

B. Details to consider

Clinical Study Agreement

This document can be used as an information sheet to the sponsor/Contract Research Organisation (CRO) in the start of the agreement process, to simplify and speed up the negotiation process. Parts that are not applicable can be erased.

Site:

Sponsor/CRO:

Protocol:

With the intention to give you the best possible service, reduce unnecessary administration and to keep all issues transparent, we would like to share our suggestions in regard of the agreement. In Sweden we recommend to use the LIF/SKL agreement (templates available in English) as a framework for the clinical trial agreement. Read more about the LIF/SKL agreement [here](#).

We usually estimate a remuneration per visit and subject when calculating the trial cost. The calculation is time based (calculated based on time for the performance of the procedures and cost per hour) and we recommend to use the cost calculation template published on www.avtalsprojektet.se. There are certain issues we prefer to keep outside of the per patient payment, see below.

Start up costs

Site shall be reimbursed for startup activities and preparations. The cost estimate is based on time needed to prepare for the study and includes reading and training of protocol and other relevant documents and systems from the sponsor/CRO such as different procedure manuals (e.g. lab, x-ray etc.).

The sponsor/CRO shall cover costs for participation in meetings related to the trial such as participation in start-up meetings (initiation visit), protocol reading/development, educational training prior to the start of the trial (e.g. eCRF, IVRS, GCP) and preparations.

Investigator meetings

The sponsor/CRO shall cover costs for travel, accommodation and preferably time spent during meeting and travelling for the staff attending from site. This includes investigators meetings, relevant scientific meetings, result meetings etc.

Patient recruitment

The sponsor/CRO shall cover costs in relation to recruitment of trial subjects e.g. advertising costs including development and administration as decided together.

The sponsor/CRO shall reimburse site for prescreening activities (e.g. telephone responses, database search etc.).

Patient travel expenses and other costs

Costs for patient travel expenses/journey, accommodation, meals shall be reimbursed by sponsor/CRO, as applicable and according to the Informed Consent Form (ICF)

Screening failures

Sponsor/CRO shall compensate site for all screening failures, unless it is clear that such failure is due to negligence, malpractice, breach of protocol, willfully wrong act or omission on the part of site. The agreement can specify a certain cap of screening failures and when reached a discussion should be made between the site and sponsor/CRO prior to further screening.

Additional visit (unscheduled visit)

The sponsor/CRO shall reimburse site for the additional work related to any non scheduled patient visits in the study, as agreed upon with the sponsor/CRO.

Unpredictable events and amendments

In the event of unexpected events such as new Case Report Form (CRF) system, protocol amendments, new Informed Consent etc, site shall be compensated for reasonable costs and time spent as reflected in an amendment to the agreement.

Administration of new Informed Consent (IC) and amendments

Administration with new IC or amendment should be reimbursed with a fixed sum per IC/amendment.

Serious Adverse Events (SAE)

In case Handling of SAE should be reimbursed and can be done separate per reported SAE.

Audit/Quality Check

The sponsor/CRO shall compensate the site for audits and other study specific extra quality checks. The calculation of the compensation will be based upon the actual hours spent. If the audit shows major quality issues, site may not be reimbursed.

Equipment and materials

In case of study specific electronic equipment site may need to have an electric security test made by hospital and sponsor/CRO shall cover the cost for this. If it is specified before the study that specific equipment is needed that is not available at site, the sponsor can place the equipment at site for the duration of the study, and shall reimburse site for any cost for maintenance and repair. Sponsor shall be responsible for the insurance of the equipment.

Site hourly rate (according to fair market value)

Physician SEK /h
Study Nurse SEK /h
Other study personnel SEK /h (depending on profession)

Currency

Payments shall preferably be in Swedish currency, SEK

Stop clause

In case of early termination of the study or a major delay, the sponsor/CRO shall pay the reasonable and verified costs incurred by site in winding down, terminating and closing or restarting the study, including non cancellable costs.

Close-out cost

Site shall be reimbursed for close-out activities and preparations. The cost estimate is based on time needed to close the study and includes preparation for archiving. The archiving costs shall be reimbursed by sponsor/CRO.

Index adjustments

For studies conducted over several years index adjustments may be made on an annual basis.

Overhead

The compensation for overhead costs is % of the respective fees.

Pharmacy

Pharmacies are separate companies and separate Agreement with the pharmacy must always be entered.

Governing law and jurisdiction

For studies conducted at sites in Sweden the governing law shall be Swedish law and Swedish courts shall be competent courts of jurisdiction.

Payments

Payments (time and interest)

Institution/Site will be paid in accordance with the agreement. Invoices shall be sent from Institution/Site on a regular basis, covering costs incurred during that period of time. Withholdment of payments will not be accepted by site. Payments shall be made within 30 days according to national policys. A longer time for payment may be acceptable, but a reminder may be sent out and interest can be charged for late payments under the Swedish Interest Act (Räntelag 1975:635), i.e. the interest will be calculated on the basis of the repo rate (reporänta) of the Swedish central bank (Sveriges Riksbank) plus 8 percentage points.

Invoicing

Visit payments shall be made from Sponsor to Site following receipt of an invoice. Site will invoice the Sponsor irrespectively of the Sponsor's performing of monitoring visits at Site. Invoicing details for agreement:

Payee Name	
Payee Address	
Bank Name	
Bank Account	
IBAN Number	
SWIFT Code	
VAT Number	

Other

In order to plan for the trial and to make accurate cost estimation site would like the following from the sponsor/CRO:

- Minutes from pre-study discussions (relevant for agreement and budget)
- Study protocol
- Lab-manual and other instructions
- Information about which documents the sponsor will provide
- Information about the trainings and study specific educations required
- Information about investigator meeting
- A test version (pdf, print or similar) of CRF and patient diaries in order to see what data is to be collected, if source data sheets shall be produced by site.