

**AGREEMENT RELATIVE TO PROTOCOL  
STUDY NUM. «N\_AGREEMENT»/«year»**

**BETWEEN THE UNDERSIGNED**

The (UNIVERSITY) HOSPITAL « .... », «ADDRESS », represented by its (General) Director Mr. « ... », hereinafter "the (U) H ",

**ON ONE HAND**

**AND**

The «SPONSOR AGREEMENT» laboratory having its registered office at «ADDRESS», represented by its (General) Director, «REPRESENTATIVE», hereinafter «the Sponsor",

**ON THE OTHER HAND,**

**IN VIEW OF**

- the Public Health Code provisions,
- the decision fixing the rules of Good Clinical Practice,
- the agreement signed by the DIRC (Interregional Clinical Research Delegation) « ... », and the GIP (Public Interest Group) « CeNGEPS »(National Centre for management of healthcare product trails), the « ... »
- the approval, certificates and documents necessary for carrying out the trail, which are presented by the (university) medical centre.

**RECITALS**

The sponsor has taken the initiative to carry out medical study called:

«NAME\_OF\_PROTOCOL»

It is stipulated that «TITRE» «Investigator» has declared to be acting as investigator and is prepared to direct and supervise the execution of said research,

set up in the (U) H of « ... » in the «UNIT» of the hospital «HOSPITAL» registered under the EUDRACT num. « X » and authorised on « 00/00/0000 » by the French Health Products Safety Agency, after being accepted by the Committee for the Protection of Individuals « region », on « date », for a period of approximately «Period», as of «Start date», concerning «Num\_of\_patients» patients for the « ... » centre, which is insured by « X (name and address) », policy num. « Y ».

**NOW, THEREFORE, THE PARTIES AGREE AS FOLLOWS:**

## **ARTICLE 1 – PURPOSE OF THE AGREEMENT**

The purpose of the present agreement is:

- a) to stipulate in which manner the additional expenditures borne by the hospital and due to the execution of the study mentioned in the recitals will be covered by the promoter;
- b) to determine which documents and information must be provided by the promoter for the information of the Director of the establishment (annex 2).

## **ARTICLE 2 - FINANCIAL ARRANGEMENTS**

### **2.1 - General financial arrangements**

In conformity with Article R.1121-4 of the Public Health Code, the promoter shall cover the additional expenditures related to possible supplies or specific exams which are required by the study protocol or for the implementation of the latter. When the study is carried out in the health establishment, coverage of these expenditures will be the object of an agreement concluded between the promoter and the legal representative of said establishment.

Annex 1 hereby details the type and method of calculation for the additional expenditures born by the (U) H of « ... » at the time of the above named study and their distribution by cost item.

Each year (preferably) and/or at the end of the trail, a document summing up the number of individuals included in the study, as well as the acts and services carried out shall be drawn up by the (U) H. A final calculation of the expenditures incurred by the latter shall be carried out on said basis.

In this regard, the promoter undertakes to give the (U) H the necessary information for said calculation and to inform them of the end of the trail.

## **2.2 - Billing**

The promoter undertakes to pay the set fees mentioned in annex 1 upon presentation of an invoice issued by the (U) H of « ... » as of signature of the present agreement regardless of the number of individuals included in the protocol (even if none).

The other fees are billed yearly on the basis of the summary mentioned in 2.1 above.

## **ARTICLE 3 – CONFIDENTIALITY**

The (U) H of « ... » undertakes to maintain the utmost confidentiality regarding all of the documents and information which will be submitted to it.

## **ARTICLE 4 - AUDIT**

In conformity with all of the legal provisions governing Good Clinical Practice, the (U) H undertakes to lend its support to the promoter (or to the promoter's proxy) for the proper execution of any audits of the clinical trial, object hereof, subject to having been informed of the identity of the auditor, the dates on which it is to take place and its content in due time.

## **ARTICLE 5 - EFFECTIVE DATE - DURATION – TERMINATION OF THE AGREEMENT**

The present agreement takes effect the day that the study begins. It binds the parties until the end of the study and the complete reimbursement of the sums due to the (U) H of « ... » by the promoter.

It may be terminated by either party before the expiry date in the event of technical or methodological impossibility which calls into question continuation of the undertaken study by registered letter with acknowledgement of receipt. It ends ipso jure in the event that AFSSAPS forbids the execution of the study.

The variable fees set forth by the (U) H of « ... » shall be paid by the promoter pro rata of the work and inclusions carried out on the day of breach of contract,--the set fees mentioned in annex 1 are due in any event.

## **ARTICLE 6 - LITIGATION - DISPUTES**

In conformity with Article 42 of the New Civil Procedure Code, the competent territorial jurisdiction is that of the location where the defender resides.

Executed in « ... », on « ... »

In three original copies.

THE (GENERAL) DIRECTOR  
of the (U) H of « ... »

PP/ THE PROMOTER  
«PROMOTER AGREEMENT »

THE GENERAL DIRECTOR

« ..... »

«REPRESENTATIVE»