsor after the patient signs the ICF. Even if the patient is a screening failure patient, the costs of the screening visit cannot be billed to SSI, private health insurance or the patient himself.

All screening failures are requested by the institution. Proportional payment is not accepted.

- **Equipment:**

  If the sponsor provides equipment for the study, the sponsor must bear the costs of maintenance, repair, and calibration. If the relevant equipment is to be taken back at the end of the work, it must be specified in the contract.

- **Contract language:**

  The language of the contract must be bilingual (English-Turkish) or Turkish.

- **GDPR**

  Privacy and Data Protection Clauses must be in accordance with the Turkish Personal Data Protection Law No. 6698 ("KVKK").

- **Payment term**

  The payment due date for all hospitals is 30 calendar days from the issuance of the invoice.

- **Invoices:**

  Add the following language.

  Institution invoices are issued in accordance with the service statements under the patient's research code opened specifically for the study.

  Project invoices are issued monthly at the end of each month based on the service statements of that month.

  Service statements are sent to the company by e-mail. If the company does not respond within 10 working days from the sending of the e-mail, it is considered approved and the invoice is issued directly.