

March 1, 2009

**Agreement concerning clinical study of medicines and  
non-interventional studies between SKL and LIF**

**Specification of resources and additional costs etc for clinical studies of medicines and non-interventional studies.**

Fill in the applicable parts of the form for the specification of resources.

**Administrative information and description of the Study**

***Points 1 and 2***

Here the parties explain where the study is to be conducted. State also the study contacts at the pharmaceutical company and the hospital, or the equivalent, for the study, and who is to be the investigator responsible.

The Company and the Health Service Principal shall be agreed about who is to be the investigator responsible and the consent of this person shall have been given.

***Point 3***

With regard to the title or name and schedule, normally the same information as in the application to the authority is used. The number of patients\*, dates of starting and finishing recruitment and the total time for the conducting of study can be stated. Also treatment period, total and per patient, can be stated. There is a possibility to define the patients as included, randomized or completed.

*\* Patients. In this agreement, when the term patients is used, it also refers to healthy volunteers, where applicable.*

In the description of the study, words and Swedish expressions which are comprehensible even to a laymen should be used as much as possible. State which investigators at the department, or the equivalent, who are assisting in the study.

***Point 4***

In multicentre studies the responsible investigator/coordinator is stated and also the other participating centres in Sweden.

**Staff/resources which the company supply**

***Point 5.1***

If staff employed or contracted by the Company assist, then this is to be stated. Also state their duties and the time spent.

***Point 5.2***

Technical or other equipment, which is provided is to be specified. From the information given it must be clear where the equipment is to be placed. When applicable, matters relating

to responsibility and insurance, as well as ownership, after the termination of the study are to be clearly elucidated.

## **Estimation of costs**

### ***Points 6.1 - 6.3***

The costs are estimated so that the Principal's additional costs for carrying out the study are covered. Additional visits/care days/tests etc. are judged to be those measures which lie outside the local routine that is followed at the clinic, or the equivalent. The pharmaceutical company is charged for all such measures. If the study results in operational costs over and above the costs of laboratory investigations and staff, including physicians, remuneration is also given for them.

*Fees for additional visits must not be charged to the patient.*

Under "introduction" an estimate is made of the time that is needed to inform and train the staff concerned at the clinic, department or the equivalent, about the study, any information that is given to the various medical service units that may be involved etc.

Patients who are to participate in a study have the right to information about the purpose and organization of the study and must give their consent to participate, in case the Ethics Committee has not approved anything else. Such information may require more time than the information about the patient's treatment that is given in routine medical care.

The working time needed for the preparation, planning and design, introduction, execution and evaluation of the study is estimated and stated for the staff who assist, including physicians.

Remuneration for the work carried out by the investigator, and possibly by other persons, may cover both supplementary work, such as examination of literature, compilation of results, writings of articles etc. and other work that is related to the study.

The economical remuneration that are paid to the Health Service Principal shall be given to those persons who execute the study or the activity about which agreement has been made between the parties.

Costs which are related to the routine medical care of patients who participate in clinical trials are not paid for by the Company.

*Clinical trials and non-interventional studies are subject to Swedish Value Added Tax (MOMS).*

With regard to additional visits in out-patient care, either the average cost to the clinic, or the equivalent, for out-patient visits can be used, or the cost of the time spent by the staff (physicians, nurses, other medical staff and medical secretaries), the use of premises, laboratory tests etc can be estimated.

Measures which are not normally part of an out-patient visit in routine medical care, e.g. gastroscopy, bronchoscopy, or exercise tests, are to be charged separately.

Cost increases which are due to prolonged periods of care or operational expenses over and above those for laboratory investigations and staff are calculated as a percentage increment in the cost of staff according to a special agreement between the parties, or alternatively a specification is made of the separate cost components.

For both alternatives, the hospital's (or the equivalent's) operational annual account may provide a basis for the calculations.

When the costs of additional laboratory investigations within the hospital are calculated, the list of rates which is used by the Principal for internal charges is used.

Other costs for the planning, introduction, execution and evaluation of the study which are paid by the Company are calculated on the basis of the direct payroll expenses for each respective category of staff, including investigators, plus payroll overheads according to law and agreement, costs for stand-ins or locums for ordinary staff during holidays, additional costs for holiday supplements and special holiday pay supplements. Direct pay denotes total pay including all supplements. For audits, initiated by the company, the extra time will be paid by the company.

When calculating resources for studies which are part of so-called multicentre study, the agreement between the so-called 'mother clinic' and, where applicable, university departments and the pharmaceutical company may provide a guideline.

#### ***Point 6.4***

Normally in a clinical trial, in the case of not approved medicines, the Company supplies study preparations free of charge. Remuneration for approved medicines used in the study is agreed upon by the parties and specified on this point.

#### ***Point 7***

If the study is to continue for more than twelve months, normally consideration is given to this when drawing up the agreement concerning remuneration.

#### ***Point 8***

The resources which the Company makes available should be taken into consideration when assessing the additional costs. Here, other conditions for the study can be stated if a study is interrupted or undergoes major modification in a manner other than according to the protocol, conditions for remunerations etc.

If the study is conducted in collaboration with a university department, or the equivalent, state whether an agreement has been made between the department (or the equivalent) and the Company.

*All remuneration for the study is to be specified in the agreement and the accompanying appendices.*